NUVELO INC Form S-4/A November 24, 2008 Table of Contents

As filed with the U.S. Securities and Exchange Commission on November 21, 2008

Registration No. 333-154839

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1 to Form S-4 REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Nuvelo, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of 2835 (Primary Standard Industrial 36-3855489 (I.R.S. Employer

incorporation or organization)

Classification Code Number) 201 Industrial Road, Suite 310 **Identification No.**)

San Carlos, CA 94070-6211

(650) 517-8000

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Ted W. Love

Chairman of the Board and Chief Executive Officer

Nuvelo, Inc.

201 Industrial Road, Suite 310

San Carlos, CA 94070-6211

(650) 517-8000

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

John M. Geschke, Esq.	Richard B. Brewer	Alan L. Dye, Esq.	
Cooley Godward Kronish LLP	President and Chief Executive Officer	Michael J. Silver, Esq.	
Five Palo Alto Square	ARCA biopharma, Inc.	Hogan & Hartson L.L.P.	
3000 El Camino Real	8001 Arista Place, Suite 200	555 Thirteenth Street, N.W.	
Palo Alto, CA 94306	Broomfield, CO 80021	Washington, D.C. 20004	
(650) 843-5757	(720) 940-2200	(202) 637-5600	

Approximate date of commencement of proposed sale of the securities to the public: As soon as practicable after the effectiveness of this registration statement and the satisfaction or waiver of all other conditions under the merger agreement described herein.

If the securities being registered on this form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting company. See the definitions of large accelerated filer, a scelerated filer and small reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer "
Non-accelerated filer "
(do not check if a smaller reporting company)

Accelerated filer x Smaller reporting company "

CALCULATION OF REGISTRATION FEE

Con	Title of Securities to be Registered nmon Stock, \$.001 par value	Amount to be Registered(1) 115,000,000	Proposed Maximum Offering Price per Share N/A	Proposed Maximum Aggregate Offering Price(2) \$11,639.37	Amount of Registration Fee(3) \$0.46
(1)	This registration statement covers the maximum number the proposed merger described herein to holders of AR ARCA common stock issuable upon conversion of AR stock, \$0.001 par value per share, holders of ARCA s \$0.001 par value per share, and to holders of ARCA s and warrants will be assumed by Nuvelo as part of the combined by a reverse stock split into a lesser amount of statement shall be proportionately reduced.	CA biopharma, Inc. s (CA s 6% Convertible F Series B-1 preferred sto outstanding options and merger. All of Nuvelo	ARCA) common stock, \$ Promissory Notes due March ck, \$0.001 par value per shall warrants to acquire ARCA s common stock covered by	0.001 par value per share (i 31, 2009), holders of ARC re, holders of ARCA s Seri common stock and preferre this registration statement v	ncluding those shares of A s Series A preferred ies B-2 preferred stock, d stock, which options vill be reclassified and
(2)	Estimated solely for the purpose of calculating the regist to Rule 457(f)(2), based on the par value (\$0.001 per shexchanged in the proposed merger.	1 *			
(3)	Previously paid.				
The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.					

The information in this proxy statement/prospectus/consent solicitation is not complete and may be changed. Nuvelo may not sell its securities pursuant to the proposed transaction until the Registration Statement filed with the Securities and Exchange Commission is effective. This proxy statement/prospectus/consent solicitation is not an offer to sell these securities and it is not soliciting an offer to buy any securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED NOVEMBER 21, 2008

Nuvelo, Inc.,

ARCA biopharma, Inc.,

a Delaware corporation

a Delaware corporation

Proxy Statement/Prospectus

Consent Solicitation

For a Special Meeting of Stockholders

to be held on January 7, 2009

Shares of Common Stock

We are furnishing this proxy statement/prospectus/consent solicitation to the holders of Nuvelo Inc. s common stock and to holders of ARCA biopharma, Inc. s common stock, Series A preferred stock, Series B-1 preferred stock and Series B-2 preferred stock.

Nuvelo is soliciting proxies for use at a special meeting of its stockholders to consider and vote upon (i) a proposal to approve the issuance of Nuvelo common stock pursuant to a merger transaction with ARCA, (ii) a proposal to approve an amendment to Nuvelo s amended and restated certificate of incorporation to effect a reverse stock split of the issued and outstanding shares of Nuvelo s common stock, (iii) a proposal to approve an amendment to Nuvelo s amended and restated certificate of incorporation to increase the number of authorized shares of Nuvelo common stock to 250 million, and (iv) an adjournment of the special meeting, if necessary, if a quorum is present, to solicit additional parties if there are not sufficient votes in favor of Proposals No. 1 and No. 2.

ARCA is soliciting written consents from its stockholders to consider and vote on a proposal to adopt the merger agreement with Nuvelo and approve the merger and other transactions contemplated thereby.

Pursuant to the merger, ARCA security holders will be entitled to receive shares of Nuvelo common stock representing approximately 67% of the shares of outstanding common stock of the combined company after giving effect to issuance of shares pursuant to ARCA soutstanding options and warrants primarily on a treasury method basis, and without giving effect to any shares issuable pursuant to Nuvelo soutstanding options and warrants. The actual number of shares of Nuvelo common stock to be issued in respect of each share of common stock of ARCA will be determined by dividing an aggregate of 109,009,278 shares of Nuvelo common stock by the number of shares of ARCA common stock outstanding and deemed outstanding pursuant to the formula set forth in the merger agreement and described in this proxy statement/prospectus/consent solicitation under the heading. The Merger.

Nuvelo s common stock is traded on the Nasdaq Global Market under the symbol NUVO and on November 21, 2008, the closing sale price of Nuvelo common stock was \$0.27 per share. Following the merger, the combined company is expected to be renamed ARCA biopharma, Inc. and to change its symbol for trading on the Nasdaq Global Market. ARCA has reserved the symbol ABIO for this purpose.

FOR A DISCUSSION OF SIGNIFICANT MATTERS THAT SHOULD BE CONSIDERED IN EVALUATING THE MERGER AND THE PROPOSALS SET FORTH HEREIN, SEE <u>RISK FACTORS</u> BEGINNING ON PAGE 28.

This proxy statement/prospectus/consent solicitation is dated on or about November 25, 2008.

, 2008, and is first being mailed to stockholders of Nuvelo and ARCA

This proxy statement/prospectus/consent solicitation incorporates or refers to important business and financial information about Nuvelo and ARCA that is not included in or delivered with this proxy statement/prospectus/consent solicitation. Such information is available without charge to stockholders of Nuvelo and ARCA upon written or oral request at the following addresses: For information concerning Nuvelo, Nuvelo, Inc., Attn: Investor Relations, 201 Industrial Road, Suite 310, San Carlos, CA or by telephone at (650) 517-8000 and for information concerning ARCA, ARCA biopharma, Inc., Attn: General Counsel, 8001 Arista Place, Suite 200, Broomfield, CO 80021 or by telephone at (720) 940-2200. To obtain timely delivery, Nuvelo stockholders must request the information no later than five business days before the date of the special meeting of Nuvelo stockholders, or no later than December 30, 2008, and ARCA stockholders must request the information before delivering their signed written consent, which must be delivered to ARCA no later than November 28, 2008.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THE MERGER OR THE NUVELO COMMON STOCK TO BE ISSUED IN THE MERGER OR DETERMINED IF THIS PROXY STATEMENT/PROSPECTUS/CONSENT SOLICITATION IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

To the Stockholders of Nuvelo, Inc.:

On September 24, 2008, Nuvelo, Inc., or Nuvelo, and ARCA biopharma, Inc., or ARCA, entered into an agreement and plan of merger and reorganization, which the parties amended on October 28, 2008, and which, as amended, unless otherwise indicated, we refer to as the merger agreement, pursuant to which a wholly-owned subsidiary of Nuvelo, Dawn Acquisition Sub, Inc., or the merger sub, will merge with and into ARCA, with ARCA continuing after the merger as the surviving corporation and a wholly owned subsidiary of Nuvelo. At the effective time of the merger, each share of ARCA capital stock issued and outstanding immediately prior to the merger (other than shares held by any wholly-owned subsidiary of ARCA, or by Nuvelo, merger sub or any other subsidiary of Nuvelo) will be automatically converted into the right to receive that number of shares of Nuvelo common stock as determined pursuant to the exchange ratio described in the merger agreement. In addition, Nuvelo will assume options and warrants to purchase shares of ARCA capital stock.

Following the merger, and subject to adjustment in accordance with the merger agreement, current stockholders of Nuvelo are expected to own approximately 33% of the combined company, and current ARCA stockholders are expected to own approximately 67% of the combined company, after giving effect to the issuance of shares pursuant to ARCA s outstanding options and warrants primarily on a treasury-method basis, and without giving effect to any shares issuable pursuant to Nuvelo s outstanding options and warrants. The actual number of shares of Nuvelo common stock to be issued in respect of each share of capital stock of ARCA will be determined by dividing an aggregate of 109,009,278 shares of Nuvelo common stock by the number of shares of ARCA common stock outstanding and deemed outstanding pursuant to the formula set forth in the merger agreement and described herein under The Merger Agreement. The exact exchange ratio per share of ARCA s capital stock will depend upon the number of shares of ARCA s capital stock outstanding or issuable pursuant to ARCA s outstanding convertible notes, options and warrants immediately prior to the effective time of the merger and the closing price per share of Nuvelo s common stock for the five consecutive days immediately proceeding the effective time of the merger and will not be calculated until that time.

Nuvelo s common stock is traded on the Nasdaq Global Market under the symbol NUVO and on November 21, 2008, the closing sale price of Nuvelo common stock was \$0.27 per share. Following the merger, the combined company is expected to be renamed ARCA biopharma, Inc. and to change its symbol for trading on the Nasdaq Global Market. ARCA has reserved the symbol ABIO for this purpose.

At Nuvelo s special meeting of stockholders, stockholders of Nuvelo will be asked to approve, among other proposals, the issuance of shares of Nuvelo common stock to the stockholders of ARCA and certain amendments to Nuvelo s certificate of incorporation. The date, time and place of the Nuvelo special meeting are as follows:

January 7, 2009

9:00 a.m., Pacific Standard Time (PST)

Nuvelo, Inc.

201 Industrial Road, Suite 310

San Carlos, CA 94070-6211

This proxy statement/prospectus/consent solicitation provides you with information about Nuvelo, ARCA and the proposed merger. We encourage you to read carefully the entire proxy statement/prospectus/consent solicitation. In particular, you should carefully consider the matters discussed under Risk Factors beginning on page 28.

Ted W. Love Chairman of the Board and Chief Executive Officer

San Carlos, California

November 21, 2008

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THE MERGER OR THE NUVELO COMMON STOCK TO BE ISSUED IN THE MERGER OR DETERMINED IF THIS PROXY STATEMENT/PROSPECTUS/CONSENT SOLICITATION IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

This proxy statement/prospectus/consent solicitation is dated , 2008, and is first being mailed to stockholders of Nuvelo on or about November 25, 2008.

NOTICE OF SPECIAL MEETING OF STOCKHOLDERS

TO BE HELD ON JANUARY 7, 2009

To the Stockholders of Nuvelo, Inc.:

A special meeting of stockholders of Nuvelo will be held on January 7, 2009 at 9:00 a.m. PST, at Nuvelo, Inc., 201 Industrial Road, Suite 310, San Carlos, California, for the following purposes:

- 1. To consider and vote upon a proposal to approve the issuance of Nuvelo common stock pursuant to the Agreement and Plan of Merger and Reorganization, dated September 24, 2008, by and among Nuvelo, Inc., Dawn Acquisition Sub, Inc., and ARCA biopharma, Inc., as amended by that Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated October 28, 2008, by and among Nuvelo, Inc., Dawn Acquisition Sub, Inc., and ARCA biopharma, Inc., as described in the attached proxy statement/prospectus/consent solicitation. A copy of the Agreement and Plan of Merger and Reorganization is attached as *Annex A* to the accompanying proxy statement/prospectus/consent solicitation and a copy of Amendment No. 1 to Agreement and Plan of Merger and Reorganization is attached as *Annex B* to the accompanying proxy statement/prospectus/consent solicitation.
- 2. To approve an amendment to Nuvelo s amended and restated certificate of incorporation in order to effect a reverse stock split of the issued and outstanding shares of Nuvelo s common stock. A copy of the amendment to Nuvelo s amended and restated certificate of incorporation to effect the reverse stock split is attached as *Annex E* to the accompanying proxy statement/prospectus/consent solicitation.
- 3. To approve an amendment to Nuvelo s amended and restated certificate of incorporation in order to increase the number of authorized shares of Nuvelo common stock to 250 million. A copy of the amendment to Nuvelo s amended and restated certificate of incorporation to increase the number of authorized shares of Nuvelo common stock to 250 million is attached as *Annex F* to the accompanying proxy statement/prospectus/consent solicitation.
- 4. To consider and vote upon an adjournment of the special meeting, if necessary, if a quorum is present, to solicit additional parties if there are not sufficient votes in favor of Proposals No. 1 and No. 2.
- 5. To transact such other business as may properly come before the special meeting or any adjournment or postponement thereof.

The board of directors of Nuvelo has fixed November 11, 2008 as the record date for the determination of stockholders entitled to notice of, and to vote at, the special meeting and any adjournment or postponement thereof. Only holders of record of shares of Nuvelo common stock at the close of business on the record date are entitled to notice of, and to vote at, the special meeting. At the close of business on the record date, Nuvelo had 53,663,805 shares of common stock outstanding and entitled to vote.

Your vote is important. The affirmative vote of the holders of a majority of the votes cast in person or by proxy at the Nuvelo special meeting is required for approval of Proposals No. 1 and No. 4 above and the affirmative vote of at least a majority of Nuvelo s issued and outstanding shares of common stock is required for approval of Proposals No. 2 and No. 3 above. Even if you plan to attend the special meeting in person, please sign and return the enclosed proxy and thus ensure that your shares will be represented at the special meeting if you are unable to attend. If you sign, date and mail your proxy card without indicating how you wish to vote, your proxy will be counted as a vote in favor of Proposals No. 1, No. 2, No. 3 and No. 4. If you fail to return your proxy card, the effect will be that your shares will not be counted for purposes of determining whether a quorum is present at the special meeting. You may revoke your proxy in the manner described in this document before it has been voted at the special meeting. If you decide to attend the Nuvelo special meeting, you may withdraw your proxy and vote in person.

By Order of the Board of Directors,

By:

Lee Bendekgey Secretary

San Carlos, California

November 21, 2008

THE NUVELO BOARD OF DIRECTORS HAS DETERMINED AND BELIEVES THAT EACH OF THE PROPOSALS OUTLINED ABOVE IS ADVISABLE, AND IN THE BEST INTERESTS OF, NUVELO AND ITS STOCKHOLDERS AND HAS APPROVED EACH SUCH PROPOSAL. THE NUVELO BOARD OF DIRECTORS RECOMMENDS THAT NUVELO STOCKHOLDERS VOTE FOR EACH SUCH PROPOSAL.

To the Stockholders of ARCA biopharma, Inc.:

On September 24, 2008, ARCA biopharma, Inc. and Nuvelo, Inc. entered into an agreement and plan of merger and reorganization, which was amended on October 28, 2008. Under the merger agreement, a wholly-owned subsidiary of Nuvelo, Dawn Acquisition Sub, Inc., will merge with and into ARCA, with ARCA continuing after the merger as the surviving corporation and a wholly-owned subsidiary of Nuvelo. At the effective time of the merger, each share of ARCA capital stock issued and outstanding immediately prior to the merger (other than shares held by any wholly-owned subsidiary of ARCA, or by Nuvelo, merger sub or any other subsidiary of Nuvelo) will automatically convert into the right to receive a number of shares of Nuvelo common stock determined according to the exchange ratio described in the merger agreement. In addition, Nuvelo will assume options and warrants to purchase shares of ARCA capital stock.

Following the merger, and subject to adjustment in accordance with the merger agreement, current stockholders of Nuvelo are expected to own approximately 33% of the combined company, and current ARCA stockholders are expected to own approximately 67% of the combined company. These percentages give effect to the issuance of shares pursuant to ARCA s outstanding options and warrants primarily on a treasury-method basis, and do not give effect to any shares issuable pursuant to Nuvelo s outstanding options and warrants. The actual number of shares of Nuvelo common stock to be issued in respect of each share of capital stock of ARCA will be determined by dividing an aggregate of 109,009,278 shares of Nuvelo common stock by the number of shares of ARCA common stock outstanding and deemed outstanding pursuant to the formula set forth in the merger agreement and described herein under The Merger Agreement. The exact exchange ratio per share of ARCA s capital stock will depend upon the number of shares of ARCA s capital stock outstanding or issuable pursuant to ARCA s outstanding convertible notes, options and warrants immediately prior to the effective time of the merger and the closing price per share of Nuvelo s common stock for the five consecutive days immediately proceeding the effective time of the merger and will not be calculated until that time.

Nuvelo s common stock is traded on the Nasdaq Global Market under the symbol NUVO and on November 21, 2008, the closing sale price of Nuvelo common stock was \$0.27 per share. Following the merger, the combined company is expected to be renamed ARCA biopharma, Inc. and to change its symbol for trading on the Nasdaq Global Market. ARCA has reserved the symbol ABIO for this purpose.

As described in this proxy statement/prospectus/consent solicitation, Nuvelo is holding a special meeting of its stockholders in order to obtain its stockholder approvals necessary to complete the merger. ARCA is soliciting written consents in order to obtain the stockholder approval of ARCA necessary to complete the merger.

This proxy statement/prospectus/consent solicitation provides you with information about Nuvelo, ARCA and the proposed merger. We encourage you to read carefully the entire proxy statement/prospectus/consent solicitation. In particular, you should carefully consider the matters discussed under _Risk Factors beginning on page 28.

Richard B. Brewer President and Chief Executive Officer

Broomfield, Colorado

November 21, 2008

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THE MERGER OR THE NUVELO COMMON STOCK TO BE ISSUED IN THE MERGER OR DETERMINED IF THIS PROXY STATEMENT/PROSPECTUS/CONSENT SOLICITATION IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

This proxy statement/prospectus/consent solicitation is dated , 2008, and is being first mailed to stockholders of ARCA on or about November 25, 2008.

THIS PROXY STATEMENT/PROSPECTUS/CONSENT SOLICITATION IS NOT AN OFFER TO SELL ANY SECURITIES AND IT IS NOT SOLICITING AN OFFER TO BUY ANY SECURITIES IN ANY JURISDICTION WHERE THE OFFER OR SALE IS NOT PERMITTED.

SOLICITATION OF WRITTEN CONSENT IN LIEU OF A MEETING

OF THE STOCKHOLDERS OF ARCA BIOPHARMA, INC.

To the Stockholders of ARCA biopharma, Inc.:

The purpose of this solicitation of written consent in lieu of a meeting of ARCA stockholders is to adopt and approve the Agreement and Plan of Merger and Reorganization dated as of September 24, 2008, by and among Nuvelo, Inc., a Delaware corporation, Dawn Acquisition Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Nuvelo, and ARCA, as amended by that Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated October 28, 2008, by and among Nuvelo, Inc., Dawn Acquisition Sub, Inc., and ARCA, and to approve the merger and the transactions contemplated thereby. A copy of the Agreement and Plan of Merger and Reorganization is attached as *Annex A* to the accompanying proxy statement/prospectus/consent solicitation and a copy of Amendment No.1 to Agreement and Plan of Merger and Reorganization is attached as *Annex B* to the accompanying proxy statement/prospectus/consent solicitation. In addition, by consenting to the adoption of the merger agreement and approving the merger and transactions contemplated thereby, each ARCA stockholder is acknowledging that (i) such stockholder is consent to the adoption of the merger agreement and approval of the merger is irrevocable; (ii) such stockholder is aware of its rights to demand appraisal for its shares pursuant to Section 262 of the Delaware General Corporation Law, which we refer to as the DGCL, and that such stockholder has received and read a copy of Section 262 of the DGCL; and (iii) such stockholder is not entitled to appraisal rights with respect to its shares in connection with the merger and that the stockholder hereby waives any rights to receive payment of the fair value of ARCA capital stock under the DGCL.

In accordance with the DGCL, the record date for determination of the holders of ARCA common stock and ARCA preferred stock entitled to vote by written consent shall be the first date on which a signed written consent approving the merger is delivered to ARCA. Only holders of record of shares of ARCA common stock and ARCA preferred stock at the close of business on the record date are entitled to vote by written consent. On November 20, 2008, ARCA had 5,713,818 shares of common stock and 15,677,836 shares of preferred stock, consisting of 9,222,257 shares of Series A preferred stock, 3,688,902 shares of Series B-1 preferred stock and 2,766,677 shares of Series B-2 preferred stock, outstanding and entitled to vote.

Your consent is important. The affirmative consent of the holders of (a) a majority of the shares of ARCA common stock and ARCA preferred stock, voting together as a single class, with holders of ARCA preferred stock voting on an as-converted basis and (b) a majority of the following ARCA stockholders, who we refer to as the Principal Series Preferred Stockholders: Atlas Venture Fund VII, L.P. and its affiliates, Boulder Ventures IV, L.P. and Boulder Ventures IV (Annex), L.P. and their respective affiliates, Skyline Venture Partners Qualified Purchaser Fund IV, L.P. and its affiliates, and InterWest Partners IX, L.P. and its affiliates is required to approve the proposal. If you fail to return your signed written consent, the effect will be that your shares will counted as votes against the proposal. Once you return your signed written consent, you may not revoke it. As described more fully under the heading Written Consent of ARCA Stockholders below, all written consents to ARCA proposals must be received at ARCA s executive offices no later than November 28, 2008.

Pursuant to certain voting agreements with ARCA, the holders of approximately 84.97% of ARCA s outstanding capital stock including approximately 92.11% of ARCA s outstanding preferred stock, on an as converted basis, and all of the Principal Series Preferred Stockholders, have agreed to consent to the proposal.

Under the DGCL, holders of ARCA s capital stock who do not execute a written consent to the adoption of the proposal will have the right to seek appraisal of the fair value of their shares as determined by the Delaware Court of Chancery if the merger is completed, but only if they submit a written demand for an appraisal within 20 days after the mailing of notice by ARCA that the merger was approved by written consent of the ARCA stockholders and they comply with the other procedures under the DGCL explained in the accompanying proxy statement/prospectus/consent solicitation. See The Merger Appraisal Rights beginning on page 101 of the accompanying proxy statement/prospectus/consent solicitation.

Your consent is important. Please complete, sign, date and return your consent in the enclosed envelope promptly. Please do not send any ARCA stock certificates at this time. After the merger is completed, you will receive written instructions for receiving your Nuvelo stock certificates.

By Order of ARCA s Board of Directors,

Richard B. Brewer President and Chief Executive Officer

Broomfield, Colorado

November 21, 2008

THE ARCA BOARD OF DIRECTORS HAS DETERMINED AND BELIEVES THAT THE PROPOSAL OUTLINED ABOVE IS ADVISABLE TO, AND IN THE BEST INTERESTS OF, ARCA AND ITS STOCKHOLDERS AND HAS APPROVED SUCH PROPOSAL. THE ARCA BOARD OF DIRECTORS RECOMMENDS THAT ARCA STOCKHOLDERS CONSENT TO SUCH PROPOSAL.

