BIOSANTE PHARMACEUTICALS INC
Form 424B3
January 22, 2013

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Table of Contents

**Filed Pursuant to Rule 424(b)(3)**
**Registration No. 333-185391**

**PROPOSED MERGER YOUR VOTE IS VERY IMPORTANT**

To our Stockholders:

On October 3, 2012, BioSante Pharmaceuticals, Inc. (BioSante) and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (ANI), entered into a merger agreement pursuant to which ANI will merge with and into BioSante, with BioSante continuing as the surviving company. The boards of directors of BioSante and ANI have approved unanimously the merger agreement and the merger and believe that the merger of the two companies will create more value than either company could achieve individually. The combined company that will result from the merger will be a fully integrated specialty pharmaceutical company focused on developing, manufacturing and marketing branded and generic prescription pharmaceuticals.

Pursuant to the terms of the merger agreement, upon completion of the merger, ANI stockholders will have the right to receive, for each share of ANI capital stock they hold, that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. Following completion of the merger, the current ANI stockholders are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and the current BioSante stockholders are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante as of a determination date prior to the closing date of the merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. If the merger had been completed on January 17, 2013, the record date for the BioSante special meeting, an aggregate of approximately 27.9 million shares of BioSante common stock would have been issuable to ANI stockholders upon completion of the merger (as determined prior to an anticipated reverse stock split of BioSante common stock), assuming BioSante's net cash is $18.0 million as of the determination date.

BioSante common stock is listed on The NASDAQ Global Market and trades under the symbol "BPAX". On January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, the closing sale price of BioSante common stock was $1.36 per share. ANI is a privately held specialty pharmaceutical company. Following completion of the merger, the combined company is expected to be renamed "ANI Pharmaceuticals, Inc." and to change its trading symbol on The NASDAQ Global Market. ANI has reserved the symbol "ANIP" for this purpose.

This joint proxy statement/prospectus provides you with detailed information about the special meetings of stockholders of BioSante and ANI to consider the merger and related business. **Your vote is very important.** Whether or not you plan to attend your respective company's special meeting of stockholders, please submit your proxy as soon as possible to make sure that your shares are represented at the applicable

meeting. In addition to being a proxy statement for both BioSante and ANI, this document is also a prospectus to be used by BioSante when issuing BioSante common stock to ANI stockholders in connection with the merger. BioSante and ANI encourage you to read the entire document carefully. **Please pay particular attention to the section entitled "Risk Factors" beginning on page 38 for a discussion of the risks related to the merger, the combined company following completion of the merger, and the business and operations of each of BioSante and ANI.**

BioSante and ANI are excited about the opportunities that the proposed merger brings to both BioSante and ANI stockholders and thank you for your consideration and continued support.

Stephen M. Simes
Vice Chairman, President and
Chief Executive Officer
BioSante Pharmaceuticals, Inc.

Arthur S. Przybyl
President and Chief Executive Officer
ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the BioSante common stock to be issued pursuant to the merger or determined if the information in this joint proxy statement/prospectus is accurate or adequate. Any representation to the contrary is a criminal offense.**

This joint proxy statement/prospectus is dated January 22, 2013 and is first being mailed or otherwise delivered to stockholders of BioSante and ANI on or about January 25, 2013.

Table of Contents

**REFERENCES TO ADDITIONAL INFORMATION**

This joint proxy statement/prospectus forms a part of a registration statement on Form S-4 filed by BioSante Pharmaceuticals, Inc. with the Securities and Exchange Commission (SEC). It constitutes a prospectus of BioSante under Section 5 of the Securities Act of 1933, as amended (the Securities Act), and the rules and regulations thereunder, with respect to the shares of BioSante common stock to be issued to holders of capital stock of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. in the merger. In addition, it constitutes a proxy statement under Section 14(a) of the Securities Exchange Act of 1934, as amended (the Exchange Act), and the rules and regulations thereunder, and a notice of meeting with respect to the BioSante special meeting of stockholders. It also constitutes a proxy statement of ANI and a notice of meeting with respect to the ANI special meeting of stockholders.

BioSante has supplied all information contained in this joint proxy statement/prospectus relating to BioSante and ANI has supplied all information contained in this joint proxy statement/prospectus relating to ANI.

If you would like to request documents from BioSante or ANI, please send a request by telephone or email to either BioSante or ANI at the following address:

BioSante Pharmaceuticals, Inc.
111 Barclay Boulevard
Lincolnshire, Illinois 60069
Attention: Investor Relations
Tel: (847) 478-0500 ext. 120
Email: info@biosantepharma.com

ANIP Acquisition Company d/b/a
ANI Pharmaceuticals, Inc.
210 Main Street West
Baudette, Minnesota 56623
Attention: Investor Relations
Tel: (218) 634-3500
Email: arthur.przybyl@anipharmaceuticals.com

**If you would like to request documents, please do so by February 22, 2013 in order to receive them before the special meetings.** See "Where You Can Find More Information" beginning on page 300.

Table of Contents

# BioSante Pharmaceuticals, Inc.

**NOTICE OF SPECIAL MEETING OF STOCKHOLDERS**
**To Be Held On March 15, 2013**

Dear BioSante Stockholder:

A special meeting of the stockholders of BioSante Pharmaceuticals, Inc. will be held on March 15, 2013 at 8:00 a.m., local time, at BioSante's corporate office located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069, for the following purposes:

1. To consider and vote upon a proposal to adopt the agreement and plan of merger dated as of October 3, 2012 between BioSante and ANI, as amended, a copy of which is attached as Annex A to the joint proxy statement/prospectus accompanying this notice, and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger.

2. To consider and vote upon a proposal to approve an amendment to BioSante's certificate of incorporation to effect a reverse split of BioSante common stock and BioSante class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five.

3. To consider and vote upon a proposal to approve an amendment to BioSante's certificate of incorporation to change the name of BioSante from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc."

4. To consider and vote upon a proposal to approve, on an advisory (non-binding) basis, the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger.

5. To consider and vote upon a proposal to approve an adjournment of the BioSante special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of BioSante Proposals No. 1, 2 and/or 3.

Stockholders also will consider and act on any other matters as may properly come before the special meeting or any adjournment or postponement thereof, including any procedural matters incident to the conduct of the special meeting.

The board of directors of BioSante has fixed January 17, 2013 as the record date for the determination of BioSante stockholders entitled to notice of, and to vote at, the BioSante special meeting or any adjournments or postponements of the BioSante special meeting. Only holders of record of BioSante common stock and BioSante class C special stock at the close of business on the BioSante record date are entitled to notice of, and to vote at, the BioSante special meeting. At the close of business on the record date, BioSante had 24,422,240 shares of common stock and 65,211 shares of BioSante class C special stock outstanding and entitled to vote.

**Your vote is important. The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, having voting power outstanding on the record date for the BioSante special meeting is required for approval of BioSante Proposals No. 1, 2 and 3. The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, present in person or represented by proxy at the BioSante special meeting, is required for approval of BioSante Proposals No. 4 and 5. Please also note that the approval of BioSante Proposal No. 1 is not conditioned upon the approval of BioSante Proposals No. 2, 3, 4 or 5; however, the approval of BioSante Proposals No. 2 and 3 is**

Table of Contents

**conditioned upon the approval of BioSante Proposal No. 1 by the BioSante stockholders and the approval of the corresponding proposal by the ANI stockholders.**

**Even if you plan to attend the BioSante special meeting in person, BioSante requests that you complete, sign and return the enclosed proxy card and thus ensure that your shares will be represented at the BioSante 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 BioSante Proposals No. 1 through 5. 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 BioSante special meeting and will count as a vote against BioSante Proposals No. 1 through 3. If you do attend the BioSante special meeting and wish to vote in person, you may withdraw your proxy and vote in person.**

**The BioSante board of directors has determined that the merger agreement and the transactions contemplated by it, including the merger and the issuance of shares of BioSante common stock in the merger, are advisable and in the best interests of BioSante and its stockholders. The BioSante board of directors unanimously has approved and adopted the merger agreement and the transactions contemplated by it, including the merger and the issuance of shares of BioSante common stock in the merger, and recommends that BioSante stockholders vote "FOR" the adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger, and "FOR" the other merger related proposals.**

By Order of the Board of Directors,

Phillip B. Donenberg
*Senior Vice President, Finance,*
*Chief Financial Officer and Secretary*

January 22, 2013
Lincolnshire, Illinois

**IMPORTANT NOTICE REGARDING THE AVAILABILITY OF PROXY MATERIALS FOR BIOSANTE'S SPECIAL MEETING TO BE HELD ON MARCH 15, 2013**

The accompanying joint proxy statement/prospectus is available at www.proxyvote.com/BioSante.

Table of Contents

# ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.

**NOTICE OF SPECIAL MEETING OF STOCKHOLDERS**
**To Be Held On March 15, 2013**

Dear ANI Stockholder:

A special meeting of the stockholders of ANI will be held on March 15, 2013 at 9:00 a.m., local time, at the offices of MVP Capital Partners located at 259 N. Radnor-Chester Road, Suite 130, Radnor, Pennsylvania 19087, for the following purposes:

1. To consider and vote upon a proposal to adopt the agreement and plan of merger dated as of October 3, 2012 between BioSante and ANI, as amended, a copy of which is attached as Annex A to the joint proxy statement/prospectus accompanying this notice, and the transactions contemplated thereby, including the merger.

2. To consider and vote upon a proposal to approve an adjournment of the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of ANI Proposal No. 1.

Stockholders also will consider and act on any other matters as may properly come before the special meeting or any adjournment or postponement thereof, including any procedural matters incident to the conduct of the special meeting.

The board of directors of ANI has fixed January 17, 2013 as the record date for the determination of ANI stockholders entitled to notice of, and to vote at, the ANI special meeting or any adjournments or postponements of the ANI special meeting. Only holders of record of ANI capital stock at the close of business on the ANI record date are entitled to notice of, and to vote at, the ANI special meeting. At the close of business on the record date, ANI had 2,375,312 shares of series D convertible preferred stock, 34,810 shares of series C convertible preferred stock, 78,491 shares of series B convertible preferred stock, 102,774 shares of series A convertible preferred stock and 23,613 shares of common stock outstanding and entitled to vote.

**Your vote is important. The affirmative vote of holders of a majority of the shares of ANI common stock, calculated on an as-converted basis and voting together as a single class, and 65 percent of the shares of ANI series D convertible preferred stock having voting power outstanding on the record date for the ANI special meeting is required for approval of ANI Proposal No. 1. The affirmative vote of holders of a majority of ANI common stock, calculated on an as-converted basis, present in person or represented by proxy at the ANI special meeting is required for approval of ANI Proposal No. 2.**

**Even if you plan to attend the ANI special meeting in person, ANI requests that you complete, sign and return the enclosed proxy card and thus ensure that your shares will be represented at the ANI 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 ANI Proposals No. 1 and 2. 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 ANI special meeting and will count as a vote against ANI Proposal No. 1. If you do attend the ANI special meeting and wish to vote in person, you may withdraw your proxy and vote in person.**

**The ANI board of directors has determined that the merger agreement and the transactions contemplated by it, including the merger, are advisable and in the best interests of ANI and its stockholders. The ANI board of directors has unanimously approved and adopted the merger**

Table of Contents

**agreement and the transactions contemplated by it, including the merger, and recommends that ANI stockholders vote "FOR" the adoption of the merger agreement and the transactions contemplated thereby, including the merger, and "FOR" the adjournment of the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of ANI Proposal No. 1.**

By Order of the Board of Directors,

Charlotte C. Arnold
*Vice President and Chief Financial Officer*

Baudette, Minnesota
January 22, 2013

Table of Contents

**TABLE OF CONTENTS**

Table of Contents

Table of Contents

Table of Contents

Table of Contents



References to "*BioSante*" and "*ANI*" in this joint proxy statement/prospectus refer to BioSante Pharmaceuticals, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc., respectively. References to the "combined company" refer to BioSante, as the surviving entity after the merger and incorporating the merged business of ANI. Except as otherwise noted, references to "*we*," "*us*" or "*our*" refer to both BioSante and ANI. References to the "*merger agreement*" refer to that certain agreement and plan of merger dated as of October 3, 2012 between BioSante and ANI, as amended from time to time.

Except as otherwise noted, references to "*BioSante common stock*" refer to shares of common stock, par value $0.0001 per share, of BioSante, and references to "*BioSante class C special stock*" refer to shares of class C special stock, par value of $0.0001 per share, of BioSante. Except as otherwise noted, references to "*BioSante capital stock*" refer to shares of BioSante common stock and BioSante class C special stock. References to the *BioSante stockholders* refer to holders of shares of BioSante common stock and/or shares of BioSante class C special stock. All BioSante share and per share

Table of Contents

numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

Except as otherwise noted, references to "*ANI series D preferred stock*," "*ANI series C preferred stock*," "*ANI series B preferred stock*," "*ANI series A preferred stock*" and "*ANI common stock*" refer to shares of series D convertible preferred stock, par value $0.10 per share, of ANI, series C convertible preferred stock, par value $0.10 per share, of ANI, series B convertible preferred stock, par value $0.10 per share, of ANI, series A convertible preferred stock, par value $0.10 per share, of ANI, and common stock, par value $0.10 per share, of ANI, respectively, and references to "*ANI preferred stock*" refer to shares of ANI series D preferred stock, ANI series C preferred stock, ANI series B preferred stock and ANI series A preferred stock, collectively. Except as otherwise noted, references to "*ANI capital stock*" refer to shares of ANI preferred stock and ANI common stock. References to the *ANI stockholders* refer to holders of shares of ANI capital stock. All ANI share and per share numbers have been adjusted retroactively to reflect the one-for-ten reverse stock split effected on January 28, 2011.

BioSante owns or has rights to various trademarks, trade names or service marks, including *BioSante®, LibiGel®, GVAX , The Pill-Plus* and *Elestrin* . ANI owns or has rights to various trademarks, trade names or service marks, including *Cortenema®* and *Reglan®*. This joint proxy statement/prospectus also contains trademarks, trade names and service marks of others.

Table of Contents

## QUESTIONS AND ANSWERS ABOUT THE MERGER

*The following section provides answers to frequently asked questions about the merger. This section, however, only provides summary information. These questions and answers may not address all issues that may be important to you as a BioSante or ANI stockholder. You should read carefully the entire joint proxy statement/prospectus, including each of the annexes.*

**Q:**

**What is the merger?**

A:

BioSante and ANI have entered into an agreement and plan of merger, which is referred to in this joint proxy statement/prospectus as the merger agreement, that contains the terms and conditions of the proposed merger of BioSante and ANI. If the merger is completed, ANI will merge with and into BioSante, with BioSante continuing as the surviving company. This transaction is referred to as the merger.

**Q:**

**Why are BioSante and ANI proposing to effect the merger?**

A:

BioSante and ANI both believe that the merger of the two companies will be able to create more value than either company could achieve individually. The combined company that will result from the merger will be a fully integrated specialty branded and generic pharmaceutical company focused on developing, manufacturing and marketing branded and generic prescription pharmaceuticals. For a more complete description of the reasons for the merger, see the sections entitled "The Merger BioSante Reasons for the Merger" beginning on page 128 and "The Merger ANI Reasons for the Merger" beginning on page 132.

**Q:**

**What will ANI stockholders receive in the merger?**

A:

Upon completion of the merger, ANI stockholders will have the right to receive, for each share of ANI capital stock they hold, that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. See the section entitled "The Merger Agreement Merger Consideration and Adjustment" beginning on page 156. The exchange ratios are subject to potential adjustment as described in the merger agreement, depending upon the amount of "net cash" of BioSante, as defined in the merger agreement, and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger, and thus will not be determined until that time. Upon completion of the merger, ANI stockholders are expected to receive shares of BioSante common stock representing an aggregate of approximately 53 percent of the outstanding shares of common stock of the combined company, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company, assuming BioSante's net cash is $18.0 million as of the determination date.

Pursuant to the terms of ANI's certificate of incorporation, (i) before any amounts are paid to the holders of shares of any other series of ANI preferred stock or ANI common stock, the holders of shares of ANI series D preferred stock are entitled to receive an amount per share equal to $30.00 plus all declared but unpaid dividends; (ii) before any amounts are paid to the holders of shares of ANI series B preferred stock, ANI series A preferred stock or ANI common stock, the holders of shares of ANI series C preferred stock are entitled to receive an amount per share equal to $110.00 plus all declared but unpaid dividends; (iii) before any amounts are paid to the holders of shares of ANI series A preferred stock or ANI common stock, the holders of shares of ANI series B preferred stock are entitled to receive an amount per share equal to $110.00 plus all declared but unpaid dividends; (iv) before any amounts are paid to the holders of shares of ANI

Table of Contents

common stock, the holders of shares of ANI series A preferred stock are entitled to receive an amount per share equal to $100.00 plus all declared but unpaid dividends; and (v) after payments have been made to all holders of ANI preferred stock, the remaining assets of ANI will be distributed ratably to the holders of ANI common stock, including holders of ANI series C preferred stock, ANI series B preferred stock and ANI series A preferred stock who elect to convert into BioSante common stock in lieu of receiving the stated dollar preference amounts described above, and ANI series D preferred stock. The stated value of each series of ANI preferred stock set forth above is subject to adjustment as provided in ANI's certificate of incorporation. The exchange ratios in the merger agreement reflect these preferential payments. **As a result of such provisions, it is likely that holders of shares of ANI series A preferred stock, ANI series B preferred stock, ANI series C preferred stock or ANI common stock will not receive any shares of BioSante common stock in connection with the merger**.

For illustrative purposes only, if the merger had been completed on December 31, 2012, and assuming BioSante's net cash as of such date was $18.0 million, the exchange ratio (without giving effect to the proposed reverse stock split of BioSante common stock and BioSante class C special stock described elsewhere in this joint proxy statement/prospectus) for the ANI series D preferred stock (including shares that would have been issued to certain executive officers of ANI immediately prior to completion of the merger) would have been approximately 10.3502 shares of BioSante common stock for each share of ANI series D preferred stock and the exchange ratio (without giving effect to the proposed reverse stock split described elsewhere in this joint proxy statement/prospectus) for the ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock would have been zero. Therefore, if the merger had been completed on such date and you owned 1,000 shares of ANI series D preferred stock as of such date, you would have had the right to receive 10,350 shares of BioSante common stock in exchange for your shares of ANI series D preferred stock. If you owned 1,000 shares of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock or ANI common stock as of such date, you would have had the right to receive no shares of BioSante common stock for such shares of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock or ANI common stock.

No fractional shares of BioSante common stock will be issued to ANI stockholders in connection with the merger. Instead, ANI stockholders will be entitled to receive cash in lieu of any fractional shares of BioSante common stock that they otherwise would be entitled to receive in connection with the merger.

For a more complete discussion of what ANI stockholders will receive in connection with the merger, see the sections entitled "The Merger Agreement  Merger Consideration and Adjustment" beginning on page 156.

**Q:**

**How will BioSante stockholders be affected by the merger?**

A:

The merger will have no effect on the number of shares of BioSante common stock or BioSante class C special stock held by BioSante stockholders as of immediately prior to completion of the merger (subject to any changes in outstanding shares of BioSante common stock and BioSante class C special stock as a result of the reverse stock split described elsewhere in this joint proxy statement/prospectus). However, it is expected that upon completion of the merger shares of BioSante common stock will represent only an aggregate of approximately 47 percent of the outstanding shares of common stock of the combined company, assuming BioSante's net cash is $18.0 million as of the determination date. If BioSante's net cash is higher than $18.0 million as of the determination date, then shares of BioSante common stock will represent a higher percentage, but no more than 49.9 percent, of the outstanding shares of common stock of the combined company. If BioSante's net cash is less than $18.0 million as of the determination date, then shares

Table of Contents

of BioSante common stock will represent a lower percentage of the outstanding shares of common stock of the combined company. One of the conditions to ANI's obligations to complete the merger is BioSante's net cash as of the closing date being no less than $17.0 million as calculated and as adjusted pursuant to the provisions of the merger agreement.

For illustrative purposes only, if you are a BioSante stockholder and hold five percent of the outstanding shares of BioSante common stock immediately prior to completion of the merger and do not also hold any shares of ANI capital stock, then upon completion of the merger, you will hold an aggregate of approximately 2.35 percent of the outstanding shares of common stock of the combined company immediately following completion of the merger, assuming BioSante's net cash is $18.0 million as of the determination date, and approximately 2.32 percent of the outstanding shares of common stock of the combined company immediately following completion of the merger, assuming BioSante's net cash is $17.0 million as of the determination date.

**Q:**

**Can the value of the transaction change between now and the time the merger is completed?**

A:

Yes. The market value of BioSante common stock can change between now and the time the merger is completed and the exchange ratios are subject to adjustment based on BioSante's net cash. The exchange ratios will not change, however, if the market value of BioSante common stock changes. Therefore, the market value of the total transaction, and of the BioSante common stock to be issued to ANI stockholders in the merger, will increase or decrease as the market value of BioSante common stock increases or decreases. In addition, the market value of the total transaction may change as a result of an adjustment of the exchange ratios triggered by a change in BioSante's net cash between now and the net cash determination date.

**Q:**

**Who will be the directors and executive officers of the combined company following the merger?**

A:

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

| Name | Current Principal Affiliation |
|---|---|
| Robert E. Brown, Jr. | ANI |
| Tracy L. Marshbanks, Ph.D. | ANI |
| Thomas A. Penn | ANI |
| Arthur S. Przybyl | ANI |
| Robert Schrepfer | ANI |
| Fred Holubow | BioSante |
| Ross Mangano | BioSante |

Robert E. Brown, Jr., ANI's chairman of the board, will be chairman of the board of the combined company.

Following the merger, the executive officers of the combined company will be the current executive officers of ANI, who are as follows:

| Name | Position |
|---|---|
| Arthur S. Przybyl | President and Chief Executive Officer |
| Charlotte C. Arnold | Vice President and Chief Financial Officer |
| James G. Marken | Vice President, Operations |
| Robert J. Jamnick | Vice President, Quality and Product Development |

Table of Contents

**Q:** **What are the conditions to the completion of the merger?**

A: The obligations of each of BioSante and ANI to consummate the merger are subject to the satisfaction or waiver (if permissible) at or before the effective time of the merger of the following conditions:

- the adoption by the requisite vote of BioSante stockholders of the merger agreement, including the merger and the issuance of shares of BioSante common stock pursuant to the merger agreement, and approval by the requisite vote of BioSante stockholders of the amendments to BioSante's certificate of incorporation to effect the reverse stock split and change the company's corporate name;
- the adoption of the merger agreement, including the merger, by the requisite vote of ANI stockholders;
- the absence of any legal prohibition to completing the merger;
- the effectiveness of, and the absence of any stop order with respect to, the registration statement on Form S-4 of which this joint proxy statement/prospectus forms a part;
- the continued listing of BioSante's common stock on The NASDAQ Global Market and the approval for listing on The NASDAQ Global Market or The NASDAQ Capital Market of the shares of BioSante common stock issuable in the merger; and
- the receipt of legal opinions from BioSante's and ANI's outside counsel that the merger will qualify as a reorganization under Section 368(a) of the Internal Revenue Code of 1986, as amended.

In addition, each party's obligation to complete the merger is further subject to the satisfaction or waiver (if permissible) by that party of the following additional conditions:

- the representations and warranties of the other party in the merger agreement being true and correct in all material respects, in each case as of the date of the merger agreement and as of the effective time of the merger, or, if such representations and warranties address matters as of a particular date, then as of that particular date;
- the other party to the merger agreement having performed or complied in all material respects with all agreements and covenants required to be performed or complied with by it at or before the closing of the merger;
- the other party having delivered a certificate signed by a duly authorized officer certifying to the satisfaction of such party of the above conditions in the merger agreement; and
- no material adverse effect on the other party shall have occurred and be continuing since the date of the merger agreement.

In addition, the obligation of ANI to complete the merger is further subject to the satisfaction or waiver at or before the effective time of the merger of the following additional conditions:

- BioSante's net cash as of the closing being no less than $17.0 million, as calculated and as adjusted pursuant to the provisions of the merger agreement; and

no new legal proceeding having been instituted against BioSante by any stockholder or holder of BioSante's convertible senior notes that has not been settled prior to the closing.

**Q:** **What will happen to BioSante or ANI if, for any reason, the merger does not close?**

A: BioSante and ANI have invested significant time and incurred, and expect to continue to incur, significant expenses related to the proposed merger. In the event the merger does not close, each

Table of Contents

of BioSante and ANI will review all alternatives then available to it. Failure to complete the merger could result in other adverse effects, as discussed in "Risk Factors  Risks Related to the Merger" beginning on page 38.

**Q:**

**When do BioSante and ANI expect the merger to be completed?**

A:

The merger will be completed upon the filing of a certificate of merger with the Secretary of State of the State of Delaware, but such filing only will be made upon the satisfaction or waiver (if permissible) of the conditions specified in the merger agreement, including receipt of the necessary approvals of BioSante and ANI stockholders at their respective special meetings and other customary closing conditions. It is possible that factors outside the control of BioSante and ANI could result in the merger not being completed or being completed later than expected. Although the exact timing of completion of the merger cannot be predicted with certainty, BioSante and ANI currently anticipate completing the merger in the first quarter of 2013.

Table of Contents

## QUESTIONS AND ANSWERS FOR BIOSANTE STOCKHOLDERS ABOUT THE BIOSANTE SPECIAL MEETING

*The following section provides answers to frequently asked questions about the BioSante special meeting of stockholders. This section, however, only provides summary information. These questions and answers may not address all issues that may be important to you as a BioSante stockholder. You should read carefully the entire joint proxy statement/prospectus, including each of the annexes.*

**Q:** **What proposals will be voted on at the BioSante special meeting?**

A: The following proposals will be voted on at the BioSante special meeting:

The first proposal to be voted upon is whether to adopt the merger agreement, a copy of which is attached as Annex A to this joint proxy statement/prospectus, and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger. See "Matters Being Submitted to a Vote of BioSante Stockholders BioSante Proposal No. 1 Adoption of Agreement and Plan of Merger and the Transactions Contemplated Thereby, including the Merger and the Issuance of Shares of BioSante Common Stock in the Merger," "The Merger" and "The Merger Agreement" beginning on pages 96, 116 and 156, respectively, for a more detailed description of the transaction.

The second proposal to be voted upon is whether to approve an amendment to BioSante's certificate of incorporation to effect a reverse split of BioSante common stock and BioSante class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five. See "Matters Being Submitted to a Vote of BioSante Stockholders BioSante Proposal No. 2 Approval of Amendment to BioSante's Certificate of Incorporation to Effect Reverse Split of BioSante Common Stock and Class C Special Stock at the Discretion of BioSante and ANI at a Ratio of Either One-for-Two, One-for-Three, One-for-Four or One-for-Five" beginning on page 97 for a more detailed description of the proposed amendment.

The third proposal to be voted upon is whether to approve an amendment to BioSante's certificate of incorporation to change the name of BioSante in connection with the merger to "ANI Pharmaceuticals, Inc." See "Matters Being Submitted to a Vote of BioSante Stockholders BioSante Proposal No. 3 Approval of Amendment to BioSante's Certificate of Incorporation to Change Corporate Name" beginning on page 108 for a more detailed description of the proposed amendment.

The fourth proposal to be voted upon is whether to approve, on an advisory (non-binding) basis, the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger. See "Matters Being Submitted to a Vote of BioSante Stockholders BioSante Proposal No. 4 Advisory Vote on Golden Parachute Compensation" beginning on page 109 for a more detailed description of the advisory vote.

The fifth proposal to be voted upon is whether to adjourn the BioSante special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the first, second and third proposals. See "Matters Being Submitted to a Vote of BioSante Stockholders BioSante Proposal No. 5 Approval of Possible Adjournment of the BioSante Special Meeting" beginning on page 110 for a more detailed description of the possible adjournment.

**Q:** **What risks should I consider before I vote on the proposed merger transaction and other merger related proposals?**

A: You should review the section entitled "Risk Factors" beginning on page 38.

Table of Contents

**Q:** **How does the BioSante board of directors recommend that BioSante stockholders vote?**

A: After careful consideration, the BioSante board of directors unanimously has approved the merger agreement, including the merger and the issuance of shares of BioSante common stock in the merger, and each of the proposals described in this joint proxy statement/prospectus that BioSante stockholders are being asked to consider, and has determined that they are advisable, fair to and in the best interests of BioSante stockholders. Accordingly, the BioSante board of directors unanimously recommends that BioSante stockholders vote "**FOR**" each such proposal.

**Q:** **Why is the proposal to amend BioSante's charter to effect the reverse stock split included in this joint proxy statement/prospectus and is it necessary for the completion of the merger?**

A: It is expected that immediately prior to the effective time of the merger, BioSante will effect a reverse split of the BioSante common stock and BioSante class C special stock at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five (with the exact ratio to be determined by BioSante and ANI immediately prior to completion of the merger). The reverse stock split is intended to ensure that the listing rules of The NASDAQ Stock Market are satisfied in connection with the issuance of shares of BioSante common stock in the merger. Under the listing rules of The NASDAQ Stock Market, the combined company must file an initial listing application in connection with the merger and comply with the initial listing rules of the applicable NASDAQ market to continue to be listed on such market following the merger. BioSante common stock is required to be listed on The NASDAQ Global Market or The NASDAQ Capital Market as a condition to closing the merger. The initial listing rules of The NASDAQ Global Market and The NASDAQ Capital Market require a company to have, among other things, a $4.00 per share minimum bid price. Because the current per share price of BioSante common stock is less than $4.00, the reverse stock split is necessary to meet the minimum bid listing requirement.

**Q:** **Why is the proposal to amend BioSante's charter to effect the change in BioSante's corporate name included in this joint proxy statement/prospectus and is it necessary for the completion of the merger?**

A: Both BioSante and ANI believe that the change in the corporate name of BioSante from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc." will allow for recognition of the combined company's business following completion of the merger. The current name will no longer accurately reflect the business of the combined company and the mission of the combined company subsequent to the completion of the merger. The approval of the amendment to BioSante's certificate of incorporation to effect the change in corporate name by the BioSante stockholders is a condition to closing the merger.

**Q:** **Can I dissent and require appraisal of my shares?**

A: No. Under the Delaware General Corporation Law, BioSante stockholders will not have appraisal rights in connection with the merger or any of the other proposals described in this joint proxy statement/prospectus that the BioSante stockholders are being asked to consider. See "The Merger  Appraisal Rights" beginning on page 152.

**Q:** **When and where is the BioSante special meeting?**

A: The BioSante special meeting of stockholders will be held on Friday, March 15, 2013 at 8:00 a.m., local time, at BioSante's corporate offices located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069 to consider and vote on the proposals related to the merger agreement and the transactions contemplated by it. For additional information relating to the BioSante special meeting, please see the section entitled "The Special Meeting of BioSante Stockholders" beginning on page 92.

Table of Contents

**Q:** **Who is soliciting my proxy?**

A: This proxy is being solicited by the BioSante board of directors.

**Q:** **What do I do now?**

A: BioSante urges you to read carefully and consider this joint proxy statement/prospectus, including its annexes, and consider how the proposed merger affects you.

In order for your shares to be represented at the BioSante special meeting:

- you can vote by telephone or through the Internet by following the instructions included on the enclosed proxy card;
- you can indicate on the enclosed proxy card how you would like to vote and sign and return the proxy card in the accompanying pre-addressed postage paid envelope; or
- you can attend the BioSante special meeting in person.

If you hold your shares in "street name," please refer to the enclosed proxy card or the information forwarded by your bank, broker or other holder of record to see what options are available to you.

**Q:** **Who is entitled to vote at the BioSante special meeting?**

A: Holders of record of BioSante common stock and BioSante class C special stock at the close of business on January 17, 2013 are entitled to notice of and to vote at the BioSante special meeting. As of January 17, 2013, 24,422,240 shares of BioSante common stock were issued and outstanding and entitled to vote and 65,211 shares of BioSante class C special stock were issued and outstanding and entitled to vote.

**Q:** **What is the difference between holding shares as a stockholder of record and as a beneficial owner?**

A: If your shares are registered directly in your name with BioSante's transfer agent, Computershare Trust Company, N.A., you are considered, with respect to those shares, the "stockholder of record." These proxy materials are sent to you by mail directly by BioSante.

If your shares are held in a stock brokerage account or by a bank or other holder of record, you are considered the "beneficial owner" of shares held in street name. These proxy materials are forwarded to you by your broker, bank or other holder of record who is considered, with respect to those shares, the stockholder of record. As the beneficial owner, you have the right to direct your broker, bank or other holder of record on how to vote your shares held in your account.