TABLE OF CONTENTS

	Page
QUESTIONS AND ANSWERS ABOUT THE MERGER, THE NUVELO SPECIAL MEETING AND THE ARCA CONSENT	
<u>SOLICITATION</u>	1
<u>SUMMARY</u>	8
MARKET PRICE AND DIVIDEND INFORMATION	19
SELECTED HISTORICAL FINANCIAL DATA	21
SELECTED UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL DATA	24
COMPARATIVE HISTORICAL AND UNAUDITED PRO FORMA PER SHARE DATA	27
RISK FACTORS	28
Risks Related to the Proposed Merger and Combined Company	28
Risks Related to Nuvelo	36
Risks Related to Nuvelo s Capital Structure and Financial Results and Stock Price Volatility	46
Risks Related to Nuvelo Intellectual Property and Other Legal Matters	53
Risks Related to ARCA s Business	57
FORWARD-LOOKING INFORMATION	71
THE SPECIAL MEETING OF NUVELO STOCKHOLDERS	72
<u>Date</u> , <u>Time and Place</u>	72
Purposes of the Nuvelo Special Meeting	72
Recommendation of the Nuvelo Board of Directors	72
Record Date and Voting Power	73
<u>Voting and Revocation of Proxies</u>	73
Quorum and Required Vote	75
Solicitation of Proxies	75
Other Matters	75
NUVELO PROPOSAL NO. 1 APPROVAL OF ISSUANCE OF SHARES OF NUVELO COMMON STOCK IN THE MERGER	76
THE MERGER	76
General Description of the Merger	76
Background of the Merger	76
Reasons for the Merger	80
Opinion of Nuvelo s Financial Advisor	85
Officers and Directors of the Combined Company Following the Merger	94
Interests of Nuvelo s Executive Officers and Directors in the Merger	94
Interests of ARCA s Executive Officers and Directors in the Merger	97
Stock Options	100
<u>Warrants</u>	100
ARCA Preferred Stock	100
Convertible Promissory Notes and Warrants	101
Regulatory Approvals	101
<u>Appraisal Rights</u>	101
Material U.S. Federal Income Tax Consequences of the Merger	104
Anticipated Accounting Treatment	106
Vote Required; Recommendation of Board of Directors	106
THE MERGER AGREEMENT	107
<u>General</u>	107
<u>Closing of the Merger</u>	107
Merger Consideration	107
Assumption of ARCA Stock Options and Warrants	109
<u>Fractional Shares</u>	109
Exchange of ARCA Stock Certificates	109

i

Table of Contents

	Page
Amended and Restated Certificate of Incorporation of Nuvelo	110
Conditions to the Completion of the Merger	110
Conduct of Business Prior to the Merger	111
Limitation on Soliciting, Discussing or Negotiating Other Acquisition Proposals	114
Change in Recommendation	115
Meeting of Stockholders; Stockholder Consent	116
Other Agreements	116
Representations and Warranties	117
Material Adverse Effect	118
Termination of the Merger Agreement	119
Termination Fees	121
Amendment and Waiver of the Merger Agreement	121
OTHER AGREEMENTS RELATED TO THE MERGER	123
Voting Agreements	123
Note and Warrant Purchase Agreement	125
NUVELO PROPOSAL NO. 2 AMENDMENT TO AMENDED AND RESTATED CERTIFICATE OF INCORPORATION TO	
EFFECT A REVERSE STOCK SPLIT OF NUVELO S COMMON STOCK	126
<u>Overview</u>	126
Reasons for the Reverse Stock Split	126
Effects of the Reverse Stock Split	128
Effective Date	129
Payment for Fractional Shares	129
Exchange of Stock Certificates	129
Accounting Consequences	129
Material U.S. Federal Income Tax Consequences of the Reverse Stock Split	129
No Appraisal Rights	131
Vote Required; Recommendation of Board of Directors	132
NUVELO PROPOSAL NO. 3 AMENDMENT TO AMENDED AND RESTATED CERTIFICATE OF INCORPORATION TO	102
INCREASE THE AUTHORIZED SHARES OF NUVELO COMMON STOCK	133
<u>Overview</u>	133
Reasons for the Increase in Authorized Shares	133
Effects of the Increase in Authorized Shares	133
Vote Required; Recommendation of Board of Directors	134
NUVELO PROPOSAL NO. 4 APPROVAL OF POSSIBLE ADJOURNMENT OF THE SPECIAL MEETING	135
Overview	135
Vote Required; Recommendation of Board of Directors	135
WRITTEN CONSENT OF ARCA STOCKHOLDERS	136
ARCA PROPOSAL APPROVAL OF THE MERGER, MERGER AGREEMENT AND THE TRANSACTIONS CONTEMPLATED	130
THEREBY	136
Recommendations of ARCA s Board of Directors	136
Record Date and Voting Power	136
Irrevocability of Written Consents	137
Execution and Delivery of Written Consents	137
Required Consent	137
Appraisal Rights	137
Appraisal rights INFORMATION ABOUT NUVELO S BUSINESS	137
Overview	138
Nuvelo s Strategy	140
Corporate Information	140
Corporate information	141

ii

Table of Contents

	Page
Research and Development Collaborations	141
<u>Manufacturing</u>	143
Patents and Trade Secrets	143
<u>Competition</u>	144
Government Regulation	144
Human Resources	145
<u>Properties</u>	145
Legal Proceedings	146
<u>INFORMATION ABOUT ARCA S BUSINES</u> S	148
<u>Overview</u>	148
Market Opportunity	149
ARCA Strategy	150
<u>Gencaro</u>	150
The Gencaro Test	156
Marketing and Sales	156
Competition	157
Other Potential Indications for Gencaro	157
Manufacturing and Product Supply	158
Government Regulation	158
Intellectual Property	163
Employees Employees	164
Facilities	164
Legal Proceedings	164
MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS FOR	
NUVELO	165
<u>Overview</u>	165
Results of Operations	167
Liquidity and Capital Resources	172
Selected Quarterly Financial Data (Unaudited)	175
Critical Accounting Policies and Estimates	175
Recent Accounting Pronouncements	180
Off-Balance Sheet Arrangements	180
Indemnifications	181
NUVELO QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	182
MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS FOR ARCA	183
Overview	183
Critical Accounting Policies and Estimates	184
Results of Operations	189
Liquidity and Capital Resources	191
Recent Accounting Pronouncements	194
Off-Balance Sheet Arrangements	194
ARCA QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK	195
ARCA CONTROLS AND PROCEDURES	196
MANAGEMENT OF THE COMBINED COMPANY AFTER THE MERGER	197
Executive Officers and Directors	197
	200
Committees of the Board of Directors Compensation of Directors	200
EXECUTIVE COMPENSATION AND OTHER INFORMATION	201
ARCA s Compensation Discussion and Analysis	202
ARCA's Compensation Discussion and Analysis Compensation Committee Interlocks and Insider Participation in Compensation Decisions	202
Compensation Committee interfocks and insider farticipation in Compensation Decisions	207

iii

Table of Contents

	Page
Summary Compensation Table	207
Grants of Plan-Based Awards	208
Holdings of Previously Awarded Equity	208
Option Exercises and Stock Vested	209
Employment Agreements and Potential Payment Upon Termination or Change of Control	209
Quantification of Termination Payments and Benefits	211
ARCA 2004 Stock Incentive Plan	213
ARCA 401(k) Plan	216
Compensation of Directors	216
Non-Employee Director Compensation	217
RELATED PARTY TRANSACTIONS INVOLVING DIRECTORS AND EXECUTIVE OFFICERS FOLLOWING THE MERGER	219
<u>Nuvelo Transactions</u>	219
ARCA Transactions	219
Procedures for Approval of Related Person Transactions	223
NUVELO SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	224
ARCA SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	226
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT FOLLOWING THE MERGER	230
<u>DESCRIPTION OF NUVELO_S CAPITAL STOC</u> K	233
Preferred Stock	233
Common Stock	233
Limitation of Liability and Indemnification	233
Additional Information Concerning Nuvelo s Capital Stock	234
COMPARATIVE RIGHTS OF NUVELO STOCKHOLDERS AND ARCA STOCKHOLDERS	236
UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS	248
<u>LEGAL MATTERS</u>	258
<u>EXPERTS</u>	258
WHERE YOU CAN FIND MORE INFORMATION	259
INDEX TO FINANCIAL STATEMENTS	F-1
ANNEXES:	

- A Agreement and Plan of Merger
- B Amendment No. 1 to Agreement and Plan of Merger and Reorganization
- C Form of Nuvelo Voting Agreement
- D Form of ARCA Voting Agreement
- E Opinion of Jefferies & Company, Inc.
- F Certificate of Amendment to the Amended and Restated Certificate of Incorporation to Effect a Reverse Stock Split
- G Certificate of Amendment to the Amended and Restated Certificate of Incorporation to Increase the Authorized Shares of Nuvelo Common Stock
- H Section 262 of the Delaware General Corporation Law

Nuvelo was incorporated as Hyseq, Inc. in Illinois in 1992 and reincorporated in Nevada in 1993. On January 31, 2003, Hyseq merged with Variagenics, Inc., a publicly traded Delaware corporation based in Massachusetts, and, in connection with the merger, changed its name to Nuvelo, Inc. On March 25, 2004, Nuvelo reincorporated from Nevada to Delaware. Nuvelo s principal executive offices are located at 201 Industrial Road, Suite 310, San Carlos, California 94070.

Nuvelo files its annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 electronically with the Securities and Exchange Commission, or SEC. The public may read or copy any materials Nuvelo files with the SEC at the SEC s Public Reference Rooms at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov.

You may obtain a free copy of Nuvelo s annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports on the day of filing with the SEC on Nuvelo s website, on the Internet at http://www.nuvelo.com or by contacting the Investor Relations Department at Nuvelo s corporate office by calling (650) 517-8000 or sending an e-mail message to ir@nuvelo.com. Information found on Nuvelo s website is not incorporated by reference into this proxy statement/prospectus/consent solicitation.

v

QUESTIONS AND ANSWERS ABOUT THE MERGER, THE NUVELO SPECIAL MEETING AND THE ARCA CONSENT SOLICITATION

The following section provides answers to frequently asked questions about the merger, the effect of the merger on holders of Nuvelo common stock and ARCA common stock and preferred stock, the Nuvelo special meeting and the ARCA consent solicitation. This section, however, only provides summary information. Nuvelo and ARCA urge you to read carefully the remainder of this proxy statement/prospectus/consent solicitation, including the annexes to this proxy statement/prospectus/consent solicitation, because the information in this section does not provide all the information that might be important to you regarding the merger and the other matters being considered at Nuvelo s special meeting and in the ARCA consent solicitation.

As used in this proxy statement/prospectus/consent solicitation, references to Nuvelo refer collectively to Nuvelo, Inc. and all of its subsidiaries unless the context requires otherwise and references to ARCA refer to ARCA biopharma, Inc.

Q: What is the merger?

A: Nuvelo, ARCA, and Dawn Acquisition Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Nuvelo, have entered into an Agreement and Plan of Merger dated as of September 24, 2008, as amended by that Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated October 28, 2008, by and among Nuvelo, Dawn Acquisition Sub, Inc. and ARCA, which, as amended, unless otherwise indicated, is referred to in this proxy statement/prospectus/consent solicitation as the merger agreement, that contains the terms and conditions of the proposed business combination of Nuvelo and ARCA. Pursuant to the merger agreement, on the terms and conditions set forth therein, Dawn Acquisition Sub, Inc. will be merged with and into ARCA, with ARCA surviving the merger as a wholly-owned subsidiary of Nuvelo.

Q: What will ARCA s stockholders receive in the merger?

Nuvelo has agreed to issue, and holders of ARCA capital stock will receive, shares of Nuvelo common stock such that following the consummation of the transactions contemplated by the merger agreement, current stockholders of Nuvelo are expected to own approximately 33% of the common stock of the combined company, and current ARCA stockholders are expected to own or have the right to acquire approximately 67% of the combined company, after giving effect to the shares issuable pursuant to ARCA s outstanding options and warrants, primarily on a treasury method basis, and without giving effect to any shares issuable pursuant to Nuvelo s outstanding options and warrants. Immediately prior to the effective time of the merger, all outstanding shares of ARCA preferred stock will convert automatically into shares of ARCA common stock at the then applicable conversion rate, and the outstanding principal and accrued interest under ARCA s 6% convertible promissory notes dated October 10, 2008 will convert automatically into shares of ARCA common stock at the conversion price stated in the notes. The actual number of shares of Nuvelo common stock to be issued in respect of each share of capital stock of ARCA will be determined by dividing an aggregate of 109,009,278 shares of Nuvelo common stock by the number of shares of ARCA common stock outstanding and deemed outstanding pursuant to the formula set forth in the merger agreement and described herein and under The Merger Agreement. The exact exchange ratio per share of ARCA s capital stock will depend upon the number of shares of ARCA s common stock outstanding or issuable pursuant to the conversion of ARCA s outstanding preferred stock and convertible notes and the exercise of ARCA s outstanding options and warrants immediately prior to the effective time of the merger and the closing price per share of Nuvelo s common stock for the five consecutive days immediately proceeding the effective time of the merger and will not be calculated until that time.

Q: Why are the two companies proposing to merge?

A: Nuvelo and ARCA believe that the combined company resulting from the merger will have a number of potential advantages, including the increased scale of a larger cardiovascular focused biotechnology company with a near term commercial opportunity represented by ARCA s product candidate, Gencaro, and

1

longer term product development opportunities represented by Nuvelo s product candidate, NU172, more secure capitalization to support product candidates and other significant potential management and business synergies and cost savings that Nuvelo and ARCA believe can be achieved by consolidating the infrastructures of the two companies and allowing management to fully leverage the combined research, development and administrative capabilities across multiple potential product candidates.

Q: What is the reverse stock split and why is it necessary?

A: Immediately prior to the effective time of the merger, the outstanding shares of Nuvelo s common stock will be reclassified and combined into a lesser number of shares to be determined by Nuvelo s board of directors prior to the effective time and publicly announced by Nuvelo. The merger constitutes a reverse merger under applicable marketplace rules established by Nasdaq, which requires the combined company to comply with the initial listing standards of the applicable Nasdaq market to continue to be listed on such market following the merger. The Nasdaq Global Select Market s and Nasdaq Global Market s initial listing standards require a company to have, among other things, a \$5.00 per share minimum bid price and the Nasdaq Capital Market s initial listing standards require a company to have, among other things, a \$4.00 per share minimum bid price. Because it is a condition precedent to the merger that Nuvelo s common stock be listed on any of the Nasdaq Global Select Market, the Nasdaq Global Market or the Nasdaq Capital Market and the current price of Nuvelo common stock is less than the minimum bid prices required by any of these markets, unless the condition is waived, the reverse stock split is necessary to consummate the merger.

Q: Why am I receiving this proxy statement/prospectus/consent solicitation?

A: You are receiving this proxy statement/prospectus/consent solicitation because you have been identified as a stockholder of Nuvelo or a stockholder of ARCA. This document serves as a proxy statement of Nuvelo, used to solicit proxies for the special meeting, and consent solicitation for ARCA, used to solicit the written consent of its stockholders, and a prospectus of Nuvelo, used to offer shares of Nuvelo common stock to ARCA stockholders in exchange for shares of ARCA common stock pursuant to the terms of the merger agreement and to offer shares of Nuvelo common stock to holders of warrants and options exercisable into shares of ARCA capital stock, which warrants and options are to be assumed by Nuvelo in the merger. If you are a stockholder of Nuvelo, you are entitled to vote at Nuvelo s special meeting. If you are a stockholder of ARCA, you are entitled to execute a written consent in lieu of a vote at a meeting. This document contains important information about the merger, the shares of Nuvelo common stock to be issued in the merger and the special meeting of Nuvelo stockholders, and you should read it carefully.

Q: What Nuvelo stockholder approvals are required to consummate the merger?

A: To consummate the merger, Nuvelo stockholders must approve:

the issuance of shares of Nuvelo common stock in the merger, which requires the affirmative vote of holders of a majority of the votes cast in person or by proxy at the Nuvelo special meeting; and

the amendment to Nuvelo s certificate of incorporation to effect the reverse stock split of the issued and outstanding shares of Nuvelo s common stock, which requires the affirmative vote of holders of a majority of the outstanding shares of Nuvelo common stock as of the record date for the special meeting.

Nuvelo s stockholders are also being asked to approve an amendment to Nuvelo s certificate of incorporation to increase the number of authorized shares of Nuvelo s common stock to 250 million, which requires the affirmative vote of holders of a majority of the outstanding shares of Nuvelo common stock as of the record date for the special meeting. While approval of this proposal is not required to consummate the merger, the Nuvelo board of directors has determined that the proposal is advisable, and in the best interests of, Nuvelo and its stockholders and recommends that you vote for this proposal.

In connection with the execution of the merger agreement, Ted W. Love and Lee Bendekgey, both officers of Nuvelo, and Mark Perry, a director of Nuvelo, entered into voting agreements with ARCA that provide, among other things, that they will vote in favor of the issuance of Nuvelo common stock pursuant to the

2

merger agreement and the amendment of Nuvelo s amended and restated certificate of incorporation to effect the reverse stock split and grant to ARCA an irrevocable proxy to vote all of their shares of Nuvelo common stock in favor of such proposals and against any proposal made in opposition to, or in competition with, such proposals.

Q: What ARCA stockholder approvals are required to consummate the merger?

A: To consummate the merger, ARCA stockholders must adopt and approve the merger agreement and approve the merger and the transactions contemplated thereby, which requires the approval of the holders of a majority of (i) the shares of ARCA common stock and ARCA preferred stock, voting together as a single class, with holders of ARCA preferred stock voting on an as-converted basis and (ii) the Principal Series Preferred Stockholders.

In connection with the execution of the merger agreement, the holders of approximately 84.97% of ARCA s outstanding common and preferred stock, including approximately 92.11% of ARCA s outstanding preferred stock, on an as converted basis, and all of the Principal Series Preferred Stockholders, have entered into voting agreements with Nuvelo that provide, among other things, that they will vote in favor of the merger and that grant to Nuvelo an irrevocable proxy to vote all of their shares of ARCA common stock and ARCA preferred stock in favor of the merger and against any proposal made in opposition to, or in competition with, the proposed merger. All of these stockholders are executive officers, directors, or entities controlled by such persons, or 5% stockholders, of ARCA, and include the Principal Series Preferred Stockholders.

Q: What other conditions must be satisfied to consummate the merger?

A: In addition to Nuvelo and ARCA obtaining stockholder approval, closing conditions include:

conditional approval for the listing of Nuvelo common stock to be issued in the merger on any of the Nasdaq Global Select Market, Nasdaq Global Market or Nasdaq Capital Market;

subject to certain exceptions, the absence of any effects, changes, events or circumstances that singularly or collectively have a material adverse effect on the business, financial condition, operations of results of operations of Nuvelo or ARCA or the ability of Nuvelo or ARCA to consummate the merger or perform their obligations under the merger agreement;

the accuracy of the representations and warranties provided by Nuvelo and ARCA pursuant to the merger agreement except where such inaccuracies do not constitute a material adverse effect;

the performance of the covenants and obligations of Nuvelo and ARCA pursuant to the merger agreement in all material respects;

the delivery of certain certifications and opinions by each party and the termination of certain stockholder and related agreements by ARCA and its stockholders; and

the absence of any injunction or order preventing the consummation of the merger or any legal proceeding in which a governmental body seeks to prohibit or restrain the consummation of the merger or otherwise materially impact the rights or operations of Nuvelo or ARCA following the consummation of the merger.

Nuvelo or ARCA may waive compliance with any closing condition intended for its benefit.

- Q: What are the material U.S. federal income tax consequences of the merger to me?
- A: The merger has been structured to qualify as a tax-free reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended, or the Code, and Nuvelo and ARCA have agreed to use their commercially reasonable efforts in order to obtain the opinion of Nuvelo s counsel, Cooley Godward Kronish LLP, and ARCA s counsel, Hogan & Hartson, LLP, regarding such qualification. Assuming that the merger qualifies as a reorganization, ARCA stockholders will not recognize gain or loss for U.S. federal income tax purposes upon the exchange of shares of ARCA capital stock for shares of Nuvelo common stock, except with respect to cash received in lieu of fractional shares of Nuvelo common stock.

3

- Q: What risks should I consider in deciding whether to vote in favor of or consent to the proposals?
- A: You should carefully review the section of this proxy statement/prospectus/consent solicitation entitled Risk Factors beginning on page 28, which sets forth certain risks and uncertainties related to the merger to which Nuvelo s and ARCA s businesses are and will be subject.
- Q: When do you expect the merger to be consummated?
- A: We anticipate that the merger will occur in the first quarter of 2009 as promptly as practicable after the Nuvelo special meeting and satisfaction or waiver of all closing conditions, but we cannot predict the exact timing.
- Q: Am I entitled to appraisal rights?
- A: Under Delaware General Corporation Law, or the DGCL, holders of Nuvelo common stock are not entitled to appraisal rights in connection with the merger or the proposals described in this proxy statement/prospectus/consent solicitation.

 Under the DGCL, ARCA stockholders who do not consent to approve the merger and who comply with the procedural requirements of Section 262 of the DGCL may demand payment in cash of the fair value of their shares of ARCA capital stock in lieu of the merger consideration, if any. These rights are commonly known as dissenters rights. If the dissenting stockholder and surviving corporation do not agree on a fair value of the shares, a court of proper jurisdiction will determine the fair value upon the dissenting stockholder s petition, which could be more than, less than or equal to the value of the merger consideration. Dissenting stockholders lose their dissenters rights if they fail to follow all of the procedures required by Section 262 of the DGCL. See The Merger Appraisal Rights beginning on page 101 of this proxy statement/prospectus/consent solicitation.
- Q: Should ARCA s and Nuvelo s stockholders send in their stock certificates now?
- A: No. After the merger is consummated, ARCA s stockholders will receive written instructions from the exchange agent for exchanging their certificates representing shares of ARCA capital stock for certificates representing shares of Nuvelo s common stock. ARCA s stockholders will also receive a cash payment for any fractional shares. Nuvelo s stockholders are not required to tender or exchange their certificates as part of the merger, but if Proposal No. 2 to effect a reverse stock split is approved and implemented, Nuvelo s stockholders will be asked by Nuvelo s transfer agent to surrender stock certificates representing pre-reverse stock split shares in exchange for post-reverse stock split shares in accordance with procedures to be set forth in a letter of transmittal.
- Q: Who is paying for this proxy and consent solicitation?
- A: Nuvelo and ARCA are conducting this proxy and consent solicitation and will each bear one-half of the costs of the proxy and consent solicitation, including the preparation, assembly, printing and mailing of this proxy statement/prospectus/consent solicitation, the proxy card and any additional information furnished to stockholders. Nuvelo and ARCA will each bear its own legal expenses. Nuvelo may also reimburse brokerage houses and other custodians, nominees and fiduciaries for their costs of forwarding proxy and solicitation materials to beneficial owners.
- Q: Who can help answer my questions?

A: If you are a Nuvelo stockholder and would like additional copies, without charge, of this proxy statement/prospectus/consent solicitation or if you have questions about the proposals described herein, including the procedures for voting your shares, you should contact: Nuvelo, Inc.

Attn: Investor Relations

201 Industrial Road, Suite 310

San Carlos, CA 94070-6211

(650) 517-8000

E-mail: ir@Nuvelo.com

4

If you are an ARCA stockholder and would like additional copies, without charge, of this proxy statement/prospectus/consent solicitation, or if you have questions about the ARCA proposal described herein, including the procedures for voting your shares by written consent, you should contact:

ARCA biopharma, Inc.

Attn: General Counsel, Executive Vice President of Business Development

8001 Arista Place, Suite 200

Broomfield, CO 80021

(720) 940-2200

E-mail: Chris.Ozeroff@arcabiopharma.com

To obtain timely delivery, ARCA stockholders must request the information before delivering their signed written consent, which must be delivered to ARCA no later than November 28, 2008.

FOR NUVELO STOCKHOLDERS:

- Q: Who is soliciting my proxy?
- A: The proxy is being solicited of Nuvelo s stockholders by Nuvelo s board of directors.
- Q: As a Nuvelo stockholder, how does Nuvelo s Board of Directors recommend that I vote?
- A: After careful consideration, Nuvelo s board of directors recommends that Nuvelo stockholders vote:
- FOR Proposal No. 1 to approve the issuance of shares of Nuvelo common stock in the merger;
- FOR Proposal No. 2 to approve the amendment to Nuvelo s amended and restated certificate of incorporation to effect a reverse stock split of the issued and outstanding shares of Nuvelo s common stock;
- FOR Proposal No. 3 to approve the amendment to Nuvelo s amended and restated certificate of incorporation to increase the number of authorized shares of Nuvelo common stock to 250 million; and
- FOR Proposal No. 4 to consider and vote upon an adjournment of the special meeting, if necessary, if a quorum is present, to solicit additional parties if there are not sufficient votes in favor of Proposals No. 1 and No. 2.
- Q: What do I need to do now?
- A: We urge you to read this proxy statement/prospectus/consent solicitation carefully, including its annexes, and to consider how the merger affects you.

If your shares of Nuvelo stock are registered directly in your name, you may provide your proxy instructions in four different ways. First, you can mail your signed proxy card in the enclosed return envelope. Alternatively, you can provide your proxy instructions via the toll-free call

center set up for this purpose at 1-877-816-0836. You can also provide your proxy instructions via the Internet at http://proxy.georgeson.com. Finally, you can deliver your completed proxy card in person or by completing a ballot in person at the special meeting. Please provide your proxy instructions only once and as soon as possible so that your shares can be voted at the special meeting of Nuvelo stockholders.

If your Nuvelo shares are held in a brokerage account in street name or by another nominee, your broker will not be able to vote your shares of Nuvelo common stock without instructions from you. You should instruct your broker to vote your shares, following the procedure provided by your broker.

- Q: What happens if I do not return a proxy card or otherwise provide proxy instructions?
- A: If you do not submit a proxy card or vote at the special meeting, your shares will not be counted as present for the purpose of determining the presence of a quorum. Also, not submitting a proxy card or voting at the special meeting will have no effect on the approval of Proposals No. 1 or No. 4 but will have the same effect

5

as voting against Proposals No. 2 and No. 3. Broker non-votes will similarly have no effect on the approval of Proposals No. 1 or No. 4, but will have the same effect as voting against Proposals No. 2 and No. 3. If you submit a proxy card and affirmatively elect to abstain from voting, your proxy will be counted as present for the purpose of determining the presence of a quorum but will not be voted at the meeting. As a result, your abstention will have no effect on the approval of Proposals No. 1 or No. 4, but will have the same effect as voting against Proposals No. 2 and No. 3.

Q: May I vote in person?

A: If your shares of Nuvelo common stock are registered directly in your name with Nuvelo s transfer agent you are considered, with respect to those shares, the stockholder of record, and the proxy materials and proxy card are being sent directly to you. If you are a Nuvelo stockholder of record as of November 11, 2008, you may attend the special meeting of Nuvelo stockholders to be held on January 7, 2009 and vote your shares in person, rather than signing and returning your proxy card or otherwise providing proxy instructions. However, we urge you to return your proxy card with your voting instructions in any event, just in case your plans should change.

If your shares of Nuvelo common stock are held in a brokerage account or by another nominee, you are considered the beneficial owner of shares held in street name, and the proxy materials are being forwarded to you together with a voting instruction card. As the beneficial owner, you are also invited to attend the special meeting of Nuvelo stockholders. Since a beneficial owner is not the stockholder of record, you may not vote these shares in person at the special meeting unless you obtain a legal proxy from the broker, trustee or nominee that holds your shares, giving you the right to vote the shares at the meeting.

Q: May I change my vote after I have provided proxy instructions?

A: Any stockholder of record, other than those stockholders who have executed voting agreements, has the right to revoke the proxy any time before its proxy is voted at the special meeting by sending a written notice stating that it would like to revoke the proxy, by submitting new proxy instructions either on a new proxy card, by telephone or via the Internet, or by attending the special meeting and voting in person. Attendance alone at the special meeting will not revoke your proxy. If a Nuvelo stockholder has instructed a broker to vote shares of Nuvelo common stock held in street name, the stockholder must follow directions received from the broker to change those instructions.

Who is soliciting my written consent?

FOR ARCA STOCKHOLDERS:

- A: The written consent is being solicited of ARCA stockholders by ARCA s board of directors.
- Q: As an ARCA stockholder, how does ARCA s Board of Directors recommend that I vote?
- A: After careful consideration, ARCA s board of directors recommends that ARCA stockholders affirmatively consent to adopt and approve the merger agreement and to approve the merger and the transactions contemplated thereby.

Q: What do I need to do now?

A: We urge you to read this proxy statement/prospectus/consent solicitation carefully, including its annexes, and to consider how the merger affects you. Then, please execute and deliver the written consent to ARCA in the enclosed envelope at ARCA biopharma, Inc., Attn:

General Counsel, 8001 Arista Place, Suite 200, Broomfield, CO 80021. Please provide your signed written consent as soon as possible and

no later than November 28, 2008.

6

- Q: What happens if I do not return a written consent?
- A: If you do not return your signed written consent, it will have the same effect as voting against the merger, the merger agreement and the transactions contemplated thereby.
- Q: May I provide my written consent in person?
- A: No. ARCA will not be holding a special meeting. The written consent is provided in lieu of a special meeting.
- Q: May I change or revoke my vote after I have provided a signed written consent?
- A: No. By consenting to the adoption of the merger agreement and approving the merger and transactions contemplated thereby, each ARCA stockholder is acknowledging, among other matters, that such stockholder is consent to the adoption of the merger, the merger agreement and the transactions contemplated thereby is irrevocable. You may not change or revoke your consent once it is provided.

7

SUMMARY

This summary highlights selected information from this proxy statement/prospectus/consent solicitation. To understand the merger fully, you should read carefully this entire document and the documents to which we refer, including the annexes attached hereto. See Where You Can Find More Information on page 259. A copy of the merger agreement is attached as Annex A to the accompanying proxy statement/prospectus/consent solicitation and a copy of the amendment to the merger agreement is attached as Annex B to the accompanying proxy statement/prospectus/consent solicitation. You are encouraged to read the merger agreement as it is the legal document that governs the merger. Page references to this proxy statement/prospectus/consent solicitation have been included in parentheses to direct you to a more detailed description of the topics presented in this summary.

The Companies

Nuvelo, Inc.

201 Industrial Road, Suite 310

San Carlos, CA 94070-6211

(650) 517-8000

Nuvelo is a biopharmaceutical company 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 that has completed Phase 1 development for use as a short-acting anticoagulant during medical or surgical procedures, and Phase 1 clinical candidate NU206, a recombinant, secreted protein for the potential treatment of gastrointestinal, or GI, diseases, including cancer therapy induced mucositis and inflammatory bowel disease, in addition to bone disease and wound healing. Nuvelo anticipates initiating a Phase 2 study evaluating NU172 in coronary artery bypass graft patients in the first half of 2009. Nuvelo initiated a Phase 1 single ascending dose trial of NU206 in healthy volunteers in July 2008 and expects data from the trial in the fourth quarter of 2008. Nuvelo also plans to initiate a Phase 1b multiple ascending dose trial in healthy volunteers in the fourth quarter of 2008 or first quarter of 2009. In addition to its NU172 and NU206 development programs, Nuvelo has research programs in leukemia therapeutic antibodies and Wnt signaling pathway therapeutics.