**Q:** **If I am a stockholder of record of BioSante capital stock, how do I vote?**

A: You may vote by proxy over the Internet by visiting the website established for that purpose at https://www.proxyvote.com and following the instructions (please note you must type an "s" after http), or you may vote by mail or by telephone. Alternatively, if you are a stockholder of record, you may vote in person at the BioSante special meeting. You will receive a ballot when you arrive.

**Q:**

**If I am a beneficial owner of shares held in street name, how do I vote?**

A:

You may vote by proxy over the Internet by visiting the website established for that purpose at https://www.proxyvote.com and following the instructions (please note you must type an "s" after http), or you may vote by mail or by telephone. If you are a beneficial owner of shares held in street name and you wish to vote in person at the BioSante special meeting, you must obtain a valid proxy from the organization that holds your shares.

Table of Contents

**Q:** **What can I do if I change my mind after I vote my shares?**

A: A stockholder of record may revoke its proxy at any time before it is used on the date of the BioSante special meeting by delivering to the corporate secretary of BioSante:

- written notice of revocation,
- a duly executed proxy bearing a later date or time than that of the previously submitted proxy, or
- a later dated vote by Internet or telephone, or a ballot cast in person at the BioSante special meeting.

If you are a beneficial owner of BioSante capital stock, you may submit new voting instructions by contacting your bank, broker or other holder of record. You also may vote in person if you obtain a legal proxy as described in the answer to the previous question. All shares that have been properly voted and not revoked will be voted at the BioSante special meeting.

**Q:** **What shares are included on the proxy card?**

A: If you are a stockholder of record of BioSante capital stock, you will receive only one proxy card for all the shares of BioSante capital stock you hold in certificate form and in book-entry form.

If you are a beneficial owner of BioSante capital stock, you will receive voting instructions, and information regarding consolidation of your vote, from your bank, broker or other holder of record.

**Q:** **What are the voting requirements to approve each of the proposals that will be voted on at the BioSante special meeting?**

A:

| Proposal | Vote Required |
|---|---|
| Adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger | Majority of the outstanding shares of BioSante common stock and BioSante class C special stock, voting together as a single class, and entitled to vote |
| Approval of amendment to effect reverse split of BioSante common stock and BioSante class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five | Majority of the outstanding shares of BioSante common stock and BioSante class C special stock, voting together as a single class, and entitled to vote |
| Approval of amendment to effect change of corporate name to "ANI Pharmaceuticals, Inc." | Majority of the outstanding shares of BioSante common stock and BioSante class C special stock, voting together as a single class, and entitled to vote |
| Approval, on an advisory (non-binding) basis, of the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger | Majority of the shares of BioSante common stock and BioSante class C special stock present in person or represented by proxy, voting together as a single class, and entitled to vote when a quorum is present |
| Approval of adjournment of the BioSante special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the first | Majority of the shares of BioSante common stock and BioSante class C special stock present in person or represented by proxy, voting together as a single class, and entitled to vote when a quorum is present |

three proposals

In connection with the execution of the merger agreement, all of BioSante's directors, executive officers and affiliated entities, who collectively held approximately two percent of the outstanding shares of BioSante capital stock as of October 3, 2012, entered into a voting agreement with ANI,

Table of Contents

pursuant to which each such BioSante stockholder agreed to vote all of their shares of BioSante capital stock in favor of adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, in favor of the two charter amendments, and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transactions contemplated thereby. As of the record date for the BioSante special meeting, the shares of BioSante capital stock owned by all of BioSante's directors, executive officers and affiliated entities and thus subject to the voting agreements constituted approximately two percent of the total outstanding voting power of BioSante on that date.

See the section entitled "Voting and Other Ancillary Agreements  BioSante Voting Agreements" beginning on page 168 for more information regarding these voting agreements.

**Q:**

**What constitutes a quorum at the BioSante special meeting?**

A:

The presence at the BioSante special meeting, either in person or by proxy, of the holders of one-third of the outstanding shares of BioSante common stock and BioSante class C special stock entitled to vote shall constitute a quorum for the transaction of business. Abstentions and broker non-votes are counted as present and entitled to vote for purposes of determining a quorum. A "broker non-vote" occurs when a bank, broker or other holder of record holding shares for a beneficial owner does not vote on a particular proposal because that holder does not have discretionary voting power for that particular item and has not received instructions from the beneficial owner.

**Q:**

**Could other matters be decided at the BioSante special meeting?**

A:

As of the date of the printing of this joint proxy statement/prospectus, neither BioSante nor ANI knew of any matters to be raised at the BioSante special meeting other than those referred to in this joint proxy statement/prospectus. If other matters are properly presented at the BioSante special meeting for consideration, the proxy committee appointed by the BioSante board of directors (the persons named in your proxy card if you are a BioSante stockholder of record) will have the discretion to vote on those matters for you.

**Q:**

**Who will count the vote?**

A:

An officer of BioSante or a designee will tabulate the votes and act as inspector of the election.

**Q:**

**Who is paying for this proxy solicitation?**

A:

BioSante will bear the cost of soliciting proxies, including the printing, mailing and filing of this joint proxy statement/prospectus, the proxy card and any additional information furnished to BioSante stockholders. BioSante has engaged Phoenix Advisory Partners, a proxy solicitation firm, to solicit proxies from BioSante stockholders. Arrangements also will be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of BioSante common stock for the forwarding of solicitation materials to the beneficial owners of BioSante common stock. BioSante will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials.

Table of Contents

**Q:**

**Whom should I call with questions?**

A:

If you have additional questions, you should contact:

**BioSante Pharmaceuticals, Inc.**
111 Barclay Boulevard
Lincolnshire, Illinois 60069
Attention: Investor Relations
Phone Number: (847) 478-0500, ext. 120
Email Address: info@biosantepharma.com

If you would like additional copies of this joint proxy statement/prospectus, you should contact:

**AST Phoenix Advisors**
110 Wall Street, 27th Floor
New York, New York 10005
Telephone: (877) 478-5038
Email Address: info@phoenixadvisorsast.com

Table of Contents

## QUESTIONS AND ANSWERS FOR ANI STOCKHOLDERS ABOUT THE ANI SPECIAL MEETING

*The following section provides answers to frequently asked questions about the ANI special meeting of stockholders. This section, however, only provides summary information. These questions and answers may not address all issues that may be important to you as an ANI stockholder. You should read carefully the entire joint proxy statement/prospectus, including each of the annexes.*

**Q:** **What proposals will be voted on at the ANI special meeting?**

A: The following proposals will be voted on at the ANI special meeting:

The first proposal to be voted upon is whether to adopt the merger agreement, a copy of which is attached as Annex A to this joint proxy statement/prospectus, and the transactions contemplated thereby, including the merger. See "Matters Being Submitted to a Vote of ANI Stockholders ANI Proposal No. 1 Adoption of Agreement and Plan of Merger and the Transactions Contemplated Thereby, including the Merger," "The Merger" and "The Merger Agreement" beginning on pages 114, 116 and 156, respectively, for a more detailed description of the transaction.

The second proposal to be voted upon is whether to adjourn the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the first proposal. See "Matters Being Submitted to a Vote of ANI Stockholders ANI Proposal No. 2 Approval of Possible Adjournment of the ANI Special Meeting" beginning on page 115 for a more detailed description of the possible adjournment.

**Q:** **What risks should I consider before I vote on the proposed merger transaction?**

A: You should review the section entitled "Risk Factors" beginning on page 38.

**Q:** **How does the ANI board of directors recommend that ANI stockholders vote?**

A: After careful consideration, the ANI board of directors has unanimously approved the merger agreement, including the merger, and each of the proposals described in this joint proxy statement/prospectus that the ANI stockholders are being asked to consider, and has determined that they are advisable, fair to and in the best interests of ANI stockholders. Accordingly, the ANI board of directors unanimously recommends that ANI stockholders vote "**FOR**" each such proposal.

**Q:** **Can I dissent and require appraisal of my shares?**

A: Yes. Under the Delaware General Corporation Law, ANI stockholders will have appraisal rights in connection with the merger. See "The Merger Appraisal Rights" beginning on page 152.

**Q:** **When and where is the ANI special meeting?**

A: The ANI special meeting of stockholders will be held on Friday, March 15, 2013 at 9:00 a.m., local time, at the offices of MVP Capital Partners located at 259 N. Radnor-Chester Road, Suite 130, Radnor, Pennsylvania 19087 to consider and vote on the proposals related to the merger agreement and the transactions contemplated by it. For additional information relating to the ANI special meeting, please see the section entitled "The Special Meeting of ANI Stockholders" beginning on page 111.

**Q:**

**Who is soliciting my proxy?**

A:

This proxy is being solicited by the ANI board of directors.

Table of Contents

**Q:** **What do I do now?**

A: ANI urges you to read carefully and consider this joint proxy statement/prospectus, including its annexes, and consider how the proposed merger affects you.

In order for your shares to be represented at the ANI special meeting:

- you can indicate on the enclosed proxy card how you would like to vote and sign and return the proxy card in the accompanying pre-addressed postage paid envelope; or
- you can attend the ANI special meeting in person.

**Q:** **Who is entitled to vote at the ANI special meeting?**

A: Every stockholder of ANI on the record date is entitled to vote at the ANI special meeting. Holders of record of ANI capital stock at the close of business on January 17, 2013 are entitled to notice of and to vote at the ANI special meeting. As of January 17, 2013, 2,375,312 shares of ANI series D preferred stock, 34,810 shares of ANI series C preferred stock, 78,491 shares of ANI series B preferred stock, 102,774 shares of ANI series A preferred stock and 23,613 shares of ANI common stock were issued and outstanding and entitled to vote.

**Q:** **How do I vote?**

A: You may vote by mail, or alternatively, you may vote in person at the ANI special meeting. You will receive a ballot when you arrive.

**Q:** **What can I do if I change my mind after I vote my shares?**

A: A stockholder of record may revoke its proxy at any time before it is used on the date of the ANI special meeting by delivering to the corporate secretary of ANI:

- written notice of revocation,
- a duly executed proxy bearing a later date or time than that of the previously submitted proxy, or
- a later dated vote by a ballot cast in person at the ANI special meeting.

**Q:** **What shares are included on the proxy card?**

A: If you are a stockholder of record of ANI capital stock, you will receive only one proxy card for all the shares of ANI capital stock you hold in certificate form.

Table of Contents

**Q:**

**What are the voting requirements to approve each of the proposals that will be voted on at the ANI special meeting?**

A:

| Proposal | Vote Required |
|---|---|
| Adoption of the merger agreement and the transactions contemplated thereby, including the merger | Majority of the outstanding shares of ANI capital stock entitled to vote, calculated on an as-converted basis, voting as a single class, and 65 percent of the outstanding shares of ANI series D preferred stock entitled to vote |
| Approval of adjournment of the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the adoption of the merger agreement and the transactions contemplated thereby, including the merger | Majority of the shares of ANI capital stock entitled to vote, calculated on an as-converted basis, present in person or represented by proxy and voting as a single class |

In connection with the execution of the merger agreement, Meridian Venture Partners II, L.P., Argentum Capital Partners II, L.P. and four funds affiliated with First Analysis Corp., who in the aggregate held approximately 85 percent of the shares of the outstanding ANI capital stock, calculated on an as-converted basis, and approximately 86 percent of the outstanding shares of the ANI series D preferred stock, as of October 3, 2012 entered into a voting agreement with BioSante, pursuant to which they agreed to vote their shares of ANI capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement.

As of the record date for the ANI special meeting, the shares of ANI capital stock owned by all of ANI's directors, executive officers and affiliated entities constituted approximately 92 percent of the outstanding shares of ANI capital stock, on an as-converted basis, and approximately 94 percent of the outstanding shares of the ANI series D preferred stock on that date.

See the section entitled "Voting and Other Ancillary Agreements  ANI Voting Agreements" beginning on page 168 for more information regarding this and other voting agreements.

**Q:**

**What constitutes a quorum at the ANI special meeting?**

A:

The presence at the ANI special meeting, either in person or by proxy, of the holders of a majority of the voting power of the issued and outstanding shares of ANI capital stock entitled to vote will constitute a quorum for the transaction of business. Abstentions are counted as present and entitled to vote for purposes of determining a quorum.

**Q:**

**Could other matters be decided at the ANI special meeting?**

A:

As of the date of the printing of this joint proxy statement/prospectus, neither BioSante nor ANI knew of any matters to be raised at the ANI special meeting other than those referred to in this joint proxy statement/prospectus. If other matters are properly presented at the ANI special meeting for consideration, the proxy committee appointed by the ANI board of directors (the persons named in your proxy card) will have the discretion to vote on those matters for you.

**Q:**

**Who will count the vote?**

A:

An officer of ANI or a designee will tabulate the votes and act as inspector of the election.

Table of Contents

**Q:**

**Who is paying for this proxy solicitation?**

A:

ANI will bear the cost of soliciting proxies, including the printing, mailing and filing of this joint proxy statement/prospectus, the proxy card and any additional information furnished to the ANI stockholders.

**Q:**

**Whom should I call with questions?**

A:

If you have additional questions, you should contact:

**ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.**
210 Main Street West
Baudette, Minnesota 56623
Telephone: (218) 634-3500
Investor Relations: arthur.przybyl@anipharmaceuticals.com

If you would like additional copies of this joint proxy statement/prospectus, you should contact:

**AST Phoenix Advisors**
110 Wall Street, 27th Floor
New York, New York 10005
Telephone: (877) 478-5038
Email Address: info@phoenixadvisorsast.com

Table of Contents

## SUMMARY

*This summary highlights selected information from this joint proxy statement/prospectus and may not contain all of the information that is important to you. To better understand the merger and the other proposals being considered at the special meetings, you should read this entire joint proxy statement/prospectus carefully, including the attached Annexes, and the other documents to which you are referred herein. See "Where You Can Find More Information" beginning on page 300.*

### The Companies

***BioSante Pharmaceuticals, Inc.***

BioSante Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. The following are BioSante's products, either approved or in clinical development:

LibiGel once daily transdermal testosterone gel in Phase III development for the treatment of female sexual dysfunction, specifically hypoactive sexual desire disorder.

Male testosterone gel once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc.

GVAX cancer vaccines a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers.

The Pill-Plus (triple component contraceptive) once daily use of various combinations of estrogens, progestogens and androgens in Phase II development.

Elestrin once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of hot flashes associated with menopause and marketed in the U.S. by Meda Pharmaceuticals, Inc., BioSante's licensee.

BioSante's corporate offices are located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069 and its telephone number is (847) 478-0500. BioSante's website is located at www.biosantepharma.com. The information contained on or connected to BioSante's website is expressly not incorporated by reference into this joint proxy statement/prospectus. Additional information about BioSante is included elsewhere in this joint proxy statement/prospectus. See the sections entitled "BioSante's Business," "BioSante's Management's Discussion and Analysis of Financial Condition and Results of Operations" and BioSante's financial statements beginning on pages 175, 193 and F-1, respectively.

***ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.***

ANI is a fully integrated specialty branded and generic pharmaceutical company developing, manufacturing and marketing branded and generic prescription pharmaceuticals. In two facilities with combined manufacturing, packaging and laboratory capacity totaling 173,000 square feet, ANI manufactures oral solid dose products, as well as liquids and topicals, including narcotics and those that must be manufactured in a fully contained environment due to their potency and/or toxicity. ANI also performs contract manufacturing for other pharmaceutical companies. Over the last two years ANI has launched three new products and currently has 11 products in development. ANI's targeted areas of product development include narcotics, anti-cancers and hormones (potent compounds), and extended release niche generic prescription product opportunities.

ANI's corporate offices are located at 210 Main Street West, Baudette, Minnesota 56623, and its telephone number is (218) 634-3500. ANI's website is located at www.anipharmaceuticals.com. The

Table of Contents

information contained on or connected to ANI's website is expressly not incorporated by reference into this joint proxy statement/prospectus. Additional information about ANI is included elsewhere in this joint proxy statement/prospectus. See the sections entitled "ANI's Business," "ANI's Management's Discussion and Analysis of Financial Condition and Result of Operations" and ANI's financial statements beginning on pages 211, 222 and F-47, respectively.

**Summary of the Merger**

If the merger is completed, ANI will be merged with and into BioSante, with BioSante surviving the merger. A copy of the merger agreement is attached as Annex A to this joint proxy statement/prospectus. You are encouraged to read the merger agreement in its entirety because it is the legal document that governs the merger. For a more complete discussion of the merger, see the sections entitled "The Merger" and "The Merger Agreement" beginning on pages 116 and 156, respectively.

**Reasons for the Merger**

The combined company that will result from the merger will be a fully integrated specialty branded and generic pharmaceutical company focused on developing, manufacturing and marketing branded and generic prescription pharmaceuticals. BioSante and ANI both believe that the merger of the two companies will be able to create more value than either company could achieve individually.

Each of the boards of directors of BioSante and ANI also considered other reasons for the merger, as described herein. For example, the BioSante board of directors considered, among other reasons:

The consideration of BioSante's anticipated near- and long-term operations and performance on an independent, stand-alone basis, the substantial additional financing that would be needed to sustain such operations assuming BioSante continued its LibiGel development program or in-licensed or acquired additional technologies or product candidates, and the risk that such substantial additional financing could not be obtained on terms favorable to BioSante, or at all, in light of a volatile economy and uncertain capital markets.

The consideration of strategic alternatives to the proposed merger with ANI, including other merger transactions with other companies, continuing to operate BioSante on a stand-alone basis, in-licensing or acquiring additional technologies or product candidates and undertaking a liquidation of BioSante, and the belief that the proposed merger with ANI would permit the BioSante stockholders with a greater potential opportunity to realize a return on their investment than any other alternative reasonably available to BioSante and its stockholders.

The belief that the combination of BioSante's and ANI's businesses would create more value for the BioSante stockholders in the long-term than BioSante could create as an independent, stand-alone company, given the anticipated costs, timing and risks associated with continuing the development of LibiGel and other BioSante products in development and/or in-licensing or acquiring additional technologies or product candidates, and the uncertain capital markets, which BioSante historically has relied upon to raise additional financing to fund its product development efforts.

Historical and current information concerning ANI's business, financial performance, financial condition, operations and management and the results of a due diligence investigation of ANI conducted by BioSante's management and advisors.

The opportunity for the BioSante stockholders to participate in the potential future value of the combined company, including future potential value from ANI's established contract manufacturing operations, niche generic prescription products and products in development.

Table of Contents

In addition, the ANI board of directors considered, among other reasons, the following:

- That the existing BioSante product lines fit well within the ANI platform of hormone-based products.
- That ANI would be able to leverage its knowledge of the hormone-based products market to further the existing BioSante product lines.
- The fact that the remaining cash resources expected to be available at the closing of the merger would provide the combined company with enough capital to enable it to meet its operational needs beyond 2013.
- The belief that the combination of the two businesses will result in accelerated growth and more value for the ANI stockholders than the ANI business could create on its own, given the combination of the product lines of the two companies, ANI's need for additional capital and the well-capitalized balance sheet that the combined company will have.
- The belief that potential future license and other royalty fees due to BioSante for its FDA-approved male testosterone gel and other products could generate significant future cash flow for the combined company.
- The belief that the combined company will have access to a greater number of capital market opportunities as a public company than ANI would have as a privately held company.
- That the exchange ratios in the merger will result in the ANI stockholders owning approximately 53 percent of the outstanding shares of the combined company following the merger, assuming BioSante's net cash on the determination date is $18.0 million.

For a more complete discussion of BioSante's and ANI's reasons for the merger, see the sections entitled "The Merger  BioSante Reasons for the Merger" and "The Merger  ANI Reasons for the Merger" beginning on pages 128 and 132, respectively.

**Opinion of Oppenheimer & Co. Inc.**

In connection with the merger, the BioSante board of directors received a written opinion, dated October 3, 2012, of BioSante's financial advisor, Oppenheimer & Co. Inc., referred to as "Oppenheimer & Co." or "BioSante's financial advisor," as to the fairness, from a financial point of view and as of the date of the opinion, to BioSante of the exchange ratios used in the merger. The full text of Oppenheimer & Co.'s written opinion, dated October 3, 2012, which describes the assumptions made, procedures followed, matters considered and limitations on the review undertaken, is attached to this joint proxy statement/prospectus as Annex G. Oppenheimer & Co.'s opinion was provided to the BioSante board of directors in connection with its evaluation of the exchange ratios from a financial point of view to BioSante and does not address any other aspect of the merger. Oppenheimer & Co.'s opinion does not address, among other things, the underlying business decision of BioSante to effect the merger, the relative merits of the merger as compared to any alternative business strategies that might exist for BioSante or the effect of any other transaction in which BioSante might engage and does not constitute a recommendation to any stockholder as to how such stockholder should vote or act with respect to any matters relating to the merger. For a more complete discussion of Oppenheimer & Co.'s opinion, see the section entitled "The Merger  Opinion of Oppenheimer & Co. Inc." beginning on page 134.

**Risk Factors**

Both BioSante and ANI are subject to various risks associated with their respective businesses and financial condition. In addition, the merger, as well as the possibility that the merger may not be

18

Table of Contents

completed, pose a number of risks to BioSante and ANI and their respective stockholders, including the following risks:

- The issuance of shares of BioSante common stock to ANI stockholders in connection with the merger will dilute substantially the voting power of current BioSante stockholders.

- The exchange ratios in the merger agreement depend on a variety of factors, including ANI's certificate of incorporation, BioSante's net cash and the market price of BioSante common stock, and changes in those ratios could result in dilution to the BioSante and/or ANI stockholders.

- The announcement and pendency of the merger could have an adverse effect on BioSante's stock price and/or the business, financial condition, results of operations, or business prospects for BioSante and/or ANI.

- Failure to complete the merger could impact negatively BioSante's and ANI's respective businesses, financial condition or results of operations or BioSante's stock price.

- Some of the directors and executive officers of BioSante and ANI have interests in the merger that are different from, or in addition to, those of the other BioSante and ANI stockholders.

- The merger agreement and the voting agreements contain provisions that could discourage or make it difficult for a third party to acquire BioSante or ANI prior to completion of the merger.

- Completion of the merger is subject to a number of customary conditions, including, but not limited to, the approval of the merger agreement by the BioSante and ANI stockholders. If any of the conditions to the merger are not satisfied or, where waiver is permissible, not waived, the merger will not be completed.

- The combined company's stock price may be volatile, and the market price of its common stock may decline in value following the merger.

In addition, BioSante, ANI and the combined company are subject to various risks associated with their respective businesses. These risks are discussed in greater detail in the section entitled "Risk Factors" beginning on page 38. BioSante and ANI both encourage you to read and consider all of these risks carefully.

**Merger Consideration and Adjustment**

Upon completion of the merger, ANI stockholders will have the right to receive, for each share of ANI capital stock they hold, that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger and thus will not be determined until that time. Upon completion of the merger, ANI stockholders are expected to receive shares of BioSante common stock representing an aggregate of approximately 53 percent of the outstanding shares of common stock of the combined company, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company, assuming BioSante's net cash is $18.0 million as of the determination date.

Pursuant to the terms of ANI's certificate of incorporation, before any amounts are paid to the holders of shares of any other series of ANI preferred stock or ANI common stock, the holders of shares of ANI series D preferred stock are entitled to receive an amount per share equal to $30.00

Table of Contents

(subject to adjustment as provided in ANI's certificate of incorporation) plus all declared but unpaid dividends. The exchange ratios in the merger agreement reflect these preferential payments. **As a result of such provisions, it is likely that holders of shares of other series of ANI preferred stock or ANI common stock will not receive any shares of BioSante common stock in connection with the merger.**

The following table illustrates the percentage ownership of the combined company by BioSante's and ANI's current stockholders assuming various amounts of net cash of BioSante as of the determination date.

| BioSante's Net Cash as of Determination Date Calculated Pursuant to Merger Agreement | BioSante Stockholder Ownership of Outstanding Shares of Combined Company | ANI Stockholder Ownership of Outstanding Shares of Combined Company |
|---|---|---|
| $23.0 million or more | 49.9% | 50.1% |
| 22.0 million | 49.4% | 50.6% |
| 21.0 million | 48.8% | 51.2% |
| 20.0 million | 48.2% | 51.8% |
| 19.0 million | 47.6% | 52.4% |
| 18.0 million | 47.0% | 53.0% |
| 17.0 million | 46.4% | 53.6% |

As described in more detail below under " Conditions to Completion of the Merger," one of the conditions to ANI's obligations to complete the merger, unless waived by ANI, is BioSante's net cash as of the closing date being no less than $17.0 million as calculated and as adjusted pursuant to the provisions of the merger agreement.

For illustrative purposes only, if the merger had been completed on December 31, 2012, and assuming BioSante's net cash as of such date was $18.0 million, the exchange ratio (without giving effect to the proposed reverse stock split of BioSante common stock and BioSante class C special stock described elsewhere in this joint proxy statement/prospectus) for the ANI series D preferred stock (including shares that would have been issued to certain executive officers of ANI immediately prior to completion of the merger) would have been approximately 10.3502 shares of BioSante common stock for each share of ANI series D preferred stock and the exchange ratio (without giving effect to the proposed reverse stock split described elsewhere in this joint proxy statement/prospectus) for the ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock would have been zero. Therefore, if the merger had been completed on such date and you owned 1,000 shares of ANI series D preferred stock as of such date, you would have had the right to receive 10,350 shares of BioSante common stock in exchange for your shares of ANI series D preferred stock. If you owned 1,000 shares of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock or ANI common stock as of such date, you would have had the right to receive no shares of BioSante common stock for such shares of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock or ANI common stock.

No fractional shares of BioSante common stock will be issued to ANI stockholders in connection with the merger. Instead, ANI stockholders will be entitled to receive cash in lieu of any fractional shares of BioSante common stock that they otherwise would be entitled to receive in connection with the merger.

BioSante will issue a press release after the final determination of the exchange ratios announcing the final exchange ratios and BioSante's net cash balance at the determination date.

There will be no adjustment to the total number of shares of BioSante common stock that ANI stockholders will be entitled to receive as a result of changes in the market price of BioSante common stock. Accordingly, the market value of the shares of BioSante common stock issued in connection with the merger will depend on the market value of the shares of BioSante common stock at the time of the

Table of Contents

merger, and could vary significantly from the market value on the date of this joint proxy statement/prospectus.

For a more complete discussion of what ANI stockholders will receive in connection with the merger and the determination of the exchange ratios, see the section entitled "The Merger Agreement Merger Consideration and Adjustment" beginning on page 156.

**Treatment of ANI Stock Options and Warrants**

All options and warrants to purchase shares of ANI capital stock outstanding immediately prior to the effective time of the merger will terminate and will no longer be outstanding immediately after the merger, except for certain warrants which although not cancelled in connection with the merger will not represent the right to acquire any equity or other interest in the combined company after the merger.

For a more complete discussion of the treatment of ANI stock options and warrants, see the section entitled "The Merger Treatment of ANI Stock Options and Warrants" beginning on page 159.

**Treatment of BioSante Stock Options, Warrants and Convertible Senior Notes**

All options and warrants to purchase shares of BioSante common stock will remain outstanding immediately after the merger, but the number of shares subject to and the exercise price applicable to such options and warrants will be adjusted to reflect the reverse stock split anticipated to take place immediately prior to the effective time of the merger. Pursuant to the terms of BioSante's equity-based compensation plans, all outstanding options to acquire shares of BioSante common stock will vest immediately and become exercisable in full upon completion of the merger. However, as a result of the anticipated reverse stock split, all such options likely will terminate unexercised since the exercise prices of such options currently range from $2.02 to $220.92 per share and the employment or other service of the holders of such options, other than those held by the two BioSante directors who will remain as directors of the combined company after the merger, will be terminated in connection with the merger. As of December 31, 2012, BioSante had an aggregate of 1.1 million shares of BioSante common stock reserved for issuance upon the exercise of outstanding stock options and an aggregate of 4.7 million shares of BioSante common stock reserved for issuance upon the exercise of outstanding warrants. The exercise prices of the warrants currently range from $1.50 to $24.00 per share.

All outstanding 3.125% convertible senior notes due May 1, 2013 of BioSante will remain outstanding immediately after the merger, but the conversion price and number of shares of BioSante common stock issuable upon any conversion of such notes will be adjusted to reflect the reverse stock split anticipated to take place immediately prior to the effective time of the merger. As of December 31, 2012, the outstanding principal amount of such notes was $8.3 million and BioSante had an aggregate of 370,871 shares of BioSante common stock reserved for issuance upon the conversion of such notes. The conversion price of the notes is currently $22.32 per share.

**Management of the Combined Company Following the Merger**

Following the merger, the board of directors of the combined company will be comprised of seven members, including two current members of the BioSante board of directors and five current members of the ANI board of directors. Robert E. Brown, Jr., ANI's chairman of the board, will be chairman of

Table of Contents

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

| Name | Current Principal Affiliation |
|---|---|
| Robert E. Brown, Jr. | ANI |
| Tracy L. Marshbanks, Ph.D. | ANI |
| Thomas A. Penn | ANI |
| Arthur S. Przybyl | ANI |
| Robert Schrepfer | ANI |
| Fred Holubow | BioSante |
| Ross Mangano | BioSante |

Following the merger, the executive officers of the combined company will be the current executive officers of ANI:

Arthur S. Przybyl President and Chief Executive Officer

Charlotte C. Arnold Vice President and Chief Financial Officer

James G. Marken Vice President, Operations

Robert J. Jamnick Vice President, Quality and Product Development

For a more complete discussion of the management of the combined company after the merger, see the section entitled "Management of the Combined Company Following the Merger" beginning on page 250.

**Interests of BioSante's Directors and Officers in the Merger**

In considering the recommendation of the BioSante board of directors to BioSante stockholders to vote in favor of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger, and the other matters to be acted upon by BioSante stockholders at the BioSante special meeting, BioSante stockholders should be aware that members of the BioSante board of directors and BioSante's officers have interests in the merger that may be different from, or in addition to, or conflict with, the interests of BioSante stockholders.

Interests of the BioSante directors and officers relate to:

The continuing service of each of Fred Holubow and Ross Mangano as directors of the combined company following completion of the merger and the payment of cash and equity compensation in consideration for such service, as described in more detail under "Management of the Combined Company After the Merger Director Compensation."

Change in control and severance payments and continued benefits to which BioSante's current executive officers will become entitled following completion of the merger and their anticipated termination of employment with BioSante. Assuming that the merger is completed on the date of the BioSante special meeting and the executive officers are terminated on such date, such individuals would receive approximately the amounts set forth in the table below.

| Name | Cash | Perquisites/ Benefits | Total |
|---|---|---|---|
| Stephen M. Simes | $ 1,490,100 | $ 87,949 | $ 1,578,049 |
| Phillip B. Donenberg | 770,000 | 74,156 | 844,156 |
| Michael C. Snabes, M.D., Ph.D. | 526,400 | 44,972 | 571,372 |

Table of Contents

The accelerated vesting of all unvested BioSante stock options held by the BioSante directors and officers, exercisable for an aggregate of 381,525 shares of BioSante common stock at exercise prices ranging from $4.08 to $220.92 per share, all of which options are currently out-of-the-money and likely will terminate unexercised either 90 days or one year after their termination of employment or service upon completion of the merger.

The right to continued indemnification and insurance coverage for directors and officers of BioSante pursuant to the terms of the merger agreement.

The BioSante board of directors was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, and to recommend that BioSante stockholders approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, and related matters. Other than full disclosure of these potential conflicts of interest, the BioSante board of directors did not take any other steps to alleviate such potential conflicts of interest since it did not consider such potential conflicts of interest to be material in connection with its decision to approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock.

For a more complete discussion of the interests of the directors and executive officers of BioSante in the merger, see the section entitled "The Merger  Interests of BioSante's Directors and Executive Officers in the Merger" beginning on page 143.

**Interests of ANI's Directors and Officers in the Merger**

In considering the recommendations of the ANI board of directors to ANI stockholders to vote in favor of the merger agreement and the transactions contemplated thereby, including the merger, and the other matters to be acted upon by ANI stockholders at the ANI special meeting, ANI stockholders should be aware that members of the ANI board of directors and ANI's officers have interests in the merger that may be different from, or in addition to, or conflict with, the interests of ANI stockholders.

Interests of the ANI directors and officers relate to:

The board of directors of the combined company will be comprised of the five individuals that are current members of the ANI board of directors and two individuals that are current members of the BioSante board of directors and such directors, with the exception of Mr. Przybyl, will receive cash and equity compensation for such services, as described in more detail under "Management of the Combined Company After the Merger  Director Compensation."

The fact that Robert E. Brown, Jr., ANI's chairman of the board, will continue as chairman of the board of the combined company.

The fact that the executive officers of the combined company will be the current executive officers of ANI and such officers will receive compensation for such service as described in more detail under "Management of the Combined Company After the Merger  Officer Compensation."

The fact that the executive officers of ANI will receive special transaction bonus payments upon closing of the merger ranging, for each officer, from approximately $707,705 to $3,309,410 (assuming BioSante's net cash as of the determination date is $18.0 million) payable in shares of ANI series D preferred stock, which shares will convert into shares of BioSante common stock in the merger, as described in more detail under "Management of the Combined Company Following the Merger  Certain Relationships and Related Transactions."

Table of Contents

The fact that MVP Capital and HVC, two firms affiliated with three of ANI's directors, will receive fees of approximately $350,000 and $40,000, respectively, upon closing of the merger. This is in addition to unpaid amounts due under existing monitoring arrangements with ANI, which will terminate at closing and which are expected not to exceed $120,000 for MVP Capital and $30,000 for HVC, assuming a closing on or before March 31, 2013.

The right to continued indemnification and insurance coverage for directors and executive officers of ANI following completion of the merger pursuant to the terms of the merger agreement.

The ANI board of directors was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the merger agreement and the transactions contemplated thereby, including the merger, and to recommend that ANI stockholders approve the merger agreement and the transactions contemplated thereby, including the merger. Other than full disclosure of these potential conflicts of interest, the ANI board of directors did not take any other steps to alleviate such potential conflicts of interest since it did not consider such potential conflicts of interest to be material in connection with its decision to approve the merger agreement and the transactions contemplated thereby, including the merger.

For a more complete discussion of the interests of the directors and executive officers of ANI in the merger, see the section entitled "The Merger  Interests of ANI's Directors and Officers in the Merger" beginning on page 148.

**Conditions to Completion of the Merger**

BioSante and ANI expect to complete the merger after all conditions to the merger in the merger agreement are satisfied or, if permissible, waived. BioSante and ANI currently expect to complete the merger in the first quarter of 2013. However, it is possible that factors outside of BioSante's or ANI's control could require BioSante and ANI to complete the merger at a later time or not complete it at all. The obligations of each of BioSante and ANI to complete the merger are subject to the satisfaction or waiver (if permissible) at or before the effective time of the merger of the following conditions:

The adoption by the requisite vote of BioSante stockholders of the merger agreement, including the merger and the issuance of BioSante common stock pursuant to the merger agreement, and approval by the requisite vote of BioSante stockholders of the amendments to BioSante's certificate of incorporation to effect the reverse stock split and change the company's corporate name.

The adoption of the merger agreement, including the merger, by the requisite vote of ANI stockholders.

The absence of any legal prohibition to completing the merger.

The effectiveness of, and the absence of any stop order with respect to, the registration statement on Form S-4, of which this joint proxy statement/prospectus forms a part, filed by BioSante with the SEC.

The continued listing of BioSante common stock on The NASDAQ Global Market and the approval for listing on The NASDAQ Global Market or The NASDAQ Capital Market of the shares of BioSante common stock issuable in the merger.

The receipt of legal opinions from BioSante's and ANI's outside counsel that the merger will qualify as a reorganization under Section 368(a) of the Internal Revenue Code of 1986, as amended.

Table of Contents

In addition, each party's obligation to complete the merger is further subject to the satisfaction or waiver (if permissible) by that party of the following additional conditions:

- The representations and warranties of the other party in the merger agreement being true and correct in all material respects, in each case as of the date of the merger agreement and as of the effective time of the merger, or, if such representations and warranties address matters as of a particular date, then as of that particular date.

- The other party to the merger agreement having performed or complied with in all material respects all agreements and covenants required to be performed or complied with by it at or before the closing of the merger.

- The other party having delivered a certificate signed by a duly authorized officer certifying to the satisfaction of such party of the above conditions in the merger agreement.

- No material adverse effect on the other party shall have occurred and be continuing since the date of the merger agreement.

In addition, the obligation of ANI to complete the merger is further subject to the satisfaction or waiver at or before the effective time of the merger of the following additional conditions:

- BioSante's net cash as of the closing being no less than $17.0 million, as calculated and as adjusted pursuant to the terms of the merger agreement.

- No new legal proceeding having been instituted against BioSante by any stockholder or holder of BioSante's convertible senior notes that has not been settled prior to the closing.

For a more complete discussion of the conditions to the completion of the merger, see the section entitled "The Merger Agreement  Conditions to Completion of the Merger" beginning on page 159.

**No Solicitation**

Each of BioSante and ANI has agreed that, with certain exceptions, BioSante and ANI and their respective officers, directors, employees and advisors will not:

- Solicit, initiate, encourage, facilitate or induce the making of any acquisition proposal.

- Enter into, continue or otherwise participate in any discussions or negotiations regarding or otherwise facilitate or induce any effort or attempt to make or implement any acquisition proposal.

- Approve, endorse or recommend any acquisition proposal.

- Agree, resolve or commit to do any of the foregoing.

The merger agreement does not, however, prohibit BioSante from considering a bona fide acquisition proposal from a third party if certain specified conditions are met. For a more complete description of the prohibition on solicitations of acquisition proposals from third parties, see "The Merger Agreement  No Solicitation" beginning on page 160.

**Termination of the Merger Agreement**

Either BioSante or ANI can terminate the merger agreement, which would prevent the merger from being consummated, under certain circumstances as set forth below:

By mutual written consent of BioSante and ANI.

By BioSante or ANI, if the merger has not been completed by May 31, 2013, subject to extension to no later than July 31, 2013 based on the date of filing of the registration statement

Table of Contents

on Form S-4 of which this joint proxy statement/prospectus forms a part, except that a party whose material breach of the merger agreement resulted in the failure of the merger to occur by such date cannot seek termination for this reason.

By BioSante or ANI, if any applicable law irrevocably prohibits or makes the merger illegal or a governmental entity has issued a final and non-appealable order, decree or ruling or taken any other action that permanently restrains, enjoins or otherwise prohibits the merger, except that the right to terminate the merger agreement for this reason is not available to any party who has not used reasonable best efforts to cause such law or order to be lifted.

By BioSante or ANI, if ANI stockholders fail to adopt the merger agreement at the ANI stockholder meeting or if BioSante stockholders fail to adopt the merger agreement, including the merger and the issuance of shares of BioSante common stock pursuant to the merger, and approve the amendments to BioSante's certificate of incorporation at the BioSante stockholder meeting.

By ANI, if either of the following occur, each a "BioSante triggering event":

BioSante fails to include in this joint proxy statement/prospectus the recommendation of the BioSante board of directors to the BioSante stockholders in favor of adoption of the merger agreement, including the merger and the issuance of shares of BioSante common stock in the merger, and approval of the amendments to BioSante's certificate of incorporation.

Prior to the BioSante special meeting the BioSante board of directors has withdrawn or made a change, or publicly proposed to withdraw or make a change, in its recommendation to its stockholders to adopt the merger agreement, including the issuance of shares of BioSante common stock in the merger, and to approve the amendments to BioSante's certificate of incorporation in a manner adverse to ANI.

By BioSante, if BioSante enters into a superior proposal in accordance with the terms of the merger agreement. For a more detailed description of BioSante's ability to terminate the merger agreement in connection with a superior proposal, see the section entitled "The Merger Agreement  No Solicitation".

By BioSante or ANI, if the other party has breached any of its representations, warranties, covenants or other agreements contained in the merger agreement or if any representation or warranty has become inaccurate, in either case such that the conditions to the closing of the merger would not be satisfied, provided that if such breach or inaccuracy is curable, then the merger agreement will not terminate pursuant to this provision as a result of a particular breach or inaccuracy until the expiration of a 30-day period after delivery of notice of such breach or inaccuracy if such breach has not been cured.

By ANI, if after BioSante receives an acquisition proposal, BioSante has materially breached its obligations under the merger agreement with respect to the acquisition proposal.

For a more complete discussion of the circumstances under which the merger agreement may be terminated, see the section entitled "The Merger Agreement  Termination" beginning on page 164.

**Termination Fees and Expenses**

If the merger agreement is terminated under certain circumstances, BioSante will be required to pay ANI a termination fee of $1.0 million. The merger agreement also provides that under specified circumstances, BioSante may be required to reimburse ANI up to $500,000 for ANI's expenses in connection with the transaction. Any expenses paid by BioSante will be credited against the termination fee if the termination fee subsequently becomes payable by BioSante. If the merger agreement is

Table of Contents

terminated under certain circumstances, ANI will be required to pay BioSante a termination fee of $750,000.

For a more complete discussion of termination fees and expenses, see the section entitled "The Merger Agreement  Termination Fees and Expenses" beginning on page 165.

**Vote Required**

The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, having voting power outstanding on the record date for the BioSante special meeting is required for approval of the proposal to adopt the merger agreement and the transactions contemplated thereby including the merger and the issuance of shares of BioSante common stock in the merger, and the proposals to approve the two BioSante charter amendments to effect the reverse stock split and change the corporate name. The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, present in person or represented by proxy at the BioSante special meeting, is required for approval of the proposal to approve, on an advisory (non-binding) basis, the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger and the proposal to approve an adjournment of the BioSante special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the proposal to adopt the merger agreement and the transactions contemplated thereby including the merger and the issuance of shares of BioSante common stock in the merger, and/or the proposals to approve the two BioSante charter amendments to effect the reverse stock split and change the corporate name. For a more complete discussion of the matters to be considered by the BioSante stockholders at the BioSante special meeting and the vote required to approve such matters, see the section entitled "Matters Being Submitted to a Vote of BioSante Stockholders" beginning on page 96.

The affirmative vote of holders of a majority of the shares of ANI common stock, calculated on an as-converted basis and voting together as a single class, and 65 percent of the shares of ANI series D convertible preferred stock having voting power outstanding on the record date for the ANI special meeting is required for approval of the proposal to adopt the merger agreement and the transactions contemplated thereby including the merger. The affirmative vote of holders of a majority of ANI common stock, calculated on an as-converted basis, present in person or represented by proxy at the ANI special meeting is required for approval of the proposal to approve an adjournment of the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the proposal to adopt the merger agreement and the transactions contemplated thereby including the merger. For a more complete discussion of the matters to be considered by the ANI stockholders at the ANI special meeting and the vote required to approve such matters, see the section entitled "Matters Being Submitted to a Vote of ANI Stockholders" beginning on page 114.

**Voting Agreements**

In connection with the execution of the merger agreement, all of BioSante's directors, executive officers and affiliated entities, who collectively held approximately two percent of the outstanding shares of BioSante capital stock as of October 3, 2012, entered into a voting agreement with ANI, pursuant to which each such BioSante stockholder agreed to vote all of their shares of BioSante capital stock in favor of adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, in favor of the two charter amendments, and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transactions contemplated thereby. As of the record date for the BioSante special meeting, the shares of BioSante capital stock owned by all of BioSante's directors, executive officers and affiliated entities and thus subject to the voting agreements constituted approximately two percent of the total outstanding voting power of BioSante on that date.

Table of Contents

In connection with the execution of the merger agreement, Meridian Venture Partners II, L.P., Argentum Capital Partners II, L.P. and four funds affiliated with First Analysis Corp., who in the aggregate held approximately 85 percent of the shares of the outstanding ANI capital stock, calculated on an as-converted basis, and approximately 86 percent of the outstanding shares of the ANI series D preferred stock, as of October 3, 2012 entered into a voting agreement with BioSante, pursuant to which they agreed to vote their shares of ANI capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement. As of the record date for the ANI special meeting, the shares of ANI capital stock owned by all of ANI's directors, executive officers and affiliated entities constituted approximately 92 percent of the outstanding shares of ANI capital stock, on an as-converted basis, and approximately 94 percent of the outstanding shares of the ANI series D preferred stock on that date.

For a more complete discussion of the voting agreements, see the section entitled "Voting and Other Ancillary Agreements" beginning on page 168. For a more complete discussion of the beneficial ownership of BioSante's and ANI's directors, executive officers and affiliates, see the sections entitled "Principal Stockholders of BioSante" and "Principal Stockholders of ANI" beginning on pages 274 and 276, respectively.

**Material U.S. Federal Income Tax Consequences of the Merger**

The merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended, and it is a condition to the completion of the merger that BioSante and ANI each receive a written opinion from their respective outside legal counsel regarding such qualification. As a result of the "reorganization," ANI stockholders generally will not recognize gain or loss for U.S. federal income tax purposes upon the exchange of their shares of ANI capital stock for shares of BioSante common stock in connection with the merger. However, if an ANI stockholder receives cash in lieu of a fractional share of BioSante common stock, then such stockholder generally will recognize gain or loss in an amount equal to the difference between such stockholder's adjusted tax basis in the fractional share and the amount of cash received. Moreover, an ANI stockholder who perfects appraisal rights and receives cash in exchange for such stockholder's shares of ANI capital stock will recognize gain or loss measured by the difference between the amount of cash received and such stockholder's adjusted tax basis in those shares. BioSante stockholders generally will not recognize gain or loss for U.S. federal income tax purposes as a result of the merger.

Tax matters are very complicated, and the tax consequences of the merger to a particular BioSante or ANI stockholder will depend in part on such stockholder's circumstances. Accordingly, BioSante and ANI urge you 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. For a more complete discussion of the material U.S. federal income tax consequences of the merger, see the section entitled "Material U.S. Federal Income Tax Consequences of the Merger" beginning on page 172.

**Regulatory Approvals**

Neither BioSante nor ANI is required to make any filings or to obtain any approvals or clearances from any antitrust regulatory authorities in the United States or other countries to consummate the merger. In the United States, BioSante must comply with applicable federal and state securities laws and The NASDAQ Stock Market rules and regulations in connection with the issuance of shares of BioSante common stock in the merger, including the filing with the SEC of the registration statement of which this joint proxy statement/prospectus is a part. For a more complete discussion of the regulatory approvals required in connection with the merger, see the section entitled "The Merger  Regulatory Approvals" beginning on page 151.

Table of Contents

**Anticipated Accounting Treatment**

The merger will be accounted for as a "reverse acquisition" pursuant to which ANI will be considered the acquiring entity for accounting purposes in accordance with U.S. generally accepted accounting principles, referred to as U.S. GAAP. As such, ANI will allocate the total purchase consideration to BioSante's tangible and identifiable intangible assets and liabilities based on their relative fair values at the date of the completion of the merger. ANI's historical results of operations will replace BioSante's historical results of operations for all periods prior to the merger. After completion of the merger, the results of operations of both companies will be included in BioSante's financial statements. For a more complete discussion of the anticipated accounting treatment of the merger, see the section entitled "The Merger Anticipated Accounting Treatment" beginning on page 151.

**Appraisal Rights**

If the merger is completed, ANI stockholders are entitled to appraisal rights under Section 262 of the Delaware General Corporation Law. Holders of BioSante common stock and BioSante class C special stock are not entitled to appraisal rights in connection with the merger. For a more complete discussion of the appraisal rights, see the provisions of Section 262 of the Delaware General Corporation Law, attached to this joint proxy statement/prospectus as Annex H, and the section entitled "The Merger Appraisal Rights" beginning on page 152.

**Comparison of Stockholder Rights**

Both BioSante and ANI 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 Delaware General Corporation Law and their respective certificates of incorporation and bylaws. If the merger is completed, ANI stockholders will become stockholders of BioSante, and their rights will be governed by the Delaware General Corporation Law, the certificate of incorporation of BioSante and the bylaws of BioSante. The rights of BioSante contained in the certificate of incorporation and bylaws of BioSante differ from the rights of ANI stockholders under the certificate of incorporation and bylaws of ANI, as more fully described under the section entitled "Comparison of Rights of Holders of BioSante Stock and ANI Stock" beginning on page 286.

**Contingent Value Rights**

BioSante plans to issue contingent value rights (referred to as CVRs) to holders of BioSante common stock as of immediately before completion of the merger. BioSante expects that one CVR will be issued for each share of BioSante common stock outstanding as of a record date of March 15, 2013. The CVRs will be non-transferable and not attached to the shares of BioSante common stock. The CVRs will be rights to receive potential cash payments in connection with a LibiGel transaction (as defined in the contingent value rights agreement) upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between BioSante and a rights agent. The aggregate cash payments to be received by holders of the CVRs, if any, will be equal to 66 percent of the net cash payments received by the combined company as a result of the sale, transfer, license or similar transaction relating to BioSante's LibiGel program during the 10-year period following completion of the merger, and will not exceed $40 million in the aggregate. The form of the contingent value rights agreement is attached to this joint proxy statement/prospectus as Annex F. For a more complete discussion of the CVRs, see the section entitled "Contingent Value Rights" beginning on page 170.

Table of Contents

## SELECTED HISTORICAL FINANCIAL INFORMATION AND UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION AND DATA

### Selected Historical Financial Data of BioSante

The selected financial data as of December 31, 2011 and 2010 and for the years ended December 31, 2011, 2010 and 2009 are derived from BioSante's audited financial statements included in this joint proxy statement/prospectus beginning on page F-1. The selected financial data as of December 31, 2009, 2008 and 2007 and for the years ended December 31, 2008 and 2007 are derived from BioSante's financial statements, which are not included in this joint proxy statement/prospectus. The statement of operations data for the nine months ended September 30, 2012 and 2011, as well as the balance sheet data as of September 30, 2012 and 2011 are derived from BioSante's unaudited financial statements included in this joint proxy statement/prospectus beginning on page F-32. The selected historical financial data below should be read in conjunction with "BioSante's Management's Discussion and Analysis of Financial Condition and Results of Operations" and BioSante's financial statements and related notes appearing elsewhere in this joint proxy statement/prospectus. The historical results are not necessarily indicative of results to be expected in any future period.

| | Nine Months Ended September 30, | | Year Ended December 31, | | | | |
|---|---|---|---|---|---|---|---|
| | 2012 | 2011 | 2011 | 2010 | 2009 | 2008 | 2007 |
| | | | | | (in thousands, except per share data) | | |
| **Statement of Operations Data:** | | | | | | | |
| Revenue | $ 333 | $ 321 | $ 435 | $ 2,474 | $ 1,258 | $ 3,781 | $ 493 |
| Expenses | | | | | | | |
| Research and development | 14,454 | 37,481 | 44,182 | 39,706 | 13,681 | 15,790 | 4,751 |
| General and administration | 5,328 | 5,258 | 6,982 | 5,940 | 5,374 | 5,125 | 4,331 |
| Acquired in-process research and development | | | | | 9,000 | | |
| Excess consideration paid over fair value | | | | | 20,192 | | |
| Licensing expense | | | 50 | 269 | 300 | 836 | |
| Depreciation and amortization | 88 | 118 | 148 | 168 | 137 | 43 | 90 |
| Total expenses | 19,870 | 42,857 | 51,362 | 46,083 | 48,684 | 21,794 | 9,172 |
| Other (expense) income Convertible note fair value adjustment | (4,037) | (1,929) | (23) | (1,871) | 33 | | |
| Other expense Investment impairment charge | | | | (286) | | | |
| Other interest (expense) income | (278) | (510) | (674) | (675) | (135) | 588 | 1,095 |
| Other income | | 15 | 15 | 245 | | | |
| Income tax benefit | 122 | | | | | | |
| Net loss | $ (23,730) | $ (44,960) | $ (51,609) | $ (46,196) | $ (47,528) | $ (17,425) | $ (7,584) |
| Basic and diluted net loss per common share(1) | $ (1.14) | $ (2.86) | $ (3.15) | $ (4.21) | $ (8.40) | $ (3.83) | $ (1.79) |
| Weighted average number of common shares and common equivalent shares outstanding(1) | 20,841 | 15,745 | 16,398 | 10,985 | 5,659 | 4,551 | 4,247 |

(1) All share and per share numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

30

Table of Contents

| | As of September 30, | | As of December 31, | | | | |
|---|---|---|---|---|---|---|---|
| | 2012 | 2011 | 2011 | 2010 | 2009 | 2008 | 2007 |
| | | | | (in thousands, except per share data) | | | |
| **Balance Sheet Data:** | | | | | | | |
| Cash, cash equivalents and short-term investments | $ 38,049 | $ 69,600 | $ 57,225 | $ 38,155 | $ 29,858 | $ 14,787 | $ 30,655 |
| Total assets | 43,212 | 74,891 | 62,380 | 44,767 | 36,437 | 17,679 | 31,241 |
| Total current liabilities (includes short-term convertible senior notes in 2010) | 10,922 | 11,500 | 7,228 | 8,183 | 3,930 | 3,853 | 1,516 |
| Convertible senior notes, total long-term | | 19,242 | 17,337 | 17,436 | 16,676 | | |
| Stockholders' equity | 32,290 | 44,149 | 37,815 | 19,147 | 15,830 | 13,826 | 29,725 |

(1) All share and per share numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

**Selected Historical Financial Data of ANI**

The selected financial data as of December 31, 2011 and 2010 and for the years ended December 31, 2011 and 2010 are derived from ANI's audited financial statements and are included in this joint proxy statement/prospectus beginning on page F-48. The statement of operations data for the nine months ended September 30, 2012 and 2011, as well as the balance sheet data as of September 30, 2012 and 2011 are derived from ANI's unaudited financial statements included in this joint proxy statement/prospectus beginning on page F-84. The financial data should be read in conjunction with "ANI's Management's Discussion and Analysis of Financial Condition and Results of Operations" and ANI's financial statements and related notes appearing elsewhere in this joint proxy statement/prospectus. The historical results are not necessarily indicative of results to be expected in any future period.

| | Nine Months Ended September 30, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2012 | 2011 | 2011 | 2010 |
| | (in thousands, except per share data) | | | |
| **Statement of Operations Data:** | | | | |
| Net revenues | $ 15,050 | $ 11,955 | $ 16,515 | $ 8,975 |
| Total operating expenses | 14,075 | 12,163 | 16,510 | 11,806 |
| Net loss | $ (351) | $ (1,768) | $ (2,428) | $ (9,273) |
| Net loss attributed to common stockholders | $ (4,782) | $ (2,642) | $ (4,914) | $ (7,810) |
| Basic and diluted net loss per common share | $ (439.32) | $ (298.31) | $ (693.61) | $ (1,673.92) |

| | As of September 30, | | As of December 31, | |
|---|---|---|---|---|
| | 2012 | 2011 | 2011 | 2010 |
| | (in thousands) | | | |
| **Balance Sheet Data:** | | | | |
| Cash, cash equivalents and short-term investments, including restricted cash and investments | $ 148 | $ 27 | $ | $ |
| Total assets | 13,559 | 11,646 | 12,676 | 10,514 |
| Total current liabilities | 6,368 | 5,876 | 6,161 | 5,955 |
| Other long-term obligations, excluding current portion | | 15,182 | 16,582 | 12,202 |
| Redeemable convertible preferred stock | 46,155 | 23,722 | 24,216 | 35,808 |
| Accumulated deficit | (40,048) | (34,126) | (35,370) | (44,444) |
| Total stockholders' deficit | (38,964) | (33,134) | (34,284) | (43,452) |

Table of Contents

**Summary Unaudited Pro Forma Condensed Combined Financial Data of BioSante and ANI**

The following summary unaudited pro forma condensed combined financial data is intended to show how the merger might have affected historical financial statements if the merger had been completed on January 1, 2011 for the purposes of the statements of operations and September 30, 2012 for the purposes of the balance sheet, and was prepared based on the historical financial results reported by BioSante and ANI. The following should be read in conjunction with the section entitled "Unaudited Pro Forma Condensed Combined Financial Statements" beginning on page 239, the audited and unaudited historical financial statements of BioSante and ANI and the notes thereto beginning on pages F-1 and F-47, respectively, the sections entitled "BioSante's Management's Discussion and Analysis of Financial Condition and Results of Operations" beginning on page 193 and "ANI's Management's Discussion and Analysis of Financial Condition and Results of Operations" beginning on page 222, and the other information contained in this joint proxy statement/prospectus. The following information does not give effect to the proposed reverse stock split of BioSante common stock and BioSante class C special stock described in BioSante Proposal No. 2.

The merger will be accounted for as a reverse acquisition under the accounting rules for business combinations. Under the reverse acquisition method of accounting, ANI will be treated as the accounting acquiror and BioSante will be treated as the "acquired" company for financial reporting purposes because, immediately upon completion of the merger, ANI stockholders prior to the merger will hold a majority of the voting interest of the combined company. In addition, the seven member board of directors of the combined company will be comprised of five of the current members of the ANI board of directors; and therefore, ANI's current board of directors will possess majority control of the board of directors of the combined company. Members of the current management of ANI will be responsible for the management of the combined company and the majority of the combined company's activities will be activities related to ANI's current business.

The unaudited pro forma condensed combined financial statements were prepared in accordance with the regulations of the SEC. The pro forma adjustments reflecting the completion of the merger are based upon the acquisition method of accounting in accordance with GAAP, and upon the assumptions set forth in the notes to the unaudited pro forma condensed combined financial statements.

The summary unaudited pro forma condensed combined balance sheet as of September 30, 2012 combines the historical balance sheets of BioSante and ANI as of September 30, 2012 and gives pro forma effect to the merger as if it had been completed on September 30, 2012.

The summary unaudited pro forma condensed combined statements of operations for the nine months ended September 30, 2012 combine the unaudited historical statements of operations of BioSante and ANI for their respective nine-month periods ended September 30, 2012 and gives pro forma effect to the merger as if it had been completed on January 1, 2011. The summary unaudited pro forma condensed combined statements of operations for the year ended December 31, 2011 combine the historical statements of operations of BioSante and ANI for their respective year ended December 31, 2011 and gives pro forma effect to the merger as if it had been completed on January 1, 2011.

The historical financial data has been adjusted to give pro forma effect to events that are (i) directly attributable to the merger, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results. The pro forma adjustments are preliminary and based on management's estimates of the fair value and useful lives of the assets acquired and liabilities assumed and have been prepared to illustrate the estimated effect of the acquisition and certain other adjustments.

Table of Contents

The unaudited pro forma condensed combined financial data is presented for illustrative purposes only and is not necessarily indicative of the financial condition or results of operations of future periods or the financial condition or results of operations that actually would have been realized had the entities been combined during the periods presented. In addition, as explained in more detail in the accompanying notes to the unaudited pro forma condensed combined financial statements (see the section entitled "Unaudited Pro Forma Condensed Combined Financial Statements" beginning on page 239), the preliminary acquisition-date fair value of the identifiable assets acquired and liabilities assumed reflected in the unaudited pro forma condensed combined financial statements is subject to adjustment and may vary from the actual amounts that will be recorded upon completion of the merger.

| | For the Year Ended December 31, 2011 | For the Nine Months Ended September 30, 2012 |
|---|---|---|
| | (in thousands) | |
| **Unaudited Pro Forma Condensed Combined Statements of Operations Data:** | | |
| Revenue | $ 16,950 | $ 15,383 |
| Operating Expenses: | | |
| Cost of sales (excluding depreciation and amortization) | 6,861 | 6,292 |
| Salaries and benefits | 12,586 | 8,318 |
| Freight | 253 | 243 |
| Research and development | 39,123 | 11,738 |
| Selling, general and administrative | 8,318 | 6,327 |
| Licensing expense | 50 | |
| Depreciation and amortization | 3,123 | 2,345 |
| Total operating expenses | 70,314 | 35,263 |
| Net loss | $ (56,479) | $ (25,399) |
| Net loss from continuing operations available to common shareholders | $ (56,685) | $ (25,503) |

| | As of September 30, 2012 |
|---|---|
| | (in thousands) |
| **Unaudited Pro Forma Condensed Combined Balance Sheet Data:** | |
| Cash and cash equivalents | $ 38,197 |
| Total assets | 76,306 |
| Accounts payable | 3,301 |
| Accrued compensation | 4,364 |
| Other accrued expenses | 4,429 |
| Returned goods reserve | 388 |
| Borrowing under line of credit | 3,429 |
| Convertible senior notes | 7,593 |
| Interest on convertible senior notes | 108 |
| Current liabilities of discontinued operations | 378 |
| Accumulated deficit | (47,302) |
| Stockholders' equity | 52,316 |

Table of Contents

## COMPARATIVE HISTORICAL AND UNAUDITED PRO FORMA PER SHARE DATA

The following table sets forth certain historical, unaudited pro forma condensed combined and pro forma condensed combined equivalent financial information and reflects:

*BioSante and ANI Historical Data:* the historical BioSante net loss and book value per share of BioSante common stock and the historical ANI net loss and book value per share of ANI common stock;

*Combined Company Pro Forma Data:* the unaudited pro forma combined company net loss after giving effect to the merger on an acquisition basis as if the merger had been completed on January 1, 2011, and book value per share after giving effect to the merger on an acquisition basis as if the merger had been completed on September 30, 2012; and

*ANI Pro Forma Equivalent Data:* the unaudited pro forma ANI equivalent share data, including net loss per series D preferred share, and book value per series D preferred share, calculated by multiplying the unaudited pro forma combined company data by an assumed exchange ratio of 10.3502 shares of BioSante common stock for each share of series D preferred stock.

The following information does not give effect to the proposed reverse stock split of BioSante common stock described in BioSante Proposal No. 2. You should read the table below in conjunction with the audited and unaudited financial statements of BioSante and ANI beginning on pages F-1 and F-47, respectively, of this joint proxy statement/prospectus, and the related notes thereto. You also are urged to read the section entitled "Unaudited Pro Forma Condensed Combined Financial Statements" beginning on page 239.

| | As of and For the Year Ended December 31, 2011 | As of and For the Nine Months Ended September 30, 2012 |
|---|---|---|
| | (in thousands) | |
| **BioSante Historical Data:** | | |
| Basic and diluted net loss per common share | $ (3.15) | $ (1.14) |
| Book value per share | | |
| **ANI Historical Data:** | | |
| Basic and diluted net loss per common share | $ (693.61) | $ (439.32) |
| Book value per share | | $ |
| **Combined Company Pro Forma Data:** | | |
| Basic and diluted net loss per common share | $ (1.28) | $ (0.52) |
| Book value per share | | $ 1.00 |
| **ANI Pro Forma Equivalent Data*:** | | |
| Basic and diluted net loss per series D preferred share | $ (13.25) | $ (5.38) |
| Book value per series D preferred share | | $ 10.35 |

* In comparison, if the ANI Pro Forma Equivalent Data were calculated by multiplying the unaudited pro forma combined company data by 0.53, which represents the percentage of ownership of the combined company expected to be held by the current ANI stockholders as of immediately following the completion of the merger (without taking into account any shares of BioSante common stock held by ANI stockholders prior to the completion of the merger), as determined pursuant to the exchange ratios, and assuming BioSante's net cash is $18.0 million as of the determination date, the basic and diluted net loss per common share as of and for the year ended December 31, 2011 would have been $(0.68) and the basic and diluted net loss per common share for the nine months ended September 30, 2012 and the book value per share as of September 30, 2012 would have been $(0.28) and $0.53, respectively.

Table of Contents

## MARKET PRICE AND DIVIDEND INFORMATION

### BioSante

The table below sets forth, for the calendar quarters indicated, the high and low daily sales prices per share of BioSante common stock, which trades on The NASDAQ Global Market under the symbol "BPAX", as reported by The NASDAQ Global Market. There is no established public trading market for BioSante class C special stock. BioSante's fiscal year ends on December 31st.

**BioSante Common Stock**

| Fiscal Year Ended December 31, 2011 | High | Low |
|---|---|---|
| First Quarter | $ 15.24 | $ 9.72 |
| Second Quarter | 19.20 | 11.58 |
| Third Quarter | 24.12 | 12.12 |
| Fourth Quarter | 16.56 | 2.28 |

| Fiscal Year Ended December 31, 2012 | High | Low |
|---|---|---|
| First Quarter | $ 7.38 | $ 2.64 |
| Second Quarter | 4.56 | 2.00 |
| Third Quarter | 2.62 | 1.21 |
| Fourth Quarter | 1.97 | 1.08 |

| Fiscal Year Ended December 31, 2013 | High | Low |
|---|---|---|
| First Quarter (through January 15, 2013) | $ 1.48 | $ 1.25 |

As of January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, BioSante had 453 holders of record of BioSante common stock and six record holders of BioSante class C special stock.

BioSante never has declared or paid cash dividends on its capital stock and does not intend to pay any cash dividends in the foreseeable future. Holders of BioSante class C special stock are not eligible to receive dividends. Any future determination to pay cash dividends will be at the discretion of the BioSante board of directors and will depend upon BioSante's financial condition, operating results, capital requirements, deployment of resources and ability to engage in strategic transactions, whether or not the merger is consummated, and such other factors as the BioSante board of directors deems relevant.

On October 3, 2012, the last trading day prior to announcement of the merger, the last reported sale price of BioSante common stock was $1.80, for an aggregate market value of BioSante of $44.0 million. On January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, the last reported sale price of BioSante common stock was $1.36, for an aggregate market value of BioSante of $33.2 million. Assuming the issuance on such date of an aggregate of 27.9 million shares of BioSante common stock based on an exchange ratio of 10.3502 for the ANI series D preferred stock and an exchange ratio of zero for all other shares of ANI capital stock, if the merger was completed on such date, the market value attributable to the ANI common stock in the aggregate, or approximately 53 percent of the outstanding shares of the combined company, would equal $38.0 million.