ARCA biopharma, Inc.

8001 Arista Place, Suite 200

Broomfield, CO 80021

(720) 940-2200

ARCA is a privately-held biopharmaceutical company developing genetically-targeted therapies for heart failure and other cardiovascular diseases. ARCA is currently developing Gencaro, a pharmacologically unique beta-blocker and mild vasodilator, for the treatment of heart failure and other indications. The U.S. Food and Drug Administration, or FDA, accepted for filing ARCA s New Drug Application, or NDA, for Gencaro in September 2008. The name Gencaro has not yet been approved for use by the FDA. ARCA was originally organized in 2001 as a Colorado corporation and reincorporated to Delaware in 2004.

Dawn Acquisition Sub, Inc.

201 Industrial Road, Suite 310

San Carlos, CA 94070-6211

(650) 517-8000

Dawn Acquisition Sub, Inc. is a wholly-owned subsidiary of Nuvelo that was incorporated in Delaware in September 2008. Dawn Acquisition Sub, Inc. does not engage in any operations and exists solely to facilitate the merger.

8

Summary of the Merger (see page 76)

If the merger is consummated, ARCA and Dawn Acquisition Sub, Inc. will merge, with ARCA surviving as a wholly-owned subsidiary of Nuvelo. It is anticipated that shortly after the merger Nuvelo will change its name to ARCA biopharma, Inc. A copy of the merger agreement is attached as *Annex A* to this proxy statement/prospectus/consent solicitation and a copy of the amendment to the merger agreement is attached as *Annex B* to this proxy statement/prospectus/consent solicitation. You are encouraged to read the merger agreement in its entirety because it is the legal document that governs the merger.

Reasons for the Merger (see page 80)

Mutual Reasons for the Merger

Nuvelo and ARCA believe that the combined company resulting from the merger will have the following potential advantages:

the combined company will be a larger cardiovascular focused biotechnology company with a near term commercial opportunity represented by ARCA s product candidate, Gencaro, and longer term product development opportunities represented by Nuvelo s product candidate, NU 172;

the combined company will be more securely capitalized to commercialize its late stage product candidate and develop its pipeline of longer term product candidates; and

there are significant potential synergies and cost savings that Nuvelo and ARCA believe can be achieved by consolidating the infrastructures of the two companies and allowing management to fully leverage the combined research, development and administrative capabilities across multiple potential product candidates.

Each of the boards of directors of Nuvelo and ARCA also considered other reasons for the merger.

Nuvelo s board of directors considered, among other things:

Nuvelo s limited prospects if it were to remain an independent, standalone company as a result of factors such as the absence of a late-stage product candidate, its declining cash balance, the expenses and fixed costs associated with its operations and its prospects for development and commercialization of Nuvelo s early stage product candidates, particularly given its limited resources;

the opportunity for Nuvelo s stockholders to participate in the potential future value of the combined company;

Nuvelo s board of directors view as to the potential for other third parties to enter into strategic relationships with or acquire Nuvelo on favorable terms, if at all, based on the interest expressed by other third parties during the strategic alternatives review process undertaken by Nuvelo; and

the belief that the merger was more favorable to Nuvelo s stockholders than any other alternative reasonably available to Nuvelo and its stockholders, including the alternative of remaining an independent, standalone company.

ARCA s board of directors considered, among other things:

ARCA s additional capital requirements, which ARCA anticipates can be met with Nuvelo s available cash, together with ARCA s other cash resources, to fund ARCA s projected operating requirements through the end of 2009, beyond the expected date of FDA approval of Gencaro; and, given market conditions, the benefits of this option over others considered by ARCA to finance its operations, such as an equity offering;

9

Nuvelo s longer term product development opportunities represented by its product candidate, NU172, that would be complimentary to development efforts undertaken for Gencaro;

ARCA s ability to leverage Nuvelo s other non-cardiovascular candidates and research platforms and its experienced clinical, regulatory and administrative employees as a compliment to ARCA s own employees; and

the merger with Nuvelo will enhance the combined company s access to capital, providing ARCA with a greater range of options than if it continued as a privately-held company.

Opinion of Nuvelo s Financial Advisor (see page 85)

Jefferies & Company, Inc., or Jefferies, served as Nuvelo s financial advisor in connection with the proposed transaction. On September 24, 2008, Jefferies delivered to the board of Nuvelo its oral opinion, subsequently confirmed in writing on such date, to the effect that, as of that date and based upon and subject to the various assumptions made, procedures followed, matters considered and limitations described in its opinion, the Exchange Ratio, representing the amount of shares of Nuvelo common stock to be exchanged for ARCA capital stock in the merger pursuant to the terms of the merger agreement, was fair, from a financial point of view, to Nuvelo.

Jefferies opinion was provided for the use and benefit of the Nuvelo board in its consideration of the proposed transaction. Jefferies opinion did not address the relative merits of the proposed transaction as compared to any alternative transaction or opportunity that might be available to Nuvelo, nor did it address the underlying business decision by Nuvelo to engage in the proposed transaction or the terms of the merger agreement or the documents referred to therein. Furthermore, Jefferies opinion did not constitute a recommendation as to how any holder of Nuvelo common stock should vote on the proposed transaction or any matter related thereto. The full text of Jefferies written opinion, dated September 24, 2008, is attached as *Annex E* to this proxy statement/prospectus/consent solicitation and is incorporated into this proxy statement/prospectus/consent solicitation by reference. Nuvelo urges its stockholders to read carefully Jefferies entire opinion. See the section captioned The Merger Opinion of Nuvelo s Financial Advisor beginning on page 85.

Overview of the Merger Agreement

Merger Consideration (see page 107)

At the effective time of the merger, each share of ARCA capital stock not held by Nuvelo, or any subsidiary of Nuvelo, shall be converted into a right to receive a number of shares of Nuvelo common stock equal to the Exchange Ratio. The Exchange Ratio is determined immediately prior to the effective time of the merger by dividing 109,009,278 by the number of shares of ARCA common stock outstanding and deemed to be outstanding pursuant to a formula set forth in the merger agreement.

Pursuant to the terms of the merger agreement, ARCA and Nuvelo have agreed upon a methodology to determine the shares of ARCA common stock outstanding and deemed outstanding which is dependent on the number of shares of ARCA capital stock outstanding and issuable upon the conversion of ARCA s outstanding preferred stock and convertible notes and the exercise of ARCA s outstanding options and warrants as well as the average closing price of Nuvelo s common stock for the five trading days preceding the date the merger is consummated. For illustration purposes, assuming the merger closed on November 19, 2008, and based on the respective capitalizations of Nuvelo and ARCA on November 19, 2008, the Exchange Ratio would have been 3.3395 per share of ARCA capital stock. Nuvelo and ARCA have used this assumed Exchange Ratio of 3.3395 elsewhere in this proxy statement/prospectus/consent solicitation to reflect, for illustration purposes, the effect of

the merger. The Exchange Ratio will be recalculated for the actual closing date of the merger using updated information.

Immediately after the merger, based on the Exchange Ratio, existing ARCA stockholders will own approximately 67% of the common stock of the combined company and Nuvelo stockholders will own approximately 33% of the common stock of the combined company, after giving effect to the issuance of shares of ARCA capital stock issuable upon exercise of options and warrants outstanding immediately prior to the effective time, primarily on a treasury stock basis, and without giving effect to options and warrants to purchase Nuvelo common stock outstanding immediately prior to the effective time.

The Exchange Ratio is subject to proportionate adjustment to account for the effect of the reverse stock split of Nuvelo s issued and outstanding common stock.

Conditions to Completion of Merger (see page 110)

Each party s obligation to complete the merger is subject to a number of conditions, which may be waived by the applicable party, and that include, among others, and subject to specified exceptions, the following:

stockholders of ARCA must have approved the merger and adopted the merger agreement, and stockholders of Nuvelo must have approved the issuance of Nuvelo common stock in the merger and the amendment to the certificate of incorporation of Nuvelo to effect the reverse stock split;

no temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Merger shall have been issued by any court of competent jurisdiction or other governmental body and remain in effect, and there shall not be any legal requirement enacted or deemed applicable to the merger that makes consummation of the merger illegal;

the initial listing application on any of the Nasdaq Global Select Market, Nasdaq Global Market or Nasdaq Capital Market shall have been conditionally approved, and the shares of Nuvelo common stock to be issued in the merger shall be conditionally approved for listing on any of such markets, both subject only to the completion of the closing and completion by Nuvelo of any reverse stock split required by Nasdaq; and

since the signing of the merger agreement, there shall not have occurred and be continuing any material adverse effect for either party.

Limitation on Soliciting, Discussing or Negotiating Other Acquisition Proposals (see page 114)

Pursuant to the merger agreement, each of Nuvelo and ARCA agreed that, except as described below, they will not, during the pre-closing period, directly or indirectly:

solicit, initiate, knowingly encourage, induce or facilitate the making, submission or announcement of any acquisition proposal or acquisition inquiry, each as defined in the merger agreement and explained in this proxy statement/prospectus/consent solicitation, or take any action that would reasonably be expected to lead to an acquisition proposal or acquisition inquiry;

furnish any nonpublic information regarding ARCA or Nuvelo, as the case may be, or any of its subsidiaries, to any person in connection with or in response to an acquisition proposal or acquisition inquiry:

engage in discussions or negotiations with any person with respect to any acquisition proposal or acquisition inquiry;

Edgar Filing: NUVELO INC - Form S-4/A

approve, endorse or recommend any acquisition proposal or acquisition inquiry; or

11

enter into any letter of intent or similar document or any contract contemplating or otherwise relating to any acquisition transaction. Notwithstanding the foregoing, prior to obtaining the consent of their stockholders, either party may furnish information regarding such party to, and may enter into discussions or negotiations with, any third party in response to a bona fide written acquisition proposal made or received after the date of the merger agreement, which such party s board of directors determines in good faith, after consultation with a nationally recognized independent financial advisor and its outside legal counsel, constitutes or is reasonably likely to result in a superior offer, (as defined in the merger agreement and explained in this proxy statement/prospectus/consent solicitation), if:

neither such party nor any representative of such party has breached the no solicitation provisions of the merger agreement described above;

such party gives the other party at least two business days prior notice of the identity of the third party and of their intention to furnish information to, or enter into discussions or negotiations with, such third party before furnishing any information or entering into discussions or negotiations with such person, and such party receives from the third party an executed confidentiality agreement; and

at least two business days prior to the furnishing of any information to a third party, the other party furnishes the same information to the other party to the extent not previously furnished.

Termination of the Merger Agreement (see page 119)

The merger agreement may be terminated prior to the effective time of the merger (whether before or after adoption of the merger agreement by ARCA s stockholders and whether before or after approval of the issuance of Nuvelo common stock in the merger by Nuvelo s stockholders):

by mutual written consent of Nuvelo and ARCA, duly authorized by their respective boards of directors;

subject to certain limitations, by either Nuvelo or ARCA if the merger shall not have been consummated by February 28, 2009;

by either Nuvelo or ARCA if a court of competent jurisdiction or other governmental body shall have issued a final and nonappealable order, or shall have taken any other final and nonappealable action, having the effect of permanently restraining, enjoining or otherwise prohibiting the consummation of the merger;

by either Nuvelo or ARCA if Nuvelo s stockholders fail to approve the issuance of the Nuvelo common stock pursuant to the merger agreement at the special meeting;

subject to certain limitations, by either party in the event of any inaccuracy of representations and warranties of the other party having a material adverse effect or a material breach by the other party of its obligations or covenants under the merger agreement;

subject to certain conditions, by Nuvelo immediately prior to entering into a definitive agreement with respect to a superior offer; or

subject to certain conditions, by ARCA immediately prior to entering into a definitive agreement with respect to a superior offer.

Termination Fees and Expenses (see page 121)

Nuvelo must pay ARCA a nonrefundable fee of \$947,112 and reimburse ARCA for up to \$500,000 in actual out of pocket legal, accounting and investment advisory fees paid or payable in connection with the transactions contemplated by the merger agreement if:

the merger agreement is terminated by Nuvelo immediately prior to Nuvelo entering into a definitive agreement with respect to a transaction that constitutes a superior offer; or

the merger agreement is terminated by Nuvelo or ARCA if the stockholders of Nuvelo do not approve the issuance of Nuvelo common stock at the Nuvelo special meeting of stockholders, and all of the following conditions are met:

prior to the Nuvelo special meeting of stockholders, an acquisition proposal with respect to Nuvelo has been publicly made and not withdrawn;

within nine months of such termination, Nuvelo enters into a definitive agreement to consummate an acquisition transaction with a party other than ARCA; and

such acquisition transaction is consummated pursuant to such definitive agreement.

ARCA must pay Nuvelo a nonrefundable fee of \$1,922,924 and reimburse Nuvelo for up to \$500,000 in actual out of pocket legal, accounting and investment advisory fees paid or payable in connection with the transactions contemplated by the merger agreement if the merger agreement is terminated by ARCA immediately prior to ARCA entering into a definitive agreement with respect to a transaction that constitutes a superior offer.

Voting Agreements (see page 123)

In order to induce Nuvelo to enter into the merger agreement, several ARCA stockholders entered into voting agreements with and granted irrevocable proxies in favor of Nuvelo pursuant to which, among other things, each of these stockholders agreed, solely in its capacity as a stockholder, to vote all of its shares of ARCA capital stock and other ARCA securities in favor of the merger, the execution and delivery by ARCA of the merger agreement and the adoption and approval of the merger agreement and the terms thereof, in favor of each of the other actions contemplated by the merger agreement and in favor of any action in furtherance of any of the foregoing, and against, among other things, any proposal made in opposition to, or in competition with, the merger.

As of October 31, 2008, the stockholders of ARCA that entered into voting agreements collectively owned 3,553,635 shares of common stock and 16,785,136 shares of preferred stock of ARCA, on an as converted basis, representing approximately 84.97% of the outstanding capital stock of ARCA, including approximately 92.11% of ARCA s outstanding preferred stock, on an as converted basis, of ARCA. All of these stockholders are executive officers, directors, or entities controlled by such persons, or 5% stockholders, of ARCA, and include all of the Principal Series Preferred Stockholders.

Under these voting agreements executed by ARCA stockholders, subject to certain exceptions, such stockholders also have agreed not to sell or transfer ARCA capital stock and securities held by them, or any voting rights with respect thereto, until the earlier of the termination of the merger agreement or the completion of the merger. To the extent that any such sale or transfer is permitted pursuant to the exceptions included in the voting agreement, each person to which any shares of ARCA capital stock or securities are so sold or transferred must agree in writing to be bound by the terms and provisions of the voting agreement.

In addition, in order to induce ARCA to enter into the merger agreement, several Nuvelo stockholders entered into voting agreements with and granted irrevocable proxies in favor of ARCA pursuant to which, among

other things, each of these stockholders agreed, solely in his capacity as a stockholder, to vote all of his shares of Nuvelo common stock in favor of issuance of the shares of Nuvelo common stock in the merger and in favor of the amendment to Nuvelo s amended and restated certificate of incorporation to effect the reverse stock split, and against, among other things, any proposal made in opposition to, or in competition with, the merger.

These Nuvelo stockholders also granted ARCA an irrevocable proxy to their respective shares in accordance with the voting agreement. These Nuvelo stockholders may vote their shares of Nuvelo common stock on all other matters not referred to in such proxy.

As of November 11, 2008, the stockholders of Nuvelo that entered into voting agreements owned in the aggregate number of shares of Nuvelo common stock representing approximately 0.29% of the outstanding Nuvelo common stock.

Management of the Combined Company After the Merger (see page 197)

Following the merger, the executive management team of the combined company is expected to be composed of the following individuals:

Name Richard B. Brewer	Position in the Combined Company Chief Executive Officer	Current Position ARCA, President and CEO and Director
Michael R. Bristow, M.D., Ph.D.	Chief Science and Medical Officer	ARCA, Chairman and Chief Science and Medical Officer
Joseph L. Turner	Chief Financial Officer	ARCA, expected to join ARCA as its Chief Financial Officer prior to the closing of the proposed merger
Christopher Ozeroff	Executive Vice President of Business Development and General Counsel	ARCA, Executive Vice President of Business Development and General Counsel
Randall St. Laurent	Executive Vice President of Commercial Operations	ARCA, Executive Vice President of Commercial Operations

Following the merger, Lee Bendekgey, Nuvelo s Sr. Vice President, Chief Financial Officer and General Counsel, will serve as the combined company s Principal Accounting Officer on a transitional basis, but will not be an executive officer of the combined company.

The Board of Directors Following the Merger (see page 197)

Following the merger, the board of directors of the combined company will be as follows:

Name Current Affiliation

Richard B. Brewer ARCA, President and CEO and Director

Michael R. Bristow, M.D., Ph.D. ARCA, Chairman and Chief Science and Medical Officer

Jean-François Formela, MD Atlas Venture, Partner, and ARCA Director

J. William Freytag, Ph.D. Freytag Holdings LLC, President, and ARCA Director

Ted W. Love, M.D. Nuvelo, Chairman and CEO

Mary K. Pendergast Consulting, President, and Nuvelo Director

Burton E. Sobel, M.D. University of Vermont and Fletcher Allen Health Care, Professor of Medicine and

Biochemistry and Director of Cardiovascular Center, and Nuvelo Director

John L. Zabriskie, Ph.D. Puretech Ventures, LLC, Co-Founder and Director, and ARCA Director

David G. Lowe, Ph.D. Skyline Ventures, Managing Director, and ARCA Director

Linda Grais, M.D. InterWest Management Partners IX, LLC, Venture Member, InterWest Partners IX, LP,

General Partner, and ARCA Director

Interests of Nuvelo s Executive Officers and Directors (see page 94)

In considering the recommendation of the Nuvelo board of directors with respect to issuing shares of Nuvelo common stock as contemplated by the merger agreement, Nuvelo stockholders should be aware that certain members of the board of directors and executive officers of Nuvelo have interests in the merger that are different from, or in addition to, their interests as Nuvelo stockholders. These interests present a conflict of interest. The Nuvelo board of directors was aware of these conflicts of interest during its deliberations on the merits of the merger and in making its decision in approving the merger, the merger agreement, the amendments to Nuvelo s certificate of incorporation and the related transactions.

Interests of ARCA s Executive Officers and Directors (see page 97)

In considering the recommendation of the ARCA board of directors with respect to approving the adoption of the merger agreement, ARCA stockholders should be aware that certain members of the board of directors and executive officers of ARCA have interests in the merger that are different from, or in addition to, their interests as ARCA stockholders. These interests present a conflict of interest. The ARCA board of directors was aware of these conflicts of interest during its deliberations on the merits of the merger and in making its decision in approving the merger, the merger agreement and the transactions contemplated thereby.

Stock Options and Warrants (see page 100)

Each option and warrant to purchase ARCA capital stock outstanding at the effective time of the merger shall be assumed by Nuvelo to the extent not previously exercised. Each such option or warrant shall be converted into a option or warrant, as applicable, to acquire that number of shares of Nuvelo common stock equal to the product obtained by multiplying (i) the number of shares of ARCA capital stock (on an as converted basis) subject to such option or warrant by (ii) the Exchange Ratio, rounded down to the nearest whole share of Nuvelo common stock. Each such option or warrant shall have a purchase price per share of Nuvelo common stock equal to the quotient obtained by dividing (x) the per share purchase price of ARCA capital stock (as adjusted for the conversion of such capital stock into common stock, as applicable) subject to such option or warrant by (y) the Exchange Ratio rounded up to the nearest whole cent. Each such option or warrant shall otherwise be subject to the same terms and conditions (including as to vesting and exercisability) as were applicable under the respective option or warrant to purchase ARCA capital stock immediately prior to the effective time of the merger. Subject to ARCA stockholder approval, prior to the effective time of the merger, ARCA plans to amend its 2004 Stock Incentive Plan, or the ARCA Plan, to increase the number of shares of ARCA common stock reserved and available for awards under the ARCA Plan by up to 2,000,000 shares to a maximum of 8,356,550. ARCA anticipates granting additional option awards prior to the effective time of the merger. Shares of ARCA common stock reserved for awards but not covered by awards made prior to the effective time of the merger will not be assumed by Nuvelo, and after such effective time, no further awards can be made under the ARCA Plan.

Conversion of Convertible Notes (see page 125)

As agreed to in the merger agreement, ARCA entered into a Note and Warrant Purchase Agreement dated September 24, 2008, as amended on October 10, 2008 with certain holders of ARCA preferred stock pursuant to which ARCA sold, for an aggregate consideration of \$8.75 million, its 6% Convertible Promissory Notes due March 31, 2009, or the Notes, and warrants, or the Warrants, to purchase a number of shares of ARCA s common stock as determined pursuant to the Warrants. The outstanding principal and accrued interest on the Notes will convert into that number of shares of ARCA common stock immediately prior to the closing of the merger equal to the amount of unpaid principal and interest due as of the date of conversion divided by the conversion price. The conversion price is equal to the lesser of: (i) \$3.253 or (ii) the product of (a) the average closing price of Nuvelo common stock on the Nasdaq Global Market for the five consecutive trading days immediately preceding (but not including) the date the merger is consummated and (b) the Exchange Ratio; provided, however that in no event will the conversion price be less than \$1.6265. The number of shares of ARCA common stock subject to the Warrants issued in the convertible bridge note financing is calculated by dividing (i) 20% of the sum of the principal amount of each Note plus the consideration paid for the associated Warrants by (ii) the conversion price for the Notes. The Warrants have an exercise price equal to the conversion price and have a five-year exercise period. Assuming the lowest conversion price possible under the Notes, the Warrants will be exercisable for an aggregate of 1,075,933 shares of ARCA common stock.

Conversion of Preferred Stock (see page 100)

In accordance with the Series A Preferred Stock Purchase Agreement, the Series B Preferred Stock Purchase Agreement and the Supplemental Agreement to Series B Preferred Stock Purchase Agreement, ARCA issued shares of its preferred stock to certain investors. Each share of Series A preferred stock will convert immediately prior to the merger into one share of ARCA common stock. Each share of Series B-1 and Series B-2 preferred stock will convert immediately prior to the merger into a number of shares of ARCA common stock equal to the original issue price for such share divided by the then effective conversion price for the Series B-1 or Series B-2 share, as applicable. The issuance of the notes and warrants under the Note and Warrant Purchase Agreement results in adjustments to the conversion prices for the Series B-1 and Series B-2 preferred stock in accordance with the anti-dilution provisions in ARCA s amended and restated certificate of incorporation, as amended,

16

which we refer to as the Restated Certificate. The amount of the adjustments depends on the actual conversion price for the notes, which will not be determined until the closing of the merger. See Agreements Related to the Merger Note and Warrant Purchase Agreement. However, in no event will the conversion price for the notes be less than \$1.6265 and in no event will the adjusted conversion prices for the Series B-1 and Series B-2 preferred stock be less than \$2.00, as set forth in ARCA s Restated Certificate.

Material U.S. Federal Income Tax Consequences of the Merger (see page 104)

The merger has been structured to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended, or the Code, and it is a closing condition to the merger that Nuvelo and ARCA receive opinions of their respective counsel regarding such qualification. There will be no U.S. federal income tax consequences to Nuvelo stockholders as a result of the merger. Assuming that the merger qualifies as a reorganization, ARCA stockholders will not recognize gain or loss for U.S. federal income tax purposes upon the exchange of shares of ARCA capital stock for shares of Nuvelo common stock, except with respect to cash received in lieu of fractional shares of Nuvelo common stock. Tax matters are highly complex, and the tax consequences of the merger to a particular ARCA stockholder will depend in part on such stockholder s circumstances. Accordingly, you are urged to consult your own tax advisor for a full understanding of the tax consequences of the merger to you, including the applicability and effect of federal, state, local and foreign income and other tax laws.

Risk Factors (see page 28)

Both Nuvelo and ARCA are subject to various risks associated with their businesses and their industries, and the combined company will also be subject to those and other risks. In addition, the merger poses a number of risks to each company and its stockholders, including the following risks:

Some of Nuvelo s and ARCA s officers and directors have interests in the merger that may be different from yours and influence them to support or approve the merger.

The merger may be completed even though material adverse changes may result from the announcement of the merger, economic or industry-wide changes and other causes.

Nuvelo s and ARCA s stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger.

Negative perceptions regarding the pending merger may harm either Nuvelo s or ARCA s business and employee relationships. **Regulatory Approvals (see page 101)**

As of the date of this proxy statement/prospectus/consent solicitation, neither Nuvelo nor ARCA is required to obtain approvals or clearances from any antitrust regulatory authorities in the United States or other countries to consummate the merger. In the United States, Nuvelo must comply with applicable federal and state securities laws and Nasdaq rules and regulations in connection with the issuance of shares of Nuvelo common stock in the merger and the filing of this proxy statement/prospectus/consent solicitation. Nuvelo has filed an initial listing application with the Nasdaq Global Market pursuant to Nasdaq s reverse merger rules to effect the initial listing of Nuvelo s common stock issuable in connection with the merger.

Anticipated Accounting Treatment (see page 106)

The merger will be treated by Nuvelo as a reverse merger and will be accounted for as a business combination using the acquisition method of accounting in accordance with U.S. generally accepted accounting principles. For accounting purposes, ARCA is considered to be acquiring Nuvelo in this transaction.

Edgar Filing: NUVELO INC - Form S-4/A

17

Appraisal Rights (see page 101)

Nuvelo s stockholders are not entitled to appraisal rights in connection with the merger or any of the proposals to be voted on at the special meeting.

ARCA s stockholders are entitled to appraisal rights if they do not consent to the adoption of the merger agreement and they comply with the conditions established by Section 262 of the DCGL.

Comparison of Stockholder s Rights (see page 236)

Both Nuvelo and ARCA are incorporated under the laws of the State of Delaware and, accordingly, the rights of the stockholders of each are currently, and will continue to be, governed by the DGCL. If the merger is completed, ARCA s stockholders will become stockholders of Nuvelo, and their rights will be governed by the DCGL, the certificate of incorporation and the bylaws of Nuvelo, as they may be amended. The rights of Nuvelo s stockholders contained in the certificate of incorporation and bylaws of Nuvelo differ from the rights of ARCA s stockholders under the certificate of incorporation and bylaws of ARCA.

18

MARKET PRICE AND DIVIDEND INFORMATION

Nuvelo

Nuvelo s common stock is listed on the Nasdaq Global Market under the symbol NUVO. Prior to July 2006, Nuvelo s common stock traded on the Nasdaq National Market, the predecessor to the Nasdaq Global Market. The following table sets forth, for the periods indicated, the high and low per share sales prices for Nuvelo s common stock as reported on Nasdaq.