The following table sets forth information concerning the beneficial ownership of:

each person known by BioSante to beneficially own more than five percent of BioSante's voting capital stock;

Table of Contents

each of BioSante's current directors and each nominee for director, including persons who are expected to become directors of the combined company following completion of the merger; and

all of BioSante's current directors and executive officers as a group, prior to the completion of the merger and immediately following the completion of the merger.

The pre-merger percentage of beneficial ownership is calculated in relation to the 24,422,240 shares of BioSante common stock that were outstanding as of December 31, 2012 and the post-merger percentage of beneficial ownership is calculated in relation to an estimated 52,337,228 shares of common stock of the combined company outstanding upon completion of the merger, assuming that the exchange ratio to be used in connection with the merger is approximately 10.3502 shares of BioSante common stock for each share of ANI series D preferred stock and zero for each share of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock (without giving effect to the proposed reverse stock split described elsewhere in this joint proxy statement/prospectus but giving effect to the anticipated issuance of an estimated 321,737 shares of ANI series D preferred stock to ANI's executive officers and an additional ANI employee in connection with the transaction bonus arrangements as described elsewhere in this joint proxy statement/prospectus). Percentage calculations assume, for each person and group, that all shares that may be acquired by such person or group pursuant to options and warrants currently exercisable or that become exercisable within 60 days of December 31, 2012 are outstanding for the purpose of computing the percentage of capital stock owned by such person or group. However, such unissued shares of capital stock are not deemed to be outstanding for calculating the percentage of capital stock owned by any other person. Except as otherwise indicated and subject to the voting agreements described under the section entitled "Voting and Other Ancillary Agreements," BioSante believes that the beneficial owners of its capital stock listed in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to community property laws where applicable.

| | Pre-Merger | | Post-Merger | |
|---|---|---|---|---|
| **Name of Beneficial Owner** | **BioSante Common Stock and Common Stock Equivalents** | **Percent of Class** | **BioSante Common Stock and Common Stock Equivalents** | **Percent of Class** |
| Louis W. Sullivan, M.D. | 52,147 | * | 52,147 | * |
| Stephen M. Simes | 275,652 | 1.1% | 275,652 | * |
| Fred Holubow | 34,372 | * | 34,372 | * |
| Ross Mangano | 418,397 | 1.7% | 418,397 | * |
| Edward C. Rosenow, III, M.D. | 27,586 | * | 27,586 | * |
| John T. Potts, Jr., M.D. | 8,636 | * | 8,636 | * |
| Stephen A. Sherwin, M.D. | 41,890 | * | 41,890 | * |
| Robert E. Brown, Jr. | 0 | * | 14,248,043 | 27.2% |
| Arthur S. Przybyl | 0 | * | 0 | * |
| Tracy L. Marshbanks, Ph.D. | 0 | * | 4,085,016 | 7.8% |
| Thomas T. Penn | 0 | * | 14,248,043 | 27.2% |
| Robert Schrepfer | 0 | * | 0 | * |
| All current BioSante directors and executive officers as a group (nine persons) | 1,042,589 | 4.2% | 18,785,828 | 35.8% |

*

Represents beneficial ownership of less than one percent.

For detailed information regarding the beneficial ownership of certain stockholders of BioSante, ANI and the combined company upon completion of the merger, see the sections entitled "Principal Stockholders of BioSante," Principal Stockholders of ANI" and "Principal Stockholders of Combined Company" in this joint proxy statement/prospectus.

Table of Contents

Because the market price of BioSante common stock is subject to fluctuation, the market value of the shares of BioSante common stock that holders of ANI capital stock will receive in the merger may increase or decrease. The foregoing information reflects only historical information. This information may not provide meaningful information to ANI stockholders in determining whether to approve ANI Proposal No. 1. ANI stockholders are urged to obtain current market quotations for BioSante common stock and to review carefully the other information contained in this joint proxy statement/prospectus or referenced in this joint proxy statement/prospectus. Historical stock prices are not indicative of future stock prices.

Following completion of the merger and assuming the successful reapplication to The NASDAQ Global Market for initial inclusion of BioSante common stock on the NASDAQ Global Market, the BioSante common stock of BioSante, including the shares of BioSante common stock issued to ANI stockholders in connection with the merger, will continue to be listed on The NASDAQ Global Market.

**ANI**

As of January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, ANI had 11 holders of record of ANI series D preferred stock, 12 holders of record of ANI series C preferred stock, 12 holders of record of ANI series B preferred stock, five holders of record of ANI series A preferred stock and 10 holders of record of ANI common stock.

Other than a one-time dividend on the ANI series A preferred stock declared and paid in additional shares of ANI series A preferred stock in 2006, ANI has never paid a dividend on its capital stock. Any determination to pay dividends to holders of ANI capital stock in the future will be at the discretion of the ANI board of directors and will depend on many factors, including ANI's financial condition, results of operations, general business conditions, and any other factors the ANI board of directors deems relevant.

ANI is a private company and shares of its capital stock are not publicly traded.

Table of Contents

## RISK FACTORS

*In addition to the other information included in this joint proxy statement/prospectus, BioSante and ANI stockholders should consider carefully the following risk factors before deciding whether to vote in favor of the adoption of the merger agreement and the approval of the transactions contemplated thereby, including the merger. If any of the risks described below actually occurs, the respective businesses, operating results, financial condition or stock prices of BioSante, ANI or the combined company could be materially adversely affected.*

### Risks Related to the Merger

***The issuance of shares of BioSante common stock to ANI stockholders in connection with the merger will dilute substantially the voting power of current BioSante stockholders.***

Pursuant to the terms of the merger agreement, it is anticipated that BioSante will issue shares of BioSante common stock to ANI stockholders representing approximately 53 percent of the outstanding shares of common stock of the combined company as of immediately following completion of the merger, assuming BioSante's net cash is $18.0 million as of the determination date. After such issuance, the shares of BioSante common stock outstanding immediately prior to completion of the merger will represent approximately 47 percent of the outstanding shares of common stock of the combined company as of immediately following completion of the merger. These ownership percentages may change depending upon the amount of BioSante's net cash as of a determination date prior to completion of the merger. Accordingly, the issuance of shares of BioSante common stock to ANI stockholders in connection with the merger will reduce significantly the relative voting power of each share of BioSante common stock held by current BioSante stockholders. Consequently, the BioSante stockholders as a group will have significantly less influence over the management and policies of the combined company after the merger than prior to the merger.

***The exchange ratios in the merger agreement are dependent upon not only the terms of the merger agreement, but also the terms of ANI's certificate of incorporation, which contains provisions that give preference to holders of shares of ANI series D preferred stock and, to a lesser extent, holder of shares of other series of ANI preferred stock. As a result of such provisions, it is likely that holders of shares of other series of ANI preferred stock or ANI common stock will not receive any shares of BioSante common stock in connection with the merger.***

Subject to the terms and conditions of the merger agreement, at the effective time of and as a result of the merger, each share of ANI capital stock issued and outstanding immediately prior to the effective time of the merger will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. Pursuant to the terms of ANI's certificate of incorporation, before any amounts are paid to the holders of shares of any other series of ANI preferred stock or ANI common stock, the holders of shares of ANI series D preferred stock are entitled to receive an amount per share equal to $30.00 (subject to adjustment as provided in ANI's certificate of incorporation) plus all declared but unpaid dividends. The exchange ratios in the merger agreement reflect these preferential payments. As a result of such provisions, it is likely that holders of shares of other series of ANI preferred stock or ANI common stock will not receive any shares of BioSante common stock in connection with the merger.

Table of Contents

***The exchange ratios in the merger agreement are subject to adjustment based on BioSante's net cash as of a determination date prior to completion of the merger, which could dilute further the ownership of either the BioSante or ANI stockholders in the combined company.***

Subject to the terms and conditions of the merger agreement, at the effective time of and as a result of the merger, each share of ANI capital stock issued and outstanding immediately prior to the effective time of the merger will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger. If BioSante has more than $18.0 million of net cash as of the determination date, then the percentage ownership of the current BioSante stockholders will be increased on a pro rata basis by 0.6 percent for each $1.0 million of net cash excess, which would dilute further the ownership of the current ANI stockholders in the combined company. If BioSante has less than $18.0 million of net cash as of the determination date, then the percentage ownership of current BioSante stockholders will be decreased on a pro rata basis by 0.6 percent for each $1.0 million of net cash shortfall, which would dilute further the ownership of the current BioSante stockholders in the combined company. In no event, however, will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. In addition, one of the conditions to ANI's obligations to complete the merger is BioSante's net cash as of the closing date being no less than $17.0 million as calculated and as adjusted pursuant to the provisions of the merger agreement.

The items that will constitute BioSante's net cash at the determination date set forth in the merger agreement are subject to a number of factors, some of which are outside the control of BioSante and many of which are outside the control of ANI. For a more detailed discussion of the calculation of BioSante's net cash at the determination date set forth in the merger agreement and to view a table that illustrates how changes in BioSante's net cash at the determination date will affect the exchange ratios, see "The Merger Agreement  Merger Consideration and Adjustment" and "The Merger Agreement  Determination of BioSante's Net Cash" beginning on page 156 and page 158, respectively.

***The exchange ratios are not adjustable based on the market price of BioSante common stock and if the market price of BioSante common stock fluctuates, the market value of the shares of BioSante common stock to be received by the ANI stockholders in connection with the merger is subject to change prior to completion of the merger.***

The aggregate number of shares of BioSante common stock to be issued to ANI stockholders is expected to represent approximately 53 percent of the outstanding shares of common stock of the combined company as of immediately following completion of the merger, assuming BioSante's net cash is $18.0 million as of the determination date. The exchange ratios, as such ratios are calculated pursuant to the formulas set forth in the merger agreement, are based on the number of shares of BioSante common stock and ANI capital stock outstanding as of immediately prior to completion of the merger, and in the case of BioSante, a certain percentage of the number of certain warrants to purchase shares of BioSante common stock outstanding as of such date, and will not be determined until that time. The exchange ratios will be adjusted upward or downward only as a result of changes to the outstanding capital stock of either or both of BioSante and ANI as of immediately prior to completion of the merger and changes to BioSante's net cash as of a determination date prior to completion of the merger. No adjustments to the exchange ratios will be made based on changes in the trading price of BioSante common stock or the value of ANI capital stock prior to completion of the merger. Changes in the trading price of BioSante common stock or the value of ANI capital stock may

Table of Contents

result from a variety of factors, including, among others, general market and economic conditions, changes in BioSante's or ANI's respective businesses, operations and prospects, market assessment of the likelihood that the merger will be completed as anticipated or at all, and regulatory considerations. Many of these factors are beyond BioSante's or ANI's control. As a result, the value of the shares of BioSante common stock issued to ANI stockholders in connection with the merger could be substantially less or substantially more than the current market value of BioSante common stock.

***The exchange ratios are not adjustable based on issuances by BioSante of additional shares of BioSante common stock either upon the exercise of options or warrants or the conversion of convertible securities or otherwise, which issuances would result in additional dilution to the BioSante stockholders.***

As of December 31, 2012, BioSante had outstanding options to purchase an aggregate of approximately 1.1 million shares of BioSante common stock, warrants to purchase an aggregate of approximately 4.7 million shares of BioSante common stock, an aggregate of 65,211 shares of BioSante class C special stock that are convertible into 65,211 shares of BioSante common stock and an aggregate of $8.3 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 that are convertible into an aggregate of 370,871 shares of BioSante common stock. BioSante is not prohibited under the terms of the merger agreement from issuing additional equity securities under certain circumstances, including securities issued pursuant to the exercise of outstanding options or warrants or the conversion or exchange of outstanding convertible senior notes. It is possible that prior to completion of the merger BioSante may issue additional equity securities. The exchange ratios in the merger agreement, which are designed to result in the issuance by BioSante of shares of BioSante common stock to ANI stockholders representing approximately 53 percent of the outstanding shares of common stock of the combined company as of immediately following completion of the merger, assuming BioSante's net cash is $18.0 million as of the determination date, are not adjustable based on issuances by BioSante of additional shares of BioSante common stock. Therefore, any such issuances by BioSante would result in additional dilution to the BioSante stockholders.

***The announcement and pendency of the merger could have an adverse effect on the trading price of BioSante common stock and/or the business, financial condition, results of operations or business prospects for BioSante and/or ANI.***

While there have been no significant adverse effects to date, the announcement and pendency of the merger could disrupt BioSante's and/or ANI's businesses in the following ways, among others:

- third parties may seek to terminate and/or renegotiate their relationships with BioSante or ANI as a result of the merger, whether pursuant to the terms of their existing agreements with BioSante and/or ANI or otherwise; and

- the attention of BioSante and/or ANI management may be directed toward completion of the merger and related matters and may be diverted from the day-to-day business operations of their respective companies, including from other opportunities that otherwise might be beneficial to BioSante or ANI.

Should they occur, any of these matters could adversely affect the trading price of BioSante common stock or harm the financial condition, results of operations or business prospects of BioSante, ANI and/or the combined company.

Table of Contents

***Failure to complete the merger could negatively impact BioSante's and ANI's respective businesses, financial condition or results of operations or the trading price of BioSante common stock.***

The completion of the merger is subject to a number of conditions and there can be no assurance that the conditions to the completion of the merger will be satisfied. If the merger is not completed, BioSante and/or ANI, as applicable, will be subject to several risks, including:

- the current trading price of BioSante common stock may reflect a market assumption that the merger will occur, meaning that a failure to complete the merger could result in a decline in the trading price of BioSante common stock;
- certain executive officers and/or directors of BioSante may seek other employment opportunities, and the departure of any of BioSante's executive officers and the possibility that the company would be unable to recruit and hire an executive could impact negatively BioSante's business and operating results;
- the BioSante board of directors will need to reevaluate BioSante's strategic alternatives, which alternatives may include a sale of the company, liquidation of the company or other strategic transaction;
- BioSante may be required to reimburse ANI for expenses of up to $500,000 or pay a termination fee of $1.0 million to ANI if the merger agreement is terminated by ANI or BioSante under certain circumstances;
- ANI may be required to pay BioSante a termination fee of $750,000 if the merger agreement is terminated by BioSante under certain circumstances;
- BioSante and ANI are expected to incur substantial transaction costs in connection with the merger whether or not the merger is completed;
- neither BioSante nor ANI would realize any of the anticipated benefits of having completed the merger; and
- under the merger agreement, each of BioSante and ANI is subject to certain restrictions on the conduct of its business prior to completion of the merger, which restrictions could adversely affect their ability to realize certain of their respective business strategies or take advantage of certain business opportunities.

If the merger is not completed, these risks may materialize and affect materially and adversely either or both companies' respective businesses, financial condition, results of operations, or, in the case of BioSante, the trading price of BioSante common stock.

***BioSante and ANI have incurred and will continue to incur significant transaction costs in connection with the merger, some of which will be required to be paid even if the merger is not completed.***

BioSante and ANI have incurred and will continue to incur significant transaction costs in connection with the merger. These costs are primarily associated with the fees of their respective attorneys and accountants and BioSante's financial advisor. Most of these costs will be paid by the party incurring the costs even if the merger is not completed. In addition, if the merger agreement is terminated due to certain triggering events specified in the merger agreement, BioSante may be required to pay ANI a termination fee of $1.0 million or ANI may be required to pay BioSante a termination fee of $750,000. The merger agreement also provides that under specified circumstances, BioSante may be required to reimburse ANI up to $500,000 for its expenses in connection with the transaction. If the merger is completed, the combined company will bear the transaction costs of both BioSante and ANI in connection with the merger, including financial advisor, legal and accounting fees and expenses.

Table of Contents

***Because the merger will be completed after the date of the BioSante and ANI special meetings of stockholders, it is possible that at the time of your special meeting, you will not know the exact number of shares of BioSante common stock that the ANI stockholders will receive upon completion of the merger.***

Subject to the terms of the merger agreement, at the effective time of the merger, each share of ANI capital stock issued and outstanding immediately prior to the merger will be canceled, extinguished and automatically converted into the right to receive that number of shares of BioSante common stock as determined pursuant to the exchange ratios described in the merger agreement. The exchange ratios depend on the net cash of BioSante as of a determination date prior to completion of the merger. The determination date is defined as the date that is 14 days prior to the date of the BioSante special meeting as set forth in this joint proxy statement/prospectus, subject to extension for adjournment of the BioSante special meeting and subject to a dispute resolution provisions in the event there is a dispute between BioSante and ANI as to the amount of net cash of BioSante as of the determination date. Under the merger agreement, BioSante's "net cash" is defined as generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger. In the event of a dispute regarding the amount of net cash of BioSante as of the determination date, it is possible that the exact number of shares of BioSante common stock that the ANI stockholders will receive upon completion of the merger may not be available at the time of the BioSante special meeting or the ANI special meeting.

***Some of the directors and executive officers of BioSante and ANI have interests in the merger that are different from, or in addition to, those of the other BioSante and ANI stockholders.***

When considering the recommendation by the BioSante board of directors that the BioSante stockholders vote "for" each of the proposals being submitted to the BioSante stockholders at the BioSante special meeting and the recommendation by the ANI board of directors that the ANI stockholders vote "for" each of the proposals being submitted to the ANI stockholders at the ANI special meeting, the BioSante and ANI stockholders should be aware that certain of the directors and executive officers of BioSante and ANI have arrangements that provide them with interests in the merger that are different from, or in addition to, those of the stockholders of BioSante and ANI.

For instance, in connection with the merger, Fred Holubow and Ross Mangano, each a current member of the BioSante board of directors, will continue to serve as a director of the combined company following completion of the merger and will receive cash and equity compensation in consideration for such service. The employment of each of BioSante's three executive officers will terminate immediately following completion of the merger and they will be entitled to receive severance benefits ranging from approximately $571,400 to $1,578,000 in connection with such termination.

All of the current directors of ANI will serve as directors of the combined company following completion of the merger and will receive certain cash and equity compensation in consideration for such service. Likewise, all of the executive officers of ANI will continue to serve as executive officers of the combined company following completion of the merger and will receive cash and equity compensation in consideration for such service. In addition, the executive officers of ANI will receive special transaction bonus payments upon closing of the merger ranging, for each officer, from approximately $707,705 to $3,309,410 (assuming BioSante's net cash as of the determination date is $18.0 million) payable in shares of ANI series D preferred stock, which shares will convert into shares of BioSante common stock in the merger, as described in more detail under "Management of the Combined Company Following the Merger  Certain Relationships and Related Transactions." In addition, certain of ANI's executive officers and directors are expected to own a significant number of shares of common stock of the combined company following completion of the merger. See "Principal Stockholders of Combined Company."

Table of Contents

The directors and executive officers of BioSante and ANI also have certain rights to indemnification and to directors' and officers' liability insurance that will be provided by the combined company following completion of the merger. See the sections entitled "The Merger Interests of BioSante's Directors and Executive Officers in the Merger" and "The Merger Interests of ANI's Directors and Officers in the Merger" beginning on pages 143 and 148, respectively.

The board of directors of each of BioSante and ANI were aware of these potential interests and considered them in making their respective recommendations to approve the proposals being submitted to the BioSante stockholders at the BioSante special meeting, with respect to the BioSante stockholders, and to approve the proposals being submitted to the ANI stockholders at the ANI special meeting, with respect to the ANI stockholders.

***The merger agreement and the voting agreements contain provisions that could discourage or make it difficult for a third party to acquire BioSante or ANI prior to completion of the merger.***

The merger agreement contains provisions that make it difficult for BioSante or ANI to entertain a third-party proposal for an acquisition of BioSante or ANI. These provisions include:

- the general prohibition on BioSante's and ANI's soliciting or engaging in discussions or negotiations regarding any alternative acquisition proposal;
- the requirement that BioSante reimburse ANI for expenses of up to $500,000 or pay a termination fee of $1.0 million to ANI if the merger agreement is terminated by ANI or BioSante under certain circumstances;
- the requirement that ANI pay BioSante a termination fee of $750,000 if the merger agreement is terminated by BioSante under certain circumstances; and
- the requirement that BioSante and ANI submit the proposals described in this joint proxy statement/prospectus, as applicable, to a vote of their respective stockholders even if their respective board of directors changes its recommendation with respect to such proposals, as applicable.

See the sections entitled "The Merger Agreement No Solicitation", "The Merger Agreement Meetings of Stockholders; Change in Board Recommendation" and "The Merger Agreement Termination Fees and Expenses" beginning on pages 160, 162 and 165, respectively.

Pursuant to the voting agreements entered into between (i) BioSante and certain stockholders of ANI and (ii) ANI and the directors, executive officers and certain stockholders of BioSante, each such director, executive officer and applicable stockholder has agreed not to take any actions that BioSante or ANI, as applicable, is prohibited from taking pursuant to the no-solicitation restrictions contained in the merger agreement. In addition, holders of shares representing approximately 85 percent of the shares of the outstanding ANI capital stock, calculated on an as-converted basis, and approximately 86 percent of the outstanding shares of the ANI series D preferred stock, as of October 3, 2012 are subject to a voting agreement, pursuant to which the holders of such shares have agreed to vote in favor of the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger, and ANI is required under the terms of the merger agreement to convene and hold the ANI special meeting regardless of any change in the recommendation of the ANI board of directors. Likewise, holders of shares representing approximately two percent of the outstanding capital stock of BioSante as of October 3, 2012 are subject to a voting agreement, pursuant to which the holders of such shares have agreed to vote in favor of the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of the shares of BioSante common stock, and the approval of the BioSante charter amendments, and BioSante is required under the terms of the merger agreement to convene and hold the BioSante

Table of Contents

special meeting regardless of any change in the recommendation of the BioSante board of directors. See the section entitled "Voting and Other Ancillary Agreements" beginning on page 168.

These provisions might discourage an otherwise interested third party from considering or proposing an acquisition of BioSante or ANI, even one that may be deemed of greater value than the merger to BioSante stockholders or ANI stockholders, as applicable. Furthermore, even if a third party elects to propose an acquisition, the concept of a termination fee or payment of the other party's expenses may result in that third party offering a lower value to BioSante stockholders or ANI stockholders, as applicable, than such third party might otherwise have offered.

***Because the lack of a public market for shares of ANI capital stock makes it difficult to evaluate the fairness of the merger, ANI stockholders may receive consideration in the merger that is greater than or less than the fair value of the shares of capital stock of ANI.***

ANI is privately held and its outstanding capital stock is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair value of ANI or its shares of capital stock. Since the percentage of BioSante's equity to be issued to the ANI stockholders was determined based on negotiations between the parties, it is possible that the value of the BioSante common stock to be issued in connection with the merger will be greater than the fair value of ANI. Alternatively, it is possible that the value of the shares of BioSante common stock to be issued in connection with the merger will be less than the fair value of ANI.

***The vote to approve the merger with BioSante is effectively controlled by the holders of ANI series D preferred stock.***

In order to approve the merger agreement and transactions contemplated under the merger agreement, ANI requires the vote of (i) the majority of the outstanding shares of ANI capital stock entitled to vote, calculated on an as-converted basis and voting as a single class, and (ii) 65 percent of the outstanding shares of ANI series D preferred stock entitled to vote. On an as-converted basis, the number of ANI series D preferred stock represents 90.8 percent of the total number of shares of ANI capital stock outstanding and entitled to vote. As a result, assuming that holders of more than 65% of the ANI series D preferred stock all vote such stock for (or against) the merger, both votes described in (i) and (ii) above would be decided, and holders of ANI common stock, or series A, B or C preferred stock, would be unable to affect the outcome of the vote.

***If the merger does not qualify as a reorganization under Section 368(a) of the Code, ANI and the ANI stockholders may be required to pay substantial U.S. federal income taxes as a result of the merger.***

BioSante and ANI intend, and will be relying on the opinion of their respective tax counsel, that the merger will qualify as a "reorganization" under Section 368(a) of the Code. BioSante and ANI currently anticipate that neither ANI nor, generally, the U.S. holders of shares of ANI capital stock will recognize taxable gain or loss as a result of the merger. However, neither BioSante nor ANI has requested, or intends to request, a ruling from the Internal Revenue Service (IRS) with respect to the tax consequences of the merger, and there can be no assurance that the companies' position or the opinion of either company's respective tax counsel would be sustained if challenged by the IRS. Accordingly, if there is a final determination that the merger does not qualify as a "reorganization" under Section 368(a) of the Code and is taxable for U.S. federal income tax purposes (i) ANI would recognize taxable gain on its deemed receipt of BioSante common stock in exchange for the sale of substantially all of ANI's assets and assumption of ANI liabilities to the extent the fair market value of the BioSante common stock deemed received plus the ANI liabilities assumed by BioSante in the merger exceed ANI's adjusted tax basis in its assets deemed sold to BioSante, with such gain offset by available net operating losses and other tax attributes of ANI, if any, and (ii) ANI stockholders generally would recognize taxable gain or loss on their receipt of BioSante common stock in connection

Table of Contents

with the merger in an amount equal to the difference between such stockholder's adjusted tax basis in their shares of ANI capital stock and the fair market value of the BioSante common stock and cash received in lieu of fractional shares, if any. Any unpaid ANI tax liability incurred if the merger does not qualify as a reorganization would be assumed by BioSante in the merger. For a more complete discussion of the material U.S. federal income tax consequences of the merger, see the section entitled "Material U.S. Federal Income Tax Consequences of the Merger" beginning on page 172.

***The shares of BioSante common stock to be received by ANI stockholders as a result of the merger will have different rights from shares of ANI preferred stock or ANI common stock.***

Following completion of the merger, ANI stockholders will no longer be stockholders of ANI, but will be stockholders of BioSante. There will be important differences between your current rights as an ANI stockholder and the rights to which you will be entitled as a BioSante stockholder. See "Comparison of Rights of Holders of BioSante Stock and ANI Stock" beginning on page 286 for a discussion of the different rights associated with BioSante common stock and ANI preferred stock and ANI common stock.

***BioSante may not issue CVRs to holders of BioSante common stock prior to the merger and, even if issued, the CVRs will not be certificated or transferable and may not result in any cash payments to holders of CVRs.***

Although BioSante currently plans to enter into the contingent value rights agreement and issue CVRs to holders of BioSante common stock, there is no assurance that the CVRs will be issued at all or based on the terms currently set forth in the form of the contingent value rights agreement. See "Contingent Value Rights" for more information on the terms of the CVRs and the contingent value rights agreement. BioSante currently has not entered into the contingent value rights agreement and the BioSante board of directors may determine in its sole discretion not to issue the CVRs based on, among other things, the anticipated tax impact of the distribution and issuance of the CVRs to the holders of BioSante common stock. Furthermore, if BioSante and ANI agree, the terms of the contingent value rights agreement as currently contemplated may be changed prior to BioSante entering into the contingent value rights agreement.

Even if CVRs are issued, they will not be certificated or transferable and may not result in any cash payments to holders of CVRs. Under the contingent value rights agreement, the combined company will not have any obligation, other than an obligation to act in good faith to pursue, engage in, negotiate, enter into or consummate an actual or potential LibiGel transaction (as such term is defined in the contingent value rights agreement).

***BioSante and ANI may waive one or more of the conditions to the merger without resoliciting stockholder approval for the merger.***

Certain conditions to BioSante's and ANI's obligations to complete the merger may be waived, in whole or in part, to the extent legally allowed, either unilaterally or by agreement of BioSante and ANI. In the event of a waiver of a condition, the boards of directors of BioSante and ANI will evaluate the materiality of any such waiver to determine whether amendment of this joint proxy statement/prospectus and resolicitation of proxies is necessary. In the event that the board of directors of BioSante or ANI determines any such waiver is not significant enough to require resolicitation of stockholders, it will have the discretion to complete the merger without seeking further stockholder approval. The conditions requiring the approval of each company's stockholders cannot, however, be waived.

Table of Contents

**Risks Related to the Combined Company if the Merger is Completed**

***If any of the events described in "Risks Related to BioSante" or "Risks Related to ANI" occur, those events could cause the potential benefits of the merger not to be realized.***

Following completion of the merger, the combined company will be susceptible to many of the risks described in the sections herein entitled "Risks Related to BioSante," "Risks Related to ANI" and "Risks Related to the Combined Company." To the extent any of the events in the risks described in those sections occur, those events could cause the potential benefits of the merger not to be realized and the market price of the combined company's common stock to decline.

***The success of the merger will depend, in large part, on the ability of the combined company following completion of the merger to realize the anticipated benefits from combining the businesses of BioSante and ANI.***

The merger involves the integration of two companies that previously have operated independently with principal offices in two distinct locations. Due to legal restrictions, BioSante and ANI are able to conduct only limited planning regarding the integration of the two companies prior to completion of the merger. Significant management attention and resources will be required to integrate the two companies after completion of the merger. The failure to integrate successfully and to manage successfully the challenges presented by the integration process may result in the combined company's failure to achieve some or all of the anticipated benefits of the merger.

Potential difficulties that may be encountered in the integration process include the following:

- using the combined company's cash and other assets efficiently to develop the business of the combined company;
- appropriately managing the liabilities of the combined company;
- potential unknown or currently unquantifiable liabilities associated with the merger and the operations of the combined company;
- potential unknown and unforeseen expenses, delays or regulatory conditions associated with the merger; and
- performance shortfalls at one or both of the companies as a result of the diversion of management's attention caused by completing the merger and integrating the companies' operations.

Delays in the integration process could adversely affect the combined company's business, financial results, financial condition and stock price following the merger. Even if the combined company were able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time.

***The merger will result in changes to the BioSante board of directors and the combined company may pursue different strategies than either BioSante or ANI may have pursued independently.***

If BioSante and ANI complete the merger, the composition of the BioSante board of directors will change in accordance with the merger agreement. Following completion of the merger, the combined company's board of directors will consist of seven members, including two of the current directors of BioSante and five of the current directors of ANI. Currently, it is anticipated that the combined company will continue to advance the product development efforts and business strategies of ANI primarily. However, because the composition of the board of directors of the combined company will

Table of Contents

consist of directors from both BioSante and ANI, the combined company may determine to pursue certain business strategies that neither ANI nor BioSante would have pursued independently.

***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.***

Upon completion of the merger, ANI's directors and executive officers continuing with the combined company, together with their respective affiliates, are expected to beneficially own or control approximately 41 percent of the combined company (see the sections entitled "Principal Stockholders of ANI" beginning on page 276 and "Principal Stockholders of Combined Company" beginning on page 280 for more information on the estimated ownership of the combined company following the merger). Accordingly, these directors, executive officers 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 also may exert influence in delaying or preventing a change in control of the combined company, even if such change in control would benefit the other stockholders of the combined company. In addition, the significant concentration of stock ownership may affect adversely the market value of the combined company's common stock due to investors' perception that conflicts of interest may exist or arise.

***Future results of the combined company may differ materially from the unaudited pro forma financial statements presented in this joint proxy statement/prospectus and the financial forecasts prepared by ANI in connection with discussions concerning the merger.***

The future results of the combined company may be materially different from those shown in the unaudited pro forma condensed combined financial statements presented in this joint proxy statement/prospectus, which show only a combination of the historical results of BioSante and ANI, and the financial forecasts prepared by ANI in connection with discussions concerning the merger. BioSante and ANI expect to incur significant costs associated with completion of the merger and combining the operations of the two companies. The exact magnitude of these costs is not yet known, but is estimated to be approximately $3.1 million. Furthermore, these costs may decrease the capital that the combined company could use for continued development of the combined company's business in the future or may cause the combined company to seek to raise new capital sooner than expected.

***The combined company's ability to utilize BioSante's or ANI's net operating loss and tax credit carryforwards in the future is subject to substantial limitations and may be further limited as a result of the merger.***

Under Section 382 of the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percent change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Further, if the historic business of BioSante is not treated as being continued by the combined entity for the two-year period beginning on the date of the merger (referred to as the "continuity of business requirement"), the pre-transaction net operating loss carryforward deductions become substantially reduced or unavailable for use by the surviving corporation in the transaction. In 2009, an "ownership change" occurred with respect to BioSante, and it is expected that the merger with ANI will result in another "ownership change" of BioSante. Accordingly, the combined company's ability to utilize BioSante's net operating loss and tax credit carryforwards may be substantially limited. These limitations, in turn, could result in increased

Table of Contents

future tax payments for the combined company, which could have a material adverse effect on the business, financial condition or results of operations of the combined company.

Under Section 384 of the Code, available net operating loss carryovers of BioSante or ANI may not be available to offset certain gains arising after the merger from assets held by the other corporation at the effective time of the merger. This limitation will apply to the extent that the gain is attributable to an unrealized built-in-gain in the assets of BioSante or ANI existing at the effective time of the merger. To the extent that any such gains are recognized in the five year period after the merger upon the disposition of any such assets, the net operating loss carryovers of the other corporation will not be available to offset such gains (but the net operating loss carryovers of the corporation that owned such assets will not be limited by Section 384 although they may be subject to other limitations under Section 382 as described above).

***The price of BioSante common stock after the merger is completed may be affected by factors different from those currently affecting the price of BioSante common stock.***

Upon completion of the merger, holders of ANI capital stock who receive shares of BioSante common stock in connection with the merger will become holders of BioSante common stock. The business of BioSante differs significantly from the business of ANI; and, accordingly, the results of operations of the combined company and the trading price of BioSante common stock following completion of the merger may be affected significantly by factors different from those currently affecting the independent results of operations of BioSante. For a discussion of the businesses of BioSante and ANI and of certain factors to consider in connection with those businesses, see the sections entitled "BioSante's Business," "BioSante's Management's Discussion and Analysis of Financial Condition and Results of Operations," "ANI's Business," "ANI's Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited and unaudited historical financial statements of BioSante and ANI, including the notes thereto, which are included elsewhere in this joint proxy statement/prospectus, and the other information contained in this joint proxy statement/prospectus.

***The NASDAQ Global Market considers the anticipated merger of BioSante and ANI to be a business combination with a non-NASDAQ entity, resulting in a change in control of BioSante; and therefore, has required that BioSante submit a new initial listing application, which requires certain actions on the part of the combined company 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.***

The NASDAQ Global Market considers the merger proposed in this joint proxy statement/prospectus to be a business combination with a non-NASDAQ entity, resulting in a change in control of BioSante and has required that BioSante submit a new initial listing application. The NASDAQ Global Market may not approve BioSante's new initial listing application for The NASDAQ Global Market on a timely basis, or at all. If this occurs and the merger is still completed, you may have difficulty converting your investments into cash effectively.

Additionally, as part of the new initial listing application, BioSante will be required to submit, among other things, a plan for the combined company to effect a reverse stock split. A reverse stock split likely would increase the per share trading price by an as 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

***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 ANI did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act 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. Certain members of ANI's management, which will continue as the management of the combined company, do not have significant 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 ANI 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 control for financial reporting and disclosure controls and procedures. In particular, the combined company must perform system and process evaluation and testing of its internal control over financial reporting to allow management and the combined company's independent registered public accounting firm to report on the effectiveness of its internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The combined company's compliance with these requirements will require that it incur substantial accounting and related expenses 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 of the Sarbanes-Oxley Act. The costs of hiring such staff may be material and there can be no assurance that such staff will be immediately available to the combined company. Moreover, if the combined company is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if the combined company or its independent registered public accounting firm identifies deficiencies in its internal control over financial reporting that are deemed to be material weaknesses, investors could lose confidence in the accuracy and completeness of the combined company's financial reports, the market price of the combined company's common 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.

***After completion of the merger, the combined company will possess not only all of the assets but also all of the liabilities of both BioSante and ANI. Discovery of previously undisclosed or unknown liabilities could have an adverse effect on the combined company's business, operating results and financial condition.***

Acquisitions involve risks, including inaccurate assessment of undisclosed, contingent or other liabilities or problems. After completion of the merger, the combined company will possess not only all of the assets, but also all of the liabilities of both BioSante and ANI. Although BioSante conducted a due diligence investigation of ANI and its known and potential liabilities and obligations, and ANI conducted a due diligence investigation of BioSante and its known and potential liabilities and obligations, it is possible that undisclosed, contingent or other liabilities or problems may arise after completion of the merger, which could have an adverse effect on the combined company's business, operating results and financial condition.

***BioSante and ANI do not expect the combined company to pay cash dividends.***

BioSante and ANI anticipate that the combined company will retain its earnings, if any, for future growth and therefore not pay any cash dividends in the foreseeable future. Investors seeking cash dividends should not invest in the combined company's common stock for that purpose.

Table of Contents

***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 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.

***The sale or availability for sale of a substantial number of shares of common stock of the combined company after the merger and after expiration of the lock-up period could adversely affect the market price of such shares after the merger.***

Sales of a substantial number of shares of common stock of the combined company in the public market after the merger or after expiration of the lock-up period, or the perception that these sales could occur, could adversely affect the market price of such shares and could materially impair the combined company's ability to raise capital through equity offerings in the future. BioSante and ANI are unable to predict what effect, if any, market sales of securities held by significant stockholders, directors or officers of the combined company or the availability of these securities for future sale will have on the market price of the combined company's common stock after the merger.

**Risks Related to BioSante**

***Risks Related to BioSante's Financial Condition and Future Capital Requirements***

***BioSante has not generated significant revenues and does not expect to in the near future. BioSante has a history of operating losses, expects continuing losses and may never become profitable.***

Substantially all of BioSante's revenue to date has been derived from upfront and milestone payments earned on licensing transactions, revenue earned from subcontracts and royalty revenue. In order to generate new and significant revenues, BioSante must develop and commercialize successfully its own products or enter into strategic partnering agreements with others who can develop and commercialize them successfully, or acquire additional new products that generate or have the potential to generate revenues. Because of the numerous risks and uncertainties associated with BioSante's and its strategic partners' product development programs and BioSante's ability to acquire additional new products, BioSante is unable to predict when it will be able to generate significant revenue or become profitable, if at all. BioSante incurred a net loss of $51.6 million for the year ended December 31, 2011 and a net loss of $23.7 million for the nine months ended September 30, 2012. As of September 30, 2012, BioSante's accumulated deficit was $241.0 million. BioSante expects to continue to incur substantial and continuing losses for the foreseeable future. These losses will increase if BioSante decides to pursue the two new LibiGel Phase III efficacy trials or in-license additional new products that require further development. Even if BioSante's approved products, products in development or any additional new products BioSante may acquire or in-license are introduced commercially, BioSante may never achieve market acceptance and it may never generate sufficient revenues or receive sufficient license fees or royalties on its licensed products and technologies in order to achieve or sustain future profitability.

Table of Contents

***Because BioSante has no source of significant recurring revenue, BioSante must depend on financing or partnering to sustain its operations. BioSante likely will need to raise substantial additional capital or enter into strategic partnering agreements to fund its operations and BioSante may be unable to raise such funds or enter into strategic partnering agreements when needed and on acceptable terms.***

Developing products requires substantial amounts of capital. BioSante estimates that the cost of the two new LibiGel Phase III efficacy trials will be approximately $15 to $18 million each, or a combined $30 to $36 million spread over 18 months. No assurance can be provided, however, that BioSante's cost estimates will be correct. It is possible that the two new LibiGel Phase III efficacy trials will cost more than BioSante anticipates. If BioSante decides to pursue the two new LibiGel Phase III efficacy trials or in-license additional new products that require further development, BioSante will need to raise substantial additional capital or enter into strategic partnering agreements to fund its operations and it may be unable to raise such funds or enter into strategic partnering agreements when needed and on acceptable terms.

BioSante's future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of its clinical development programs, including the two new LibiGel Phase III efficacy trials if BioSante decides to pursue them and if BioSante in-licenses additional new products that require further development;
- the cost, timing and outcome of regulatory actions with respect to BioSante's products;
- the success, progress, timing and costs of BioSante's business development efforts to implement business collaborations, licenses and other business combinations or transactions, and its efforts to evaluate various strategic alternatives available with respect to its products and its company.
- BioSante's ability to obtain value from its current products and technologies and its ability to out-license its products and technologies to third parties for development and commercialization and the terms of such out-licenses;
- BioSante's ability to acquire or in-license additional new products and technologies and the costs and expenses of such acquisitions or licenses;
- the timing and amount of any royalties, milestone or other payments BioSante may receive from or be obligated to pay to current and potential licensors, licensees and other third parties;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights;
- the emergence of competing products and technologies, and other adverse market developments;
- the perceived, potential and actual commercial success of BioSante's products;
- the outstanding principal amount of BioSante's 3.125% convertible senior notes due May 1, 2013 (convertible senior notes) that are scheduled to mature and become due and payable on May 1, 2013 and BioSante's ability to avoid a "fundamental change" or an "event of default" under the indenture governing such notes, which may cause such notes to become due and payable prior to their maturity date on May 1, 2013;
- BioSante's operating expenses; and

the resolution of BioSante's pending purported class action and shareholder derivative litigation and any amount it may be required to pay in excess of its directors' and officers' liability insurance.

BioSante's future capital requirements and projected expenditures are based upon numerous assumptions and subject to many uncertainties, and actual requirements and expenditures may differ

Table of Contents

significantly from its projections. To date, BioSante has relied primarily upon proceeds from sales of its equity securities to finance its business and operations. BioSante likely will need to raise additional capital to fund its operations. As of September 30, 2012, BioSante had $38.0 million of cash and cash equivalents. BioSante does not have any existing credit facilities under which it may borrow funds. Absent the receipt of any additional licensing income or financing, BioSante expects its cash and cash equivalents balance to decrease as it continues to use cash to fund its operations, including in particular the two new LibiGel Phase III efficacy trials if BioSante decides to pursue them. As of September 30, 2012, BioSante has $8.3 million in principal amount of convertible senior notes outstanding that mature on May 1, 2013. Assuming the merger is completed during the first quarter of 2013 and BioSante decides not to commence the two new efficacy trials for LibiGel, BioSante expects its cash equivalents as of September 30, 2012 to meet its liquidity requirements through at least its anticipated closing of the merger, including the closing condition under the merger agreement to have at least $17.0 million of "net cash," as defined in the merger agreement, available upon the closing of the merger. If the merger is not completed, BioSante will need to reevaluate its strategic alternatives, which may include continuing to operate its business as an independent, stand-along company, a sale of the company, liquidation of the company or other strategic transaction. BioSante's liquidity position will be dependent upon the strategic alternative selected; however, assuming BioSante does not enter into another strategic transaction, and assuming BioSante decides not to commence the two new efficacy trials for LibiGel, BioSante expects its cash and cash equivalents as of September 30, 2012 will be sufficient to meet its liquidity requirements for at least the next three to five years. Additional financing would be required should BioSante decide to commence the two new efficacy trials for LibiGel. These estimates may prove incorrect or BioSante, nonetheless, may choose to raise additional financing earlier in order to create a "cash cushion" and take advantage of favorable financing conditions.

The December 2011 announcement of the results of BioSante's prior completed LibiGel Phase III efficacy trials has significantly depressed the trading price of BioSante common stock and harmed BioSante's ability to raise additional capital. BioSante can provide no assurance that additional financing, if needed, will be available on terms favorable to BioSante, or at all. This is particularly true if investors are not confident in BioSante's LibiGel Phase III development program, the future value of the company and/or if economic and market conditions deteriorate. BioSante has on file effective shelf registration statements that allow it to raise up to an aggregate of $102.4 million from the sale of common stock, preferred stock, warrants or units comprised of the foregoing. However, under applicable SEC rules, if BioSante has a public float of less than $75.0 million, it can only offer to sell under the registration statement up to one-third of its public float during any 12-month period. BioSante can provide no assurance that additional financing, if needed, will be available on terms favorable to it, or at all. If adequate funds are not available or are not available on acceptable terms when BioSante needs them, BioSante may need to make changes to its operations to reduce costs. As an alternative to raising additional financing, BioSante may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product, e.g., GVAX cancer vaccines, to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights BioSante has under its existing license agreements or decide or be forced to explore other strategic alternatives, such as selling or merging the company or winding down its operations and liquidating the company. In such case, the BioSante stockholders could lose some or all of their investment.

Table of Contents

***Raising additional funds by issuing additional equity securities may cause dilution to existing BioSante stockholders, raising additional funds by issuing additional debt financing may restrict BioSante's operations and raising additional funds through licensing arrangements may require BioSante to relinquish proprietary rights.***

If BioSante raises additional funds through the issuance of additional equity or convertible debt securities, the percentage ownership of its stockholders could be diluted significantly, and these newly issued securities may have rights, preferences or privileges senior to those of its existing stockholders. In addition, the issuance of any equity securities could be at a discount to the market price.

If BioSante incurs additional debt financing, the payment of principal and interest on such indebtedness may limit funds available for its business activities, and BioSante could be subject to covenants that restrict its ability to operate its business and make distributions to its stockholders. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of BioSante's assets, as well as prohibitions on the ability of BioSante to create liens, pay dividends, redeem its stock or make investments. There is no assurance that any equity or debt financing transaction will be available on terms acceptable to BioSante, or at all.

As an alternative to raising additional financing by issuing additional equity or debt securities, BioSante may choose to license one or more of its products or technologies to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under BioSante's existing license agreements or enter into other business collaborations or combinations, including a possible sale or merger of its company. If BioSante raises additional funds through licensing arrangements, BioSante may be required to relinquish greater or all rights to BioSante's products at an earlier stage of development or on less favorable terms than BioSante otherwise would choose.

***BioSante has substantial indebtedness, in the form of convertible senior notes, which notes BioSante may not be able to pay when they become due and payable on May 1, 2013, or earlier if BioSante experiences a "fundamental change" or an "event of default" under the indenture governing such notes.***

As of December 31, 2012, BioSante had $8.3 million in aggregate principal amount of convertible senior notes outstanding. The annual interest payment on these notes is approximately $259,000. At maturity, on May 1, 2013, the entire then remaining aggregate outstanding principal amount of the convertible senior notes will become due and payable. In addition, upon the occurrence of a "fundamental change", holders of the convertible senior notes may require BioSante to purchase their notes prior to the May 1, 2013 maturity date. A fundamental change includes a significant change in BioSante's ownership; the first day the majority of its board of directors does not consist of continuing directors; the consummation of certain recapitalizations, reclassifications, or changes of common stock, share exchanges or consolidations or mergers; or the termination of trading of its common stock (which will be deemed to have occurred if its common stock is neither listed for trading on a United States national securities exchange nor any United States system of automated dissemination of quotations of securities prices or traded in over-the-counter securities markets). The proposed merger between BioSante and ANI will not amount to a "fundamental change" under the indenture. Additionally, the aggregate principal amount of the outstanding convertible senior notes will become due and payable upon an uncured or unwaived event of default. Although BioSante believes it will be able to pay the aggregate outstanding principal amount of its convertible senior notes plus accrued interest when the notes mature on May 1, 2013, it is possible that BioSante may not have sufficient funds to pay the aggregate principal amount of its then outstanding convertible senior notes when they mature on May 1, 2013, or become due and payable earlier if BioSante were to experience a "fundamental change" or an "event of default" under the indenture governing such notes.

Table of Contents

***The indentures governing BioSante's convertible senior notes contains covenants, which if not complied with, could result in an event of default and the acceleration of all amounts due under the notes.***

The indenture governing BioSante's convertible senior notes contains covenants, such as the requirement to pay accrued interest on May 1 and November 1 of each year, the requirement to repurchase the notes upon a "fundamental change," as defined in the indenture, if a note holder so elects and the requirement to file periodic reports electronically with the SEC. If BioSante does not comply with the covenants in the indenture, an event of default could occur and all amounts due under the notes could become immediately due and payable. Upon the occurrence of an event of default under the indenture, the trustee has available a range of remedies customary in these circumstances, including declaring all such indebtedness, together with accrued and unpaid interest thereon, to be due and payable. Although it is possible BioSante could negotiate a waiver with the trustee and the holders of the notes, such a waiver likely would involve significant costs. It also is possible that BioSante could refinance or restructure its obligations under the notes; however, such a refinancing or restructuring also likely would involve significant costs and likely would result in higher interest rates than the current 3.125% annual interest rate on the notes.

***Future purchases, exchanges or restructurings of BioSante's outstanding convertible senior notes could dilute the percentage ownership of the BioSante stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of BioSante's existing stockholders and/or decrease its cash balance.***

In February 2012, BioSante entered into privately-negotiated securities exchange agreements with one of the holders of its convertible senior notes pursuant to which BioSante issued an aggregate of 1,868,055 shares of its common stock, as adjusted to reflect its one-for-six reverse stock split effected on June 1, 2012, to the note holder in exchange for the cancellation of an aggregate of $9.0 million principal amount of BioSante's convertible senior notes, including accrued and unpaid interest. In July 2012, BioSante entered into a privately-negotiated securities exchange agreement with two of the holders of its convertible senior notes pursuant to which BioSante issued an aggregate of 1,784,070 shares of its common stock to the note holder in exchange for the cancellation of an aggregate of $3.5 million principal amount of BioSante's convertible senior notes and accrued and unpaid interest of $20,686. As a result of these exchanges, an aggregate of $8.3 million principal amount of the convertible senior notes remained outstanding as of September 30, 2012. From time-to-time, BioSante again may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of its company, in open market purchases, privately negotiated transactions and/or a tender offer. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the trading price and volume of BioSante common stock, the willingness of the note holders to sell, exchange or restructure their notes, BioSante's available cash and cash equivalents, its liquidity requirements, regulatory limitations, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the BioSante stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of existing BioSante stockholders and/or decrease BioSante's cash balance. A significant decrease in BioSante's cash balance may impair its ability to execute strategic alternatives, including the proposed merger with ANI, or leave BioSante without sufficient cash remaining for operations.

***BioSante is subject to pending purported securities class action and shareholder derivative litigation, which could divert management's attention, harm its business and/or reputation and result in significant liabilities, as well as harm its ability to raise additional financing and execute certain strategic alternatives.***

BioSante is subject to pending purported securities class action and shareholder derivative litigation.

Table of Contents

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes naming BioSante and its President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of BioSante's disclosures relating to the efficacy of LibiGel and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of BioSante's securities resulting in violations of Section 10(b) of the Securities Exchange Act of 1934, as amended, Rule 10b-5 and Section 20(a) of the Exchange Act. Although a substantially similar complaint was filed in the same court on February 21, 2012, such complaint was voluntarily dismissed by the plaintiff in April 2012. The plaintiff seeks to represent a class of persons who purchased BioSante's securities between February 12, 2010 and December 15, 2011, and seeks unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys' fees on behalf of such purchasers. BioSante believes the action is without merit and intends to defend the action vigorously. On November 6, 2012, the plaintiff filed a consolidated amended complaint. BioSante and Mr. Simes filed motions to dismiss the consolidated amended complaint on December 28, 2012.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of BioSante filed a shareholder derivative action in the United States District Court for the Northern District of Illinois under the caption Weinstein v. BioSante Pharmaceuticals, Inc. et al., naming BioSante's directors as defendants and BioSante as a nominal defendant. A substantially similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits generally related to the same events that are the subject of the class action litigation described above. The complaints allege breaches of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment as causes of action occurring from at least February 2010 through December 2011. The complaints seek unspecified damages, punitive damages, costs and disbursements and unspecified reform and improvements in BioSante's corporate governance and internal control procedures. On September 24, 2012, the District Court consolidated the two cases before it and on November 20, 2012 plaintiffs filed their consolidated amended complaint. On January 11, 2013, the defendants filed a motion to dismiss this complaint. On November 27, 2012, the plaintiff in the action pending in Illinois state court filed an amended complaint. On January 11, 2013, the defendants filed a motion to dismiss this complaint.

The lawsuits are in their early stages; and, therefore, BioSante is unable to predict the outcome of the lawsuits and the possible loss or range of loss, if any, associated with their resolution or any potential effect the lawsuits may have on BioSante's operations. Depending on the outcome or resolution of these lawsuits, they could have a material effect on BioSante's operations, including its financial condition, results of operations, or cash flows.

BioSante is not involved in any other legal actions, however, from time to time may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time.

***Risks Related to BioSante's Business***

***BioSante's two pivotal LibiGel Phase III efficacy trials did not meet the co-primary and secondary endpoints, and it is possible that the two new LibiGel Phase III efficacy trials, if BioSante decides to pursue them, will not meet the co-primary and secondary endpoints, which could harm BioSante's business and further disappoint BioSante stockholders and cause the trading price of BioSante common stock to decrease.***

BioSante's lead near term product in development is LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved product. In June 2012,

Table of Contents

BioSante announced a plan to initiate two new LibiGel Phase III efficacy trials. This decision was based on an extensive analysis of previous efficacy data, consultation with key opinion leaders in FSD, testosterone therapy and placebo effects, as well as a meeting with the FDA. The protocol for the two new efficacy trials is in development. BioSante intends to apply for an FDA Special Protocol Assessment (SPA) agreement prior to initiating the two new efficacy trials. Currently, it is expected that the efficacy trials will include the same FDA-required efficacy endpoints as prior Phase III efficacy trials: an increase in the number of satisfying sexual events and sexual desire, and decreased distress associated with low desire.

The initiation of the two new LibiGel Phase III efficacy trials involves risk, especially since BioSante's prior LibiGel Phase III efficacy trials failed to meet the co-primary or secondary endpoints. Although the results indicated that LibiGel performed as predicted based on previous experience with testosterone products for female sexual dysfunction, the placebo response in the two efficacy trials was greater than expected; and therefore, LibiGel's results were not shown to be statistically different from placebo. No assurance can be provided that BioSante will be able to design the two new LibiGel Phase III efficacy trials to minimize sufficiently the placebo effect and meet the co-primary and secondary endpoints for the trials. In addition, BioSante can provide no assurance that it will be able to obtain an FDA SPA agreement for such trials or that BioSante will initiate or complete the trials on a timely basis, or ever. Any of these possible results could harm BioSante's business and further disappoint BioSante stockholders and cause the trading price of BioSante common stock to decrease.

***Although BioSante's male testosterone gel is approved by the FDA, BioSante is uncertain as to when Teva will begin to market and sell the male testosterone gel and thus when or if BioSante would begin to receive royalties from such sales in light of Teva's settlement agreement with a subsidiary of Abbott Laboratories.***

BioSante's male testosterone gel initially was developed by BioSante, and then licensed by BioSante to Teva for late stage clinical development. Teva submitted a New Drug Application, which NDA was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. The Teva/Abbott Laboratories patent infringement litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been publicly disclosed. In light of the settlement agreement, BioSante is uncertain as to when or if Teva will begin to market and sell its male testosterone gel and thus when or if BioSante would begin to receive royalties from such sales.

***Several of BioSante's products are in the clinical development stages and, depending on the product, likely will not be approved by regulatory authorities or introduced commercially for at least several years and likely more, if at all.***

Several of BioSante's products are in the clinical development stages and will require further development, preclinical and clinical testing and investment prior to obtaining required regulatory approvals and commercialization in the United States and abroad. Other than Elestrin and BioSante's male testosterone gel, none of BioSante's products have been approved by the FDA or other regulatory authorities; and accordingly, none of BioSante's products have been introduced commercially and most are not expected to be for several years and likely more, if at all. BioSante cannot assure you that any of its products in clinical development will:

be developed successfully;

prove to be safe and effective in clinical studies;

meet applicable regulatory standards or obtain required regulatory approvals;

Table of Contents

demonstrate substantial protective or therapeutic benefits in the prevention or treatment of any disease;

be capable of being produced in commercial quantities at reasonable costs;

obtain coverage and favorable reimbursement rates from insurers and other third-party payors; or

be marketed successfully or achieve market acceptance by physicians and patients.

***If BioSante fails to obtain regulatory approval to manufacture commercially or sell any of its future products, or if approval is delayed or withdrawn, BioSante will be unable to generate revenue from the sale of its products.***

BioSante must obtain regulatory approval to sell any of its products in the United States and abroad. In the United States, BioSante must obtain the approval of the FDA for each product or drug that BioSante intends to commercialize. The FDA approval process typically is very lengthy and expensive, and approval never is certain. Products to be commercialized abroad are subject to similar foreign government regulation.

Generally, only a very small percentage of newly discovered pharmaceutical products that enter preclinical development eventually are approved for sale. Because of the risks and uncertainties in biopharmaceutical development, BioSante's products could take a significantly longer time to gain regulatory approval than BioSante expects or may never gain approval. If regulatory approval is delayed or never obtained, the credibility of BioSante's management, the value of BioSante and its operating results and liquidity would be affected adversely. Even if a product gains regulatory approval, the product and the manufacturer of the product may be subject to continuing regulatory review and BioSante may be restricted or prohibited from marketing or manufacturing a product if previously unknown problems with the product or its manufacture of the product subsequently are discovered. The FDA also may require BioSante to commit to perform lengthy post-approval studies, for which BioSante would have to expend significant additional resources, which could have an adverse effect on its operating results and financial condition.

To obtain regulatory approval to market many of BioSante's products, costly and lengthy human clinical trials are required, and the results of the studies and trials are highly uncertain. As part of the FDA approval process, BioSante must conduct, at its own expense or the expense of current or potential licensees or other entities, clinical trials in human subjects on each of BioSante's products. BioSante expects the number of human clinical trials that the FDA will require will vary depending on the product, the disease or condition the product is being developed to address and regulations applicable to the particular product. Depending on the stage of development, BioSante may need to perform multiple pre-clinical studies using various doses and formulations before BioSante can begin human clinical trials, which could result in delays in BioSante's ability to market its products. Furthermore, even if BioSante obtains favorable results in pre-clinical studies on animals, the results in humans may be different.

In order to receive regulatory approval for commercial sale, BioSante must demonstrate that its products are safe and effective for use in the target human population. The data obtained from pre-clinical and human clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. BioSante faces the risk that the results of its clinical trials in later phases of clinical trials may be inconsistent with those obtained in earlier phases. As an example, BioSante's prior two pivotal LibiGel Phase III efficacy trials did not meet the co-primary endpoints of an increase in satisfying sexual events and an increase in desire and the secondary endpoint of a decrease in distress compared to placebo even though treatment with LibiGel in BioSante's Phase II clinical trial significantly increased satisfying sexual events compared to placebo. A number of companies in the

Table of Contents

biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal or human testing. Adverse or inconclusive human clinical results would prevent BioSante from submitting for regulatory approval of its products.

Additional factors that can cause delay or termination of BioSante's human clinical trials include:

- slow subject enrollment;
- timely completion of clinical site protocol approval and obtaining informed consent from subjects;
- longer treatment time required to demonstrate efficacy or safety;
- new or additional trials or studies that are designed differently in order to increase the chances of demonstrating efficacy or safety;
- adverse medical events or side effects in treated subjects;
- lack of effectiveness of the product being tested; and
- lack of funding.

Delays in BioSante's clinical trials could allow its competitors additional time to develop or market competing products and thus can be extremely costly in terms of lost sales opportunities and increased clinical trial costs.

***The process for obtaining FDA approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources.***

BioSante's products in development will require the submission and approval of an NDA in order to obtain required approval by the FDA to commercially market the product. The FDA conducts in-depth reviews of NDAs to determine whether to approve products for commercial marketing for the indications proposed. If the FDA is not satisfied with the information provided, the FDA may refuse to approve an NDA or may require a company to perform additional studies or provide other information in order to secure approval. The FDA may delay, limit or refuse to approve an NDA for many reasons, including:

- the information submitted may be insufficient to demonstrate that a product is safe and effective;
- the FDA might not approve the processes or facilities of a company, or those of its vendors, that will be used for the commercial manufacture of a product; or
- the FDA's interpretation of the nonclinical, clinical or manufacturing data provided in an NDA may differ from a company's interpretation of such data.

If the FDA determines that the clinical studies submitted for a product candidate in support of an NDA are not conducted in full compliance with the applicable protocols for these studies, as well as with applicable regulations and standards, or if the FDA does not agree with a company's interpretation of the results of such studies, the FDA may reject the data that resulted from such studies. The rejection of data from clinical studies required to support an NDA could affect negatively a company's ability to obtain marketing authorization for a product and would have a material adverse effect on a company's business and financial condition. In addition, an NDA may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval during development or the review period.

58

Table of Contents

***BioSante may not achieve projected goals and objectives in the time periods that BioSante anticipates or announce publicly, which could have an adverse effect on its business and could cause the price of BioSante common stock to decline.***

BioSante sets goals and objectives for, and makes public statements regarding, the timing of certain accomplishments and milestones regarding its business, such as the initiation and completion of clinical studies, the completion of enrollment for clinical studies, the submission of applications for regulatory approvals, the receipt of regulatory approvals and other developments and milestones. The actual timing of these events can vary dramatically due to a number of factors including without limitation delays or failures in BioSante's current clinical studies, the amount of time, effort and resources committed to its programs by BioSante and its current and potential future strategic partners and the uncertainties inherent in the clinical studies and regulatory approval process. As a result, there can be no assurance that clinical studies involving BioSante's products in development will advance or be completed in the time periods that BioSante or its strategic partners announce or expect, that BioSante or its current and potential future strategic partners will make regulatory submissions or receive regulatory approvals as planned or that BioSante or its current and potential future strategic partners will be able to adhere to its current schedule for the achievement of key milestones under any of its development programs. If BioSante or any of its strategic partners fail to achieve one or more of these milestones as planned, BioSante's business could be affected adversely and materially and the trading price of BioSante common stock could decline. As an example, prior to BioSante's receipt of the results from its prior two pivotal LibiGel Phase III efficacy trials in December 2011, its objective with respect to LibiGel was to submit an NDA in 2012. This is obviously no longer an objective of BioSante's in light of the fact that unexpectedly BioSante's two pivotal LibiGel Phase III efficacy trials did not meet the co-primary and secondary endpoints.

BioSante also discloses from time-to-time projected financial information, including its cash position and anticipated cash burn rate and other expenditures, for future periods. These financial projections are based on management's current expectations and may not contain any margin of error or cushion for any specific uncertainties, or for the uncertainties inherent in all financial forecasting.

***If the market opportunities for BioSante's products are smaller than BioSante anticipates, then its future revenues and business may be affected adversely.***

From time-to-time, BioSante discloses estimated market opportunity data for its products and products in development. Although BioSante believes it has a reasonable basis for its market opportunity estimates, BioSante estimates may prove to be incorrect. If the market opportunities for BioSante's products are smaller than BioSante anticipates, its anticipated revenues from the sales or licensure of such products will be lower than BioSante anticipates.

***Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could adversely affect the market for BioSante's hormone therapy products and the trading price of BioSante common stock.***

The market for hormone therapy products has been affected negatively by the Women's Health Initiative (WHI) study and other studies that have found that the overall health risks from the use of certain hormone therapy products may exceed the benefits from the use of those products among postmenopausal women. In July 2002, the National Institutes of Health (NIH) released data from its WHI study on the risks and benefits associated with long-term use of oral hormone therapy by women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for

Table of Contents

an average of 5.2 year follow-up among postmenopausal women. Also, in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom also was halted. BioSante's products differ from the products used in the WHI study and the primary products observed in the National Cancer Institute and United Kingdom studies. In March 2004, the NIH announced that the estrogen-alone study was discontinued after nearly seven years because the NIH concluded that estrogen alone does not affect (either increase or decrease) heart disease, the major question being evaluated in the study. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture and breast cancer. Preliminary data from the memory portion of the WHI study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment.

Researchers continue to analyze data from both arms of the WHI study and other studies. Some reports indicate that the safety of estrogen products may be affected by the age of the woman at initiation of therapy. There currently are no studies published comparing the safety of BioSante's products against other hormone therapies. The markets for female hormone therapies for menopausal symptoms declined as a result of these published studies, although the market now seems to have stabilized. The release of any follow-up or other studies that show adverse effects from hormone therapy, including in particular, hormone therapies similar to BioSante's products, also could adversely affect BioSante's business and decrease the trading price of BioSante common stock.

***If clinical studies for BioSante's products are terminated, prolonged or delayed, it may be difficult for BioSante to find a strategic partner to assist it in the development and commercialization of its non-partnered products or commercialize such products on a timely basis, which would require BioSante to incur additional costs and delay or prevent its receipt of any revenue from potential product sales or licenses.***

BioSante may encounter problems with its completed, ongoing or planned clinical studies for its products that may cause it or the FDA to delay, suspend or terminate those studies or delay the analysis of data derived from them. A number of events, including any of the following, could delay the completion of, or cause BioSante to suspend or terminate its ongoing and planned clinical studies for its products and negatively impact BioSante's ability to obtain regulatory approval or enter into strategic partnerships for, or market or sell, a particular product:

- conditions imposed on BioSante by the FDA or any foreign regulatory authority regarding the scope or design of its clinical studies;
- delay in developing, or BioSante's inability to obtain, a clinical dosage form, insufficient supply or deficient quality of its products or other materials necessary to conduct its clinical studies;
- negative or inconclusive results from clinical studies, or results that are inconsistent with earlier results, that necessitate additional clinical study or termination of a clinical program;
- serious and/or unexpected product-related side effects experienced by subjects in BioSante's clinical studies; or
- failure of BioSante's third-party contractors or its investigators to comply with regulatory requirements or otherwise meet their contractual obligations to BioSante in a timely manner.