Nuvelo Common Stock

	High	Low
Year Ended December 31, 2006		
First Quarter	\$ 18.71	\$ 8.16
Second Quarter	18.20	14.15
Third Quarter	20.98	15.13
Fourth Quarter	20.37	3.35
Year Ended December 31, 2007		
First Quarter	\$ 4.12	\$ 3.04
Second Quarter	6.63	2.55
Third Quarter	3.03	1.52
Fourth Quarter	2.70	1.26
Year Ended December 31, 2008		
First Quarter	\$ 1.88	\$ 0.55
Second Quarter	0.97	0.55
Third Quarter	0.75	0.34
Fourth Quarter (through November 21, 2008)	0.47	0.21

On September 24, 2008, the last day prior to the public announcement of the merger, the closing price per share of Nuvelos common stock as reported on the Nasdaq Global Market was \$0.40, for an aggregate market value of Nuvelo of approximately \$21.5 million. Accordingly, if the merger had been consummated on that day, the value attributable to the shares of Nuvelos common stock issued or issuable to holders of ARCA soutstanding common stock, preferred stock, options, warrants and convertible notes in connection with the merger would have been approximately \$43.6 million, based on approximately 109 million shares of Nuvelos common stock issued or issuable in the merger, multiplied by \$0.40.

On November 21, 2008, the last practicable date before the printing of this proxy statement/prospectus/consent solicitation, the closing price per share of Nuvelo s common stock as reported on the Nasdaq Global Market was \$0.27, for an aggregate market value of Nuvelo of approximately \$14,489,227. Accordingly, if the merger had been consummated on that day, the value attributable to the shares of Nuvelo s common stock issued to holders of ARCA s common stock, preferred stock, options, warrants and convertible notes in connection with the merger would have been approximately \$30,373,967, based on approximately 112,496,177 shares of Nuvelo s common stock issued or issuable in the merger multiplied by \$0.27.

Because the market price of Nuvelo s common stock is subject to fluctuation, the market value of the shares of Nuvelo s common stock that holders of ARCA s common stock, preferred stock, options, warrants and convertible notes will be entitled to receive in the merger may increase or decrease.

Shares of Nuvelo common stock are currently listed on the Nasdaq Global Market under the symbol NUVO. Following the merger, the combined company is expected to be renamed ARCA biopharma, Inc. and to change its symbol for trading on the Nasdaq Global Market. ARCA has reserved the symbol ABIO for this purpose.

Nuvelo has never declared or paid cash dividends on its capital stock. Nuvelo currently intends to retain earnings, if any, to finance the growth and development of its business, and does not expect to pay any cash dividends to its stockholders in the foreseeable future. Payment of future dividends, if any, will be at the discretion of Nuvelo s board of directors.

As of the record date of November 11, 2008, there were approximately 190 holders of record of Nuvelo common stock.

ARCA

ARCA is a privately-held company and its shares are not publicly traded.

ARCA has never declared or paid any cash dividends on its capital stock nor does it intend to do so in the foreseeable future.

As of November 20, 2008, there were approximately 53 holders of record of ARCA common stock and preferred stock.

20

SELECTED HISTORICAL FINANCIAL DATA

Nuvelo Selected Historical Consolidated Financial Data

The statements of operations data for the years ended December 31, 2007, 2006 and 2005 and the balance sheet data as of December 31, 2007 and 2006 are derived from Nuvelo s audited consolidated financial statements, which are included in this proxy statement/prospectus/consent solicitation beginning on page F-15. The statements of operations data for the nine months ended September 30, 2008 and 2007 and the balance sheet data as of September 30, 2008 are derived from Nuvelo s unaudited consolidated financial statements, which are included in this proxy statement/prospectus/consent solicitation beginning on page F-2. The unaudited financial data as of September 30, 2008 and for the nine months ended September 30, 2008 and 2007 include all adjustments (consisting only of normal recurring adjustments) that Nuvelo considers necessary for a fair presentation of the financial position and operating results for the periods presented. The statements of operations data for the years ended December 31, 2004 and 2003 and the balance sheet data as of December 31, 2005, 2004 and 2003 are derived from Nuvelo s audited consolidated financial statements, which are not included in this proxy statement/prospectus/consent solicitation. Historical results are not necessarily indicative of future results, and results for any interim period are not necessarily indicative of results to be expected for a full fiscal year. The following selected historical consolidated financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations for Nuvelo and Nuvelo s consolidated financial statements and related notes thereto included in this proxy statement/prospectus/consent solicitation.

	Nine Mont Septemb 2008 (Unauc	ber 30, 2007	2007	Year E 2006	nded Decemb	er 31, 2004	2003
	(Chuu	unicu)	(In thousand	s, except per sh	are amounts)		
Statement of Operations Data:			,	• •	·		
Contract revenues	\$ 15,188	\$ 46,798	\$ 46,861	\$ 3,888	\$ 545	\$ 195	\$ 1,024
Operating expenses:							
Research and development	24,555	33,452	42,654	89,370	57,778	39,970	30,014
General and administrative	11,359	16,843	20,762	30,632	15,805	8,869	16,294
Restructuring	2,470	2,336	2,336				
Facility exit charges	1,472			24,460			
Impairment of goodwill	4,671						
-							
Total operating expenses	44,527	52,631	65,752	144,462	73,583	48,839	46,308
Total operating expenses	,627	02,001	00,702	111,102	75,555	.0,027	.0,000
Operating loss	(29,339)	(5,833)	(18,891)	(140,574)	(73,038)	(48,644)	(45,284)
Interest and other income	2,186	5,269	6,693	8,385	2,431	1,063	458
Interest expense	(4)	(101)	(103)	(588)	(1,004)	(1,361)	(1,403)
Loss from continuing operations	(27,157)	(665)	(12,301)	(132,777)	(71,611)	(48,942)	(46,229)
Discontinued operations, including loss on disposal	, , ,					(3,547)	(3,958)
						() /	. , ,
Loss before cumulative effect of change in							
accounting principle	(27,157)	(665)	(12,301)	(132,777)	(71,611)	(52,489)	(50,187)
Cumulative effect of change in accounting principle				2,224			
Net loss	\$ (27,157)	\$ (665)	\$ (12,301)	\$ (130,553)	\$ (71,611)	\$ (52,489)	\$ (50,187)
		. ()					
Basic and diluted net loss per share:							
Loss from continuing operations	\$ (0.51)	\$ (0.01)	\$ (0.23)	\$ (2.58)	\$ (1.73)	\$ (1.59)	\$ (2.20)
Discontinued operations	+ (0.01)	÷ (0.01)	+ (0.20)	+ (2.50)	+ (11.73)	(0.11)	(0.19)
Cumulative effect of change in accounting principle				0.04		(===)	(3.27)
principle							
Basic and diluted net loss per share	\$ (0.51)	\$ (0.01)	\$ (0.23)	\$ (2.54)	\$ (1.73)	\$ (1.70)	\$ (2.38)

Edgar Filing: NUVELO INC - Form S-4/A

Weighted average shares used in computing basic and							
diluted net loss per share	53,536	53,310	53,333	51,451	41,279	30,874	21,054

ARCA Selected Historical Financial Data

	September 30,	2007	2006	December 31,	2004	2003
	2008 (Unaudited)	2007	2000	2005	2004	2003
	(Chadairea)		(In tho	usands)		
Balance Sheet Data:						
Cash and cash equivalents, marketable securities						
and restricted cash	\$ 65,132	\$ 103,567	\$ 153,126	\$ 70,336	\$ 50,625	\$ 34,189
Working capital	46,572	81,799	122,496	49,582	45,261	25,772
Total assets	75,399	120,683	184,405	108,046	79,264	57,809
Bank loans			1,492	3,032	2,600	
Notes payable				4,000	4,000	6,600
Related party line of credit			2,292	5,042	7,792	10,542
Other non-current liabilities	16,339	34,837	70,598	11,315	1,992	6,631
Accumulated deficit	(497,670)	(470,513)	(458,212)	(327,659)	(256,048)	(203,559)
Total stockholders equity	44,715	67,659	69,843	56,764	45,589	22,701

The statements of operations data for the years ended December 31, 2007, 2006 and 2005 and the balance sheet data as of December 31, 2007 and 2006 were derived from ARCA s audited financial statements which are included in this proxy statement/prospectus/consent solicitation beginning on page F-45. The statements of operations data for the years ended December 31, 2004 and 2003 and the balance sheet data as of December 31, 2005, 2004 and 2003 were derived from both ARCA s audited and unaudited financial statements which are not included in this proxy statement/prospectus/consent solicitation. The statement of operations data for the nine months ended September 30, 2008 and 2007 and for the period from inception, December 17, 2001, through September 30, 2008, and the balance sheet data as of September 30, 2008 were derived from ARCA s unaudited financial statements which are included in this proxy statement/prospectus/consent solicitation beginning on page F-45.

The unaudited pro forma basic and diluted weighted average shares outstanding and net loss per common share data for the year ended December 31, 2007 and for the nine-month period ended September 30, 2008 reflect the mandatory conversion, upon the consummation of the proposed merger, of all outstanding shares of preferred stock at their respective conversion rates then in effect into shares of ARCA common stock, as if the conversion had occurred on January 1, 2007 or the date of issuance, if later.

Historical results are not necessarily indicative of future results and results for any interim periods are not necessarily indicative of results for a full fiscal year.

The following selected historical financial data should be read in conjunction with ARCA s Management s Discussion and Analysis of Financial Condition and Results of Operations for ARCA and ARCA s financial statements and related notes thereto included in this proxy statement/prospectus/consent solicitation. ARCA is considered to be a development stage company for financial reporting purposes.

	Nine Moi Septer				Year E	nded Decen	nber 31,		Dec 20	riod from ember 17, 001 (date of eption) to
	2008 (Unaudited)	(Uı	2007 naudited)	2007	2006	2005	2004	2003 audited)	•	tember 30, 2008 naudited)
				(In tho	usands, exc	ept per shai	re data)			
Statement of operations data:										
Operating expenses:										
Research and development	\$ 8,363	\$	7,270	\$ 10,244	\$ 3,978	\$ 846	\$ 60	\$	\$	23,491
General and administrative	6,037		3,332	4,210	1,545	569	444	134		12,971
Loss from operations	(14,400)		(10,602)	(14,454)	(5,523)	(1,415)	(504)	(134)		(36,462)
Other income (expense), net	144		355	460	282	(44)	(7)	18		885
Net loss	\$ (14,256)	\$	(10,247)	\$ (13,994)	\$ (5,241)	\$ (1,459)	\$ (511)	\$ (116)	\$	(35,577)
Less: Accretion of redeemable convertible preferred stock	(42)		(25)	(37)	(17)					(97)
Net loss attributable to common stockholders	\$ (14,298)	\$	(10,272)	\$ (14,031)	\$ (5,258)	\$ (1,459)	\$ (511)	\$ (116)	\$	(35,674)
Basic and diluted net loss attributable to common stockholders per share	\$ (3.29)	\$	(2.73)	\$ (3.71)	\$ (1.62)	\$ (1.16)	\$ (1.88)	\$ (1.24)		
Weighted average shares outstanding basic and dilute	d 4,343		3,769	3,781	3,247	1,258	272	93		
Pro forma basic and diluted net loss attributable to common stockholders per share (unaudited)	\$ (0.71)			\$ (0.92)						
Pro forma weighted average shares outstanding basic and diluted (unaudited)	20,020			15,189						

	As of September 30	0.	As of			
	2008 (Unaudited)	2007	2006	2005	2004 (Unau	2003 (dited)
			(In thousar	nds)	`	
Balance sheet data:						
Cash and cash equivalents	\$ 5,457	\$ 15,862	\$ 9,712	\$ 373	\$ 251	\$ 8
Working capital	840	12,986	9,010	(745)	(678)	(115)
Total assets	7,528	16,204	9,941	452	322	8
Total liabilities	8,492	3,084	766	1,130	941	123
Redeemable convertible preferred stock	32,851	32,809	14,919			
Accumulated deficit	(35,577)	(21,321)	(7,327)	(2,086)	(627)	(116)
Total stockholders deficit	(33,815)	(19,689)	(5,744)	(678)	(619)	(115)

SELECTED UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL DATA

The following unaudited pro forma financial data should be read in conjunction with the historical financial statements and the accompanying notes of ARCA and Nuvelo, and the respective Management s Discussion and Analysis of Financial Condition and Results of Operations for Nuvelo, and Management s Discussion and Analysis of Financial Condition and Results of Operations for ARCA, which are included elsewhere in this proxy statement/prospectus/consent solicitation, and the other information contained in this proxy statement/prospectus/consent solicitation. See Where You Can Find More Information beginning on page 259 and the financial statements of Nuvelo and ARCA beginning on pages F-2 and F-44, respectively. The following information does not give effect to the reverse stock split of Nuvelo common stock described in Nuvelo Proposal No. 2.

The following selected unaudited pro forma condensed combined financial information presents the effect of the merger of Nuvelo and ARCA pursuant to the merger agreement. For accounting purposes, ARCA is considered to be acquiring Nuvelo in the merger. The following unaudited pro forma condensed combined balance sheet data assume that the merger took place on September 30, 2008, and combine the ARCA historical balance sheet at September 30, 2008 with the Nuvelo historical condensed consolidated balance sheet at September 30, 2008 and \$8.75 million of notes payable issued by ARCA in October 2008, which convert into common stock upon the closing of the proposed merger. The unaudited pro forma condensed combined statement of operations data assume that the merger took place as of January 1, 2007, and combine the historical results of Nuvelo and ARCA for the nine months ended September 30, 2008 and the year ended December 31, 2007. The ARCA balance sheet information was derived from its unaudited balance sheet as of September 30, 2008 included herein. The Nuvelo balance sheet information was derived from its unaudited condensed consolidated balance sheet included in its Form 10-Q for the quarterly period ended September 30, 2008 and also included herein. The historical results of Nuvelo were derived from its unaudited condensed consolidated statement of operations for the nine months ended September 30, 2008 included in its Form 10-Q for the quarterly period ended September 30, 2008 included in its Form 10-Q for the quarterly period ended September 30, 2008, and its audited consolidated statement of operations included in its Annual Report on Form 10-K for the year ended December 31, 2007, which are also included herein.

The selected unaudited pro forma condensed combined financial data are presented for illustrative purposes only and are not necessarily indicative of the combined financial position or results of operations of future periods or the results that actually would have been realized had the entities been a single entity during these periods. The selected unaudited pro forma condensed combined financial data as of and for the nine months ended September 30, 2008 and for the year ended December 31, 2007 are derived from the unaudited pro forma condensed combined financial information appearing elsewhere in this proxy statement/prospectus/consent solicitation, and should be read in conjunction with that information. In the selected unaudited pro forma condensed combined financial data included in the proxy statement/prospectus/consent solicitation filed on October 30, 2008, the proposed merger transaction was presented as a business combination using the purchase method of accounting in accordance with Statement of Financial Accounting Standards No. 141, *Business Combinations*, as the transaction was assumed to be consummated on or before December 31, 2008. The stockholders meeting and consummation of the transaction is now expected to be in the first quarter of 2009; therefore, the transaction is being presented in the selected unaudited pro forma condensed combined financial data using the acquisition method of accounting in accordance with Statement of Financial Accounting Standards No. 141R, *Business Combinations*. Please see Note 2 to the unaudited pro forma condensed combined financial statements.

For purposes of the unaudited pro forma condensed combined financial statements, presented elsewhere herein, Nuvelo and ARCA have made allocations of the estimated acquisition consideration to the assets to be acquired and liabilities to be assumed based on preliminary estimates of their fair value. A final determination of these estimated fair values, which cannot be made prior to the completion of the merger, will be based on the actual net assets of Nuvelo that exist as of the date of consummation of the merger. The actual amounts recorded

24

as of the consummation of the merger may differ materially from the information presented in the unaudited pro forma condensed combined financial statements as a result of:

net cash used in the Nuvelo operations between the pro forma balance sheet date of September 30, 2008 and the closing of the merger;

a change in the fair value of Nuvelo s common stock;

the timing of completion of the merger;

a change in the methodology used to account for the consideration transferred; and

other changes in the Nuvelo net assets that may occur prior to completion of the merger, which could cause material differences in the information presented below.

The estimated acquisition consideration of the Nuvelo acquisition in the unaudited pro forma condensed combined financial statements was based on the market capitalization of Nuvelo as of September 30, 2008, the date on which the proposed merger occurred for purposes of the pro forma financial statements, and the fair values of its vested stock options and warrants outstanding on that date. This was deemed the best estimate of the fair value of Nuvelo as the entity being acquired for accounting purposes on that date and the consideration paid in the transaction. The September 30, 2008 balance sheet of Nuvelo reflected approximately \$59 million of cash, cash equivalents, and marketable securities, and aggregate net assets with a fair value of approximately \$46 million, which significantly exceeded Nuvelo s market capitalization at that date. The application of the rules governing the preparation of the unaudited pro forma condensed combined balance sheet results in significant excess of fair value of acquired net assets over acquisition consideration, on a pro forma basis, which would be recognized as a gain on bargain purchase upon consummation.

The final acquisition consideration allocation will differ significantly from preliminary estimates. The actual acquisition accounting upon consummation of the merger will be based on the fair value of the consideration paid and fair values of Nuvelo s assets and liabilities as determined at the time of consummation. Nuvelo s market capitalization has experienced significant fluctuations during 2008 as a result of market and company-specific factors, and such fluctuations may continue. Further, Nuvelo continues to use its cash and other liquid assets to finance its ongoing operations. As a result, at the date the merger is consummated, Nuvelo s cash, cash equivalents, and marketable securities are expected to be significantly less than at September 30, 2008, and its market capitalization cannot be predicted. ARCA and Nuvelo will re-evaluate the accounting method used to determine the consideration at the time of merger consummation, taking into consideration Nuvelo s market capitalization at the time of consummation, and may consider alternative approaches, such as basing the acquisition consideration on the fair value of Nuvelo s net assets, or based on the fair value of ARCA s common and redeemable convertible preferred stock, rather than Nuvelo s common stock. ARCA and Nuvelo do not anticipate that the final acquisition accounting performed when the merger is consummated will result in a significant gain on bargain purchase amount because the proposed merger is not considered a bargain purchase transaction. Please see Note 2 to the unaudited pro forma condensed combined financial statements for further discussion.

	Nine Months Ended September 30, 2008		Ye	ar Ended
			Dec	December 31, 2007
Unaudited Pro Forma Condensed Combined Statement of Operations Data (in thousands,				
except per share amounts):				
Total revenues(1)	\$	15,188	\$	46,861
Research and development expenses		32,999		53,002
Sales, general and administrative expenses		16,887		24,315
Restructuring		2,470		2,336

Edgar Filing: NUVELO INC - Form S-4/A

Facility exit charges	1,472	
Loss from operations	(38,640)	(32,792)
Net loss	(36,314)	(25,742)
Basic and diluted net loss per share	\$ (0.22)	\$ (0.16)

	Sept	tember 30, 2008
Unaudited Pro Forma Condensed Combined Balance Sheet Data (in thousands):		
Cash and cash equivalents, marketable securities and restricted cash(2)	\$	79,339
Working capital(2)		48,009
Total assets(2)		91,164
Accumulated deficit		(20,299)
Total stockholders equity(2)		48,918

(1) In the nine months ended September 30, 2008, Nuvelo recorded as revenue \$15.0 million that was received from Bayer HealthCare AG (Bayer) in connection with the termination of its collaboration agreement in June 2007. Following Nuvelo s decision to discontinue further clinical development of alfimeprase, the \$15.0 million, which had been recorded as deferred revenue, was recognized as revenue upon the expiration of the notice period, as defined in the termination agreement with Bayer.

In 2007, Nuvelo recorded as revenue \$45.8 million of the \$50.0 million up-front license fee received from Bayer in January 2006 as a result of the termination of its collaboration agreement in June 2007. The up-front license fee had been recorded as deferred revenue upon receipt and was being recognized on a straight-line basis over the performance period under the agreement, originally estimated to be through September 2020.

(2) Includes \$8.75 million of notes payable issued by ARCA in October 2008, which convert into common stock upon the closing of the proposed merger.

26

COMPARATIVE HISTORICAL AND UNAUDITED PRO FORMA PER SHARE DATA

The following information does not give effect to the reverse stock split of Nuvelo common stock described in Nuvelo Proposal No. 2.

The following information reflects the historical net loss and book value per share of Nuvelo common stock and the historical net loss and book value per share of ARCA common stock in comparison with the unaudited pro forma net loss and book value per share after giving effect to the proposed merger of Nuvelo with ARCA under the acquisition method of accounting. The combined company pro forma per common share data are provided for informational purposes only and are not necessarily indications of the results that would have been achieved had the transaction been completed as of the dates indicated or that may be achieved in the future. We have derived the combined company pro forma per common share data from the unaudited pro forma condensed combined financial statements presented elsewhere in this proxy statement/prospectus/consent solicitation.

You should read the tables below in conjunction with the audited and unaudited financial statements of Nuvelo and the notes related thereto included in this proxy statement/prospectus/consent solicitation and the audited and unaudited financial statements of ARCA and the notes related thereto included in this proxy statement/prospectus/consent solicitation and the unaudited pro forma condensed combined financial information and notes related thereto included elsewhere in this proxy statement/prospectus/consent solicitation.

	I Sept	e Months Ended ember 30, 2008	Dece	r Ended ember 31, 2007
Nuvelo Historical Per Common Share Data:				
Basic and diluted net loss per share	\$	(0.51)	\$	(0.23)
Book value per share as of the period end		0.83		1.27
ARCA Historical Per Common Share Data:				
Basic and diluted net loss per share	\$	(3.29)	\$	(3.71)
Book value per share as of the period end		(5.92)		(4.45)
Combined Company Pro Forma Per Common Share Data:				
Basic and diluted net loss per share	\$	(0.22)	\$	(0.16)
Book value per share as of the period end		0.30		N/A

27

RISK FACTORS

You should consider the following factors in evaluating whether to approve the proposals described in this proxy statement/prospectus/consent solicitation. These factors should be considered in conjunction with the other information included by Nuvelo and ARCA in this prospectus/proxy statement/consent solicitation.

Risks Related to the Proposed Merger and Combined Company

Nuvelo and ARCA anticipate that immediately following the merger the business of the combined company will have the same risks associated with ARCA and Nuvelo immediately prior to the merger. As a result, you should give attention to the risk factors set forth below under the headings Risks Related to ARCA, Risks Related to Nuvelo and the following risks related to the proposed merger and the combined company.

If the combined company is not able to successfully develop and commercialize Gencaro, or another product candidate, it may not be able to continue its business operations.

ARCA and Nuvelo currently have no products that have received regulatory approval for commercial sale. The process to develop, obtain regulatory approval for and commercialize potential product candidates is long, complex and costly. Following the merger, Gencaro, which is currently the subject of an NDA awaiting FDA approval, will be the combined company s only product candidate at a late stage of clinical development. As a result, the combined company s business is expected to be substantially dependent on its ability to obtain regulatory approval for and successfully commercialize Gencaro in a timely manner.

In addition to Gencaro, the combined company will have two product candidates in clinical trials, NU172 and NU206. These product candidates must be rigorously tested in clinical trials, and be shown to be safe and effective, before the FDA or other regulatory authorities outside the U.S. will consider them for approval. Failure to demonstrate that one or more of the combined company s product candidates is safe and effective, or significant delays in demonstrating such safety and efficacy, could diminish the benefits of the merger. Failure to obtain marketing approval of one or more of the combined company s product candidates from appropriate regulatory authorities, or significant delays in obtaining such approval, could diminish the benefits of the merger. If approved for sale, the combined company s product candidates must be successfully commercialized. Failure to successfully commercialize one or more of the combined company s product candidates could diminish the benefits of the merger, and, in particular, if the NDA for Gencaro is not approved, or is substantially delayed, or if the combined company is unable to successfully commercialize Gencaro, it may not be able to earn sufficient revenues to continue its business.

If the combined company fails to obtain additional financing, it may be unable to fund its operations and commercialize its product candidates.

The combined company expects that the cash used in its operations will increase for the next several years, and that it will spend substantial amounts to complete the development, regulatory approval and commercialization of Gencaro and other product candidates and to license or acquire other product candidates. ARCA believes that, if the merger is completed, existing cash and cash equivalents will be sufficient to meet the combined company s projected operating requirements through 2009.

The combined company s future funding requirements will depend on many factors, including:

whether or when Gencaro is approved for sale;

whether or when Gencaro s companion product, the Gencaro companion genetic test, or the Gencaro Test, is approved for sale;

the costs of establishing sales, marketing and distribution capabilities;

28

the terms and timing of any collaborative, licensing and other arrangements that it has or may establish;

cash requirements of any future acquisitions of product candidates;

the scope, results and timing of preclinical studies and clinical trials and other development activities;

the effects of competing clinical, technological and market developments; and

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights. Even if the combined company receives FDA approval to commercialize Gencaro, it cannot predict the amount of revenue it will generate from sales of Gencaro. Until the combined company can generate a sufficient amount of product revenue, it expects to finance future cash needs through public or private securities offerings or debt financings. To the extent that additional funds are raised by issuing equity securities, the combined company s stockholders may experience dilution.

If additional debt financing is raised in the future, the combined company may be required to grant any lenders a security interest in all or a portion of its assets and issue warrants to acquire its equity securities, resulting in dilution to its stockholders. In addition, any such debt financing may involve restrictive covenants, including limitations on the combined company s ability to incur additional debt, limitations on its ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact its ability to conduct its business.

The combined company may also be required to:

seek collaborators for its product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and

relinquish, license or otherwise dispose of rights to technologies, product candidates or products that it would otherwise seek to develop or commercialize itself.

Future additional funding may not be available on acceptable terms, or at all. If the combined company is unable to raise additional capital when required or on acceptable terms, then the combined company may have to significantly delay, scale back or discontinue the development or commercialization of one or more of its product candidates.

The combined company will be relying upon LabCorp to obtain marketing clearance or approval of the companion Gencaro Test. There is no guarantee that the FDA will grant timely clearance or approval of the Gencaro Test, if at all, and failure to obtain such timely clearance or approval would adversely affect the combined company s ability to market Gencaro.

The drug label being sought for Gencaro would identify the patient receptor genotypes with a likelihood of enhanced efficacy, as well as those with a likelihood of a standard beta-blocker response and the smaller unfavorable subgroup with a low probability of benefit. Accordingly, the combined company believes it will be critical to the successful commercialization of Gencaro to develop a companion genetic test, or the Gencaro Test, that is simple to administer, useful and widely available.

The Gencaro Test is subject to regulation by the FDA and by comparable agencies in various foreign countries. The process of complying with the requirements of the FDA and comparable agencies is costly, time consuming and burdensome.

Under ARCA s agreement with Laboratory Corporation of America, or LabCorp, LabCorp is responsible for determining the appropriate regulatory pathway for the Gencaro Test and obtaining market clearance or approval from the FDA. Based on FDA guidance, LabCorp plans to submit a PMA regulatory submission in the

fourth quarter of 2008. The FDA may decide that the Gencaro Test should be evaluated for clearance under the FDA s 510(k) notification process. LabCorp and ARCA do not believe that any further clinical trials will be required for the Gencaro Test PMA, though there is no guarantee that FDA will not require additional clinical data.