Regulatory authorities, clinical investigators, institutional review boards, data safety monitoring boards and the sites at which BioSante's clinical studies are conducted all have the power to stop or recommend stopping its clinical studies prior to completion. BioSante's clinical studies for its products in development may not begin as planned, may need to be amended, suspended or terminated and may not be completed on schedule, if at all. This is particularly true if BioSante no longer believes it can

Table of Contents

obtain regulatory approval for a particular product or if BioSante no longer has the financial resources to dedicate to a clinical development program for a particular product.

***BioSante relies on third parties to assist it in certain aspects of its clinical studies. If these third parties do not perform as required contractually or expected, BioSante's clinical studies may be extended, delayed or terminated or may need to be repeated, and BioSante may not be able to obtain regulatory approval for or commercialize the product being tested in such studies.***

BioSante relies on third parties, such as medical institutions, academic institutions, clinical investigators and contract laboratories, to assist it in certain aspect of its clinical studies. BioSante is responsible for confirming that BioSante's studies are conducted in accordance with applicable regulations and that each of its clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires BioSante to comply with regulations and standards, commonly referred to as good clinical practices for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. BioSante's reliance on these few third parties does not relieve it of these responsibilities. If the third parties assisting BioSante with certain aspects of its clinical studies do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with the FDA's good clinical practice regulations, do not adhere to BioSante's protocols or otherwise fail to generate reliable clinical data, BioSante may need to enter into new arrangements with alternative third parties and its clinical studies may be extended, delayed or terminated or may need to be repeated, and BioSante may not be able to obtain regulatory approval for or commercialize the product being tested in such studies. In addition, if a third party fails to perform as agreed, BioSante's ability to collect damages may be limited contractually.

***BioSante's products will remain subject to ongoing regulatory review even if BioSante receives marketing approval. If BioSante fails to comply with continuing regulations, BioSante could lose these approvals, and the sale of any future products could be suspended.***

Even if BioSante receives regulatory approval to market a particular product in development, the FDA or a foreign regulatory authority could condition approval on conducting additional costly post-approval studies or could limit the scope of BioSante's approved labeling or could impose burdensome post-approval obligations under a Risk Evaluation and Mitigation Strategy (REMS). If required, a REMS may include various elements, such as publication of a medication guide, a patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug or other measures that the FDA deems necessary to assure the safe use of the drug. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, result in more restrictive labeling than originally approved, force BioSante to withdraw it from the market, cause the FDA to impose additional REMS obligations or impede or delay BioSante's ability to obtain regulatory approvals in additional countries. In addition, BioSante will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the FDA imposes extensive regulatory requirements on the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product.

If BioSante fails to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities or previously unknown problems with any future products, suppliers or manufacturing processes are discovered, BioSante could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, suppliers or manufacturing processes;
- warning letters or untitled letters;

Table of Contents

civil or criminal penalties or fines;

injunctions;

product seizures, detentions or import bans;

voluntary or mandatory product recalls and publicity requirements;

suspension or withdrawal of regulatory approvals;

total or partial suspension of production; and

refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

***BioSante may enter into additional strategic relationships with third parties to help develop and commercialize its products in development. If BioSante does not enter into such relationships, BioSante will need to undertake development and commercialization efforts on its own, which would be costly and could delay BioSante's ability to obtain required approvals for and commercialize its future products.***

A key element of BioSante's business strategy is BioSante's intent to partner selectively with pharmaceutical, biotechnology and other companies to obtain assistance for commercialization and, in some cases, development of its products. For example, BioSante has a strategic relationship with Meda Pharmaceuticals, Inc. with respect to Elestrin, with Teva with respect to BioSante's male testosterone gel, with Pantarhei Science with respect to The Pill Plus and with several third parties with respect to BioSante's GVAX cancer vaccines. BioSante currently does not have a strategic partner for LibiGel.

BioSante may enter into additional strategic relationships with third parties to develop, and if regulatory approval is obtained commercialize, its products in development, including LibiGel, and any additional new products BioSante may acquire or in-license. BioSante faces significant competition in seeking appropriate strategic partners, and these strategic relationships can be intricate and time consuming to negotiate and document. BioSante may not be able to negotiate additional strategic relationships on acceptable terms, or at all. BioSante is unable to predict when, if ever, it will enter into any additional strategic relationships because of the numerous risks and uncertainties associated with establishing such relationships. If BioSante is unable to negotiate additional strategic relationships for its products, BioSante may be forced to curtail the development of a particular product, reduce, delay or terminate its development program or one or more of its other development programs, delay its potential commercialization, reduce the scope of anticipated sales or marketing activities or undertake development or commercialization activities at BioSante's own expense. In addition, BioSante would then bear all the risk related to the development and commercialization of that product. If BioSante elects to increase its expenditures to fund development or commercialization activities on its own, BioSante may need to obtain additional capital, which may not be available to BioSante on acceptable terms, or at all. If BioSante does not have sufficient funds, BioSante will not be able to bring its products in development and any additional new products BioSante may acquire or in-license if they receive regulatory approvals to market and generate product revenue.

***If BioSante is unable to partner with a third party and obtain assistance for the potential commercialization of its products, if approved for commercial sale, BioSante would need to establish its own sales and marketing capabilities, which involves risk.***

BioSante does not have an internal sales and marketing organization and has limited experience in the sales, marketing and distribution of pharmaceutical products. There are risks involved with establishing BioSante's own sales capabilities and increasing its marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if

Table of Contents

BioSante enters into arrangements with third parties to perform sales, marketing and distribution services, revenues from sales of the product or the profitability of these product revenues are likely to be lower than if BioSante markets and sells any products that BioSante develops itself.

Although BioSante's preferred alternative would be to engage a pharmaceutical or other healthcare company with an existing sales and marketing organization and distribution systems to sell, market and distribute its products, if approved for commercial sale, if BioSante is unable to engage such a sales and marketing partner, BioSante may need to establish its own specialty sales force. Factors that may inhibit BioSante's efforts to commercialize any future products without strategic partners or licensees include:

- BioSante's inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put BioSante at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Because the establishment of sales and marketing capabilities depends on the progress towards commercialization of BioSante's products and because of the numerous risks and uncertainties involved with establishing its own sales and marketing capabilities, BioSante is unable to predict when, if ever, BioSante will establish its own sales and marketing capabilities. If BioSante is not able to partner with additional third parties and are unsuccessful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, BioSante will have difficulty commercializing its products, which would harm its business and financial condition.

***BioSante's current strategic relationships and any future additional strategic relationships it may enter into involve risks with respect to the development and commercialization of its products.***

A key element of BioSante's business strategy is to selectively partner with pharmaceutical, biotechnology and other companies to obtain assistance for commercialization and, in some cases, development of BioSante's products. For example, BioSante has strategic relationships with Meda Pharmaceuticals, Inc. with respect to Elestrin, with Teva with respect to its male testosterone gel and with Pantarhei Science with respect to The Pill Plus and several third parties with respect to its GVAX cancer vaccines.

BioSante's current strategic relationships and any future additional strategic relationships BioSante may enter into involve a number of risks, including:

- business combinations or significant changes in a strategic partner's business strategy may affect adversely a strategic partner's willingness or ability to complete its obligations under any arrangement;
- BioSante may not be able to control the amount and timing of resources that its strategic partners devote to the development or commercialization of its partnered products;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a partnered product, repeat or conduct new clinical trials or require a new version of a product for clinical testing;

Table of Contents

strategic partners may not pursue further development and commercialization of partnered products resulting from the strategic partnering arrangement or may elect to delay research and development programs or commercialization of a partnered product;

strategic partners may not commit adequate resources to the marketing and distribution of BioSante's partnered products, limiting BioSante's potential revenues from these products;

disputes may arise between BioSante and its strategic partners that result in the delay or termination of the research, development or commercialization of its partnered products or that result in costly litigation or arbitration that diverts management's attention and consumes resources;

strategic partners may experience financial difficulties;

strategic partners may not maintain properly or defend BioSante's intellectual property rights or may use its proprietary information in a manner that could jeopardize or invalidate its proprietary information or expose BioSante to potential litigation;

strategic partners independently could move forward with competing products developed either independently or in collaboration with others, including BioSante's competitors; and

strategic partners could terminate or delay the arrangement or allow it to expire, which would delay the development or commercialization of the partnered product and may increase the cost of developing or commercializing the partnered product.

***Although BioSante maintains the right to receive sales-based milestones of up to $140 million, its ability to receive these milestones is dependent upon Meda Pharmaceuticals, Inc.'s ability to market and sell Elestrin, and based on Elestrin sales to date, BioSante believes it is unlikely that it will receive any sales-based milestone payments from Meda Pharmaceuticals in the foreseeable future, or at all.***

Meda Pharmaceuticals, Inc. (which acquired Jazz Pharmaceuticals, Inc.'s women's health business, and which in turn had acquired BioSante's original licensee, Azur Pharma International II Limited (Azur)), is marketing Elestrin in the U.S. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur pursuant to which BioSante received $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to BioSante related to sales of Elestrin. BioSante continues to recognize certain royalty revenue from sales of Elestrin; however, such revenue is offset by its corresponding obligation to pay royalties to Antares, from whom BioSante licensed the technology underlying its Elestrin product. BioSante maintains the right to receive up to $140 million in sales-based milestone payments from Meda Pharmaceuticals if Elestrin reaches certain predefined sales per calendar year. BioSante can provide no assurance that Meda Pharmaceuticals will be successful in marketing Elestrin, Elestrin will be accepted widely in the marketplace or that Meda Pharmaceuticals will remain focused on the commercialization of Elestrin, especially if Meda Pharmaceuticals does not experience significant Elestrin sales. Based on current sales of Elestrin, BioSante believes it is unlikely that BioSante will receive any sales-based milestone payments from Meda Pharmaceuticals in the near term, if at all.

***If BioSante's products in development receive FDA approval and are introduced commercially, they may not achieve expected levels of market acceptance, which could harm BioSante's business, financial position and operating results and could cause the trading price of BioSante common stock to decline.***

The commercial success of BioSante's products in development, if BioSante receives the required FDA or other regulatory approvals, and the commercial success of its male testosterone gel, which is FDA approved, but not yet commercially launched, are dependent upon acceptance by physicians, patients, third-party payors and the medical community. Levels of market acceptance for such products,

Table of Contents

if approved for commercial sale with respect to BioSante's products in development, could be affected by several factors, including:

- demonstration of efficacy and safety in clinical trials with respect to BioSante's products in development;
- the existence, prevalence and severity of any side effects;
- the availability of competitive or alternative treatments and potential or perceived advantages or disadvantages compared to competitive or alternative treatments;
- the timing of market entry relative to competitive treatments;
- relative convenience, product dependability and ease of administration;
- the strength of marketing and distribution support;
- the sufficiency of coverage and reimbursement of BioSante's products by third-party payors and governmental and other payors; and
- the product labeling or product insert required by the FDA or regulatory authorities in other countries.

Some of these factors are not within BioSante's control, especially if BioSante has transferred all of the marketing rights associated with the product, as BioSante has with the U.S. marketing rights to Elestrin to Meda Pharmaceuticals, and the U.S. development and marketing rights to its male testosterone gel to Teva. BioSante's products may not achieve expected levels of market acceptance.

Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by other companies, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the use, safety and efficacy of previously marketed products. In some cases, these studies have resulted, and in the future may result, in the discontinuance of product marketing. These situations, should they occur, could harm BioSante's business, financial position and results of operations, and the trading price of BioSante common stock could decline.

***Even if BioSante or its strategic partners successfully develop, obtain required regulatory approvals and commercialize any of its products under development, BioSante faces uncertainty with respect to pricing, third-party reimbursement and healthcare reform, all of which could affect adversely the commercial success of BioSante's products.***

BioSante's ability to collect significant revenues from sales of its products, if approved and commercialized, may depend on its ability, and the ability of any current or potential future strategic partners or customers, to obtain adequate levels of coverage and reimbursement for such products from third-party payers such as:

- private health insurers;
- health maintenance organizations;
- pharmacy benefit management companies;

government health administration authorities; and

other healthcare-related organizations.

Third-party payers increasingly are challenging the prices charged for medical products and services. For example, third-party payers may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances

Table of Contents

from the FDA, or foreign equivalent, or other government regulators, is not used in accordance with cost-effective treatment methods as determined by the third-party payer, or is experimental, unnecessary or inappropriate. Prices also could be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. If third-party payers deny coverage or offer inadequate levels of reimbursement, BioSante or any of its strategic partners may not be able to market its products effectively or it may be required to offer its products at prices lower than anticipated.

In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect BioSante's ability to sell its products profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for BioSante's products, which could affect adversely its business strategy, operations and financial results. For example, in March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, which is referred to as the PPACA. This legislation may have far reaching consequences for life science companies like BioSante. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare and Medicaid, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals and medical devices. If reimbursement for BioSante's products, if approved, is substantially less that BioSante expects in the future, its business could be affected materially and adversely.

The cost-containment measures that healthcare providers are instituting and the results of healthcare reforms such as the PPACA may prevent BioSante from maintaining prices for its products that are sufficient for BioSante to realize profits and may otherwise significantly harm its business, financial condition and operating results. In addition, to the extent that BioSante's approved products are marketed outside of the United States, foreign government pricing controls and other regulations may prevent BioSante from maintaining prices for such products that are sufficient for BioSante to realize profits and may otherwise significantly harm its business, financial condition and operating results.

***BioSante and its licensees depend on third-party manufacturers to produce its products and if these third parties do not manufacture successfully these products BioSante's business would be harmed.***

BioSante has no manufacturing experience or manufacturing capabilities for the production of its products for its clinical studies or, if approved, commercial sale. In order to continue to develop products, apply for regulatory approvals and commercialize BioSante's products following approval, if obtained, BioSante or its licensees must be able to manufacture or contract with third parties to manufacture its products in clinical and commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. The manufacture of BioSante's products may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing BioSante's products may make them prohibitively expensive. If supplies of any of BioSante's products become unavailable on a timely basis or at all or are contaminated or otherwise lost, BioSante's clinical studies could be seriously delayed or compromised, and with respect to its

Table of Contents

approved products, its future revenue from royalties and milestone payments could be affected adversely.

***To the extent that BioSante or its licensees enter into manufacturing arrangements with third parties, BioSante and such licensees will depend upon these third parties to perform its obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond BioSante's control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for BioSante.***

BioSante's existing and future 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 BioSante's products. If a natural disaster, business failure, strike or other difficulty occurs, BioSante may be unable to replace these contract manufacturers in a timely or cost-effective manner and the production of its products would be interrupted, resulting in delays and additional costs. Switching manufacturers or manufacturing sites would be difficult and time-consuming because the number of potential manufacturers is limited. In addition, before a product from any replacement manufacturer or manufacturing site can be commercialized, the FDA must approve that site. This approval would require regulatory testing and compliance inspections. A new manufacturer or manufacturing site also would have to be educated in, or develop substantially equivalent processes for, production of BioSante's products. It may be difficult or impossible to transfer certain elements of a manufacturing process to a new manufacturer or for BioSante to find a replacement manufacturer on acceptable terms quickly, or at all, either of which would delay or prevent its ability to develop and commercialize its products.

If third-party manufacturers fail to perform their obligations, BioSante's competitive position and ability to generate revenue may be affected adversely in a number of ways, including:

- BioSante and its strategic partners may be unable to initiate or continue clinical studies of its products that are under development;
- BioSante and its strategic partners may be delayed in submitting applications for regulatory approvals for its products that are under development; and
- BioSante and its strategic partners may be unable to meet commercial demands for any approved products.

In addition, if a third-party manufacturer fails to perform as agreed, BioSante's ability to collect damages may be contractually limited.

***If BioSante reallocates its resources to other products and technologies in its current product portfolio or any additional new products and technologies that BioSante may acquire or in-license, BioSante may not be successful in developing such products and technologies and BioSante will be subject to all the risks and uncertainties associated with research and development of products and technologies.***

BioSante has explored the possibility of reallocating its resources towards other products and technologies in its current product portfolio or any additional new products and technologies that BioSante may acquire or in-license. It BioSante decides to reallocate its resources towards other products and technologies in its current product portfolio or any additional new products and technologies that BioSante may acquire or in-license, BioSante cannot guarantee that any such allocation would result in the identification and successful development of one or more approved and

Table of Contents

commercially viable products. The development of products and technologies is subject to a number of risks and uncertainties, including:

- the time, costs and uncertainty associated with the clinical testing required to demonstrate the safety and effectiveness of BioSante's products and obtain regulatory approvals;
- the ability to raise sufficient funds to fund the research and development of BioSante's products;
- the ability to find third party strategic partners to assist or share in the costs of product development, and potential dependence on such strategic partners, to the extent BioSante relies on them for future sales, marketing or distribution;
- the ability to protect the intellectual property rights associated with BioSante's products;
- litigation;
- competition;
- ability to comply with ongoing regulatory requirements;
- government restrictions on the pricing and profitability of products in the United States and elsewhere; and
- the extent to which third-party payers, including government agencies, private health care insurers and other health care payers, such as health maintenance organizations, and self-insured employee plans, will cover and pay for newly approved therapies.

***BioSante has very limited staffing and is dependent upon key employees and the limited use of independent contractors, the loss of some of which could affect adversely its operations.***

BioSante's success is dependent upon the efforts of a relatively small management team and staff. BioSante also has engaged independent contractors from time-to-time on an as needed, project by project, basis. In January 2012, in order to reduce BioSante's operating expenses, BioSante terminated several of its independent contractor arrangements and reduced its total employee headcount. In December 2012, BioSante terminated the remaining independent contractor arrangements and in January 2013 reduced its total employee headcount further. Such reductions in force, combined with BioSante's future business prospects and financial condition, put BioSante at risk of losing key personnel who BioSante will need going forward to implement its business strategies. BioSante has no redundancy of personnel in key development areas, including clinical, regulatory, strategic planning and finance. BioSante has employment arrangements in place with its executive and other officers, but none of these executive and other officers is bound legally to remain employed with BioSante for any specific term. BioSante does not have key man life insurance policies covering its executive and other officers or any of its other employees. If key individuals leave BioSante, its business could be affected adversely if suitable replacement personnel are not recruited quickly. There is competition for qualified personnel in the biotechnology and biopharmaceutical industry in the suburban Chicago, Illinois area in all functional areas, which makes it difficult to retain and attract the qualified personnel necessary for the development and growth of BioSante's business. BioSante's financial condition and recent reductions in force and expense reductions may make it difficult for BioSante to retain current personnel and attract qualified employees and independent contractors in the future.

***If plaintiffs bring product liability lawsuits against BioSante, BioSante may incur substantial liabilities and may be required to delay development or limit commercialization of any of BioSante's products approved for commercial sale.***

BioSante faces an inherent risk of product liability as a result of the clinical testing of its products in development and the commercial sale of its products that have been or will be approved for

Table of Contents

commercial sale. BioSante may be held liable if any product it develops causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, liability claims may result in decreased demand for BioSante's products, injury to its reputation, withdrawal of clinical studies, costs to defend litigation, substantial monetary awards to clinical study participants or patients, loss of revenue and the inability to commercialize any products that BioSante develops.

BioSante currently maintains limited product liability insurance. BioSante may not have sufficient resources to pay for any liabilities resulting from a personal injury or other claim excluded from, or beyond the limit of, BioSante's insurance coverage. BioSante's insurance does not cover third parties' negligence or malpractice, and its clinical investigators and sites may have inadequate insurance or none at all. In addition, in order to conduct BioSante's clinical studies or otherwise carry out its business, BioSante may have to assume liabilities contractually for which it may not be insured. If BioSante is unable to look to its own or a third party's insurance to pay claims against them, BioSante may have to pay any arising costs and damages themselves, which may be substantial. Even if BioSante ultimately is successful in product liability litigation, the litigation likely would consume substantial amounts of its financial and managerial resources and may create adverse publicity, all of which likely would impair BioSante's ability to generate sales of the affected product and its other products. Moreover, product recalls may be issued at BioSante's discretion or at the direction of the FDA, other governmental agencies or other companies having regulatory control for its product sales. Product recalls generally are expensive and often have an adverse effect on the reputation of the products being recalled and of the product's developer or manufacturer.

BioSante may be required to indemnify third parties against damages and other liabilities arising out of its development, commercialization and other business activities, which could be costly and time-consuming and distract management. If third parties that have agreed to indemnify BioSante against damages and other liabilities arising from their activities do not fulfill their obligations, then BioSante may be held responsible for those damages and other liabilities.

***Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on the trading price of BioSante common stock.***

Section 404 of the Sarbanes-Oxley Act of 2002 requires BioSante's management to assess the effectiveness of its internal control over financial reporting and to provide a report by its registered independent public accounting firm addressing the effectiveness of BioSante's internal control over financial reporting. The Committee of Sponsoring Organizations of the Treadway Commission (COSO) provides a framework for companies to assess and improve their internal control systems. If BioSante is unable to assert that its internal control over financial reporting is effective or if BioSante's registered independent public accounting firm is unable to express an opinion on the effectiveness of the internal controls or identifies one or more material weaknesses in BioSante's internal control over financial reporting, BioSante could lose investor confidence in the accuracy and completeness of its financial reports, which in turn could have an adverse effect on the trading price of BioSante common stock. If BioSante fails to maintain the adequacy of its internal controls, BioSante may not be able to ensure that it can conclude on an ongoing basis that BioSante has effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective internal control over financial reporting could have an adverse effect on the trading price of BioSante common stock.

***BioSante's business is subject to increasingly complex corporate governance, public disclosure and accounting requirements that could affect adversely its business and financial results.***

BioSante is subject to changing rules and regulations of federal and state governments as well as the stock exchange on which BioSante common stock is listed. These entities, including the SEC and

Table of Contents

The NASDAQ Stock Market, continue to issue new requirements and regulations in response to laws enacted by Congress. In July 2010, the Dodd-Frank Wall Street Reform and Protection Act (the Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC and The NASDAQ Stock Market to adopt additional rules and regulations in these areas. BioSante's efforts to comply with these requirements have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from its other business activities.

***BioSante's operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.***

BioSante's principal executive office and its only business location is in Lincolnshire, Illinois, which is a suburb of Chicago. Natural disasters or other catastrophic events could disrupt BioSante's operations or those of its strategic partners, contractors and vendors. Even though BioSante believes it carries commercially reasonable business interruption and liability insurance, and its contractors may carry liability insurance that protect BioSante in certain events, BioSante might suffer losses as a result of business interruptions that exceed the coverage available under its and its contractors' insurance policies or for which it or its contractors do not have coverage. Any natural disaster or catastrophic event could have a significant negative impact on BioSante's operations and financial results, and could delay its efforts to identify and execute any strategic opportunities.

**Risks Related to BioSante's Industry**

***Because BioSante's industry is very competitive, BioSante may not succeed in bringing certain of its products to market and any products BioSante or its strategic partners introduce commercially may not be successful.***

Competition in the pharmaceutical industry is intense. Potential competitors in the United States and abroad are numerous and include pharmaceutical and biotechnology companies, most of which have substantially greater capital resources and more experience in research and development, manufacturing and marketing than BioSante. Academic institutions, hospitals, governmental agencies and other public and private research organizations also are conducting research and seeking patent protection and may develop and commercially introduce competing products or technologies on their own or through joint ventures. BioSante cannot assure you that its potential competitors, some of whom are BioSante's strategic partners, will not succeed in developing similar technologies and products more rapidly than it does, commercially introducing such technologies and products to the marketplace prior to BioSante, or that these competing technologies and products will not be more effective or successful than any of those that BioSante currently is developing or will develop.

***Because the pharmaceutical industry is heavily regulated, BioSante faces significant costs and uncertainties associated with its efforts to comply with applicable regulations. Should BioSante fail to comply, it could experience material adverse effects on its business, operating results and financial position, and the trading price of BioSante common stock could decline.***

The pharmaceutical industry is subject to regulation by various federal authorities, including principally the FDA and, to a lesser extent, the U.S. Drug Enforcement Administration, and state governmental authorities. The U.S. Federal Food, Drug, and Cosmetic Act, the Controlled Substances Act of 1970 and other federal statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of BioSante's products. Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunction, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, civil penalties, debarment and criminal prosecution.

Table of Contents

In addition to compliance with "current good manufacturing practice" regulations, commonly referred to as "cGMP" regulations and requirements, drug manufacturers must register each manufacturing facility with the FDA and list their drugs with the FDA. Manufacturers and distributors of prescription drug products also are required to be registered in the states where they are located and in certain states that require registration by out-of-state manufacturers and distributors. Manufacturers also must be registered with the U.S. Drug Enforcement Administration and similar applicable state and local regulatory authorities if they handle controlled substances, and also must comply with other applicable U.S. Drug Enforcement Administration and state requirements.

Despite BioSante's efforts at compliance, there is no guarantee that BioSante may not be deemed to be deficient in some manner in the future. If BioSante was deemed to be deficient in any significant way, its business, financial position and results of operations could be materially affected and the trading price of BioSante common stock could decline.

***The trend towards consolidation in the pharmaceutical and biotechnology industries may affect BioSante adversely.***

There is a trend towards consolidation in the pharmaceutical and biotechnology industries. This consolidation trend may result in the remaining companies in these industries having greater financial resources and technological capabilities, thus intensifying competition in these industries. This trend also may result in fewer potential strategic partners or licensees for BioSante's products and technology. Also, if a consolidating company is already doing business with its competitors, BioSante may lose existing licensees or strategic partners as a result of such consolidation. This trend may affect adversely BioSante's ability to enter into strategic arrangements for the development and commercialization of its products, and as a result may harm its business.

***Risks Related to BioSante's Intellectual Property***

***BioSante licenses rights to the technology underlying LibiGel and many of its other products and technologies from third parties. The loss of these rights, including in particular, BioSante's rights underlying LibiGel, could have an adverse effect on its business and future prospects and could cause the trading price of BioSante common stock to decline.***

BioSante licenses rights to certain technology underlying its gel products, including LibiGel, but not its male testosterone gel, from Antares Pharma, Inc., its GVAX cancer vaccines from The Johns Hopkins University and The Whitehead Institute for Biomedical Research, and The Pill Plus from Wake Forest University Health Sciences. BioSante may lose its rights to these technologies if BioSante breaches its obligations under the license agreements. Although BioSante intends to use commercially reasonable efforts to meet these obligations and to cause its sublicensees to meet these obligations, if BioSante violates or fails to perform any term or covenant of the license agreements, the other party to these agreements under certain circumstances may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve BioSante of its obligation to pay any royalty or license fees owed at the time of termination. In addition, it is possible that the licensors of the technology licensed by BioSante will not continue to maintain certain patents and other intellectual property rights, breach the agreements or take actions inconsistent with BioSante's license rights, which could harm BioSante's business.

Table of Contents

***BioSante has licensed some of its products to third parties and any breach by these parties of their obligations under these license agreements or a termination of these license agreements by these parties could affect adversely the development and marketing of its licensed products. In addition, these third parties also may compete with BioSante with respect to some of its products.***

BioSante has licensed some of its products to third parties, including Meda Pharmaceuticals, Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V., Valeant Pharmaceuticals, Aduro BioTech, Inc. and The John P. Hussman Foundation. All of these parties, except for Meda Pharmaceuticals, have agreed to be responsible for continued development, regulatory filings and manufacturing and marketing associated with the products, except for Valeant Pharmaceuticals, which has not agreed to be responsible for manufacturing the products. In addition, in the future BioSante may enter into additional similar license agreements. BioSante's products that it has licensed to others thus are subject to not only customary and inevitable uncertainties associated with the drug development process, regulatory approvals and market acceptance of products, but also depend on the respective licensees for timely development, obtaining required regulatory approvals, commercialization and otherwise continued commitment to the products. BioSante's current and future licensees may have different and, sometimes, competing priorities. BioSante cannot assure you that its strategic partners or any future third party to whom it may license its products will remain focused on the development and commercialization of its partnered products or will not otherwise breach the terms of its agreements with them, especially since these third parties also may compete with BioSante with respect to some of its products. Any breach of BioSante's agreements by its strategic partners or any other third party of their obligations under these agreements or a termination of these agreements by these parties could harm development of the partnered products in these agreements if BioSante is unable to license the products to another party on substantially the same or better terms or continue the development and future commercialization of the products itself. As an example, BioSante's male testosterone gel initially was developed by BioSante, and then licensed to Teva for late stage clinical development and commercialization. Teva submitted an NDA for BioSante's male testosterone gel that was approved by the FDA in February 2012. Subsequent to Teva's NDA submission, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. The Teva/Abbott Laboratories patent infringement litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been disclosed publicly. In light of the settlement agreement, BioSante is uncertain as to when or if Teva will begin to market and sell its male testosterone gel and thus when or if BioSante would begin to receive royalties from such sales.

***If BioSante is unable to protect its proprietary technology, it may not be able to compete as effectively.***

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. BioSante's success will depend, in part, upon its ability to obtain, enjoy and enforce protection for any products it develops or acquires under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of its trade secrets and operate without infringing the proprietary rights of third parties. BioSante relies on patent protection, as well as a combination of copyright and trademark laws and nondisclosure, confidentiality and other contractual arrangements to protect its proprietary technology. These legal means, however, afford only limited protection and may not adequately protect BioSante's rights or permit BioSante to gain or keep any competitive advantage.

Where appropriate, BioSante seeks patent protection for certain aspects of its technology. BioSante owned and licensed patents and patent applications, however, may not ensure the protection of its intellectual property for a number of other reasons:

BioSante does not know whether its licensor's patent applications will result in issued patents.

Table of Contents

Competitors may interfere with BioSante's patents and patent process in a variety of ways. BioSante issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit its ability to stop competitors from marketing related products. Competitors also may have BioSante's patents reexamined by demonstrating to the U.S. Patent and Trademark Office examiner that the invention was not novel or was obvious.

BioSante is engaged in the process of developing products. Even if BioSante receives a patent, it may not provide much practical protection. There is no assurance that third parties will not be able to design around BioSante's patents. If BioSante receives a patent with a narrow scope, then it will be easier for competitors to design products that do not infringe on BioSante's patent. Even if the development of BioSante's products is successful and approval for sale is obtained, there can be no assurance that applicable patent coverage, if any, will not have expired or will not expire shortly after this approval. Though patent term extension may be possible for particular products, any expiration of the applicable patent could have a material adverse effect on the sales and profitability of BioSante's products.

Litigation also may be necessary to enforce patent rights BioSante holds or to protect trade secrets or techniques it owns. Intellectual property litigation is costly and may affect adversely BioSante's operating results. Such litigation also may require significant time by BioSante's management. In litigation, a competitor could claim that BioSante's issued patents are not valid or unenforceable for a number of reasons. If the court agrees, BioSante would lose protection on products covered by those patents.

BioSante also may support and collaborate in research conducted by government organizations or universities. BioSante cannot guarantee that it will be able to acquire any rights to technology or products derived from these collaborations. If BioSante does not obtain required licenses or rights, it could encounter delays in product development while it attempts to design around other patents or it may be prohibited from developing, manufacturing or selling products requiring these licenses. There also is a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties.

BioSante also relies on unpatented proprietary technology. It is unclear whether efforts to secure BioSante's trade secrets will provide useful protection. BioSante relies on the use of registered trademarks with respect to the branded names of some of its products. BioSante also relies on common law trademark protection for some branded names, which are not protected to the same extent as its rights in the use of its registered trademarks. BioSante cannot assure you that it will be able to meaningfully protect all of its rights in its unpatented proprietary technology or that others will not independently develop and obtain patent protection substantially equivalent proprietary products or processes or otherwise gain access to its unpatented proprietary technology. BioSante seeks to protect its know-how and other unpatented proprietary technology, in part with confidentiality agreements and intellectual property assignment agreements with BioSante's employees and consultants. Such agreements, however, may not be enforceable or may not provide meaningful protection for BioSante's proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that its competitors discover or independently develop similar or identical designs or other proprietary information. Enforcing a claim that someone else illegally obtained and is using BioSante's trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

Table of Contents

***The patent protection for BioSante's products may expire before BioSante is able to maximize their commercial value which may subject BioSante to increased competition, inhibit its ability to find strategic partners and reduce or eliminate its opportunity to generate product revenue.***

The patents for BioSante's commercialized products and products in development have varying expiration dates and, when these patents expire, BioSante may be subject to increased competition and it may not be able to recover its development costs. For example, the U.S. patents covering the formulations used in Elestrin and LibiGel which BioSante licenses from Antares Pharma are scheduled to expire in June 2022 and the U.S. patent covering the "method of use" of LibiGel for treating FSD and HSDD will expire in December 2028. Although BioSante has filed additional U.S. patent applications covering LibiGel, it can provide no assurance that such applications will be granted and that the patent applications will issue. In addition to patents, BioSante may receive three years of marketing exclusivity in the United States for LibiGel under the Hatch-Waxman Act and an additional six months of pediatric exclusivity, if BioSante decides to pursue regulatory approval for LibiGel. Depending upon if and when BioSante receives regulatory approval for LibiGel and its other products in development and the then expiration dates of the patents underlying LibiGel and such other products, BioSante may not have sufficient time to recover its development costs prior to the expiration of such patents and consequently it may be difficult to find a strategic partner for such products.