Despite the time and expense expended, regulatory clearance or approval is never guaranteed. If regulatory clearance or approval is delayed, or if LabCorp is unable to obtain FDA approval of the Gencaro Test at all or in parallel with the approval of Gencaro, or is unable to commercialize the test successfully and in a manner that effectively supports the combined company s commercial efforts, or if the information concerning the differential response to Gencaro resulting from certain genetic variation is not included in the approval label for Gencaro, the commercial launch of Gencaro may be significantly and adversely affected. In such cases, the combined company could be forced to identify a new third-party test provider and obtain regulatory approval for that provider s genetic test, which could substantially delay and negatively affect the commercial prospects for Gencaro.

If Gencaro is approved, the FDA may require that the companion genetic test be administered to all patients before they receive Gencaro, which could limit its potential market.

Gencaro is a pharmacologically unique beta-blocker and mild vasodilator for heart failure that is more effective in certain patient populations but less effective in other patient populations than other beta-blockers currently being marketed, or potentially not effective at all. Based on certain genetic markers, ARCA believes that it can be determined whether Gencaro will be more effective or less effective for potential patients. ARCA has a contractual relationship with LabCorp to develop, obtain regulatory approval of and commercialize a genetic test to detect these genetic variations in patients.

Because Gencaro may not be effective in some patient populations, and these populations can be identified using the Gencaro Test, the FDA may require that the Gencaro Test be administered to all patients before they receive Gencaro. The FDA could also prohibit prescribing Gencaro to that patient population that is not positively affected by Gencaro. As a result, the market for Gencaro could be restricted, and the combined company s business could be harmed.

Future sales of Gencaro may suffer if its marketplace acceptance is negatively affected by the companion genetic test.

The companion genetic test for Gencaro is an important component of the commercial strategy for Gencaro. ARCA believes that the genetic test helps predict response to Gencaro, and that this aspect of the drug is important to its ability to compete effectively with current therapies. The companion genetic test adds an additional step in the prescribing process, an additional cost for the patient, the risk that the test results may not be rapidly available and the possibility that it may not be available at all hospitals and medical centers. Any one of these factors could affect prescriber behavior, which in turn may substantially impede market acceptance of the genetic test, which could cause significant harm to Gencaro s ability to compete, and in turn harm the combined company s business.

If Nuvelo and ARCA are not successful in integrating their organizations, the combined company may not be able to operate efficiently after the merger or to realize any benefits from the merger.

Achieving the benefits of the merger will depend in part on the successful integration of Nuvelo s and ARCA s technical and business operations and personnel in a timely and efficient manner. The integration process requires coordination of the personnel of both companies, involves the integration of systems, applications, policies, procedures, business processes and operations and is a complex, costly and time-consuming process. The difficulties of combining the operations of the companies include, among others:

consolidating research and development operations; retaining key employees;

30

consolidating corporate and administrative infrastructures;

preserving the research and development and other important relationships of the companies;

integrating and managing the technology of two companies;

using the combined company s liquid capital and other assets efficiently to develop the business of the combined company;

appropriately managing the liabilities of the combined company;

diverting management s attention from ongoing business concerns; and

coordinating geographically separate organizations.

Neither Nuvelo nor ARCA can assure you that they will receive any benefits of this or any other merger or acquisitions, or that any of the difficulties described above will not adversely affect the combined company. The integration process may be difficult and unpredictable because of possible conflicts and differing opinions on business, scientific and regulatory matters. If Nuvelo and ARCA cannot successfully integrate their technical and business operations and personnel, the combined company may not realize the expected benefits of the merger.

Nuvelo and ARCA expect to incur significant costs integrating the companies into a single business.

Nuvelo and ARCA expect to incur significant costs integrating their technical and business operations and personnel, which may include costs for employee redeployment, relocation or severance, conversion of information systems, reorganization of facilities, disposition of excess facilities and relocation or disposition of excess equipment. The benefits of the merger may not be sufficient to justify these integration costs.

Integrating Nuvelo and ARCA may divert the attention of the combined company s management away from its operations.

The successful integration of Nuvelo s and ARCA s technical and business operations and personnel may place a significant burden on the combined company s management and internal resources. The diversion of management s attention and any difficulties encountered in the transition and integration process could result in delays in clinical trial and product development programs of the combined company and could otherwise harm the combined company s business, financial condition and operating results.

Nasdaq considers the anticipated merger a reverse merger and therefore has required that the combined company submit a new listing application, which requires certain actions on the combined company s part which may not be successful and, if unsuccessful, could make it more difficult for holders of shares of the combined company to sell their shares.

Nasdaq considers the merger proposed in this proxy statement/prospectus/consent solicitation as a reverse merger and has required that the combined company submit a new listing application. Nasdaq may not approve the combined company s new listing application. If this occurs and the merger is still consummated, you may have difficulty converting your investments into cash effectively.

Additionally, as part of the new listing application, the combined company will be required to submit, among other things, a plan for the combined company to conduct a reverse stock split. A reverse stock split would increase the per share trading price by a yet undetermined multiple. The change in share price may affect the volatility and liquidity of the combined company s stock, as well as the marketplace s perception of the stock. As a result, the relative price of the combined company s stock may decline and/or fluctuate more than in the past, and you may have trouble converting your investments in the combined company into cash effectively.

Table of Contents 63

31

Failure to complete the merger could adversely affect Nuvelo s stock price and Nuvelo s and ARCA s future business and operations.

The merger is subject to the satisfaction of closing conditions, including approval by Nuvelo and ARCA stockholders, and neither Nuvelo nor ARCA can assure you that the merger will be approved. In the event that the merger is not consummated, Nuvelo and ARCA may be subject to many significant costs, including legal, accounting and advisory fees related to the merger, which must be paid even if the merger is not completed, and the payment of a termination fee under certain circumstances. If the merger is not consummated, the market price of Nuvelo common stock could decline as a result.

Completion of the merger may result in dilution of future earnings per share to the stockholders of Nuvelo or ARCA.

The completion of the merger may result in greater net losses or a weaker financial condition compared to that which would have been achieved by either Nuvelo or ARCA on a stand-alone basis. The merger could fail to produce the benefits that the companies anticipate, or could have other adverse effects that the companies currently do not foresee. In addition, some of the desired outcomes of the merger, such as the achievement of operating synergies, may not be realized. In this event, the merger could result in greater losses as compared to the losses that would have been incurred by Nuvelo or ARCA on a stand alone basis if the merger had not occurred.

The costs associated with the merger are difficult to estimate, may be higher than expected and may harm the financial results of the combined company.

Nuvelo and ARCA estimate that they will incur aggregate direct transaction costs of approximately \$7.7 million associated with the merger, and additional costs associated with the consolidation and integration of operations, which cannot be estimated accurately at this time. If the total costs of the merger exceed Nuvelo s and ARCA s estimates or the benefits of the merger do not exceed the total costs of the merger, the financial results of the combined company could be adversely affected.

Nuvelo and ARCA executive officers and directors may have interests that are different from, or in addition to, those of Nuvelo and ARCA stockholders generally.

The executive officers and directors of Nuvelo and ARCA may have interests in the merger that are different from, or are in addition to, those of Nuvelo and ARCA stockholders generally. These interests include ownership through affiliated entities of Nuvelo common stock, certain ARCA directors being appointed to and replacing certain Nuvelo directors from the Nuvelo board of directors immediately after the effective time of the merger, certain Nuvelo executive officers receiving change in control payments in connection with the merger and the adoption of new employment agreements for certain ARCA executives in connection with the merger and/or the provision and continuation of indemnification and insurance arrangements for current directors of ARCA following consummation of the merger. See the sections entitled Interests of Nuvelo s Executive Officers and Directors in the Merger starting on page 94 and Interests of ARCA s Executive Officers and Directors in the Merger starting on page 97.

The combined company will need to significantly increase the size of its organization and may experience difficulties in managing its growth.

ARCA and Nuvelo are small companies. As of October 31, 2008, ARCA has approximately 49 employees and Nuvelo has approximately 51 employees. The merger will make certain positions redundant; such redundancies will result in terminations. While the merger will create redundancies and result in terminations, the combined company expects that it will need to substantially increase and modify its operations in the future to conduct clinical trials for any future product candidates and commercialize Gencaro and any other future product

32

candidates that the combined company acquires or develops. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. The combined company s future financial performance and its ability to commercialize its product candidates and to compete effectively will depend, in part, on its ability to manage any future growth effectively. To that end, the combined company must be able to:

manage its clinical trials effectively;

integrate current and additional management, administrative, financial and sales and marketing personnel;

hire new personnel necessary to effectively commercialize product candidates it licenses;

develop its administrative, accounting and management information systems and controls; and

hire and train additional qualified personnel.

The combined company s management will be required to devote substantial time to comply with public company regulations.

As a public company, the combined company will incur significant legal, accounting and other expenses that ARCA did not incur as a private company. The Sarbanes-Oxley Act of 2002 as well as rules implemented by the SEC and the Nasdaq Global Market, impose various requirements on public companies, including those related to corporate governance practices. The combined company s management and other personnel will need to devote a substantial amount of time to these requirements. ARCA s management, which will substantially continue as the management of the combined company, does not have recent experience in addressing these requirements. Moreover, these rules and regulations will increase the combined company s legal and financial compliance costs relative to those of ARCA and will make some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that the combined company maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, the combined company must perform system and process evaluation and testing of its internal controls over financial reporting to allow management and the combined company s independent registered public accounting firm to report on the effectiveness of its internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The combined company s compliance with Section 404 will require that it incur substantial accounting and related expense and expend significant management efforts. The combined company will need to hire additional accounting and financial staff to satisfy the ongoing requirements of Section 404. Moreover, if the combined company is not able to comply with the requirements of Section 404, or if the combined company or its independent registered public accounting firm identifies deficiencies in its internal controls over financial reporting that are deemed to be material weaknesses, the market price of the combined company s stock could decline and the combined company could be subject to sanctions or investigations by the Nasdaq Global Market, the SEC or other regulatory authorities.

Material weaknesses may exist when the combined company reports on the effectiveness of its internal control over financial reporting for purposes of its reporting requirements.

Prior to the filing of the registration statement of which this proxy statement/prospectus/consent solicitation forms a part, ARCA was not subject to the Sarbanes-Oxley Act of 2002. Therefore, ARCA s management and independent registered public accounting firm did not perform an evaluation of ARCA s internal control over financial reporting as of December 31, 2007 in accordance with the provisions of the Sarbanes-Oxley Act. Material weaknesses may exist when the combined company reports on the effectiveness of its internal control over financial reporting for purposes of its reporting requirements under the Exchange Act or Section 404 of the Sarbanes-Oxley Act after the merger. The existence of one or more material weaknesses would preclude a conclusion that the combined company maintains effective internal control over financial reporting. Such a

conclusion would be required to be disclosed in the combined company s future Annual Reports on Form 10-K and could impact the accuracy and timing of its financial reporting and the reliability of its internal control over financial reporting, which could harm the combined company s reputation and cause the market price of its common stock to drop.

Ownership of the combined company s common stock may be highly concentrated, and it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the combined company s stock price to decline.

ARCA security Ownership of Certain Beneficial Owners and Management beginning on page 226 for more information on how ARCA beneficial ownership percentage is calculated and Security Ownership of Certain Beneficial Owners and Management Following the Merger beginning on page 230 for more information on the estimated ownership of the combined company following the merger). Accordingly, these executive officers, directors and their affiliates, acting individually or as a group, will have substantial influence over the outcome of a corporate action of the combined company requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the combined company s assets or any other significant corporate transaction. These stockholders may also delay or prevent a change in control of the combined company, even if such change in control would benefit the other stockholders of the combined company. The significant concentration of stock ownership may adversely affect the value of the combined company s common stock due to investors perception that conflicts of interest may exist or arise.

The combined company s stock price is expected to be volatile, and the market price of its common stock may decline following the merger.

The market price of the combined company s common stock could be subject to significant fluctuations following the merger. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of the combined company s common stock to fluctuate include:

the regulatory status of Gencaro and the Gencaro Test, and whether and when they are approved for sale, if at all;

the results of the combined company s current and any future clinical trials and NDAs of its current and future product candidates;

the entry into, or termination of, key agreements, including key strategic alliance agreements;

the results and timing of regulatory reviews relating to the approval of the combined company s product candidates;

failure of any of the combined company s product candidates, if approved, to achieve commercial success;

general and industry-specific economic conditions that may affect the combined company s research and development expenditures;

the results of clinical trials conducted by others on drugs that would compete with the combined company s product candidates;

issues in manufacturing the combined company s product candidates or any approved products;

the initiation of material developments in or the conclusion of litigation to enforce or defend any of the combined company s intellectual property rights;

Edgar Filing: NUVELO INC - Form S-4/A

the loss of key employees;

34

the introduction of technological innovations or new commercial products by competitors of the combined company;

changes in estimates or recommendations by securities analysts, if any, who cover the combined company s common stock;

future sales of the combined company s common stock;

changes in the structure of health care payment systems; and

period-to-period fluctuations in the combined company s financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the combined company s common stock.

In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the combined company s profitability and reputation.

Nuvelo and ARCA do not expect the combined company to pay cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment in the combined company.

Nuvelo and ARCA anticipate that the combined company will retain its earnings, if any, for future growth and therefore does not anticipate paying cash dividends in the future. As a result, only appreciation of the price of the combined company s common stock will provide a return to stockholders. Investors seeking cash dividends should not invest in the combined company s common stock.

Anti-takeover provisions in the combined company s charter and bylaws may prevent or frustrate attempts by stockholders to change the board of directors or current management and could make a third-party acquisition of the combined company difficult.

The combined company s certificate of incorporation and bylaws, as amended, will contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could limit the price that investors might be willing to pay in the future for shares of the combined company s common stock.

Nuvelo and ARCA may not be able to complete the merger or may elect to pursue a different strategic transaction, which may not occur on commercially reasonably terms or at all.

Neither Nuvelo nor ARCA can assure you that they will close the pending merger in a timely manner or at all. The merger agreement is subject to many closing conditions and termination rights, as set forth in more detail in The Merger Agreement Conditions to the Completion of the Merger and The Merger Agreement Termination below. If Nuvelo and ARCA do not close the pending merger, Nuvelo s and ARCA s board of directors may elect to attempt to complete a different strategic transaction. Attempting to complete a different strategic transaction would prove to be costly and time consuming, and neither Nuvelo nor ARCA can make any assurances that a future strategic transaction will occur on commercially reasonable terms or at all.

Risks Related to Nuvelo

Nuvelo may not be able to develop and commercialize any of Nuvelo s product candidates successfully.

Nuvelo has two product candidates in clinical development, and does not know whether it will be able to develop them successfully. In January 2008, Nuvelo announced its enrollment of the first patient in a single-center, Phase 1 trial to determine the safety, tolerability and pharmacokinetics of escalating bolus doses of NU172. In April 2008, Nuvelo announced positive results from this Phase 1 trial. In August 2008, Nuvelo completed a Phase 1b proof-of-concept trial, in which NU172 rapidly produced and maintained anticoagulation with a rapid return toward baseline after the infusion ended. Nuvelo anticipates initiating a Phase 2 study evaluating NU172 in coronary artery bypass graft, or CABG, patients in the first half of 2009. Nuvelo cannot predict whether the results of the anticipated Phase 2 study will be consistent with the results of the earlier studies. Nuvelo cannot predict whether it will be able to initiate and complete the Phase 2 study, or whether it will be successful. Nuvelo has only tested NU172 in healthy, normal volunteers, and does not know how active it will be, or how well it will be tolerated, in patients undergoing medical or surgical procedures.

Nuvelo initiated a Phase 1 single ascending dose healthy volunteer trial for NU206 in Australia in July 2008 and expects top-line data from this trial in the fourth quarter of 2008. Nuvelo cannot predict whether Nuvelo will be able to successfully complete the Phase 1 trial for NU206 in healthy volunteers. Currently, Nuvelo does not have approval from the FDA to study NU206 in healthy volunteers. Nuvelo does not know how active NU206 will be in humans, or how well NU206 will be tolerated.

Nuvelo has had material clinical development failures in the past and may again in the future. In 2006, Nuvelo s clinical-stage product candidate, alfimeprase, did not meet its primary endpoint in the first of two planned Phase 3 trials for the treatment of acute peripheral arterial occlusion, or PAO, and in the first of two planned Phase 3 trials for the treatment of catheter occlusion, or CO. All clinical trials for alfimeprase were suspended in December 2006. Nuvelo subsequently reported its decision to close the suspended PAO trial. In the second quarter of 2007, Nuvelo reported its decision to pursue alfimeprase for the treatment of CO in a Phase 2 trial using a single, higher and more concentrated dose of alfimeprase and reported Nuvelo s decision to pursue alfimeprase for the treatment of acute ischemic stroke in a Phase 2 clinical trial. On March 17, 2008, Nuvelo announced that the data from its alfimeprase Phase 2 trial in CO did not show sufficient improvement in catheter opening at the higher dose and concentration evaluated in the study to meet the desired target product profile. As a result, Nuvelo ended further clinical development of alfimeprase, including the programs in CO and acute ischemic stroke.

In August 2007, Nuvelo announced the suspension of its clinical development of Nuvelo s product candidate, rNAPc2, for the treatment of metastatic colorectal cancer and acute coronary syndromes.

Other than Nuvelo s NU172 and NU206 product development programs, all of Nuvelo s potential products and programs, including its research programs in leukemia therapeutic antibodies and Wnt signaling pathway therapeutics, are currently in research or preclinical development, and revenues from the sales of any products may not occur for several years, if at all. If Nuvelo is unable to successfully develop and commercialize its products, Nuvelo s business, results of operations and financial condition will be affected in a materially adverse manner.

Nuvelo s success is dependent on the proper management of Nuvelo s current and future business operations, and the expenses associated with them.

Nuvelo s business strategy requires it to manage its operations to provide for the continued research and development of its product candidates. Nuvelo s strategy also calls for it to manage relationships with collaborators and other third parties, while simultaneously managing the expenses generated by these activities. In August 2007, Nuvelo announced a reduction of approximately 30% of its workforce, across its research,

36

clinical development and administrative functions. This reduction in force was a part of Nuvelo s efforts to reduce its operating expenses through prioritization of Nuvelo s development portfolio and streamlining Nuvelo s infrastructure. As a result of the reduction in force, Nuvelo recorded a restructuring charge of approximately \$2.3 million in the third quarter of 2007. On March 17, 2008, Nuvelo announced the decision to discontinue alfimeprase clinical development and restructure to make additional resources available for its other research and development programs. As a result of the reduction in force, Nuvelo recorded a restructuring expense of \$2.5 million in the first quarter of 2008.

Nuvelo continues to believe that strict cost containment in the near term is essential if its current funds are to be sufficient to allow it to continue its currently planned operations. If Nuvelo is unable to effectively manage its current operations, it may not be able to implement its business strategy and its financial condition and results of operations will be adversely affected. If Nuvelo is unable to effectively manage its expenses, Nuvelo may find it necessary to reduce its expenses through another reduction in its workforce, which could adversely affect Nuvelo s operations.

If Nuvelo encounters difficulties enrolling patients in its clinical trials, its trials could be delayed or otherwise adversely affected.

Clinical trials for Nuvelo s product candidates require that Nuvelo identify and enroll a large number of patients with the disorder or condition under investigation. Nuvelo may not be able to enroll a sufficient number of patients to complete its clinical trials in a timely manner.

Patient enrollment is affected by factors including:

design of the protocol;
the size of the patient population;
eligibility criteria for the study in question;
perceived risks and benefits of the drug under study;
availability of competing therapies, including the off-label use of therapies approved for related indications;
efforts to facilitate timely enrollment in clinical trials;
the success of Nuvelo s personnel in making the arrangements with potential clinical trial sites necessary for those sites to begin enrolling patients;
patient referral practices of physicians;
availability of clinical trial sites; and

other clinical trials seeking to enroll subjects with similar profiles.

If Nuvelo has difficulty enrolling a sufficient number of patients to conduct its clinical trials as planned, Nuvelo may need to delay or terminate ongoing or planned clinical trials, either of which would have a negative effect on its business. Delays in enrolling patients in Nuvelo s clinical trials would also adversely affect its ability to generate product, milestone and royalty revenues, and could impose significant additional costs on

Edgar Filing: NUVELO INC - Form S-4/A

Nuvelo or on its collaborators.

Nuvelo s clinical trials for its product candidates may not yield results that will enable Nuvelo to further develop its products and obtain the regulatory approvals necessary to sell them.

Nuvelo, and its collaborators, will only receive regulatory approval for its product candidates if Nuvelo can demonstrate in carefully designed and conducted clinical trials that the product candidate is safe and effective. Nuvelo does not know whether its current or any future clinical trials will demonstrate sufficient safety and

37

efficacy to obtain the requisite regulatory approvals or will result in marketable products. Clinical trials are lengthy, complex and expensive processes with uncertain results. Nuvelo has spent, and expects to continue to spend, significant amounts of time and money in the clinical development of its product candidates. It will take Nuvelo several years to complete its testing, and failure can occur at any stage of testing. The results Nuvelo obtains in preclinical testing and early clinical trials may not be predictive of results that are obtained in later studies. Nuvelo may suffer significant setbacks in advanced clinical trials, even after promising results in earlier studies. For example, in December 2006, Nuvelo announced that alfimeprase did not meet its primary endpoint in the first of two planned Phase 3 trials for the treatment of acute PAO and in the first of two planned Phase 3 trials for the treatment of CO. In the second quarter of 2007, Nuvelo reported its decision to close the suspended PAO trial. In March 2008, Nuvelo announced that the data from its alfimeprase Phase 2 program in CO did not show sufficient improvement in catheter opening at the higher dose and concentration evaluated in the study to meet the desired target product profile. As a result, Nuvelo ended further clinical development of alfimeprase, including the programs in CO and acute ischemic stroke. Based on results at any stage of clinical trials, Nuvelo may decide to repeat or redesign a trial or discontinue development of one or more of Nuvelo s product candidates. If Nuvelo fails to adequately demonstrate the safety and efficacy of its products under development, Nuvelo will not be able to obtain the required regulatory approvals to commercialize Nuvelo s product candidates, and its business, results of operations and financial condition would be materially adversely affected.

Clinical trials are subject to continuing oversight by governmental regulatory authorities and institutional review boards, or IRBs, and must meet the requirements of these authorities in the U.S. and in foreign countries, including those for informed consent and good clinical practices. Nuvelo may not be able to comply with these requirements and the FDA, a similar foreign authority, an IRB, or Nuvelo may suspend or terminate clinical trials at any time.

Administering Nuvelo s product candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of Nuvelo s product candidates and could result in the FDA or other regulatory authorities denying approval of its product candidates for any or all targeted indications.

If clinical trials for a product candidate are unsuccessful, Nuvelo will be unable to commercialize the product candidate. If one or more of Nuvelo s clinical trials are delayed, it will be unable to meet its anticipated development timelines. Either circumstance could cause the market price of Nuvelo s common stock to decline. For example, in December 2006, after Nuvelo announced that alfimeprase did not meet its primary endpoint in Phase 3 trials for the treatment of PAO and a Phase 3 trial for CO, the closing price of Nuvelo s common stock was \$4.05 on the day of the announcement, as compared with \$19.55 on the trading day prior to the announcement. Similarly, when Nuvelo announced it was terminating all clinical development of alfimeprase in March 2008, the closing price of Nuvelo s common stock was \$0.73 the day after the announcement, as compared with \$1.36 prior to the announcement.

If Nuvelo fails to maintain existing licenses, or fails to develop new collaborations, its business will be harmed.

The success of Nuvelo s business is dependent, in significant part, upon its ability to maintain current licensing and collaborative relationships, and to enter into multiple new licenses and collaboration agreements. Nuvelo also must manage effectively the numerous issues that arise from such arrangements and agreements. Management of Nuvelo s relationships with these third parties has required and will require:

a significant amount of Nuvelo s management team s time and effort;

effective allocation of Nuvelo and third-party resources to multiple projects;

agreements with third parties as to ownership of proprietary rights and development plans, including clinical trials or regulatory approval strategy; and

the recruitment and retention of management, scientific and other personnel.

In March 2005, Nuvelo entered into a collaboration agreement with the Kirin Pharma Company, Limited for the development and commercialization of NU206. Nuvelo initiated a Phase 1 single ascending dose healthy volunteer trial for NU206 in Australia in July 2008, and expects top-line data expected from this trial in the fourth quarter of 2008. All operating expenses and any profits related to the development and commercialization of NU206 are being shared 60 percent by Nuvelo and 40 percent by Kirin. If this agreement is terminated, or Nuvelo or Kirin elect under certain circumstances to no longer actively participate in the collaboration, the relationship with respect to NU206 will convert from an expense and profit sharing structure to a royalty-based structure. If the agreement is terminated by Kirin, Nuvelo will be responsible for all costs and expenses associated with Nuvelo s research and development of NU206.

On July 31, 2006, Nuvelo entered into an agreement with Archemix Corporation. Under the agreement, Archemix is responsible for the discovery of short-acting aptamers targeting the coagulation cascade for use in acute cardiovascular procedures, and Nuvelo is responsible for development and worldwide commercialization of these product candidates. Under the agreement, Nuvelo made an upfront license fee payment to Archemix of \$4.0 million. Nuvelo is also funding at least \$5.25 million of Archemix is research in the area of short-acting aptamer discovery over the first six years of the agreement. In addition, Nuvelo may have to make payments to Archemix totaling up to \$35.0 million per development compound on the achievement of specified development and regulatory milestones, along with potential royalty payments based on sales of licensed compounds. In August 2008, Nuvelo completed a Phase 1b proof-of-concept trial, in which NU172 rapidly produced and maintained anticoagulation with a rapid return toward baseline after the infusion ended. Nuvelo anticipates initiating a Phase 2 study evaluating NU172 in CABG patients in the first half of 2009. If and when Nuvelo enrolls the first patient in a Phase 2 study of NU172, a \$3.0 million milestone fee becomes payable to Archemix. At the initiation of the first Phase 3 study for any licensed compound, Archemix has the option to elect to participate in profits from sales of the compound by funding its pro rata share of prior and future product development and commercialization expenses, in lieu of receiving milestone payments and royalties with respect to that compound. Nuvelo also is obligated to purchase Archemix common stock having a value equal to the lesser of \$10.0 million or 15 percent of the total gross proceeds raised by Archemix in a qualified public offering of Archemix stock occurring within five years of the effective date of the collaboration agreement.

Due to the factors discussed above and other possible disagreements with current or potential collaborative partners, Nuvelo may be delayed or prevented from developing or commercializing NU172, NU206 or other preclinical product candidates, or Nuvelo may become involved in litigation or arbitration with its partners, which would be time-consuming or expensive and could have a material adverse effect on Nuvelo s stock price. Nuvelo s relationships with its collaboration partners also may be materially adversely affected by any failure to successfully enroll or complete any of its planned trials of its product candidates. Nuvelo s efforts to manage simultaneously a number of collaboration arrangements may not be successful, and its failure to manage effectively such collaborations would significantly harm its business, financial condition and results of operations.