***Claims by others that BioSante's products infringe their patents or other intellectual property rights could adversely affect BioSante's operating results and financial condition.***

The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Patent applications are maintained in secrecy in the United States and outside the United States until the application is published. Accordingly, BioSante cannot determine whether its technology would infringe on patents arising from these unpublished patent applications of others. Any claims of patent infringement asserted by third parties would be time-consuming and could likely:

result in costly litigation;

divert the time and attention of BioSante's technical personnel and management;

cause product development delays;

require BioSante to develop non-infringing technology; or

require BioSante to enter into royalty or licensing agreements.

Although patent and intellectual property disputes in the pharmaceutical industry often have been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt BioSante's potential gross margins. In addition, BioSante cannot be sure that the necessary licenses would be available to BioSante on satisfactory terms, or that it could redesign its products or processes to avoid patent infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent BioSante from developing, manufacturing and selling some of its products, which could harm its business, financial condition and operating results. With respect to products which BioSante has licensed to others, BioSante's licensees may be responsible for the defense of any patent infringement claims, which would result in its dependence upon them to defend its intellectual property rights.

Table of Contents

***Risks Related to BioSante Common Stock***

***The trading price of BioSante common stock has been volatile, and your investment in BioSante common stock or convertible senior notes could decline in value.***

The price of BioSante common stock has fluctuated in the past and it is likely that the price of BioSante common stock will continue to fluctuate in the future. Since January 1, 2011 through December 31, 2012, the sale price of BioSante common stock ranged from $1.08 per share to $24.12 per share. These prices reflect the one-for-six reverse stock split of BioSante's common stock that was effective at the close of business on June 1, 2012. The securities of small capitalization, biopharmaceutical companies, including BioSante, from time-to- time experience significant price fluctuations, often unrelated to the operating performance of these companies. In addition, as BioSante's convertible senior notes are convertible into shares of BioSante common stock, volatility or depressed prices of BioSante common stock could have a similar effect on the trading price of the notes. Interest rate fluctuations also can affect the price of BioSante's convertible senior notes. In particular, the market price of BioSante common stock and its convertible senior notes may fluctuate significantly due to a variety of factors, including:

- general stock market and general economic conditions in the United States and abroad, not directly related to BioSante or its business;
- actual or anticipated governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to BioSante's products in development or its competitors' products;
- actual or anticipated results of BioSante's clinical studies or those of its competitors;
- changes in anticipated or actual timing of BioSante's development programs, including delays or cancellations of clinical studies for its products;
- announcements of technological innovations or new products by BioSante or its competitors;
- announcements by licensors or licensees of BioSante's technology;
- entering into new strategic partnering arrangements or termination of existing strategic partnering arrangements;
- developments concerning BioSante's efforts to identify and implement strategic opportunities and the terms and timing of any resulting transactions;
- public concern as to the safety or efficacy of or market acceptance of products developed by BioSante or its competitors;
- BioSante's cash and cash equivalents and its need and ability to obtain additional financing;
- equity sales by BioSante to fund its operations or restructure its outstanding convertible senior notes;
- changes in laws or regulations applicable to BioSante's products;

the resolution of BioSante's pending purported class action and shareholder derivative litigation;

developments or disputes concerning patents or other proprietary rights;

period-to-period fluctuations in BioSante's financial results, including its cash and cash equivalents, operating expenses, cash burn rate or revenues;

loss of key management;

Table of Contents

- common stock sales and purchases in the public market by one or more of BioSante's larger stockholders, officers or directors;

- reports issued by securities analysts regarding BioSante common stock and articles published regarding its business and/or products;

- changes in the market valuations of other life science or biotechnology companies; and

- other financial announcements, including delisting of BioSante common stock from The NASDAQ Global Market, review of any of its filings by the SEC, changes in accounting treatment or restatement of previously reported financial results, delays in its filings with the SEC or its failure to maintain effective internal control over financial reporting.

In addition, the occurrence of any of the risks described in this report or in subsequent reports BioSante files with or submits to the SEC from time to time could have a material and adverse impact on the market price of BioSante common stock. Securities class action litigation is sometimes brought against a company following periods of volatility in the market price of its securities or for other reasons. BioSante currently is subject to such litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm BioSante's business and financial condition, as well as the market price of BioSante common stock.

***Provisions in BioSante's charter documents and Delaware law could discourage or prevent a takeover, even if an acquisition would be beneficial to BioSante stockholders.***

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

- authorizing the issuance of "blank check" preferred shares that could be issued by the BioSante board of directors to increase the number of outstanding shares and thwart a takeover attempt;

- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and

- advance notice provisions in connection with stockholder proposals and director nominations that may prevent or hinder any attempt by BioSante stockholders to bring business to be considered by its stockholders at a meeting or replace its board of directors.

***BioSante does not intend to pay any cash dividends in the foreseeable future; and, therefore, any return on an investment in BioSante common stock must come from increases in the fair market value and trading price of BioSante common stock.***

BioSante does not intend to pay any cash dividends in the foreseeable future; and, therefore, any return on an investment in BioSante common stock must come from increases in the fair market value and trading price of BioSante common stock.

Table of Contents

**Risks Related to ANI**

*In determining whether to approve the merger, you should read carefully the following risk factors. BioSante and ANI anticipate that immediately following the merger the business of the combined company will primarily be the business conducted by ANI immediately prior to the merger. You therefore should read carefully and consider the risks associated with the business of ANI because these risks also relate to the combined company following completion of the merger.*

***ANI has a history of losses and negative cash flow, expects losses and negative cash flow to continue for the foreseeable future and cannot offer any assurances that it will ever achieve profitability.***

ANI has never been profitable, has an accumulated deficit of $35.4 million as of December 31, 2011 and $40.0 million as of September 30, 2012, and other than during the nine months ended September 30, 2012, has not generated positive cash flows from operations. To bridge the gap between revenues and operating and capital needs, ANI has been dependent on a variety of financing sources, including the issuance of equity securities and convertible notes, and revolving lines of credit.

ANI cannot guarantee that it will achieve sufficient revenues for profitability. Even if it achieves profitability, it cannot guarantee that it can sustain or increase profitability on a quarterly or annual basis in the future. If revenues grow more slowly than anticipated, or if operating expenses exceed ANI's expectations or cannot be adjusted accordingly, then ANI's business, results of operations, financial condition and cash flows will be materially and adversely affected.

***ANI's future capital requirements will depend on a variety of factors, many of which are beyond its control, and ANI can offer no assurances that it will be successful in obtaining sufficient financing to cover such requirements on commercially reasonable terms or at all.***

ANI's future capital requirements will depend on many factors, including, but not limited to:

- relative proportions of net revenues comprised of contract manufacturing and sales of ANI generic and branded products;
- pricing and payment terms with customers;
- costs of raw materials and payment terms with suppliers;
- capital expenditures and equipment purchases to support product launches;
- business and product acquisitions; and
- regulatory actions.

Many of these factors will depend on circumstances beyond ANI's control. For example, ANI's net revenues are concentrated among three customers representing 21 percent, 16 percent and 16 percent of net revenues, respectively, during the year ended December 31, 2011, and 24 percent, 21 percent and 12 percent of net revenues, respectively, during the nine months ended September 30, 2012. As of September 30, 2012, accounts receivable from these three customers totaled $3.6 million, or approximately 64 percent of ANI's net accounts receivable. As a result, negotiated payment terms with these customers have a material impact on ANI's liquidity and working capital.

In addition, two of ANI's generic pharmaceutical products, Opium Tincture and Fluvoxamine Maleate tablets, account for approximately 30 percent of ANI's net revenues. As a result, regulatory actions with respect to these products, market pricing for these products, combined with the costs of raw materials and payment terms with suppliers, have a material impact on ANI's liquidity and working capital.

Table of Contents

If ANI continues to incur losses and is not able to raise adequate funds to cover those losses, it may be required to curtail its activities, which could have a material adverse effect on its business, financial condition and/or results of operations. The continuing global economic uncertainty, exacerbated by the European debt crisis and the "fiscal cliff" in the United States, has resulted in extreme volatility in the capital markets and is threatening to once again tighten the credit markets. As a result, there can be no assurances that ANI would be successful in obtaining sufficient financing on commercially reasonable terms or at all. To the extent that ANI raises additional capital through the sale of securities, the issuance of those securities or shares underlying such securities would result in dilution that could be substantial to its and the combined company's stockholders. In addition, if ANI incurs additional debt financing, a substantial portion of its operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for business activities. If adequate funds are not available, ANI's business, financial condition and/or results of operations could be materially and adversely affected.

***ANI's anticipated revenue growth and profitability, if achieved, is dependent upon ANI's ability to develop and/or license, or otherwise acquire, and introduce new products on a timely basis in relation to its competitors' product introductions, and to navigate the regulatory hurdles before, during and after the introduction of its new products. ANI's failure to do so successfully could have a material adverse effect on its business, financial position and results of operations.***

ANI's future revenues and profitability will depend, to an extent, upon its ability to successfully develop, license or otherwise acquire, and commercialize, branded and generic pharmaceutical products in a timely manner. Product development is inherently risky and time-consuming. Likewise, product licensing involves inherent risks including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to the supply of product meeting specifications and terms such as license scope or termination rights. The development and commercialization process also requires substantial time, effort and financial resources. ANI may not be successful in commercializing products on a timely basis, if at all, which could adversely affect its business, financial position and results of operations.

Before any new prescription drug product can be marketed in the United States, marketing authorization approval is required by the FDA. The process of obtaining regulatory approval to manufacture and market branded and generic pharmaceutical products is rigorous, time consuming, costly and largely unpredictable. ANI may be unable to obtain requisite approvals on a timely basis for branded or generic products that it may develop, license or otherwise acquire. Moreover, if ANI obtains regulatory approval for a drug, it may be limited with respect to the indicated uses and delivery methods for which the drug may be marketed, which in turn could restrict its potential market for the drug. Also, for products pending approval, ANI may obtain raw materials or produce batches of inventory to be used in bioequivalence testing, as well as in anticipation of the product's launch. In the event that regulatory approval is denied or delayed, ANI could be exposed to the risk of this inventory becoming obsolete. The timing and cost of obtaining regulatory approvals could adversely affect ANI's product introduction plans, business, financial position and results of operations.

The approval process for generic pharmaceutical products often results in the FDA granting simultaneous final approval to a number of generic pharmaceutical products at the time a patent claim for a corresponding branded product or other market exclusivity expires. This often forces a generic firm to face immediate competition when it introduces a generic product into the market. Additionally, further generic approvals often continue to be granted for a given product subsequent to the initial launch of the generic product. These circumstances generally result in significantly lower prices, as well as reduced margins, for generic products compared to branded products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle.

Table of Contents

The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), provides for a period of 180 days of generic marketing exclusivity for each abbreviated new drug application (ANDA) applicant that is first-to-file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, which under certain circumstances may be required to be shared with other applicable ANDA sponsors with Paragraph IV certifications, the FDA cannot grant final approval to other ANDA sponsors holding applications for the same generic equivalent. If an ANDA containing a Paragraph IV certification is successful and the applicant is awarded exclusivity, the applicant generally enjoys higher market share, net revenues and gross margin for that product than otherwise would be the case. However, an ANDA sponsor's ability to obtain 180 days of generic marketing exclusivity may be dependent upon its ability to obtain FDA approval or tentative approval within 30 months of the FDA's acceptance of its ANDA. If ANI is unable to obtain approval or tentative approval within that time period, it may risk forfeiture of such marketing exclusivity. Even if ANI obtains FDA approval for its generic drug products, if it is not the first ANDA applicant to challenge a listed patent for such a product, it may lose significant advantages to a competitor that filed its ANDA containing such a challenge. The same would be true in situations where ANI is required to share its exclusivity period with other ANDA sponsors with Paragraph IV certifications. Such situations could have a material adverse effect on ANI's ability to market that product profitably and on its business, financial position and results of operations.

If ANI is unable to navigate its products through all of the regulatory hurdles it faces in a timely manner, its product introduction plans, business, financial position and results of operations could be materially adversely affected.

The FDA regulates and monitors all promotion advertising and of prescription drugs after approval. All promotion must be consistent with the conditions of approval and submitted to the agency. Failure to adhere to FDA promotional requirements can result in enforcement letters, warning letters, changes to existing promotional material, and corrective notices to healthcare professionals. Promotion of a prescription drug for uses not approved by the FDA can have serious consequences and result in lawsuits by private parties, state governments and the federal government, significant civil and criminal penalties, and compliance agreements that require the company to change current practices and prevent unlawful activity in the future.

***ANI's operating results and financial condition may fluctuate.***

ANI's operating results and financial condition may fluctuate from quarter to quarter and year to year for a number of reasons. The following events or occurrences, among others, could cause fluctuations in ANI's financial performance from period to period:

development of new competitive products or generics by others;

the timing and receipt of approvals by the FDA;

the failure to obtain, delay in obtaining or restrictions or limitations on approvals from the FDA;

difficulties or delays in resolving FDA-observed deficiencies at ANI's manufacturing facilities, which could delay ANI's ability to obtain approvals of pending FDA product applications;

serious or unexpected health or safety concerns with ANI's products or product candidates;

changes in the amount ANI is required to spend to develop, acquire or license new products, technologies or businesses;

changes in the amount ANI spends to promote ANI's products;

Table of Contents

delays between ANI's expenditures to acquire new products, technologies or businesses and the generation of revenues from those acquired products, technologies or businesses;

changes in treatment practices of physicians that currently prescribe ANI's products;

changes in coverage and reimbursement policies of health plans and other health insurers, including changes that affect newly developed or newly acquired products;

changes in laws and regulations concerning coverage and reimbursement of pharmaceutical products, including changes to Medicare, Medicaid, and similar state programs;

increases in the cost of raw materials used to manufacture ANI's products;

manufacturing and supply interruptions, including failure to comply with manufacturing specifications;

the impact of third party patents and other intellectual property rights which ANI may be found to infringe, or may be required to license, and the potential damages or other costs it may be required to pay as a result of a finding that it infringes such intellectual property rights or a decision that it is required to obtain a license to such intellectual property rights;

the mix of products that ANI sells during any time period;

lower than expected demand for ANI's products;

ANI's responses to price competition;

ANI's ability to successfully integrate and commercialize the products, technologies and businesses it acquires or licenses, as applicable;

expenditures as a result of legal actions;

market acceptance of ANI's products;

the impairment and write-down of goodwill or other intangible assets;

disposition of ANI's primary products, technologies and other rights;

termination or expiration of, or the outcome of disputes relating to, trademarks, patents, license agreements and other rights;

changes in insurance rates for existing products and the cost and availability of insurance for new and existing products;

general economic and industry conditions, including changes in interest rates affecting returns on cash balances and investments that affect customer demand;

ANI's level of research and development activities;

impairment or write-down of investments;

costs and outcomes of any tax audits;

costs and outcomes of any litigation involving intellectual property, drug pricing or reimbursement, product liability, customers or other issues; and

timing of revenue recognition related to licensing agreements and/or strategic collaborations.

As a result, ANI believes that period-to-period comparisons of ANI's results of operations are not necessarily meaningful, and these comparisons should not be relied upon as an indication of future performance. The above factors may cause ANI's operating results to fluctuate and adversely affect ANI's financial condition and results of operations.

Table of Contents

***ANI's obligations under its line of credit are secured by substantially all of its assets. If ANI defaults under the line of credit, the lender may take immediate possession of the collateral and dispose of it.***

Under its line of credit with Alostar Bank of Commerce, ANI may borrow on a revolving basis, based on a percentage of eligible accounts receivable and inventory, up to a maximum of $5.0 million. The loan agreement bears interest daily at the greater of (i) LIBOR plus 5 percent or (ii) 6 percent. The line of credit is secured by substantially all of ANI's assets. The principal is repayable at the termination date, unless accelerated as a result of certain events of default. If ANI generates any proceeds from the collateral securing the line of credit, such proceeds must be paid to the lender up to the amount of any outstanding balance. Interest is due and payable on the first of every month and at the termination date, unless accelerated as a result of an event of default. In addition, a usage fee equal to 0.375 percent per annum of the unused amounts under the facility and a management fee equal to $18,000 per annum are assessed monthly. The revolving loan agreement expires in June 2015, but can be terminated early in the following circumstances: (a) automatically upon the commencement of insolvency proceedings by or against ANI, (b) at the option of the lender without notice upon any other event of default, and (c) at the option of ANI upon ten business days' prior written notice.

In the event of early termination, whether effected by ANI, the lender or automatically, ANI is obligated to pay an amount corresponding to a percentage of $5.0 million, with such percentage being: 3 percent if termination occurs in the first year, 2 percent if termination occurs in the second year and 1 percent if termination occurs after the second year but prior to the last day of the term. The loan agreement contains customary representations, warranties and covenants. As of September 30, 2012, approximately $3.4 million was outstanding under the loan agreement, at an effective interest rate of 6.0 percent.

Events of default under the agreement include, but are not limited to: (i) liquidation, bankruptcy or similar events; (ii) failure to pay any debts due on a timely basis; (iii) failure to observe any covenant or condition under the loan agreement, which failure, in most cases, is not cured within 30 days of written notice by lender; (iv) material misrepresentations; (v) ANI is restrained by court order from continuing to conduct all or any material part of ANI's business; (vi) certain money judgments are entered against ANI; and (vii) ANI challenges the validity or enforceability of the loan agreement in any proceeding. Remedies for events of default include acceleration of amounts owing under the loan agreement and taking immediate possession of, and selling, any collateral securing the loan, which would have a material adverse effect on ANI's profitability, business, financial position and results of operations.

***ANI's approved products may not achieve expected levels of market acceptance, which could have a material adverse effect on its profitability, business, financial position and results of operations.***

Even if ANI is able to obtain regulatory approvals for its pharmaceutical products, the success of those products is dependent upon market acceptance. Levels of market acceptance for products could be impacted by several factors, including but not limited to:

- the availability of alternative products from ANI's competitors;
- the price of ANI's products relative to that of ANI's competitors;
- the timing of ANI's market entry;
- the ability to market ANI's products effectively to the retail level; and
- the acceptance of ANI's products by government and private formularies.

Some of these factors are not within ANI's control. Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and

Table of Contents

techniques, can call into question the utilization, safety and efficacy of previously marketed products. In some cases, studies have resulted, and in the future may result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry. These situations, should they occur, could have a material adverse effect on ANI's profitability, business, financial position and results of operations.

***Certain of ANI's generic products are marketed without approved NDAs or ANDAs and ANI can offer no assurances that the FDA will not require ANI to seek approval for these products or withdraw them from the market. In either case, ANI's business, financial position and results of operations could be materially adversely affected.***

Certain of ANI's generic products are marketed without approved NDAs or ANDAs, specifically, Esterified Estrogen with Methyltestosterone and Opium Tincture. During the nine months ended September 30, 2012 and 2011, combined net revenues for these products were $3.6 million and $2.2 million, respectively and during the years ended December 31, 2011 and 2010, combined net revenues for these products were $3.5 million and $95,000, respectively.

The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide, titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While ANI believes that so long as it complies with applicable manufacturing and labeling standards, it will not be targeted for enforcement under the FDA's current enforcement policy, it can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products.

In October 2012, ANI received a telephone call requesting a meeting with the FDA representatives from the Minneapolis district of the FDA to discuss continued manufacturing and distribution of Opium Tincture, which is an unapproved product. That meeting was held on October 25, 2012 by conference telephone call and included FDA representatives from the Office of Compliance at the Center for Drug Evaluation and Research (CDER). Discussions with CDER are continuing. If, as a result of such discussions or otherwise, the FDA were to make a determination that ANI could not continue to sell Opium Tincture as an unapproved product, ANI would be required to seek FDA approval for such product or withdraw such product from the market. If ANI determined to withdraw the product from the market, ANI's net revenues for generic pharmaceutical products would decline materially, and if ANI decided to seek FDA approval, it would face increased expenses and might need to suspend sales of the product until such approval is obtained, and there are no assurances that ANI would receive such approval.

In addition, one group of products that ANI manufactures on behalf of a contract customer, and based on the sale of which ANI receives royalties, is marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market, which could materially adversely affect ANI's contract manufacturing and royalty revenue. ANI's contract manufacturing revenue for this group of products for the nine months ended September 30, 2012 and 2011 was $775,000 and $1.1 million, respectively. ANI's royalties on the net sales of these products for the nine months ended September 30, 2012 and 2011 were $220,000 and $249,000, respectively. ANI's contract manufacturing revenue for the group of unapproved products for the years ended December 31, 2011 and 2010 was $1.3 million and $623,000, respectively. ANI's royalties on the net sales of these unapproved products for the years ended December 31, 2011 and 2010 were $320,000 and $118,000, respectively.

Table of Contents

ANI's manufacture and distribution of drugs without approved NDAs or ANDAs could also result in legal actions by private parties, state governments or the federal government. These entities may allege that ANI has misrepresented the regulatory status of Esterified Estrogen with Methyltestosterone and Opium Tincture resulting in the submission of false claims to federal and state health care programs. Such legal actions could result in fines, penalties, reimbursement, and legal settlements that could bind the company going forward and materially affect ANI's ability to market these products as well as the profitability of ANI's business, financial position and results of operations.

***ANI began its own product development program in 2011 and expects to spend a significant amount of resources on research and development efforts that may not lead to successful product introductions. Failure to successfully introduce products into the market could have a material adverse effect on its business, financial position and results of operations.***

ANI conducts research and development primarily to enable it to manufacture and market approved pharmaceuticals in accordance with applicable regulations. As ANI develops new products, its research expenses likely will increase. Because of the inherent risk associated with research and development efforts in the industry, ANI's research and development expenditures may not result in the successful introduction of new pharmaceutical products approved by the FDA. Also, after ANI submits a marketing authorization application for a generic product, the FDA may change standards and/or request that ANI conduct additional studies and, as a result, ANI may incur total research and development costs to develop a particular product in excess of what it anticipated. Finally, ANI cannot be certain that any investment made in developing products will be recovered, even if it is successful in commercialization. To the extent that ANI spends significant resources on research and development efforts and is not able, ultimately, to introduce successful new products as a result of those efforts, its business, financial position and results of operations may be materially adversely affected.

***ANI is entirely dependent on periodic approval by the DEA for the supply of the active pharmaceutical ingredient needed to make Opium Tincture and inability to obtain such approval would reduce or eliminate revenues from the sale of Opium Tincture. In addition, ANI is subject to strict regulation by the DEA and is subject to sanctions if it is unable to comply with related regulatory requirements.***

The Drug Enforcement Administration (DEA) regulates certain drug products containing controlled substances, such as opium, pursuant to the U.S. Controlled Substances Act (CSA). The CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

In addition, each year, ANI must submit a request to the DEA for a quota to purchase the amount of active pharmaceutical ingredient needed to manufacture Opium Tincture. Without an approved quota from DEA, ANI would not be able to purchase this ingredient from its supplier. As a result, ANI is entirely dependent upon the DEA to approve, on an annual basis, a quota of active pharmaceutical ingredient that is sufficiently large to support the continued manufacture of Opium Tincture at levels that would maximize ANI's revenues or profits.

Table of Contents

***ANI may have to engage in litigation, which could result in substantial cost or distraction, to enforce or defend its proprietary rights and which, if ANI did not prevail, could harm its business and make it more vulnerable to competition.***

In the future, ANI may have to engage in litigation to enforce or defend its proprietary rights, for example, its rights of market exclusivity with respect to certain of its products, or any trademarks it owns for its branded products, such as Cortenema® and Reglan®. In the branded pharmaceutical industry, the majority of an innovative product's commercial value is usually realized during the period in which the product has market exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there often can be very substantial and rapid declines in the branded product's sales; however, following patent expiration, branded products often continue to have market viability based upon the goodwill of the product name, which typically benefits from trademark protection. ANI believes that sales of its branded products have and will continue to benefit from the goodwill of the product name. ANI, therefore, considers market exclusivity and its trademark names to be of material value and acts to protect these rights from infringement.

***ANI may in the future be accused of infringing intellectual property rights of third parties and may have to engage in litigation to determine the scope and validity of third party patents and proprietary rights, which, if it does not prevail, could harm its business, results of operations, financial condition, cash flow and future prospects.***

Third parties in the future may file patent applications and obtain patents relating to ANI's products and technologies. Regardless of their ultimate merit, any infringement or other intellectual property claims against ANI's products and technologies may be expensive and time-consuming to litigate and may divert management attention. If any such claim were successful, ANI could be required to obtain licenses to a third party's technologies, patents or other proprietary rights or to their biological or chemical reagents in order to develop and market ANI's products. Moreover, ANI may choose to voluntarily seek such a license in order to avoid the expense and uncertainty of fully defending its position. In either event, such a license may not be available to ANI on acceptable terms or at all, and ANI may have to discontinue that portion of its business. In addition, to the extent ANI licenses its intellectual property to other parties, ANI may incur expenses as a result of contractual agreements in which ANI indemnifies those licensing its technologies against losses incurred if practicing its intellectual property infringes upon the proprietary rights of others. The failure to license any technologies or biological or chemical reagents required to develop or commercialize ANI's technologies or products at reasonable cost may harm ANI's business, results of operations, financial condition, cash flow and future prospects.

***ANI does not own or license any patents associated with its products, and its ability to protect and control unpatented trade secrets, know-how and other technological innovation is limited.***

Generally, the branded pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. ANI does not own or license any patents associated with its products and therefore does not enjoy the same level of intellectual property protection with respect to such products as would a pharmaceutical manufacturer that markets a patented product. ANI has a limited ability to protect and control trade secrets, know-how and other technological innovation, all of which are unpatented. Others independently may develop similar or better proprietary information and techniques and disclose them publicly. Also, others may gain access to ANI's trade secrets, and ANI may not be able to meaningfully protect its rights to its unpatented trade secrets. In addition, confidentiality agreements and other measures may not provide meaningful protection for ANI's trade secrets in the event of unauthorized use or disclosure of such information. Failure to protect and

Table of Contents

control such trade secrets, know-how and innovation could harm the value of ANI's trade secrets, know-how and other technological innovation.

***ANI faces vigorous competition from other pharmaceutical manufacturers that threatens the commercial acceptance and pricing of its products. Such competition could have a material adverse effect on its business, financial position and results of operations and cash flows.***

The generic pharmaceutical industry is highly competitive. ANI faces competition from many U.S. and foreign manufacturers, some of whom are significantly larger than ANI. Its competitors may be able to develop products and processes competitive with or superior to ANI's for many reasons, including but not limited to the possibility that they may have:

- proprietary processes or delivery systems;
- larger research and development and marketing staffs;
- larger production capabilities in a particular therapeutic area;
- more products; or
- more experience in developing new drugs and greater financial resources, particularly with regard to manufacturers of branded products.

Any of these factors and others could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.

***The use of legal, regulatory and legislative strategies by competitors, both branded and generic, including "authorized generics" and citizen's petitions, as well as the potential impact of proposed legislation, may increase ANI's costs associated with the introduction or marketing of ANI's generic products, could delay or prevent such introduction and/or could reduce significantly ANI's profit potential. These factors could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.***

ANI's competitors, both branded and generic, often pursue strategies to prevent or delay competition from generic alternatives to branded products. These strategies include, but are not limited to:

- entering into agreements whereby other generic companies will begin to market an authorized generic, a generic equivalent of a branded product, at the same time generic competition initially enters the market;
- launching a generic version of their own branded product at the same time generic competition initially enters the market;
- filing citizen's petitions with the FDA or other regulatory bodies, including timing the filings so as to thwart generic competition by causing delays of ANI's product approvals;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence or meet other approval requirements;
- initiating legislative and regulatory efforts to limit the substitution of generic versions of branded pharmaceuticals;

filing suits for patent infringement that may delay regulatory approval of many generic products;

introducing "next-generation" products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the first generic product for which ANI seeks regulatory approval;

Table of Contents

obtaining extensions of market exclusivity by conducting clinical trials of branded drugs in pediatric populations or by other potential methods;

persuading regulatory bodies to withdraw the approval of branded name drugs for which the patents are about to expire, thus allowing the branded name company to obtain new patented products serving as substitutes for the products withdrawn; and

seeking to obtain new patents on drugs for which patent protection is about to expire.

In the United States, some companies have lobbied Congress for amendments to the Hatch-Waxman Act that would give them additional advantages over generic competitors. For example, although the term of a company's drug patent can be extended to reflect a portion of the time an NDA is under regulatory review, some companies have proposed extending the patent term by the full amount of time spent in clinical trials rather than by only one half of the time that is currently permitted.

If proposals like these were to become effective, ANI's entry into the market and its ability to generate revenues associated with new products may be delayed, reduced or eliminated, which could have a material adverse effect on its business, financial position, results of operations and cash flows.

***ANI faces significant uncertainty with respect to the litigation brought against it and other manufacturers of metoclopramide and cannot provide assurances that the outcome of the matter will not have an adverse effect on its financial position, results of operations and/or cash flows from operations. In addition, ANI may be exposed to other product liability claims in the future.***

In February 2009, the FDA mandated a "black box" warning for the drug metoclopramide, specifically highlighting the risks of patients developing tardive dyskinesia, a movement disorder, when taking metoclopramide for longer than 12 weeks. As a result, numerous state-level lawsuits were brought against pharmaceutical manufacturers, both branded and generic, who ever had manufactured and/or sold metoclopramide. Among the defendants is ANI, which manufactures the generic version and since 2011 has been manufacturing the branded version under the name Reglan®. The plaintiffs in these lawsuits claim to have incurred bodily injuries as a result of ingestion of metoclopramide or Reglan® prior to the FDA's black box warning requirement. The allegations involve a failure, based on various state-level consumer protection laws, to adequately warn patients and doctors about the risks of using metoclopramide for longer than 12 weeks as evidenced by the FDA's mandate to strengthen the labeled warning. ANI has been named and served in 79 separate complaints between December 2009 and November 2012, including three in Pennsylvania, nine in New Jersey, and 67 in California, covering 2,921 plaintiffs in total. In August 2012, ANI was dismissed with prejudice as a defendant in all of the cases brought in New Jersey.

As the state-level litigation progressed, the generic pharmaceutical defendants appealed to the U.S. Supreme Court arguing that generic companies could not comply with state laws that required them to strengthen their labels because generic companies are prohibited by federal law from making any changes except those adopted by the brand or mandated by FDA for all manufacturers, e.g. federal pre-emption. The U.S. Supreme Court decided in favor of the generic companies in June 2011 in what is known now as the Mensing decision. While many cases since have been dismissed by state courts, several judges, including in Pennsylvania and California, have allowed the plaintiffs to resubmit their complaints.

At the present time, ANI's management is unable to assess the likely outcome of the remaining cases. ANI's insurance company has assumed the defense of this matter. In addition, ANI's insurance company renewed ANI's product liability insurance on September 1, 2011 and 2012 with absolute exclusions for claims related to Reglan® and metoclopramide. ANI cannot provide assurances that the outcome of these matters will not have an adverse effect on its business, results of operations, financial

Table of Contents

condition and cash flow. Furthermore, like all pharmaceutical manufacturers, ANI in the future may be exposed to other product liability claims, which could harm its business, results of operations, financial condition and cash flow.

***ANI may experience declines in the sales volume and prices of its products as the result of the continuing trend toward consolidation of certain customer groups, such as the wholesale drug distribution and retail pharmacy industries, as well as the emergence of large buying groups. These developments could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.***

Consolidation among wholesale distributors, chain drug stores, and group purchasing organizations, has resulted in a smaller number of companies each controlling a larger share of pharmaceutical distribution channels. For example, ANI's net revenues are concentrated among three customers representing 24 percent, 21 percent and 12 percent of net revenues, respectively, during the nine months ended September 30, 2012. As of September 30, 2012, accounts receivable from these three customers totaled $3.6 million, or approximately 64 percent of ANI's net accounts receivable. Drug wholesalers and retain pharmacy chains, which represent an essential part of the distribution chain of generic pharmaceutical products, have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing ANI's business. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions potentially enable those groups to extract price discounts on ANI's products. The result of these developments may have a material adverse effect on ANI's business, financial position, results of operations and cash flows.

***Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could affect adversely the market for ANI's hormone products.***

The market for hormone therapy products has been affected negatively by the Women's Health Initiative (WHI) study and other studies that have found that the overall health risks from the use of certain hormone therapy products may exceed the benefits from the use of those products among postmenopausal women. In July 2002, the NIH released data from its WHI study on the risks and benefits associated with long-term use of oral hormone therapy by women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for an average of 5.2 year follow-up among postmenopausal women. Also, in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom also was halted. In March 2004, the NIH announced that the estrogen-alone study was discontinued after nearly seven years because the NIH concluded that estrogen alone does not affect (either increase or decrease) heart disease, the major question being evaluated in the study. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture and breast cancer. Preliminary data from the memory portion of the WHI study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment.