In addition to Nuvelo s existing collaborations, Nuvelo may enter into new collaborative arrangements whereby Nuvelo would share costs of identifying, developing and marketing product candidates. Nuvelo cannot assure you that it will be able to negotiate new collaboration arrangements of this type on acceptable terms, or at all.

Nuvelo heavily depends on third parties for manufacturing and a variety of other functions, including clinical trials management. Nuvelo s current and future arrangements with its manufacturers and other third parties may not provide it with the benefits Nuvelo expects.

Nuvelo does not have the resources, facilities or experience to manufacture its product candidates on its own. Nuvelo relies on third parties, such as contract research and manufacturing organizations, to manufacture its product candidates for clinical trials, and, if Nuvelo s product candidates are approved, in quantities for commercial sales. Nuvelo currently relies on a number of sole-source service providers and suppliers to manufacture bulk drug substance, fill and finish its product candidates and label and package them. Nuvelo does

39

not have long-term supply agreements with these third-party manufacturers. Nuvelo may not be able to finalize contractual arrangements, transfer technology or maintain relationships with such organizations in order to file an investigational new drug application, or IND, with the FDA, and proceed with clinical trials for any of Nuvelo s product candidates.

Since a Phase 2 study of NU172 is to be initiated, and NU206 is in Phase 1 clinical trials, Nuvelo is dependent upon third-party contract manufacturers to develop the necessary production processes and produce the volume of cGMP-grade material needed to complete such trials. Nuvelo has entered into and intends to enter into additional contractual relationships with third parties in order to (i) complete the Good Laboratory Practices, or GLP, toxicology and other studies necessary to file INDs with the FDA, (ii) produce a sufficient volume of cGMP-grade material in order to conduct clinical trials of these other product candidates and (iii) fill and finish and label and package Nuvelo s material. Nuvelo cannot be certain that it will be able to complete these tasks on a timely basis or that it will be able to obtain sufficient quantities of material or other manufacturing services on commercially reasonable terms. In addition, the failure of any of these third parties to perform their obligations may delay Nuvelo s filing for an IND or impede Nuvelo s progress through the clinical trial phase. Any significant delay or interruption would have a material adverse effect on Nuvelo s ability to file an IND with the FDA and/or proceed with the clinical trial phase for any of its product candidates.

Moreover, contract manufacturers that Nuvelo may use must continually adhere to cGMP enforced by the FDA through a facilities inspection program. If one of Nuvelo s contract manufacturers fails to maintain compliance, the production of Nuvelo s product candidate could be interrupted, resulting in delays, additional costs and potentially lost revenues. In addition, if the facilities of such manufacturers do not pass a pre-approval plant inspection, the FDA will not grant pre-market approval of Nuvelo s product candidates.

Nuvelo also currently relies upon third parties to perform administrative functions and functions related to the research, development, preclinical testing and clinical trials of its product candidates. Nuvelo s reliance on third-party contract research organizations and consultants that manage and monitor its clinical trials may result in delays in completing, or in failing to complete, Nuvelo s clinical trials if they fail to perform with the speed and competency Nuvelo expects. Nuvelo s reliance on third-party contract research organizations to conduct research and testing, including GLP, and toxicology studies necessary to gather the data necessary to file INDs with the FDA for any of Nuvelo s product candidates may result in delays in Nuvelo s regulatory filings if the third parties do not conduct their research or testing properly, or if they fail to complete their contract research or testing on the anticipated schedule. In either case, the progress of Nuvelo s clinical programs may be delayed and Nuvelo s research and development costs may increase, which may in turn have a material adverse affect on Nuvelo s business.

Nuvelo s reliance on these manufacturing and other contract services relationships poses a number of risks, including:

inability of third parties to manufacture, including filing and finishing and labeling and packaging, Nuvelo s product candidates in a cost-effective or timely manner or in quantities needed for clinical trials;

changes to current raw material suppliers or product manufacturers (whether the change is attributable to Nuvelo or the supplier or manufacturer), resulting in delayed clinical studies, regulatory submissions and commercialization of Nuvelo s product candidates;

failure to identify acceptable manufacturers or other suppliers or enter into favorable long-term agreements with them;

ineffective clinical trials management or monitoring resulting in delays in or interruptions to Nuvelo s clinical trials;

delays in, or failures to achieve, scale-up to commercial quantities of Nuvelo s product candidates resulting in delayed regulatory submissions and commercialization of Nuvelo s product candidates;

40

Nuvelo s inability to effectively control the resources devoted by Nuvelo s partners to its programs or products;

disagreements with third parties that could disrupt Nuvelo s operation or delay or terminate the research, development or manufacturing of product candidates, or result in litigation or arbitration;

inadequate contractual protection or difficulty in enforcing the contracts if one of Nuvelo s partners fails to perform;

failure of these third parties to comply with regulatory requirements;

conflicts of interest between third parties work for Nuvelo and their work for another entity or entities, and the resulting loss of their services; and

lack of all necessary intellectual property rights to manufacture and sell Nuvelo s product candidates. Given these risks, Nuvelo s current and future arrangements with third parties may not be successful. If these efforts fail, Nuvelo would be required to devote additional internal resources to the activities currently performed, or to be performed, by third parties, to seek alternative third-party sources, or to delay Nuvelo s product development or commercialization.

Nuvelo is dependent on key personnel, and it must attract and retain qualified employees, collaborators and consultants.

The success of Nuvelo s business is highly dependent on the principal members of Nuvelo s scientific and management staff, including Nuvelo s senior management team. The loss of the services of any such individual might seriously harm Nuvelo s product development efforts. Retaining and training personnel with the requisite skills is challenging and extremely competitive, particularly in Northern California, where Nuvelo is located.

Nuvelo s success will depend on Nuvelo s ability to attract and retain qualified employees to help develop its potential products and execute its research and development strategy. Nuvelo has programs in place to retain personnel, including programs to create a positive work environment and competitive compensation packages. Because competition for employees in Nuvelo s field is intense, however, Nuvelo may be unable to retain its existing personnel or attract qualified individuals to fill open positions. In addition, in August 2007 and again in March 2008 Nuvelo reduced its workforce as part of its efforts to reduce operating expenses through prioritization of its development portfolio and streamlining its infrastructure. These reductions in Nuvelo s workforce, together with its evaluation of strategic alternatives, may impair its ability to recruit and retain qualified employees and to effectively complete administrative and development functions. If Nuvelo needs to rehire terminated individuals or hire individuals with similar skills, it may be unable to do so. Nuvelo s success also depends on the continued availability of outside scientific collaborators, including collaborators at research institutions, to perform research and develop processes to advance and augment Nuvelo s internal research efforts. Competition for collaborators is intense. Nuvelo also relies on services provided by outside consultants. Attracting and retaining qualified outside consultants is competitive, and, generally, outside consultants can terminate their relationship with Nuvelo at will. If Nuvelo does not retain qualified personnel, outside consultants and scientific collaborators, or if it experiences turnover or difficulties recruiting new employees or outside consultants, Nuvelo s research and development programs could be delayed, and it could experience difficulties in generating sufficient revenue to maintain its business.

Nuvelo may not achieve its projected development goals in the time frames it announces and expects.

Nuvelo sets goals for, and makes public statements regarding, the timing of certain accomplishments, such as the commencement and completion of clinical trials and the disclosure of trial results, which Nuvelo sometimes refers to as milestones. These milestones may not be achieved, and the actual timing of these events can vary dramatically due to a number of factors such as delays or failures in Nuvelo s clinical trials, disagreements with current or future collaborative partners, the uncertainties inherent in the regulatory approval

Table of Contents 75

41

process and manufacturing scale-up and delays in achieving manufacturing or marketing arrangements sufficient to commercialize Nuvelo s products. There can be no assurance that Nuvelo s clinical trials will be completed, or that it will make regulatory submissions or receive regulatory approvals as planned. If Nuvelo fails to achieve one or more of these milestones as planned, its business will be materially adversely affected, and the price of Nuvelo s shares will decline.

The success of Nuvelo s potential products in research and preclinical studies does not guarantee that these results will be replicated in humans.

Several of Nuvelo s drug development programs are currently in the research stage or in preclinical development, including Nuvelo s research programs in leukemia therapeutic antibodies and Wnt signaling pathway therapeutics. Although Nuvelo s clinical development-stage product candidates have shown favorable results in preclinical studies, these results may not be replicated in Nuvelo s clinical trials with humans. Before Nuvelo makes any products available to the public from its research and development programs, Nuvelo or its collaboration partners will need to conduct further research and development and complete laboratory testing and animal studies. These programs may not move beyond their current stages of development. Even if Nuvelo s research does advance, Nuvelo will need to engage in certain additional preclinical development efforts to determine whether a product is sufficiently safe and effective to enter clinical trials. Nuvelo has little experience with these activities with respect to protein candidates and may not be successful in developing these products. Consequently, there is no assurance that the results in Nuvelo s research and preclinical studies are predictive of the results that Nuvelo may see in its clinical trials with humans or that they are predictive of whether any resulting products will be safe and effective in humans.

FDA and international regulatory approval of Nuvelo s products is uncertain.

The research, testing, manufacturing and marketing of drug products such as those proposed to be developed by Nuvelo or its collaboration partners are subject to extensive regulation by federal, state and local governmental authorities, including the FDA and comparable agencies in other countries. To obtain regulatory approval of a drug product, Nuvelo or its collaboration partners must demonstrate to the satisfaction of the applicable regulatory agency, among other things, that the product is safe and effective for its intended uses. In addition, Nuvelo must show that the manufacturing facilities used to produce the products are in compliance with current cGMP and that the process for manufacturing the product has been validated in accordance with the requirements of the FDA and comparable agencies in other countries.

The process of obtaining FDA and other required regulatory approvals and clearances typically takes several years and will require Nuvelo to expend substantial capital and resources. Despite the time and expense expended, regulatory approval is never guaranteed. The number of preclinical and clinical tests that will be required for FDA and international regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is in development for, and the regulations applicable to that particular product candidate. The FDA or comparable international regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

a product candidate may not be safe or effective;

the FDA or comparable international regulatory authorities may interpret data from preclinical and clinical testing in different ways than Nuvelo and Nuvelo s collaboration partners interpret them;

the FDA or comparable international regulatory authorities may not approve Nuvelo s manufacturing processes or facilities or the processes or facilities of Nuvelo s collaboration partners; or

the FDA or comparable international regulatory officials may change their approval polices or adopt new regulations.

42

In addition, in order to market any products outside of the U.S., Nuvelo and its collaborators must establish and comply with numerous and varying regulatory requirements of other jurisdictions, including the European Medicines Evaluation Agency, or EMEA, regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries differs from that required to obtain FDA approval. The regulatory approval process in other countries can include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U.S.

If and when Nuvelo s products obtain such approval or clearances, the manufacturing, marketing and distribution of such products would remain subject to extensive ongoing regulatory requirements. Failure to comply with applicable regulatory requirements could result in:

	warning letters;
	fines;
	civil penalties;
	injunctions;
	recall or seizure of products;
	total or partial suspension of production;
	refusal of the government to grant approvals; or
any delay	withdrawal of approvals and criminal prosecution. or failure by Nuvelo, or its collaboration partners, to obtain regulatory approvals for Nuvelo s product candidates:
	would adversely affect Nuvelo s ability to generate product, milestone and royalty revenues;
	could impose significant additional costs on Nuvelo or its collaboration partners;
	could diminish competitive advantages that Nuvelo may attain;
	would adversely affect the marketing of Nuvelo s products; and

could cause the price of Nuvelo s shares to decline.

Even if Nuvelo receives regulatory approval for its product candidates, the FDA or international regulatory authorities may impose limitations on the indicated uses for which Nuvelo s products may be marketed and subsequently withdraw approval or take other actions against Nuvelo, or its products, that are adverse to Nuvelo s business. The FDA and comparable international regulatory authorities generally approve products for particular indications. An approval for a limited indication reduces the size of the potential market for the product. Product approvals, once granted, may be withdrawn if problems occur after initial marketing.

Nuvelo has not yet commercialized any of its product candidates; Nuvelo s ability to commercialize products is unproven.

Nuvelo has not yet commercialized any of its in-licensed therapeutic product candidates. Nuvelo s commercialization of products is subject to several risks, including but not limited to:

the possibility that a product is toxic, ineffective or unreliable;

failure to obtain regulatory approval for the product;

43

Table of Contents
difficulties in manufacturing the product on a large scale;
difficulties in planning, coordinating and executing the commercial launch of the product;
difficulties in marketing, distribution or sale of the product;
the possibility of a failure to comply with laws and regulations related to the marketing sale and reimbursement of the product;
competition from superior products; or
third-party patents that preclude Nuvelo from marketing a product. Any regulatory approvals that Nuvelo or its collaboration partners receive for Nuvelo s product candidates may be subject to limitations on the intended uses for which the product candidates may be marketed or contain requirements for potentially costly post-marketing follow-up studies. The labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping for any approved product will be subject to extensive regulatory requirements. Additionally, Nuvelo, its collaborators and its suppliers may not be able to produce any products in commercial quantities at a reasonable cost or may not be able to successfully market such products. If Nuvelo does not develop a commercially viable product, then Nuvelo will suffer significant harm to its business, financial condition and operating results.
Even if a product candidate is approved for commercial sale, significant strategic planning and resources will be necessary to effectively coordinate the commercial launch of the product in the approved indication or indications, and to effectively market, distribute and sell the product for use in the approved indication or indications. In addition, the marketing, distribution, sale and reimbursement of pharmaceutical products is heavily regulated, and Nuvelo must comply with all such applicable laws and regulations, or incur costs, fees, fines and other liabilities associated with non-compliance. If Nuvelo s or a collaboration partner s commercial launch of a product approved for commercial sale were to be unsuccessful, or if Nuvelo or a collaboration partner were to fail in Nuvelo s or their efforts to properly market, distribute or sell any product approved for sale, Nuvelo s business, financial condition and operating results would suffer significant harm.
Even if approved, Nuvelo s products may not be accepted in the marketplace, and Nuvelo may not be able to generate significant revenue, if any.
Even if they are approved for marketing, Nuvelo s products, if any, may never achieve market acceptance among physicians, patients and the medical community. The degree of market acceptance of any products developed by Nuvelo, alone or in conjunction with collaboration partners, will depend on a number of factors, including:
the establishment and demonstration of the clinical efficacy and safety of the products;
convenience and ease of administration;
cost-effectiveness;
Nuvelo s products potential advantages over alternative treatment methods;

Table of Contents 79

marketing, sales and distribution support of Nuvelo s products; and

reimbursement policies of government and third-party payers.

Physicians, patients or the medical community in general may not accept and utilize any of the products that Nuvelo alone, or in conjunction with Nuvelo s collaboration partners, develops. In practice, competitors may be more effective in marketing their drugs. The lack of such market acceptance would significantly harm Nuvelo s business, financial condition and results of operations. Even if Nuvelo s product candidates are approved for marketing and are accepted by physicians, patients and the medical community, the size of the market for these

44

Table of Contents

products may be insufficient to sustain Nuvelo s business, or may not provide an acceptable return on Nuvelo s investment in the development of these products. As a result, the commercialization of any of Nuvelo s product candidates could fail even if Nuvelo receives marketing approval from the FDA or similar foreign authorities, and acceptance by the medical and patient communities.

Nuvelo faces intense competition.

The biopharmaceutical industry is intensely competitive, which is accentuated by the rapid pace of technological development. Nuvelo s products, if successfully developed, will compete with a number of traditional drugs and therapies and with new products currently under development. Nuvelo also expects to face increased competition in the future as new companies enter Nuvelo s markets. Research and discoveries by others may result in breakthroughs that render Nuvelo s potential products obsolete even before they begin to generate any revenue. The competitors for Nuvelo s drugs currently in development will vary depending on the particular indication pursued, and may include major pharmaceutical, medical device and biotechnology firms, many of which have substantially greater research and product development capabilities and financial, scientific, marketing and human resources than Nuvelo has. Nuvelo s lead clinical-stage product candidate, NU172, is an anticoagulant that has the potential for predictable anticoagulant effects and rapid self-reversal. If approved, it could face competition from other drugs or devices that are used to anticoagulate a patient in the setting of medical or surgical procedures where human blood is exposed to foreign materials such as coronary artery bypass graft surgery, kidney dialysis and a variety of vascular surgical and coronary interventions. Competition differs depending on the indication and includes, for example, heparin and its antidote, protamine, as well as Angiomax® bivalirudin, an approved product of The Medicines Company. Nuvelo s second product candidate, NU206, if approved for the treatment of mucositis, could face competition from drugs such as palifermin, an approved Amgen product.

Nuvelo s competitors may obtain patents and regulatory approvals for their competing products more rapidly than Nuvelo or its collaboration partners, or develop products that are more effective than those developed by Nuvelo or its collaboration partners. All of Nuvelo s products will face competition from companies developing similar products as well as from companies developing other forms of treatment for the same conditions.

Many of the companies developing competing products have greater expertise than Nuvelo or its collaboration partners have in discovery, research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing. Other smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies as well as other organizations compete with Nuvelo in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to Nuvelo s programs. Nuvelo may face competition with respect to:

product efficacy and safety;
the timing and scope of regulatory approvals;
availability of resources;
reimbursement coverage; and

price and patent position, including the potentially dominant patent positions of others.

There can be no assurance that research and development by others will not render the products that Nuvelo may develop obsolete or uneconomical, or result in treatments or cures superior to any therapy developed by Nuvelo or that any therapy Nuvelo develops will be preferred to any existing or newly-developed alternative products.

Nuvelo is subject to the risk of natural disasters.

Nuvelo s facilities are located in Northern California. If a fire, earthquake, flood or other natural disaster disrupts Nuvelo s research or development efforts, Nuvelo s business, financial condition and operating results could be materially adversely affected. Although Nuvelo maintains personal property and general business interruption coverage, it does not maintain earthquake or flood insurance coverage for personal property or resulting business interruption.

Risks Related to Nuvelo s Capital Structure and Financial Results and Stock Price Volatility

Nuvelo will need to raise additional capital, and such capital may be unavailable to Nuvelo when it needs it or not available on acceptable terms

Nuvelo will need to raise significant additional capital to finance the research and clinical development of Nuvelo s product candidates. If future securities offerings are successful, they could dilute Nuvelo s current stockholders equity interests and reduce the market price of Nuvelo s common stock. Financing may be unavailable when Nuvelo needs it or may not be available on acceptable terms. The unavailability of financing may require Nuvelo to delay, scale back or eliminate expenditures for the research and development of Nuvelo s potential biopharmaceutical products. Nuvelo may also be required to raise capital by granting rights to third parties to develop and market product candidates that Nuvelo would prefer to develop and market on its own, potentially reducing the ultimate value that Nuvelo could realize from these product candidates.

If Nuvelo is unable to obtain additional financing when it needs it, the capital markets may perceive that Nuvelo is not able to raise the amount of financing it desires, or on the terms that it desires. This perception, if it occurs, may negatively affect the market price of Nuvelo s common stock. If sufficient capital is not available, Nuvelo may be forced to delay, reduce the scope of, eliminate or divest one or more of Nuvelo s research or development programs. As an example, in August 2007, Nuvelo announced that it suspended the clinical development of rNAPc2. Any such action could significantly harm Nuvelo s business, financial condition and results of operations.

Nuvelo s future capital requirements and the adequacy of Nuvelo s currently available funds will depend on many factors, including, among others, the following:

any business transactions or arrangements through which the Company acquires or purchases new products, product candidates or other companies;

Nuvelo s ability to maintain, and the financial commitments involved in, Nuvelo s existing collaborative and licensing arrangements, including Nuvelo s ability to continue to receive cost-sharing reimbursements from Kirin;

progress in current and anticipated clinical studies of Nuvelo s products, including NU172 and NU206;

Nuvelo s need to develop, acquire or license new technologies or products;

future funding commitments to new and existing collaborators, such as Archemix, from which Nuvelo is obligated to purchase Archemix common stock having a value equal to the lesser of \$10.0 million or 15% of the total gross proceeds raised by Archemix in a qualified public offering;

the cost of manufacturing Nuvelo s material for preclinical and clinical purposes;

Nuvelo s ability to establish new collaborative relationships with other companies to share costs and expertise of identifying, developing and commercializing product candidates;

the magnitude and scope of Nuvelo s research and development programs, including development of product candidates;

continued scientific progress in Nuvelo s research and development programs, including progress in Nuvelo s research and preclinical studies;

46

the cost involved in maintaining facilities to support research and development of Nuvelo s product candidates;

the cost of prosecuting and enforcing Nuvelo s intellectual property rights;

the time and cost involved in obtaining regulatory approvals;

competing technological and market developments;

current conditions and the uncertainty of future conditions in the financial markets and in the biotech sector; and

other factors not within Nuvelo s control.

As of September 30, 2008, Nuvelo s stock price does not meet the minimum bid price for continued listing on the Nasdaq Global Market. Nuvelo s ability to publicly or privately sell equity securities and the liquidity of Nuvelo s common stock could be adversely affected if Nuvelo is delisted from the Nasdaq Global Market or if Nuvelo is unable to transfer its listing to another stock market.

Nasdaq Global Market listing standards require that for continued listing, the bid price of Nuvelo s common stock must be a minimum of \$1.00 per share. Since Nuvelo announced on March 17, 2008 that it was terminating the development of alfimeprase, the bid price of Nuvelo s common stock has been less than \$1.00 each trading day since March 18, 2008. On May 1, 2008, Nuvelo received notice from Nasdaq indicating that, for 30 consecutive business days, the bid price for Nuvelo s common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on the Nasdaq Global Market. Nuvelo was given 180 calendar days, or until October 28, 2008, to regain compliance with this listing requirement, which would be accomplished if the bid price of Nuvelo s common stock closed at \$1.00 per share or more for a minimum of 10 consecutive business days. As of September 30, 2008, the bid price of Nuvelo s common stock closed at \$0.44 per share. The notice from Nasdaq also indicated that, if Nuvelo does not regain compliance by October 28, 2008, Nasdaq would provide a staff determination letter notifying Nuvelo that its common stock will be delisted, after which Nuvelo may appeal the staff determination to the Nasdaq Listing Qualifications Panel. On October 16, 2008, Nasdaq advised Nuvelo that it had suspended until January 19, 2009 the enforcement of the rules requiring a minimum \$1.00 closing bid price for all Nasdaq listed companies.

Following the end of this suspension period and the 12 days balance of Nuvelo s initial 180 days compliance period, Nuvelo expects to receive a staff determination letter if it has not regained compliance by that time. Upon receipt of the determination letter, Nuvelo intends to submit a request to appeal the determination and present a plan for compliance at an oral hearing with Nasdaq in Washington, D.C. The request for appeal will automatically stay the determination until the appeal is heard and a Nasdaq panel rules on whether to grant conditional listing for up to 180 days following the staff determination in order for Nuvelo to complete its plan of compliance. There can be no assurance that the appeal will be successful or on the timeline presented above or that the plan of compliance and the combined company will be able to satisfy the requirements for maintaining a Nasdaq Global Market listing.

As part of this prospectus/proxy statement/consent solicitation, Nuvelo is seeking stockholder approval for a reverse split of its common stock in order to regain compliance with Nasdaq s minimum bid price requirement. See the section of this prospectus/proxy statement/consent solicitation titled Nuvelo Proposal No. 2 Amendment to Amended and Restated Certificate of Incorporation to Effect a Reverse Stock Split of Nuvelo s Common Stock. There can be no assurance that the reverse split will be approved or will have its desired effect.

If Nuvelo does not regain compliance with this listing requirement by the new deadline imposed by Nasdaq, but meets the initial inclusion criteria for the Nasdaq Capital Market (except for the bid price requirement), Nuvelo may apply to transfer the listing of Nuvelo s common stock to this market. If accepted by the Nasdaq Capital Market, Nuvelo will be provided with an additional 180-day period to demonstrate compliance. If Nuvelo

is not eligible for an additional compliance period at that time, Nasdaq will provide written notification that Nuvelo s securities will be delisted. Upon such notice, Nuvelo may appeal the determination to the Nasdaq Listing Qualifications Panel. There can be no assurance that Nuvelo s common stock would be eligible for transfer to the Nasdaq Capital Market, or, if Nuvelo appeals Nasdaq staff s determination, that such appeal would be successful.

If Nuvelo s common stock is delisted by Nasdaq, its common stock may be eligible for quotation on the OTC Bulletin Board maintained by Nasdaq, another over-the-counter quotation system, or on the pink sheets. Upon any such delisting, Nuvelo s common stock would become subject to the regulations of the Securities and Exchange Commission relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than \$5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for Nuvelo s common stock and could limit your ability to sell your securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of Nuvelo s common stock, although there can be no assurance that Nuvelo s common stock will be eligible for trading or quotation on any alternative exchanges or markets.

Delisting from Nasdaq could adversely affect Nuvelo s ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade Nuvelo s securities and would negatively affect the value and liquidity of Nuvelo s common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

Nuvelo s stock price has historically been and is likely to remain highly volatile, and an investment in Nuvelo s stock could suffer a decline in value.

Stock prices and trading volumes for many biopharmaceutical companies fluctuate widely for a number of reasons, including factors which may be unrelated to their businesses or results of operations, such as media coverage, legislative and regulatory measures and the activities of various interest groups or organizations. This market volatility, as well as general domestic or international economic, market and political conditions, could materially and adversely affect the market price of Nuvelo s common stock and the return on any investment in Nuvelo s common stock.

Historically, Nuvelo s stock price has been extremely volatile. Between January 1, 2007 and December 31, 2007, the price ranged between a high of \$6.63 per share and a low of \$1.26 per share. Between January 1, 2008 and October 31, 2008, the price ranged between a high of \$1.88 per share and a low of \$0.21 per share. In March 2008, Nuvelo announced that the data from Nuvelo s Phase 2 program in catheter occlusion did not show sufficient improvement in catheter opening at the higher dose and concentration evaluated in the study to meet the desired target product profile and that Nuvelo ended further clinical development of alfimeprase. The closing price of Nuvelo s common stock was \$0.73 the day after this announcement, as compared with \$1.36 prior to this announcement. Significant market price fluctuations of Nuvelo s common stock can be due to a variety of factors, including:

any announcements of or speculation about strategic transactions involving Nuvelo, such as its merging with, being acquired by, or acquiring another entity;

the experimental nature of, and public concern or expectations with respect to, Nuvelo s product candidates;

actual or anticipated fluctuations in Nuvelo s operating results;

the depth of demand for Nuvelo s common stock;

sales of Nuvelo s common stock by existing holders, or sales of shares issuable upon exercise of outstanding options and warrants;

market conditions relating to the biopharmaceutical and pharmaceutical industries;

any announcements of technological innovations, new commercial products or collaborations, or clinical progress or lack thereof by Nuvelo, its collaborative partners or its competitors;

announcements concerning regulatory developments or developments with respect to proprietary rights;

changes in Nuvelo s collaborative arrangements;

changes in or Nuvelo s failure to meet market or, to the extent securities analysts follow Nuvelo s common stock, securities analysts expectations;

loss of key personnel;

changes in accounting principles; and

general market conditions.

In addition, the stock market in general, and the market for biotechnology and other life science stocks in particular, has recently and historically been subject to extreme price and volume fluctuations. This volatility has had a significant effect on the market prices of securities issued by many companies for reasons unrelated to the operating performance of these companies.

Nuvelo has a significant accumulated deficit and anticipates continuing losses.

Nuvelo has incurred significant net losses, including \$130.6 million in 2006, \$12.3 million in 2007 and \$27.2 million in the nine months ended September 30, 2008. As of September 30, 2008, Nuvelo had an accumulated deficit of \$497.7 million and Nuvelo anticipate continuing losses for the foreseeable future.

All of Nuvelo s product candidates are in various stages of product development, and some are still in research or in early development. None of them are approved for sale. The process of developing Nuvelo s drug products will require significant additional research and development, preclinical testing, clinical trials and regulatory approvals.

These activities, together with drug manufacturing, general administrative and other expenses, are expected to result in operating losses for the foreseeable future. To date, Nuvelo has not generated any revenues from product sales. Nuvelo does not expect to achieve significant product sales or royalty revenue from product sales for several years, and it may never do so. Nuvelo expects to incur additional operating losses in the future, and these losses may increase significantly as Nuvelo continues preclinical research and clinical trials, applies for regulatory approvals and develops its product candidates. These losses, among other things, have caused and may cause Nuvelo s stockholders—equity and working capital to decrease. Nuvelo may not be successful in developing its product candidates and obtaining regulatory approvals. Nuvelo may never generate profits and, as a result, the market price of Nuvelo—s common stock could decline.

Moreover, utilization of Nuvelo s net operating loss and research and development credit carryforwards are subject to an annual limitation under the change in ownership provisions of the Internal Revenue Code of 1986 and similar state law provisions, as a result of certain transactions that Nuvelo has entered into prior to 2006. If the proposed merger with ARCA is consummated, a change in ownership of Nuvelo will occur and Nuvelo s ability to utilize these carryforwards will be substantially reduced.

Nuvelo may face fluctuations in operating result	Nuvelo m	nav face	fluctuations i	in operatin	g results.
--	----------	----------	----------------	-------------	------------

Nuvelo s operating results may rise or fall significantly from period to period as a result of many factors, including:

any business transactions or arrangements through which Nuvelo acquires or purchases new products or product candidates;

the amount of research and development Nuvelo engages in;

if Nuvelo is obligated to purchase Archemix common stock having a value equal to the lesser of \$10.0 million or 15 percent of the total gross proceeds, in accordance with the collaboration agreement with Archemix;

the number of product candidates Nuvelo has, their progress in research, preclinical and clinical studies and the costs involved in manufacturing them;

Nuvelo s ability to maintain existing and enter into new strategic relationships;

the scope, duration and effectiveness of Nuvelo s licensing and collaborative arrangements;

Nuvelo s ability to maintain its facilities to support its operations;

the costs involved in prosecuting, maintaining and enforcing patent claims;

the possibility that others may have or obtain patent rights that are superior to Nuvelo s;

changes in government regulation;

changes in the price of Nuvelo s common stock or other variables used as a basis for valuing stock-based awards;

changes in accounting policies or principles; and

release of successful products into the market by Nuvelo s competitors.

In addition, as a result of Nuvelo s adoption of SFAS 123(R), Nuvelo must measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee s requisite service period. As the variables that Nuvelo uses as a basis for valuing future awards change over time, the magnitude of the expense that Nuvelo must recognize may vary significantly. Any such variance from one period to the next could cause a significant fluctuation in Nuvelo s operating results.

All of Nuvelo s potential products are currently in research, preclinical or clinical development, and revenues from the sales of any products resulting from this research and development may not occur for several years, if at all. Nuvelo has a significant amount of fixed costs such as lease obligations, and certain charges to Nuvelo s statement of operations are dependent on movements in the price of Nuvelo s common stock, which historically has been and is likely to remain highly volatile. As a result, Nuvelo may experience fluctuations in its operating results from quarter to quarter and continue to generate losses. Quarterly comparisons of Nuvelo s financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of Nuvelo s future performance. In addition, investors may react adversely if Nuvelo s reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors or the financial community, which may result in a drop in the market price of Nuvelo s common stock.

Future sales or the possibility of future sales of Nuvelo s common stock may depress the market price of Nuvelo s common stock.

Sales in the public market of substantial amounts of Nuvelo s common stock could depress prevailing market prices of its common stock. As of October 31, 2008, Nuvelo had 53,663,805 shares of common stock

50

outstanding. All of these shares are freely transferable without restriction or further registration under the Securities Act, except for shares held by Nuvelo s directors, officers and other affiliates and unregistered shares held by non-affiliates. As of October 31, 2008, Nuvelo s directors, officers and greater than five percent stockholders held approximately 13 percent of the shares of Nuvelo s outstanding common stock. Although Nuvelo does not believe that Nuvelo s directors, officers and greater than five percent stockholders have any present intentions to dispose of large amounts of any shares of common stock owned by them, there can be no assurance that such intentions will not change in the future. The sale of these additional shares could depress the market price of Nuvelo s common stock.

As of October 31, 2008, Nuvelo had approximately 12,427,026 shares of Nuvelo s common stock which may be issued under Nuvelo s 2004 Equity Incentive Plan, 2002 Equity Incentive Plan, 1995 Stock Option Plan, Non-Employee Director Stock Option Plan, stock option agreements entered into outside of any of Nuvelo s stock option plans, and Nuvelo s Employee Stock Purchase Plan. Included in these 12,427,026 shares are (i) 5,140,278 shares of Nuvelo s common stock issuable under outstanding options to purchase Nuvelo s common stock under the specified plans, (ii) 439,386 shares of Nuvelo s common stock issuable under stock option agreements entered into outside of any of Nuvelo s stock option plans, (iii) 27,332 shares of Nuvelo s common stock issuable under restricted stock units, (iv) 6,537,957 shares of Nuvelo s common stock reserved for future grants under Nuvelo s 2004 Equity Incentive Plan, and (v) 282,073 shares of Nuvelo s common stock reserved for future issuance under Nuvelo s Employee Stock Purchase Plan. As of October 31, 2008, outstanding options to purchase 4,139,459 shares of common stock were exercisable, and no restricted stock units have been vested. If and when these options are exercised, such shares are available for sale in the open market without further registration under the Securities Act. The existence of these outstanding options and share reserves may negatively affect Nuvelo s ability to complete future equity financings at acceptable prices and on acceptable terms. The exercise of those options, and the prompt resale of shares of Nuvelo s common stock received, may also result in downward pressure on the price of Nuvelo s common stock.

As of October 31, 2008, 850,224 shares of Nuvelo s common stock were issuable upon the exercise of outstanding warrants, which were all exercisable as of this date. Once a warrant is exercised, the holder can arrange for the resale of shares either by invoking any applicable registration rights, causing the shares to be registered under the Securities Act and thus freely transferable, or by relying on an exemption to the Securities Act. If these registration rights, or similar registration rights that may apply to securities Nuvelo may issue in the future, are exercised, it could result in additional sales of Nuvelo s common stock in the market, which may have an adverse effect on Nuvelo s stock price.

Nuvelo will need to raise significant additional capital to finance the research, development and commercialization of Nuvelo s drug products. If future securities offerings are successful, they could dilute Nuvelo s current stockholders equity interests and reduce the market price of its common stock.

Nuvelo s investments in marketable debt securities are subject to credit risk that may adversely affect their fair value.

Nuvelo maintains a significant portfolio of investments in marketable debt securities, which are recorded at fair value. To minimize Nuvelo s exposure to credit risk, Nuvelo invests in securities with strong credit ratings and has established guidelines relative to diversification and maturity with the objective of maintaining safety of principal and liquidity. Nuvelo does not invest in derivative financial instruments, mortgage-backed securities or auction rate securities, and Nuvelo has not recorded any losses on Nuvelo s securities due to credit or liquidity issues. In 2007 and 2008, rising delinquency and default rates on subprime mortgages and declining home prices had caused a significant decline in the value of residential mortgage-backed securities, which had negatively impacted the entire credit market in the U.S. In recent months, certain other financial instruments had also sustained downgrade in credit ratings and decline in value. Further deterioration in the credit market may have an adverse effect on the fair value of Nuvelo s investment portfolio.

51

Nuvelo does not intend to pay cash dividends on its common stock in the foreseeable future.

Nuvelo does not anticipate paying cash dividends on its common stock in the foreseeable future. Any payment of cash dividends will depend upon Nuvelo s financial condition, results of operations, capital requirements and other factors and will be at the discretion of Nuvelo s board of directors. Furthermore, Nuvelo may incur additional indebtedness that may severely restrict or prohibit the payment of dividends.

Nuvelo has implemented anti-takeover provisions that could discourage, prevent or delay a takeover, even if the acquisition would be beneficial to Nuvelo s stockholders.

Provisions of Nuvelo s certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire Nuvelo, even if doing so would benefit Nuvelo s stockholders. These provisions:

establish a classified board of directors so that not all members of Nuvelo s board may be elected at one time;

authorize the issuance of up to 5,000,000 shares of preferred stock that could be issued by Nuvelo s board of directors to increase the number of outstanding shares and hinder a takeover attempt;

limit who may call a special meeting of stockholders;

prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of Nuvelo s stockholders; and

establish advance notice requirements for nominations for election to Nuvelo s board of directors or for proposing matters that can be acted upon at a stockholder meeting.

Specifically, Nuvelo s certificate of incorporation provides that all stockholder action must be effected at a duly called meeting and not by a written consent. The bylaws provide, however, that Nuvelo s stockholders may call a special meeting of stockholders only upon a request of stockholders owning at least 50 percent of Nuvelo s common stock. These provisions of Nuvelo s certificate of incorporation and bylaws could discourage potential acquisition proposals and could delay or prevent a change in control. Nuvelo designed these provisions to reduce Nuvelo s vulnerability to unsolicited acquisition proposals and to discourage certain tactics that may be used in proxy fights. These provisions, however, could also have the effect of discouraging others from making tender offers for Nuvelo s shares. As a consequence, they also may inhibit fluctuations in the market price of Nuvelo s shares that could result from actual or rumored takeover attempts. Such provisions also may have the effect of preventing changes in Nuvelo s management.

Nuvelo is permitted to issue shares of Nuvelo s preferred stock without stockholder approval upon such terms as Nuvelo s board of directors determines. Therefore, the rights of the holders of Nuvelo s common stock are subject to, and may be adversely affected by, the rights of the holders of Nuvelo s preferred stock that may be issued in the future. In addition, the issuance of preferred stock could have a dilutive effect on the holdings of Nuvelo s current stockholders.

Nuvelo is subject to the Delaware anti-takeover laws regulating corporate takeovers. These anti-takeover laws prevent a Delaware corporation from engaging in a merger or sale of more than ten percent of its assets with any stockholder, including all affiliates and associates of the stockholder, who owns 15 percent or more of the corporation s outstanding voting stock, for six years following the date that the stockholder acquired 15 percent or more of the corporation s stock unless:

the board of directors approved the transaction where the stockholder acquired 15 percent or more of the corporation s stock;

after the transaction in which the stockholder acquired 15 percent or more of the corporation s stock, the stockholder owned at least 85 percent of the corporation s outstanding voting stock, excluding

52

shares owned by directors, officers and employee stock plans in which employee participants do not have the right to determine confidentially whether shares held under the plan will be tendered in a tender or exchange offer; or

on or after this date, the merger or sale is approved by the board of directors and the holders of at least two-thirds of the outstanding voting stock that is not owned by the stockholder.

The provisions of Nuvelo s governing documents, stockholder rights plan and current Delaware law may, collectively:

lengthen the time required for a person or entity to acquire control of Nuvelo through a proxy contest for the election of a majority of Nuvelo s board of directors;

discourage bids for Nuvelo s common stock at a premium over market price; and

generally deter efforts to obtain control of Nuvelo.

Nuvelo has adopted Change in Control and Severance Benefit Plans that could discourage, prevent or delay a takeover, even if the acquisition would be beneficial to Nuvelo s stockholders.

In December 2004, Nuvelo s board of directors approved an Executive Change in Control and Severance Benefit Plan for Nuvelo s executive officers and other eligible employees, which was amended and restated in August 2007. The purpose of the plan is to provide for the payment of severance benefits and/or change in control benefits to certain of Nuvelo s eligible employees, and the plan supersedes and replaces any change in control and/or severance plans adopted by Nuvelo previously. All of Nuvelo s executive employees at the level of vice president or above have been designated as participants in the plan and Nuvelo s board of directors may designate other eligible individuals as participants. The plan provides that, upon a change in control of the company as defined under the plan, all Nuvelo stock options and stock awards held by a plan participant will become fully vested. Such shares held by a plan participant will also become fully vested if the participant is terminated without cause, or constructively terminated, within one month preceding Nuvelo s change in control. If a participant is terminated without cause or constructively terminated one month before or one year after Nuvelo s change in control, he or she will also be entitled to certain cash severance and continued medical benefits. In June 2008, the compensation committee of Nuvelo s board of directors approved a Change in Control Severance Benefit Plan for Nuvelo s employees who are not eligible for benefits under the Executive Change in Control and Severance Benefit Plan, entitling these employees to certain cash severance and continued medical benefits if terminated without cause within one year after Nuvelo s change of control.

The change in control and severance benefits for certain of Nuvelo s employees provided for under these plans are expected to be triggered by the merger with ARCA. If the merger with ARCA is not consummated, these provisions could make it more difficult and expensive, or less desirable, for a third party to acquire Nuvelo, even if doing so would benefit Nuvelo s stockholders.

Risks Related to Nuvelo Intellectual Property and Other Legal Matters

Nuvelo is party to securities litigation, and defending these lawsuits could hurt Nuvelo s business. The volatility of the market price of Nuvelo s securities could engender additional class action securities litigation.

Following periods of volatility in the market price of a company s securities, class action securities litigation has often been instituted against such a company. This risk is especially acute for Nuvelo, because biotechnology companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. Any such litigation instigated against Nuvelo could result in substantial costs and a diversion of management s attention and resources, which could significantly harm Nuvelo s business, financial condition and operating results. For example, in December 2006, after Nuvelo announced that alfimeprase did not meet its primary

Table of Contents 92

53

endpoint in the first of two planned Phase 3 trials for the treatment of acute peripheral arterial occlusion and in the first of two planned Phase 3 trials for the treatment of catheter occlusion, the closing price of one share of Nuvelo s common stock was \$4.05 on the day of the announcement, as compared with a closing price of \$19.55 on the trading day prior to the announcement. On February 9, 2007, Nuvelo, Inc. and certain of Nuvelo s former and current officers and directors were named as defendants in a purported securities class action lawsuit filed in the U.S. District Court for the Southern District of New York. The suit alleges violations of the Securities Exchange Act of 1934 related to the clinical trial results of alfimeprase, which Nuvelo announced on December 11, 2006, and seeks damages on behalf of purchasers of Nuvelo s common stock during the period between January 5, 2006 and December 8, 2006. Specifically, the suit alleges that Nuvelo misled investors regarding the efficacy of alfimeprase and the drug s likelihood of success. The plaintiff seeks unspecified damages and injunctive relief. Three additional lawsuits were filed in the Southern District of New York on February 16, 2007, March 1, 2007 and March 6, 2007, respectively. On April 10, 2007, three separate motions to consolidate the cases, appoint lead plaintiff, and appoint lead plaintiff s counsel were filed. On April 18, 2007. Nuvelo filed a motion to transfer the four cases to the Northern District of California. The Court granted Nuvelo s motion to transfer the cases to the Northern District of California in July 2007. Plaintiffs have filed motions for consolidation, lead plaintiff and lead plaintiff s counsel in the Northern District of California. Plaintiffs filed their consolidated complaint in the Northern District of California on November 9, 2007. Nuvelo filed a motion to dismiss plaintiffs consolidated complaint on December 21, 2007. Plaintiffs filed an opposition to Nuvelo s motion to dismiss on February 4, 2008. On June 12, 2008, the Court held a hearing on the motion to dismiss. The motion to dismiss the consolidated complaint is still pending. Nuvelo currently cannot determine the impact that this litigation will have on Nuvelo s business, results of operations or financial condition.

In addition, Variagenics, with which Nuvelo merged in 2003, has been named as a defendant in a securities class action lawsuit alleging the failure to disclose additional and excessive commissions purportedly solicited by and paid to underwriters who are also named defendants in the lawsuit. Plaintiffs in the suit allege that underwriters took these commissions and in exchange allocated shares of Variagenics—stock to their preferred customers through alleged agreements with these preferred customers that tied the allocation of initial public offering shares to agreements by the customers to make additional aftermarket purchases at pre-determined prices. As a result of Nuvelo—s merger with Variagenics, Nuvelo is obligated to continue to defend against this litigation. Nuvelo believes that any attorneys—fees, loss or settlement payment with respect to this suit will not be material to Nuvelo—s financial position or results of operations, and that any loss, settlement payment or attorneys—fees accrued with respect to the suit will be paid by Nuvelo—s insurance provider. Because of a recent court ruling, the settlement class, as defined in the settlement papers, is no longer feasible. While a new complaint has not been filed against Nuvelo, there are several—focus—cases against other issuers in which new complaints have been filed. Defendant issuers in the—focus—cases filed motions to dismiss the new complaints. On March 26, 2008, the District Court issued an order granting in part and denying in part the—focus—issuers motions to dismiss. The—focus—issuers had been advised that plaintiffs intended to file new complaints against Nuvelo, but none have been filed yet. Nuvelo—could be forced to incur—material expenses in the litigation if the parties cannot achieve a settlement, and in the event there is an adverse outcome, Nuvelo—s business could be harmed.

The commercial success of Nuvelo s products will depend upon Nuvelo s ability to protect the intellectual property rights associated with Nuvelo s products and product candidates.

Nuvelo s competitive success will depend, in part, on Nuvelo s ability to obtain and maintain patent protection for its inventions, technologies and discoveries, including intellectual property that Nuvelo licenses. The patent positions of biotechnology companies involve complex legal and factual questions, and Nuvelo cannot assure you that Nuvelo s patents and licenses will successfully preclude others from using Nuvelo s technology. Nuvelo could incur substantial costs in seeking enforcement of its proprietary rights against infringement.

Nuvelo currently has, or has in-licensed, issued patents and pending patent applications that include claims to Nuvelo $\,$ s in-licensed clinical products. Nuvelo also currently has patents that cover some of Nuvelo $\,$ s

54

Table of Contents

technological discoveries and patent applications that Nuvelo expects to protect some of its gene, protein and technological discoveries. Nuvelo will continue to apply for patents for its discoveries. Nuvelo cannot assure you that any of its applications, or its licensors applications, will issue as patents, or that any patent issued or licensed to Nuvelo will not be challenged, invalidated, circumvented or held unenforceable by way of an interference proceeding or litigation.

The timing of the grant of a patent cannot be predicted. Patent applications describing and seeking patent protection of methods, compositions, or processes relating to proprietary inventions involving human therapeutics could require Nuvelo to generate data, which may involve substantial costs. Nuvelo s pending patent applications may lack priority over others applications or may not result in the issuance of patents. Even if issued, Nuvelo s patents may not be sufficiently broad to provide protection against competitors with similar technologies and may be challenged, invalidated or circumvented.

In addition to patents, Nuvelo relies on a combination of trade secrets, copyright and trademark laws, nondisclosure agreements, licenses and other contractual provisions and technical measures to maintain and develop Nuvelo s competitive position with respect to intellectual property. Nevertheless, these measures may not be adequate to safeguard the technology underlying Nuvelo s products. For example, employees, consultants and others who participate in the development of Nuvelo s products may breach their agreements with Nuvelo regarding its intellectual property, and Nuvelo may not have adequate remedies for the breach. Nuvelo s trade secrets could become known through other unforeseen means. Nuvelo depends on its collaborators and other third parties that license intellectual property to Nuvelo to protect its licensed intellectual property. These collaborators and other third parties could fail to take a necessary step to protect Nuvelo s licensed intellectual property, which could seriously harm Nuvelo s intellectual property position.

Nuvelo also may not be able to effectively protect its intellectual property rights in some foreign countries, as many countries do not offer the same level of legal protection for intellectual property as the U.S. Furthermore, certain of the patent applications describing Nuvelo s proprietary methods are filed only in the U.S. Even where Nuvelo has filed its patent applications internationally, for some cases and in certain countries, Nuvelo has chosen not to maintain foreign patent protection by opting not to enter national phase or opting not to pay maintenance annuities.

Notwithstanding Nuvelo s efforts to protect its intellectual property, Nuvelo s competitors may independently develop similar or alternative technologies or products that are equal or superior to Nuvelo s technology. Nuvelo s competitors may also develop similar products without infringing on any of Nuvelo s intellectual property rights or design around Nuvelo s proprietary technologies.

If the manufacture, use or sale of Nuvelo s products infringe on the intellectual property rights of others, Nuvelo could face costly litigation, which could cause Nuvelo to pay substantial damages or licensing fees and limit its ability to sell some or all of its products.

Extensive litigation regarding patents and other intellectual property rights has been common in the biopharmaceutical industry. Litigation may be necessary to assert infringement claims, enforce patent rights, protect trade secrets or know-how and determine the enforceability, scope and validity of certain proprietary rights. The defense and prosecution of intellectual property lawsuits, U.S. Patent and Trademark Office interference proceedings, and related legal and administrative proceedings in the U.S. and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time-consuming to pursue, and their outcome is uncertain.

Regardless of merit or outcome, Nuvelo s involvement in any litigation, interference or other administrative proceedings could cause Nuvelo to incur substantial expense and could significantly divert the efforts of Nuvelo s technical and management personnel. An adverse determination may subject Nuvelo to the loss of its proprietary position or to significant liabilities, or require Nuvelo to seek licenses that may include substantial

55

cost and ongoing royalties. Licenses may not be available from third parties, or may not be obtainable on satisfactory terms. An adverse determination or a failure to obtain necessary licenses may restrict or prevent Nuvelo from manufacturing and selling its products, if any. These outcomes could materially harm Nuvelo s business, financial condition and results of operations.

Nuvelo s market success depends in part on Nuvelo neither infringing valid, enforceable patents or proprietary rights of third parties, nor breaching any licenses that may relate to Nuvelo s technologies and products. Nuvelo is aware of third-party patents and proprietary rights that may relate to Nuvelo s technology. Nuvelo may be required to obtain licenses to patents or other proprietary rights of others for itself, its collaboration partners and its service providers in order to conduct research, development or commercialization of some or all of Nuvelo s programs. Nuvelo plans to seek licenses, as it deem appropriate, but it is possible that Nuvelo may infringe upon these patents or proprietary rights of third parties. If Nuvelo does not obtain these licenses, it may encounter delays in product market introductions, incur substantial costs while Nuvelo attempts to design around existing patents or not be able to develop, manufacture or sell products. In response, third parties may assert infringement or other intellectual property claims against Nuvelo, its collaboration partners or its service providers. Nuvelo may consequently be subjected to substantial damages for past infringement or be required to modify its products if it is ultimately determined that Nuvelo s products infringe a third party s proprietary rights. Further, Nuvelo may be prohibited from selling its products before it obtains a license, which, if available at all, may require Nuvelo to pay substantial royalties, which could adversely impact Nuvelo s product costs and have a negative impact on its business. Further, if Nuvelo does obtain these licenses, the agreed terms may necessitate reevaluation of the potential commercialization of any one of Nuvelo s programs. Failing to obtain a license could result in litigation. Even if these claims are without merit, defending a lawsuit takes significant time, may be expensive and may divert management attention from other business concerns. Any public announcements related to litigation or interference proceedings initiated or threatened against Nuvelo could cause Nuvelo s stock price to decline.

Nuvelo faces product liability exposure and potential unavailability of insurance.

Nuvelo risks financial exposure to product liability claims in the event that the use of products developed by Nuvelo, or its collaboration partners, if any, result in personal injury. Nuvelo may experience losses due to product liability claims in the future. Nuvelo has obtained limited product liability insurance coverage. Such coverage, however, may not be adequate or may not continue to be available to Nuvelo in sufficient amounts or at an acceptable cost, or at all. Nuvelo may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing. A product liability claim or other claim, product recalls, as well as any claims for uninsured liabilities or in excess of insured liabilities, may significantly harm Nuvelo s business, financial condition and results of operations.

Nuvelo faces heavy government regulation, and any disputes relating to business practices or improper handling, storage or disposal of hazardous materials, chemicals and patient samples could be time consuming and costly.

Nuvelo s research and development and production activities involve the controlled use of hazardous or radioactive materials, chemicals, including oxidizing and reducing reagents, infectious disease agents, patient tissue and blood samples. Nuvelo, its collaborators, and service providers are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and certain waste products. Nuvelo could be liable for accidental contamination or discharge or any resultant injury from hazardous materials, and conveyance, processing, and storage of and data on patient samples. If Nuvelo, its collaborators, or service providers fail to comply with applicable laws or regulations, Nuvelo could be required to pay penalties or be held liable for any damages that result, and this liability could exceed Nuvelo s financial resources. Further, future changes to environmental health and safety laws could cause Nuvelo to incur additional expense or restrict its operations. In addition, Nuvelo s collaborators and service providers may be working with hazardous materials, including viruses and hazardous chemicals, in connection with Nuvelo s collaborations. In the event of

56

a lawsuit or investigation, Nuvelo could be held responsible for any injury caused to persons or property by exposure to, or release of, patient samples that may contain viruses and hazardous materials. The cost of this liability could exceed Nuvelo s resources.

Nuvelo also is subject to numerous federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, general business practices, the experimental use of animals, and the environment. In addition, Nuvelo cannot predict the extent of government regulations or the impact of new governmental regulations that might significantly harm the discovery, development, production and marketing of Nuvelo s products. Nuvelo may be required to incur significant costs to comply with current or future laws or regulations, and Nuvelo may be adversely affected by the cost of such compliance.

Risks Related to ARCA s Business

If ARCA is not able to successfully develop and commercialize Gencaro, ARCA may not generate sufficient revenues to continue its business operations.

ARCA currently has no products that have received regulatory approval for commercial sale. The process to develop, obtain regulatory approval for and commercialize potential product candidates is long, complex and costly. Gencaro is ARCA s only product candidate at a late stage of clinical development and is currently awaiting approval of its NDA. ARCA has no other product candidates. As a result, ARCA s business is currently substantially dependent on its ability to obtain regulatory approval for and successfully commercialize Gencaro in a timely manner. If the NDA is not approved, or is substantially delayed, or if ARCA is unable to successfully commercialize Gencaro, it may not be able to earn sufficient revenues to continue its business.

Unless ARCA is able to generate sufficient product revenue, ARCA will continue to incur losses from operations and may not achieve or maintain profitability.

ARCA is a development stage biopharmaceutical company with a limited operating history. To date, it has not generated any product revenue and has historically funded its operations through investment capital. ARCA has incurred losses in each year since its inception. For its fiscal years ended December 31, 2007, 2006 and 2005, ARCA s net losses were \$14.0 million, \$5.2 million and \$1.5 million, respectively. For its nine months ended September 30, 2008, ARCA s net losses were \$14.3 million. As of September 30, 2008, ARCA had incurred \$35.6 million in net losses since its inception. These losses, among other things, have had and will continue to have an adverse effect on ARCA s stockholders equity and working capital. Even if ARCA receives regulatory approval for any product candidates, sales of such products may not generate sufficient revenue for it to achieve or maintain profitability. ARCA s ability to generate revenue depends on a number of factors, including its ability to:

develop and obtain regulatory approval for GencaroTM or other product candidates;

obtain commercial quantities of Gencaro or other product candidates at acceptable cost levels;

successfully market and sell Gencaro or other product candidates;

successfully partner a companion genetic test with the commercial launch of Gencaro; and

successfully conduct and complete clinical trials for Gencaro and other product candidates.

ARCA expects to incur increased general and administrative expenses due to higher sales and marketing expenses. As a result, it expects to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing therapeutic drugs, ARCA may experience larger than expected future losses and may never reach profitability.

ARCA s product candidates are subject to extensive regulation, which can be costly and time-consuming, and unsuccessful or delayed regulatory approvals could increase ARCA s future development costs or impair ARCA s future revenue.

The preclinical and clinical development, testing, manufacture, safety, efficacy, labeling, storage, recordkeeping, advertising, promotion, sale, and marketing, and distribution of ARCA s product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and elsewhere. These regulations also vary in important, meaningful ways from country to country. ARCA is not permitted to market a potential drug in the United States until ARCA receives approval of a New Drug Application, or NDA, from the FDA. ARCA has not received an NDA approval from the FDA. There can be no guarantees with respect to ARCA s product candidates that clinical studies will support an ARCA NDA, that the products will receive necessary regulatory approvals, or that they will prove to be commercially successful.

To receive regulatory approval for the commercial sale of any product candidates, ARCA must demonstrate safety and efficacy in humans to the satisfaction of regulatory authorities through preclinical studies and adequate and well-controlled clinical trials of the product candidates. This process is expensive and can take many years, and failure can occur at any stage of the testing. ARCA s failure to adequately demonstrate the safety and efficacy of its product candidates will prevent regulatory approval and commercialization of such products. With respect to Gencaro, the FDA could determine that the preclinical studies and clinical trials conducted by or on Gencaro s behalf were inadequate, and such a determination would prevent regulatory approval and commercialization of Gencaro. For instance, ARCA filed an NDA for Gencaro in July 2008, based primarily on a single Phase 3 trial. The FDA guidelines generally suggest that sponsors conduct two adequate and well-controlled studies to demonstrate the safety and efficacy of a product candidate such as Gencaro in support of FDA approval. FDA interpretation of the statutory requirements also states that a single study may be sufficient to support approval if the FDA determines that, based on relevant science and other confirmatory evidence, there is strong evidence to establish the safety and efficacy of the drug candidate using a single adequate and well-controlled study. If the FDA determines that the clinical data for Gencaro is not sufficiently strong to demonstrate Gencaro s safety and efficacy for chronic heart failure, then Gencaro may not be approved by the FDA for ARCA s proposed indications, may be approved for a more limited indication, or the FDA may require ARCA to conduct additional studies before approving Gencaro for chronic heart failure. Even if ARCA conducted additional studies and submitted the attendant data, FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

In the event that ARCA or its contractors conduct preclinical studies that did not comply with GLP or incorrectly design or carry out human clinical trials or those clinical trials fail to demonstrate clinical significance, ARCA will not likely be able to obtain FDA approval for product development candidates. ARCA s inability to successfully and effectively complete clinical trials for any product candidates on schedule or at all will severely harm ARCA s business. Significant delays in clinical development could materially increase product development costs or allow ARCA s competitors to bring products to market before it does, impairing ARCA s ability to effectively commercialize any future product candidates. ARCA does not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including:

delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to ARCA s product candidates or similar product candidates of ARCA s competitors or failure to follow regulatory guidelines;

delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in trials;

delays or failures in reaching agreement on acceptable terms with prospective study sites;

delays or failures in obtaining approval of ARCA s clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;

58

delays in recruiting patients to participate in a clinical trial, which may be due to the size of the patient population, eligibility criteria, protocol design, perceived risks and benefits of the drug, availability of other approved and standard of care therapies, availability of clinical trial sites;

other clinical trials seeking to enroll subjects with similar profile;

failure of ARCA s clinical trials and clinical investigators to be in compliance with the FDA s Good Clinical Practices, or GCP;

unforeseen safety issues, including negative results from ongoing preclinical studies;

inability to monitor patients adequately during or after treatment;

difficulty monitoring multiple study sites; and

failure of ARCA s third-party contract research organizations, clinical site organizations and other clinical trial managers, to satisfy their contractual duties, comply with regulations or meet expected deadlines.

In addition, any approvals ARCA may obtain may not cover all of the clinical indications for which it seeks approval. In addition, if ARCA chooses to make claims of superiority over currently marketed competitive products, ARCA must substantiate those claims with scientific evidence from prospectively designed head-to-head clinical trials. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions or contraindications with respect to conditions of use. If the FDA determines that a risk evaluation and mitigation strategy, or REMS, is necessary to ensure that the benefits of the drug outweigh the risks, ARCA may be required to include as part of the NDA a proposed REMS that may include a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug s distribution, or a Medication Guide to provide better information to consumers about the drug s risks and benefits. Finally, an approval could be conditioned on ARCA s commitment to conduct further clinical trials, which ARCA may not have the resources to conduct or which may negatively impact ARCA s financial situation.

In September 2008, the FDA formally accepted for filing ARCA s NDA, for Gencaro, with the goal of reviewing the NDA by May 31, 2009. Filing of the NDA indicates that the application is sufficiently complete to allow for FDA to review ARCA s data supporting the safety profile and effectiveness of Gencaro, but does not guarantee approval. All of ARCA s product candidates are prone to the risks of failure inherent in drug development. The results from preclinical animal testing and early human clinical trials may not be predictive of results obtained in later human clinical trials. Further, although a new product may show promising results in preclinical or early human clinical trials, it may subsequently prove unfeasible or impossible to generate sufficient safety and efficacy data to obtain necessary regulatory approvals. The data obtained from preclinical and clinical studies are susceptible to varying interpretations that may delay, limit or prevent regulatory approval, and the FDA and other regulatory authorities in the United States and elsewhere exercise substantial discretion in the drug approval process. The numbers, size and design of preclinical studies and clinical trials that will be required for FDA or other regulatory approval will vary depending on the product candidate, the disease or condition for which the product candidate is intended to be used and the regulations and guidance documents applicable to any particular product candidate. The FDA or other regulators can delay, limit or deny approval of any product candidate for many reasons, including, but not limited to:

side effects;
safety and efficacy;
defects in the design of clinical trials;

the fact that the FDA or other regulatory officials may not approve ARCA $\,$ s or ARCA $\,$ s third party manufacturer $\,$ s processes or facilities; or

59

the fact that new regulations may be enacted by the FDA or other regulators may change their approval policies or adopt new regulations requiring new or different evidence of safety and efficacy for the intended use of a product candidate.

In light of widely publicized events concerning the safety of certain drug products, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of certain drug products, revisions to certain drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and approval. Data from clinical trials may receive greater scrutiny with respect to safety and the product s risk/benefit profile, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense, and a delay or failure in obtaining approval or approval for a more limited indication than originally sought. Aside from issues concerning the quality and sufficiency of submitted preclinical and clinical data, the FDA may be constrained by limited resources from reviewing and determining the approvability of the Gencaro NDA by May 31, 2009. Indeed, in early 2008, the FDA announced that due to a lack of resources, NDAs may not be reviewed within the performance goals under the Prescription Drug User Fee Act, and from time to time, the FDA has extended the review period for NDAs.

In addition, the manufacture and tableting of Gencaro is done by third party suppliers, who must pass a pre-approval inspection of their facilities before ARCA can obtain marketing approval. The FDA could also request additional information or data, including data from an additional Phase 3 study, which may extend the review period.

In its NDA, ARCA has requested that the FDA approve Gencaro as a therapy that can be prescribed by physicians for patients with heart failure, and specifically for its effect on certain clinical outcomes for these heart failure patients. ARCA has also requested that certain information be included in the prescribing information distributed with Gencaro that shows the effect of genetic differences in patients on the clinical results for Gencaro. The FDA could approve Gencaro, but without including some or all of the prescribing information that ARCA has requested. For instance, FDA could approve Gencaro without some or all of the pharmacogenetic information in the labeling. This, in turn, could substantially and detrimentally impact ARCA is ability to successfully commercialize Gencaro.

ARCA has no manufacturing capacity which puts it at risk of lengthy and costly delays of bringing its products to market.

ARCA does not currently operate manufacturing facilities for clinical or commercial production of its product candidates, including their active pharmaceutical ingredients, or API. ARCA has no experience in drug formulation or manufacturing, and it lacks the resources and the capabilities to manufacture any of its product candidates on a clinical or commercial scale. ARCA does not intend to develop facilities for the manufacture of product candidates for clinical trials or commercial purposes in the foreseeable future.

ARCA has contracted with Groupe Novasep to manufacture commercial quantities of the API for Gencaro. For drug production, ARCA has contracted with Patheon, Inc. to manufacture the Gencaro tablets. These contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute ARCA s products. In the event of a natural disaster, equipment malfunctions or failures, technology malfunctions, strikes, lock-outs or work stoppages, regional power outages, product tampering, war or terrorist activities, actions of regulatory authorities, business failure, strike or other difficulty, ARCA may be unable to replace a third-party manufacturer in a timely manner and the production of its product candidates would be interrupted, resulting in delays and additional costs.

60

ARCA or its contract manufacturers may also fail to achieve and maintain required manufacturing standards, which could result in patient injury or death, product recalls or withdrawals, an order by governmental authorities to halt production, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt its business. Contract manufacturers also often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. In addition, its contract manufacturers are subject to ongoing inspections and regulation by the FDA, the U.S. Drug Enforcement Agency and corresponding state agencies and they may fail to meet these agencies—acceptable standards of compliance. If ARCA—s contract manufacturers fail to comply with applicable governmental regulations, such as quality control, quality assurance and the maintenance of records and documentation, ARCA may not be able to continue production of the API or finished product. If the safety of any API or product supplied is compromised due to failure to adhere to applicable law or for other reasons, this may jeopardize ARCA—S regulatory approval for Gencaro and other product candidates, and may be held liable for any injuries sustained as a result.

Upon the occurrence of one of the aforementioned events, the ability to switch manufacturers may be difficult for a number of reasons, including:

the number of potential manufacturers is limited and ARCA may not be able to negotiate agreements with alternative manufacturers on commercially reasonable terms;

long lead times are often needed to manufacture drugs;

the manufacturing process is complex and may require a significant learning curve; and

the FDA must approve any replacement prior to manufacturing, which requires new testing and compliance inspections.

If ARCA s product candidates receive regulatory approval, ARCA would be subject to ongoing regulatory obligations and restrictions, which may result in significant expenses and limit its ability to commercialize its potential products.

If a product candidate of ARCA is approved by the FDA or by another regulatory authority, ARCA would be held to extensive regulatory requirements over product manufacturing, testing, distribution, labeling, packaging, adverse event reporting and other reporting to regulatory authorities, storage, advertising, marketing, promotion, distribution, and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the product candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the product candidate, including adverse events of unanticipated severity or frequency, may result in additional regulatory controls or restrictions on the marketing or use of the product or the need for postmarketing studies, and could include withdrawal of the products from the market.

Furthermore, ARCA s third-party manufacturers and the manufacturing facilities that they use to make ARCA s product candidates are regulated by the FDA. Quality control and manufacturing procedures must continue to conform to cGMP after approval. Drug manufacturers and their subcontractors are required to register their facilities and products manufactured annually with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA, state and/or other foreign authorities. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by ARCA or its collaborators, may result in restrictions on the product, or on the manufacturing or laboratory facility, including a withdrawal of the drug from the market or suspension of manufacturing. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. ARCA and its third-party manufacturers will also be subject to ongoing FDA requirements for submission of safety and other post-market information.

61

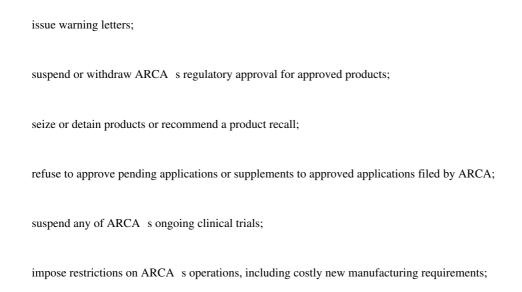
The marketing and advertising of ARCA s drug products by its collaborators or ARCA will be regulated by the FDA, certain state agencies or foreign regulatory authorities. Violations of these laws and regulations, including promotion of ARCA s products for unapproved uses or failing to disclose risk information, are punishable by criminal and civil sanctions and may result in the issuance of enforcement letters or other enforcement action by the FDA, Department of Justice, state agencies, or foreign regulatory authorities that could jeopardize ARCA s ability to market the product.

In addition to the FDA, state or foreign regulations, the marketing of ARCA s drug products by ARCA or its collaborators will be regulated by federal, state or foreign laws pertaining to health care—fraud and abuse,—such as the federal anti-kickback law prohibiting bribes, kickbacks or other remuneration for the order or recommendation of items or services reimbursed by federal health care programs. Many states have similar laws applicable to items or services reimbursed by commercial insurers. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including the Medicare, Medicaid and Veterans Affairs healthcare programs. Because of the far-reaching nature of these laws, ARCA may be required to discontinue one or more of its practices to be in compliance with these laws. Health care fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. Any violations of these laws, or any action against ARCA for violations of these laws, even if ARCA successfully defends against it, could have a material adverse effect on ARCA—s business, financial condition and results of operations.

ARCA could also become subject to false claims litigation under federal statutes, which can lead to civil money penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid and other federal and state health care programs. These false claims statutes include the False Claims Act, which allows any person to bring a suit on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, under federal programs or contracts claims or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. These suits against pharmaceutical companies have increased significantly in volume and breadth in recent years. Some of these suits have been brought on the basis of certain sales practices promoting drug products for unapproved uses. This new growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay fines or restitution, or be excluded from the Medicare, Medicaid, Veterans Affairs and other federal and state healthcare programs as a result of an investigation arising out of such action. ARCA may become subject to such litigation and, if ARCA is not successful in defending against such actions, those actions may have a material adverse effect on its business, financial condition and results of operations.

Additionally, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of ARCA s product candidate. ARCA cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the U.S. or elsewhere.

If ARCA, its collaborators or its third-party manufacturers fail to comply with applicable continuing regulatory requirements, ARCA s business could be seriously harmed because a regulatory agency may:



62

seek an injunction;

close the facilities of ARCA s contract manufacturers; or

impose civil or criminal penalties.

If LabCorp or certain of its third-party suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if there are unanticipated problems with the Gencaro Test, these products could be subject to restrictions or withdrawal from the market.

Any medical device for which LabCorp obtains clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. With respect to the Gencaro Test, to the extent applicable, LabCorp and certain of its suppliers will be required to comply with the FDA s Quality System Regulation, or QSR, and International Standards Organization, or ISO, requirements which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which clearance or approval is obtained. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by LabCorp, or certain of its third-party manufacturers or suppliers, as the case may be, to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, enforcement actions. If any of these actions were to occur, it could harm ARCA s reputation and cause product sales and profitability of Gencaro to suffer and may prevent ARCA from generating revenue.

Even if regulatory clearance or approval is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce ARCA s potential to successfully commercialize the product and generate revenue from the product.

Medical devices related to Gencaro, such as the Gencaro Test, may in the future be subject to product recalls that could harm the combined company s reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a mandatory recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. In addition, foreign governmental bodies have the authority to require the recall of ARCA s products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, initiate a field correction or removal, known as a recall, for a product if any material deficiency in a device is found. A government-mandated or voluntary recall by ARCA s third-party suppliers, including LabCorp, could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Any such recalls would divert managerial and financial resources and may have an adverse effect on the combined company s and ARCA s financial condition and results of operations.

If medical devices related to Gencaro, such as the Gencaro Test, cause or contribute to a death or a serious injury, or malfunction in certain ways, ARCA s third-party suppliers will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of ARCA s similar devices were to recur. If ARCA s third-party suppliers, including LabCorp, fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement

63

action against ARCA s third-party suppliers, including LabCorp. Any such adverse event involving the Gencaro Test also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, taken by ARCA s third-party suppliers, including LabCorp, may significantly affect the combined company ability to market Gencaro. In such cases, ARCA or the combined company could be forced to identify a new third-party test provider for the Gencaro Test.

LabCorp may need to conduct clinical trials to support current or future versions of the Gencaro Test. Delays or failures in any such clinical trials may prevent LabCorp from commercializing any modified or new versions of the Gencaro Test and will adversely affect the combined company s business, operating results and prospects.

Based on discussions with the FDA, ARCA and LabCorp do not believe that additional clinical data are needed for the Gencaro Test submission. However, the FDA may require clinical data for the Gencaro Test submission and/or future products. Initiating and completing clinical trials necessary to support 510(k)s or PMAs, if required, for current or future products will be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product ARCA or its third party suppliers, including LabCorp, advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including: the size of the patient population; the number of patients to be enrolled; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites; and the patients—ability to meet the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of ARCA—s products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required, and LabCorp, the combined company or ARCA may not adequately develop such protocols to support clearance and approval. Significant risk trials will require the submission and approval of an IDE from the FDA. There is no guarantee that the FDA will approve LabCorp s or ARCA s future IDE submissions. Further, the FDA may require LabCorp or ARCA to submit data on a greater number of patients than originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to ARCA s clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of future products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in such clinical trials, the FDA may not consider the data to be adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect ARCA s third party suppliers , the combined company s or ARCA s business, operating results and prospects.

Federal regulatory reforms may adversely affect ARCA s or its suppliers ability to sell products profitably.

From time to time, legislation is drafted and introduced in the U.S. Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a medical device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect the way that medical devices are marketed and promoted. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

64

Without limiting the generality of the foregoing, last year, the Food and Drug Administration Amendments Act of 2007, or the Amendments, were enacted. The Amendments require, among other things, that the FDA propose, and ultimately implement, regulations that will require manufacturers to label medical devices with unique identifiers unless a waiver is received from the FDA. Once implemented, compliance with those regulations may require manufacturers to take additional steps in the manufacture and labeling of medical devices. These steps may require additional resources and could be costly. In addition, the Amendments require medical device manufacturers to, among other things, comply with clinical trial registration requirements once clinical trials are initiated.

The loss of any rights to market key products would significantly impair ARCA s operating results.

ARCA has licensed from Cardiovascular Pharmacology and Engineering Consultants, LLC, or CPEC, who has licensed rights in Gencaro from Bristol Myers Squibb, or BMS, the exclusive rights to Gencaro for all therapeutic and diagnostic uses in any country until the later of (i) 10 years from the first commercial sale of Gencaro in such country, or (ii) the termination of ARCA s commercial exclusivity in such country. ARCA is obligated to use commercially reasonable efforts to develop and commercialize Gencaro, including obtaining regulatory approvals. ARCA s ability to develop and commercialize Gencaro is dependent on numerous factors, including some factors that are outside of its control. CPEC has the right to terminate ARCA s license if ARCA materially breaches its obligations under the license agreement and fails to cure any such breach within the terms of the license.

If ARCA s license agreement with CPEC is terminated for reasons related to non-payment of fees, or for any other breach, then ARCA would have no further rights to develop and commercialize Gencaro for any indication. The termination of this license, or of any other agreement which enables ARCA to market a key product or product candidate, could significantly and adversely affect ARCA s business.

If ARCA is unable to establish a direct sales force in the U.S., its business may be harmed.

ARCA is currently building its sales organization. Assuming Gencaro is approved by the FDA for commercial sale, ARCA intends to market Gencaro in the U.S. to physicians, hospitals and other health care providers using its own sales force. While certain ARCA employees have experience in establishing and managing a sales force, these employees have no such experience since being with ARCA. ARCA will need to incur significant additional expenses and commit significant additional management resources to establish a sufficient sales force for Gencaro.

ARCA may not be able to successfully establish these capabilities despite these additional expenditures. If ARCA elects to rely on third parties to sell Gencaro and any other products, then it may receive less revenue than if it sold such products directly. In addition, ARCA may have little or no control over the sales efforts of those third parties. In the event ARCA is unable to sell Gencaro and other selected product candidates, either directly or through third parties, the commercialization of Gencaro may be delayed indefinitely and ARCA s business may be harmed.

ARCA s failure to establish and manage a distribution network for its products could delay or compromise the commercialization of Gencaro and other future products.

ARCA has not yet established systems and processes necessary for distributing products to customers. ARCA plans to contract with one or more wholesale distributors to warehouse its products and distribute them to retail, hospital and other pharmacy suppliers that would then distribute its products directly to patients. This distribution network will require significant coordination with its sales and marketing and finance organizations. Failure to secure contracts with distribution services could negatively impact the distribution of ARCA s products, if any, and failure to coordinate financial systems could negatively impact its ability to accurately report product revenue, if any. If ARCA is unable to effectively establish and manage the distribution process, then the commercialization of Gencaro and other product candidates may be delayed or severely compromised and ARCA s results of operations may be harmed.

65

If approved by the FDA, Gencaro will be entering into a competitive marketplace and may not succeed.

Gencaro is a new type of beta-blocker and vasodilator being developed for heart failure and other indications. While ARCA anticipates that this drug will be the first genetically-targeted cardiovascular drug, Gencaro will be one of a number of successful drugs in the beta-blocker class currently on the market. Currently, there are three branded beta-blockers indicated for chronic heart failure in NYHA class II-IV patients: TOPROL-XL (once-a-day formulation), Coreg and Coreg CR (once-a-day). TOPROL-XL and Coreg have generic equivalents commercially available in the U.S. (Metoprolol Succinate and Carvedilol respectively). The price of the generic forms of these drugs will be less than the anticipated price of Gencaro, if approved. As a result, Gencaro may not be successful in competing against these existing drugs.

Additionally, Forest Laboratories may apply for approval to use Bystolic, a drug currently used to treat high blood pressure, for treatment of heart failure. If approved for treatment of heart failure, Gencaro may not be successful in competing against Bystolic, an already well-known name brand. Accordingly, ARCA may not achieve its revenue goals, and its business may be harmed.

ARCA s commercial opportunity may be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than Gencaro. If products with any of these properties are developed, or any of the existing products are better marketed, then prescriptions of Gencaro by physicians and patient use of Gencaro could be significantly reduced or rendered obsolete and noncompetitive. Further, public announcements regarding the development of any such competing drugs could adversely affect the market price of ARCA s common stock.

Future sales of ARCA s products may suffer if they are not accepted in the marketplace by physicians, patients and the medical community.

Gencaro or ARCA s other product candidates may not gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of Gencaro or ARCA s other product candidates will depend on a number of factors, such as its effectiveness and tolerability, as compared with competitive drugs. Also, prevalence and severity of side-effects could negatively affect market acceptance of Gencaro. Side-effects observed during clinical trials included fatigue, dizziness and slowed heart beat. Failure to achieve market acceptance of Gencaro would significantly harm ARCA s business.

If ARCA is unable to obtain acceptable prices or adequate reimbursement from third-party payors for Gencaro, or any other product candidates that ARCA may seek to commercialize, then its revenues and prospects for profitability will suffer.

ARCA s ability to commercialize Gencaro, or any other product candidates that it may seek to commercialize, is highly dependent on the extent to which coverage and reimbursement for these product candidates will be available from:

governmental payors, such as Medicare and Medicaid;

private health insurers, including managed-care organizations; and

other third-party payors.

Many patients will not be capable of paying for ARCA s potential products themselves and will rely on third-party payors to pay for their medical needs. A primary current trend in the U.S. health care industry is toward cost containment. Large private payors, managed-care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly approved health care products. In particular, third-party payors may limit the reimbursed indications.

66

Cost-control initiatives could decrease the price ARCA might establish for products, which could result in product revenues lower than anticipated. If the prices for ARCA s product candidates decrease or if governmental and other third-party payors do not provide adequate coverage and reimbursement levels, then ARCA s revenue and prospects for profitability will suffer.

ARCA s competitors may be better positioned in the marketplace and thereby may be more successful than ARCA at developing, manufacturing and marketing approved products.

Many of ARCA s competitors currently have significantly greater financial resources and expertise in conducting clinical trials, obtaining regulatory approvals, managing manufacturing and marketing approved products than ARCA. Other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. In addition, these third parties compete with ARCA in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring therapies and therapy licenses complementary to ARCA s programs or advantageous to its business. ARCA expects that its ability to compete effectively will depend upon its ability to:

successfully and rapidly complete clinical trials for any future product candidates and obtain all requisite regulatory approvals in a cost-effective manner;
build an adequate sales and marketing infrastructure;
develop competitive formulations of its product candidates;
attract and retain key personnel; and

identify and obtain other product candidates on commercially reasonable terms.

If ARCA fails to identify and license or acquire other products or product candidates, then it may be unable to expand its business, and the acquisition or licensing of other products or product candidates may put a strain on ARCA s operations and will likely require ARCA to seek additional financing.

One of ARCA s key strategies is to license or acquire clinical-stage products or product candidates and further develop them for commercialization. The market for licensing and acquiring products and product candidates is intensely competitive and many of ARCA s competitors may have greater resources than ARCA. Other than this transaction with Nuvelo, ARCA has no definitive agreement regarding any material acquisitions. If ARCA undertakes any additional acquisitions, whether product candidates or other biopharmaceutical companies, the process of integrating an acquired product, candidate or complementary company into ARCA s business may put a strain on its operations, divert personnel, financial resources and management—s attention. If ARCA is not successful in identifying and licensing or acquiring other products or product candidates or completing future acquisitions, then it may be unable expand its pipeline of product candidates beyond Gencaro. In addition, any future acquisition would give rise to additional operating costs and will likely require ARCA to seek additional financing. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect ARCA—s operating results.

Any future product revenues could be reduced by imports from countries where ARCA s product candidates are available at lower prices.

Even if ARCA obtains FDA approval to market Gencaro or other products in the U.S., ARCA s sales in the U.S. may be reduced if ARCA s products are imported into the U.S. from lower priced markets, whether legally or illegally. In the U.S., prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico. There have been proposals to legalize the import of pharmaceuticals from outside the U.S. If such legislation were enacted, then ARCA s future revenues could be reduced.

67

If product liability lawsuits are successfully brought against ARCA, then ARCA will incur substantial liabilities and may be required to limit commercialization of Gencaro or other product candidates.

ARCA faces product liability exposure related to the testing of its product candidates in human clinical trials, and may face exposure to claims by an even greater number of persons once it begins marketing and distributing its products commercially. If ARCA cannot successfully defend itself against product liability claims, then it will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for its products and product candidates;
injury to its reputation;
withdrawal of clinical trial participants;
costs of related litigation;
substantial monetary awards to patients and others;
loss of revenues; and

the inability to commercialize its products and product candidates.

ARCA does not maintain product liability insurance to cover clinical trials. While ARCA intends to expand its insurance coverage to include the sale of commercial products if marketing approval is obtained for Gencaro or any other product candidate, it does not currently maintain such insurance. Insurance coverage is increasingly expensive; ARCA may not be able to secur