Researchers continue to analyze data from both arms of the WHI study and other studies. Some reports indicate that the safety of estrogen products may be affected by the age of the woman at initiation of therapy. The markets for female hormone therapies for menopausal symptoms declined as

Table of Contents

a result of these published studies, although the market now seems to have stabilized. The release of any follow-up or other studies that show adverse effects from hormone therapy, including in particular, hormone therapies similar to ANI's products, also could affect adversely ANI's business.

***ANI has a limited number of manufacturing facilities producing a substantial portion of its products. Production at any one of these facilities could be interrupted, which could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.***

A substantial portion of ANI's capacity as well as its current production is attributable to a limited number of manufacturing facilities and certain third party suppliers. During the nine months ended September 30, 2012, ANI purchased approximately 43 percent of total costs of goods sold from two suppliers. A significant disruption at any one of the facilities within ANI's internal supply chain, even on a short-term basis, whether due to a labor strike, failure to reach acceptable agreement with labor and unions, adverse quality or compliance observation, act of God, civil or political unrest, or other events could impair ANI's ability to produce and ship products to the market on a timely basis and, among other consequences, could subject ANI to exposure to claims from customers. Any of these events could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.

Virtually all contracts for the supply of pharmaceutical products by ANI to customers contain "failure to supply" clauses. Under these clauses, if ANI is unable to supply the requested quantity of product within a certain period after receipt of a customer's purchase order, the customer is entitled to procure a substitute product elsewhere and ANI must reimburse its customer for the difference between ANI's contract price and the price the customer was forced to pay to procure the substitute product. This difference can be substantial because of the much higher spot price at which the customer must cover its requirements, and can be far in excess of the revenue that ANI would otherwise have received on the sale of its own product. The ability to produce and ship a sufficient quantity of product is therefore critical to ANI.

***ANI depends on a limited number of suppliers for active pharmaceutical ingredients.***

ANI's ability to manufacture and distribute drug products is dependent, in part, upon ingredients and components supplied by others, including entities based outside the United States. Any disruption in the supply of these ingredients or components or any problems in their quality could materially affect ANI's ability to manufacture and distribute drug product and could result in legal liabilities that could materially affect ANI's ability to realize profits or otherwise harm ANI's business, financial, and operating results. ANI sources the raw materials for its products, including active pharmaceutical ingredients (API) from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers must usually be approved through a Prior Approval Supplement by the FDA. As the API typically comprises the majority of a product's manufactured cost, and qualifying an alternative is costly and time-consuming, API suppliers must be selected carefully based on quality, reliability of supply and long-term financial stability.

As described above, virtually all contracts for the supply of pharmaceutical products by ANI to customers contain "failure to supply" clauses. The ability to source sufficient quantities of active pharmaceutical ingredients for manufacturing is therefore critical to ANI. For Opium Tincture, this ability to source adequate amounts of raw material is in turn dependent on the quota set by the DEA. See also "Risks Related to ANI  ANI is entirely dependent on periodic approval by the DEA for the supply of the active pharmaceutical ingredient needed to make Opium Tincture and inability to obtain such approval would reduce or eliminate revenues from the sale of Opium Tincture. In addition, ANI is subject to strict regulation by the DEA and is subject to sanctions if it is unable to comply with related regulatory requirements."

Table of Contents

***Legislative or regulatory programs that may influence prices of pharmaceutical products could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.***

Current or future federal, state or foreign laws and regulations may influence the prices of drugs and, therefore, could adversely affect the prices that ANI receives for its products. For example, programs in existence in certain states in the U.S. seek to set prices of all drugs sold within those states through the regulation and administration of the sale of prescription drugs. Expansion of these programs, in particular state Medicaid programs, or changes required in the way in which Medicaid rebates are calculated under such programs, could adversely affect the prices ANI receives for its products and could have a material adverse effect on its business, financial position, results of operations and cash flows.

***Healthcare reform legislation could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.***

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States, and it is likely that federal and state legislatures and health agencies will continue to focus on health care reform in the future. The Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education and Reconciliation Act, which amends the PPACA (collectively the Health Reform Laws), were signed into law in March 2010. While the Health Reform Laws may increase the number of patients who have insurance coverage for ANI's products, they also include provisions such as the assessment of a pharmaceutical manufacturer fee and an increase in the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs.

The cost-containment measures that healthcare providers are instituting and the results of healthcare reforms such as the PPACA may prevent ANI from maintaining prices for its products that are sufficient for ANI to realize profits and may otherwise significantly harm its business, financial condition and operating results. In addition, to the extent that ANI's approved products are marketed outside of the United States, foreign government pricing controls and other regulations may prevent ANI from maintaining prices for such products that are sufficient for ANI to realize profits and may otherwise significantly harm its business, financial condition and operating results.

ANI is unable to predict the future course of federal or state healthcare legislation. The Health Reform Laws and further changes in the law or regulatory framework that reduce ANI's revenues or increase its costs could have a material adverse effect on its business, financial condition, results of operations and cash flows.

***If third-party payers deny coverage or offer inadequate levels of reimbursement, ANI or any of its strategic partners may not be able to market its products effectively or it may be required to offer its products at prices lower than anticipated.***

Third-party payers increasingly are challenging the prices charged for medical products and services. For example, third-party payers may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA, or foreign equivalent, or other government regulators, is not used in accordance with cost-effective treatment methods as determined by the third-party payer, or is experimental, unnecessary or inappropriate. Prices also could be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. If third-party payers deny coverage or offer inadequate levels of reimbursement, ANI or any of its strategic partners may not be able to market its products effectively or it may be required to offer its products at prices lower than anticipated.

Table of Contents

***ANI is subject to federal, state and local laws and regulations, and complying with these may cause ANI to incur significant costs.***

The pharmaceutical industry is subject to regulation by various federal authorities, including principally the FDA and, to a lesser extent, the U.S. Drug Enforcement Administration, and state governmental authorities. The U.S. Federal Food, Drug, and Cosmetic Act, the Controlled Substances Act of 1970 and other federal statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of ANI's products. Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunction, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, civil penalties, debarment and criminal prosecution.

ANI's research, product development and manufacturing activities have involved the controlled use of hazardous materials, and ANI may incur significant costs as a result of the need to comply with numerous laws and regulations. ANI is subject to laws and regulations enforced by the FDA, the DEA, and other regulatory statutes including the Occupational Safety and Health Act (OSHA), the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of ANI's products, materials used to develop and manufacture such products, and resulting waste products. For example, certain of ANI's products, including Esterified Estrogen with Methyltestosterone, must be manufactured in a fully contained environment due to their potency and/or toxicity, and compliance with related OSHA requirements is costly.

ANI cannot completely eliminate the risk of contamination or injury, by accident or as the result of intentional acts from these materials. In the event of an accident, ANI could be held liable for any damages that result, and any resulting liability could exceed its resources. ANI may also be required to incur significant costs to comply with environmental laws and regulations in the future. ANI is also subject to laws generally applicable to businesses, including but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistle-blowing. Any actual or alleged failure to comply with any regulation applicable to its business or any whistle-blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm ANI's business, results of operations, financial condition, cash flow and future prospects.

Table of Contents

## CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This joint proxy statement/prospectus contains "forward-looking statements" of BioSante within the meaning of the Private Securities Litigation Reform Act of 1995, which is applicable to BioSante, but not ANI, because BioSante, unlike ANI, is a public company subject to the reporting requirements of the Exchange Act. For this purpose, any statements contained herein regarding BioSante, other than statements of historical fact, may be forward-looking statements under the provisions of the Private Securities Litigation Reform Act of 1995. In addition, any statements contained herein regarding ANI, other than statements of historical fact, should be considered forward-looking statements. Such statements can be identified by the fact that they do not relate strictly to historical or current facts. Statements that include words such as "expect," "believe," "will," "may," "might," "anticipate," "continue," "plan," "estimate," "intend," "should," "can," "likely," "could," "predict," "project," "forecast," "potential," "possible" or the negative of these words or other words or expressions of similar meaning may identify forward-looking statements. These forward-looking statements are found at various places throughout this joint proxy statement/prospectus and relate to a variety of matters, including but not limited to:

- the timing and anticipated completion of the proposed merger between BioSante and ANI;
- the expected benefits of and potential value created by the proposed merger for the stockholders of BioSante and ANI;
- the amount of cash and cash equivalents that will be available to fund the combined company's business after the merger and the length of time that the combined company anticipates such cash and cash equivalents will be available to fund the combined company's operating plan after the merger;
- the likelihood of the satisfaction of certain conditions to completion of the merger and whether and when the merger will be completed;
- the amount of shares of BioSante common stock that BioSante expects to issue in the proposed merger and the post-capitalization of the combined company after the merger;
- BioSante's and ANI's respective results of operations, financial condition and businesses and their respective objectives, plans and expectations; and
- information about the combined company and the expected impact of the proposed merger on the combined company and its future business, operating results and financial condition.

These statements are subject to risks and uncertainties, including the risks described in this joint proxy statement/prospectus under the section "Risk Factors," that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements in this joint proxy statement/prospectus. Forward-looking statements are not guarantees of performance. These statements are based upon the current beliefs and expectations of management of BioSante and ANI and are subject to a number of factors that could cause actual outcomes and results to be materially different from those projected or anticipated. Readers are cautioned not to place undue reliance on these forward-looking statements which speak only as of the date hereof. Except to the extent required by applicable law or regulation, neither BioSante nor ANI undertakes any obligation to update or publish revised forward-looking statements to reflect events or circumstances after the date hereof or the date of the forward-looking statements or to reflect the occurrence of unanticipated events.

Table of Contents

## THE SPECIAL MEETING OF BIOSANTE STOCKHOLDERS

### General

This joint proxy statement/prospectus is being furnished to stockholders of BioSante on or about January 25, 2013. BioSante is sending this joint proxy statement/prospectus to its stockholders in connection with the solicitation of proxies by the BioSante board of directors for use at the BioSante special meeting and any adjournments or postponements of the meeting.

### Date, Time and Place

The special meeting of BioSante stockholders will be held at 8:00 a.m., local time, on Friday, March 15, 2013, at BioSante's corporate office located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069.

### Purposes of the BioSante Special Meeting

The purposes of the BioSante special meeting are to consider and act upon the following matters:

1. To consider and vote upon a proposal to adopt the merger agreement, a copy of which is attached as Annex A to this joint proxy statement/prospectus, and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger.

2. To consider and vote upon a proposal to approve an amendment to BioSante's certificate of incorporation to effect a reverse split of BioSante common stock and BioSante class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five.

3. To consider and vote upon a proposal to approve an amendment to BioSante's certificate of incorporation to change the name of BioSante from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc."

4. To consider and vote upon a proposal to approve, on an advisory (non-binding) basis, the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger.

5. To consider and vote upon a proposal to approve an adjournment of the BioSante special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of BioSante Proposals No. 1, 2 and/or 3.

BioSante stockholders also will consider and act on any other matters as may properly come before the BioSante special meeting or any adjournment or postponement of the meeting, including any procedural matters incident to the conduct of the meeting.

### Recommendations of the BioSante Board of Directors

The BioSante board of directors has determined and believes that the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger, is advisable, fair to, and in the best interests of BioSante and its stockholders and unanimously has approved such proposal. The BioSante board of directors unanimously recommends that BioSante stockholders vote "**FOR**" BioSante Proposal No. 1 to approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger.

The BioSante board of directors has determined and believes that the amendment to BioSante's certificate of incorporation to effect a reverse split of BioSante common stock and BioSante class C

92

Table of Contents

special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five, as described in this joint proxy statement/prospectus, is advisable, fair to, and in the best interests of BioSante and its stockholders and unanimously has approved such proposal. The BioSante board of directors recommends unanimously that BioSante stockholders vote "**FOR**" BioSante Proposal No. 2 to approve the amendment to BioSante's certificate of incorporation to effect the reverse stock split.

The BioSante board of directors has determined and believes that the amendment to BioSante's certificate of incorporation to change the name of BioSante from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc.", as described in this joint proxy statement/prospectus, is advisable, fair to, and in the best interests of BioSante and its stockholders and unanimously has approved such proposal. The BioSante board of directors recommends unanimously that BioSante stockholders vote "**FOR**" BioSante Proposal No. 3 to approve the amendment to BioSante's certificate of incorporation to effect the corporate name change.

The BioSante board of directors unanimously recommends that BioSante stockholders vote "**FOR**" BioSante Proposal No. 4 to approve, on an advisory (non-binding) basis, the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger.

The BioSante board of directors unanimously recommends that BioSante stockholders vote "**FOR**" BioSante Proposal No. 5 to adjourn the BioSante special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of BioSante Proposals No. 1, 2 and/or 3.

**Record Date and Voting Power**

The close of business on January 17, 2013 has been fixed as the BioSante record date for the determination of BioSante stockholders entitled to notice of, and to vote at, the BioSante special meeting or any adjournments or postponements of the meeting. Only holders of record of BioSante common stock and BioSante class C stock at the close of business on the BioSante record date are entitled to notice of, and to vote at, the BioSante special meeting. At the close of business on the record date, BioSante had 24,422,240 shares of common stock and 65,211 shares of class C special stock outstanding and entitled to vote. Each share of BioSante common stock and BioSante class C special stock entitles the holder thereof to one vote on each matter submitted for stockholder approval. See "Principal Stockholders of BioSante" for information regarding persons known to management of BioSante to be the beneficial owners of more than five percent of the outstanding shares of BioSante common stock and BioSante class C special stock.

**Voting and Revocation of Proxies**

The proxy accompanying this joint proxy statement/prospectus is solicited on behalf of the BioSante board of directors for use at the BioSante special meeting. If you are a BioSante stockholder of record as of the record date for the BioSante special meeting, you may vote in person at the BioSante special meeting or vote by proxy over the Internet, by telephone or by using the enclosed proxy card. Whether or not you plan to attend the BioSante special meeting, BioSante urges you to vote by proxy to ensure your vote is counted. You still may attend the BioSante special meeting and vote in person if you already have voted by proxy. BioSante stockholders of record as of the close of business on January 17, 2013 may submit their proxies:

**through the Internet**, by visiting the website established for that purpose at https://www.proxyvote.com and following the instructions (please note you must type an "s" after http); or

Table of Contents

**by telephone**, by calling the toll-free number 1-800-690-6903 in the United States, Canada or Puerto Rico on a touch-tone phone, providing the unique 10-digit control number shown on the enclosed proxy card and following the recorded instructions; or

**by mail**, by marking, signing and dating the enclosed proxy card and returning it in the postage-paid envelope provided or returning it pursuant to the instructions provided in the proxy card.

If your shares are held in "street name," you must request a legal proxy from your nominee as proof of ownership in order to vote in person at the BioSante special meeting. **If you hold your shares in "street name," please refer to your proxy card or the information forwarded by your bank, broker or other holder of record to see which options are available to you.**

All properly executed proxies that are not revoked will be voted at the BioSante special meeting and at any adjournments or postponements of the meeting in accordance with the instructions contained in the proxy. If a holder of BioSante capital stock executes and returns a proxy and does not specify otherwise, the shares represented by that proxy will be voted "**FOR**" BioSante Proposal No. 1 to approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger; "**FOR**" BioSante Proposal No. 2 to approve an amendment to BioSante's certificate of incorporation to effect the reverse stock split described in this joint proxy statement/prospectus; "**FOR**" BioSante Proposal No. 3 to approve an amendment to BioSante's certificate of incorporation to effect the corporation name change; "**FOR**" BioSante Proposal No. 4 to approve on an advisory basis the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger; and "**FOR**" BioSante Proposal No. 5 to adjourn the BioSante special meeting, if necessary, if a quorum is present, to solicit additional proxies if there are not sufficient votes in favor of BioSante Proposals No. 1, 2 and/or 3 in accordance with the recommendation of the BioSante board of directors.

Any BioSante stockholder of record voting by proxy, other than those stockholders who have executed a voting agreement and irrevocable proxy, has the right to revoke the proxy at any time before the polls close at the BioSante special meeting by sending a written notice stating that it would like to revoke its proxy to the corporate secretary of BioSante, by voting again over the Internet or by telephone, by providing a duly executed proxy card bearing a later date than the proxy being revoked or by attending the BioSante special meeting and voting in person. Attendance alone at the BioSante special meeting will not revoke a proxy. A beneficial owner of BioSante common stock that holds shares in "street name" must follow directions received from the bank, broker or other nominee that holds the shares to change its voting instructions.

**Quorum and Required Vote**

The presence at the BioSante special meeting, in person or by proxy, of the holders of one-third (8,162,484 shares) of the outstanding shares of BioSante capital stock as of the record date will constitute a quorum for the transaction of business at the BioSante special meeting. In general, shares of BioSante common stock and shares of BioSante class C special stock represented by a properly signed and returned proxy card will be counted as shares present and entitled to vote at the BioSante special meeting for purposes of determining a quorum. Shares represented by proxies marked "Abstain" or "Withheld" are counted in determining whether a quorum is present. In addition, a "broker non-vote" is considered in determining whether a quorum is present. A "broker non-vote" is a proxy returned by a broker on behalf of its beneficial owner customer that is not voted on a particular matter because voting instructions have not been received by the broker from the customer, and the broker does not have discretionary authority to vote on behalf of such customer on such matter. If a quorum is not present at the BioSante special meeting, BioSante expects that the BioSante special meeting will be adjourned or postponed to solicit additional proxies.

Table of Contents

A description of the vote required to approve each proposal being submitted to a vote of BioSante stockholders is included with the description of each proposal. For BioSante Proposals No. 1, 2 and 3, a failure to vote by proxy or in person at the BioSante special meeting, or an abstention, vote withheld or "broker non-vote" for such proposals, will have the same effect as a vote against the approval of such proposals. For BioSante Proposals No. 4 and 5, a failure to submit a proxy card or vote at the BioSante special meeting, or an abstention, vote withheld or "broker non-votes" will have no effect on the outcome of such proposals.

The approval of the merger agreement and the transactions contemplated by it is not conditioned upon approval of the amendments to BioSante's certificate of incorporation to effect the reverse stock split or corporation name change. However, the approval of the amendments to BioSante's certificate of incorporation is conditioned upon approval of the merger agreement. Therefore, the proposals to amend BioSante's certificate of incorporation will only be effected if the merger agreement is approved by the stockholders of BioSante and ANI.

In connection with the execution of the merger agreement, all of BioSante's directors and officers, who collectively held approximately two percent of the outstanding shares of BioSante capital stock as of October 3, 2012, entered into a voting agreement with ANI, pursuant to which each stockholder agreed to vote all of their shares of BioSante capital stock in favor of adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger, in favor of the charter amendments and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transactions contemplated thereby.

**Solicitation of Proxies**

In addition to solicitation by mail, the directors, officers, employees and agents of BioSante may solicit proxies from BioSante stockholders by personal interview, telephone, telegram or other electronic means. BioSante will bear the costs of the solicitation of proxies by BioSante from BioSante stockholders. Arrangements also will be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of BioSante common stock for the forwarding of solicitation materials to the beneficial owners of BioSante common stock and BioSante class C special stock. BioSante will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials. BioSante has retained Phoenix Advisory Partners, a proxy solicitation firm, to assist in the solicitation of proxies for the merger for a fee of approximately $8,000.

**Delivery of Proxy Materials to Households Where Two or More Stockholders Reside**

Some banks, brokers and other nominee record holders may be participating in the practice of "householding" proxy statements. This means that only one copy of this joint proxy statement/prospectus to any BioSante stockholder may have been sent to multiple stockholders in each household. BioSante will promptly deliver a separate copy of this joint proxy statement/prospectus to any BioSante stockholder upon written or oral request to BioSante's Investor Relations Department, BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Lincolnshire, Illinois 60069, telephone: (847) 478-0500 ext. 120; e-mail: info@biosantepharma.com.

**Other Matters**

As of the date of this joint proxy statement/prospectus, the BioSante board of directors does not know of any business to be represented at the BioSante special meeting other than as set forth in the notice accompanying this joint proxy statement/prospectus. If any other matters should properly come before the BioSante special meeting, or any adjournment or postponement of the BioSante special meeting it is intended that the shares represented by proxies will be voted with respect to such matters in accordance with the judgment of the person voting the proxies.

Table of Contents

## MATTERS BEING SUBMITTED TO A VOTE OF BIOSANTE STOCKHOLDERS

**BioSante Proposal No. 1 Adoption of Agreement and Plan of Merger and the Transactions Contemplated Thereby, including the Merger and the Issuance of Shares of BioSante Common Stock in the Merger**

***General***

At the BioSante special meeting, BioSante stockholders will be asked to adopt the agreement and plan of merger dated as of October 3, 2012 by and between BioSante and ANI, as amended, a copy of which is attached as Annex A to this joint proxy statement/prospectus, and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger.

If the merger is completed, ANI will be merged with and into BioSante, with BioSante surviving the merger.

Pursuant to the terms of the merger agreement, upon completion of the merger, ANI stockholders will have the right to receive, for each share of ANI capital stock they hold, that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. Following completion of the merger, the current ANI stockholders are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current BioSante stockholders are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company, assuming BioSante's net cash as of the determination date is $18.0 million. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. If the merger had been completed on January 17, 2013, the record date for the BioSante special meeting, an aggregate of approximately 27.9 million shares of BioSante common stock would have been issuable to ANI stockholders upon completion of the merger (as determined prior to an anticipated reverse stock split of BioSante common stock), assuming BioSante's net cash as of the determination date was $18.0 million.

The terms of, reasons for and other aspects of the merger agreement, the merger and the issuance of shares of BioSante common stock in the merger are described in detail in the other sections of this joint proxy statement/prospectus. The full text of the merger agreement is attached to this joint proxy statement/prospectus as Annex A.

***Vote Required; Recommendation of BioSante Board of Directors***

The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, having voting power outstanding on the record date for the BioSante special meeting is required for approval of BioSante Proposal No. 1.

A failure to submit a proxy card or vote at the BioSante special meeting, or an abstention or "broker non-vote" will have the same effect as a vote against the approval of BioSante Proposal No. 1.

**The BioSante board of directors unanimously recommends that BioSante stockholders vote "FOR" BioSante's Proposal No. 1 to adopt the agreement and plan of merger and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger.**

Table of Contents

**BioSante Proposal No. 2 Approval of Amendment to BioSante's Certificate of Incorporation to Effect a Reverse Split of BioSante Common Stock and Class C Special Stock at the Discretion of BioSante and ANI at a Ratio of Either One-for-Two, One-for-Three, One-for-Four or One-for-Five.**

***General***

The BioSante board of directors has approved unanimously a proposal to amend BioSante's certificate of incorporation to effect a reverse stock split of the issued and outstanding shares of BioSante common stock and BioSante class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one for-four or one-for-five, with the exact ratio to be determined by BioSante and ANI prior to completion of the merger. The BioSante board of directors has recommended that this proposal be presented to the BioSante stockholders for approval. The text of the form of proposed amendment to BioSante's certificate of incorporation to effect a reverse stock split of the issued and outstanding shares of BioSante common stock and BioSante class C special stock is attached to this joint proxy statement/prospectus as Annex I.

The proposed amendment to BioSante's certificate of incorporation will effect a reverse stock split of the issued and outstanding shares of BioSante common stock and BioSante class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five, with the exact ratio to be determined by BioSante and ANI prior to completion of the merger. The BioSante board of directors believes that stockholder approval of an amendment granting this discretion, rather than approval of one specified ratio, provides BioSante and ANI the appropriate flexibility to react to then-current market conditions and, therefore, is in the best interests of BioSante and its stockholders.

By approving this amendment, BioSante stockholders will (i) approve a series of amendments to BioSante's certificate of incorporation pursuant to which a one-for-two, one-for-three, one-for-four or one-for-five reverse split of BioSante common stock and BioSante class C special stock will be effected, and (ii) authorize the BioSante board of directors to (a) file only one such amendment, as determined immediately prior to completion of the merger in the manner described herein and (b) abandon each amendment not selected. In addition, BioSante may elect not to undertake a reverse stock split.

If, following approval by the BioSante stockholders, it is determined that an amendment to BioSante's certificate of incorporation to effect a reverse stock split is in the best interests of BioSante and its stockholders, the reverse stock split will become effective upon filing one such amendment with the Secretary of State of the State of Delaware. Such amendment will effect either a one-for-two, one-for-three, one-for-four or one-for-five reverse split of BioSante common stock or BioSante class C special stock.

If, following approval by the BioSante stockholders, a reverse stock split is undertaken, the number of issued and outstanding shares of BioSante common stock and BioSante class C special stock will be reduced in accordance with a reverse stock split ratio determined by BioSante and ANI immediately prior to completion of the merger. Except for adjustments that may result from the treatment of fractional shares, as described below, each BioSante stockholder will hold the same percentage of BioSante common stock and BioSante class C special stock outstanding immediately following the reverse stock split as such stockholder held immediately prior to the reverse stock split and immediately prior to completion of the merger. The par value of BioSante common stock and BioSante class C special stock will remain unchanged at $0.0001 per share.

***Reasons for the Reverse Stock Split***

The BioSante board of directors approved the proposal authorizing the reverse stock split because it believes that a reverse stock split may allow the shares of BioSante common stock to be issued in connection with the merger to become listed on The NASDAQ Global Market or The NASDAQ

Table of Contents

Capital Market, which listing is a condition to completion of the merger. In addition, the BioSante board of directors believes that the increased market price of BioSante common stock expected to result from the implementation of a reverse stock split will improve the marketability and liquidity of BioSante common stock.

*NASDAQ Requirements for Listing on The NASDAQ Global Market*

BioSante common stock currently is listed on The NASDAQ Global Market. According to the listing rules of The NASDAQ Stock Market, in a transaction in which an issuer combines with a non-NASDAQ entity, resulting in a change of control of the issuer and potentially allowing the non-NASDAQ entity to obtain a NASDAQ listing, the issuer must apply for initial inclusion on the applicable NASDAQ market.

The merger agreement requires that BioSante use its reasonable best efforts to cause the shares of BioSante common stock to be issued in the merger to be approved, at or prior to completion of the merger, for listing (subject to notice of issuance) on The NASDAQ Global Market or The NASDAQ Capital Market, and the listing of the shares of BioSante common stock issuable pursuant to the merger agreement is a condition to ANI's obligation to complete the merger.

The listing standards of The NASDAQ Global Market and The NASDAQ Capital Market require, among other things, a $4.00 per share minimum bid upon completion of the merger. As of the date of the mailing of this joint proxy statement/prospectus, BioSante has filed an initial listing application for The NASDAQ Global Market in connection with the merger. The BioSante board of directors expects that a reverse stock split of BioSante common stock will increase the market price of BioSante common stock so that the combined company is able to achieve the initial listing requirements for The NASDAQ Global Market upon completion of the merger and thereafter maintain compliance with the NASDAQ minimum bid price listing standard of $4.00 per share. In determining the exact ratio for the reverse stock split, BioSante and ANI intend to use either a one-for-two, one-for-three, one-for-four or one-for-five ratio that would result in a per share price of greater than $4.00 per share following the reverse stock split. Notwithstanding the foregoing, there can be no assurance that the market price per share following the merger and the reverse stock split will remain in excess of the minimum bid price for a sustained period of time. In addition, there can be no assurance that the BioSante common stock, or the common stock of the combined company following completion of the merger, will not be delisted due to a failure to meet other continued listing requirements even if the market price per share of BioSante common stock on a post-reverse-stock-split basis remains in excess of the minimum bid requirement.

Additionally, the BioSante board of directors believes that a listing on The NASDAQ Global Market for the shares of common stock of the combined company may provide a broad market for the common stock of the combined company and facilitate the use of the common stock of the combined company in financing and other transactions.

*Potential Increased Investor Interest*

On January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, the closing sale price of BioSante common stock was $1.36 per share. An investment in BioSante common stock may not appeal to brokerage firms that are reluctant to recommend lower-priced stocks to their clients. Investors also may be dissuaded from purchasing lower-priced stocks because the brokerage commissions, as a percentage of the total transaction, tend to be higher for such stocks. Moreover, analysts at many brokerage firms do not monitor the trading activity or otherwise provide coverage of lower-priced stocks. Also, the BioSante board of directors believes that most investment funds are reluctant to invest in lower-priced stocks.

Table of Contents

There are risks associated with the reverse stock split, including that the reverse stock split may not result in an increase in the per share price of BioSante common stock. There is no assurance that (i) the market price per share of BioSante common stock following the reverse stock split will rise in proportion to the reduction in the number of shares of BioSante common stock outstanding before the reverse stock split; (ii) the reverse stock split will result in a market price per share of BioSante common stock that will attract brokers and investors who do not trade in lower-priced stocks; (iii) the market price per share of BioSante common stock will either exceed or remain in excess of the $4.00 minimum bid price as required for initial listing on The NASDAQ Global Market or The NASDAQ Capital Market; or (iv) BioSante otherwise will meet the initial listing requirements for The NASDAQ Global Market or The NASDAQ Capital Market.

The market price per share of BioSante common stock also will be based on the performance of BioSante and other factors, some of which are unrelated to the number of shares of BioSante common stock outstanding. If the reverse stock split is affected and the market price per share of BioSante common stock declines, the percentage decline as an absolute number and as a percentage of the overall market capitalization of BioSante may be greater than would occur in the absence of a reverse stock split. Furthermore, the liquidity of BioSante common stock could be adversely affected by the reduced number of shares of BioSante common stock that will be outstanding following the reverse stock split.

***Effects of the Reverse Stock Split***

If approved and implemented, the principal effects of the reverse stock split would include the following, all of which have been considered by the BioSante board of directors in approving the reverse stock split amendment:

The number of outstanding shares of BioSante common stock and BioSante class C special stock will be reduced and each BioSante stockholder will own fewer shares than they currently own.

The number of authorized shares of BioSante common stock and BioSante class C special stock will not be affected, thereby resulting in an increase in the authorized but unissued shares of BioSante common stock and BioSante class C special stock. This could result in BioSante or the combined company having the ability to issue more shares without further stockholder approval. Neither BioSante nor ANI has any current plan, commitment, arrangement, understanding or agreement, written or oral, to issue shares of BioSante common stock or BioSante class C special stock, other than in connection with the merger and to satisfy obligations under outstanding options and warrants to purchase shares of BioSante common stock.

The number of shares of BioSante common stock reserved and available for issuance under BioSante's equity-based compensation plans and the number of shares of BioSante common stock issuable upon exercise of outstanding options and warrants will be reduced proportionately based on the reverse stock split ratio selected by BioSante and ANI and the exercise price of all outstanding options and warrants will be increased proportionately. The reverse stock split will not in and of itself change the value of a BioSante stock option or warrant. The number of shares of BioSante common stock issuable upon conversion of BioSante's convertible senior notes will be reduced proportionately based on the reverse stock split ratio selected by BioSante and ANI and the conversion price of such notes will be increased proportionately. The number of shares of BioSante common stock issuable upon conversion of BioSante class C special stock will be reduced proportionately based on the reverse stock split ratio selected by BioSante and ANI and the per share conversion or purchase price of such shares will be increased proportionately.

Except for adjustments that may result from the treatment of fractional shares resulting from the reverse stock split, which are explained below under the heading " Fractional Shares," each

Table of Contents

BioSante stockholder will hold the same percentage of BioSante outstanding common stock or BioSante class C special stock immediately following the reverse stock split as the stockholder held immediately prior to the reverse stock split.

The voting rights, rights to dividends and distributions and other rights of BioSante common stock and BioSante class C special stock will not be changed as a result of the reverse stock split, except for the per share conversion or purchase price of the BioSante class C special stock as described above.

The number of BioSante stockholders of record will not be affected by the reverse stock split, except to the extent that any BioSante stockholder holds only a fractional share following the reverse stock split and receives cash for such fractional share following the reverse stock split as described below under the heading " Fractional Shares."

Because the number of outstanding shares of BioSante common stock will be reduced, the liquidity of BioSante common stock could be adversely affected as a result of the reverse stock split. This effect, however, may be mitigated to some extent by the additional shares of BioSante common stock that would be issued in connection with the merger between BioSante and ANI.

The following tables show the number of shares of BioSante common stock and BioSante class C special stock that would be (1) issued and outstanding prior to completion of the merger; (2) authorized and reserved for issuance upon the exercise of outstanding stock options and warrants and conversion of convertible senior notes and in the case of BioSante common stock, conversion of the BioSante class C special stock prior to completion of the merger; (3) authorized and unreserved for issuance prior to completion of the merger; and (4) authorized, in each case upon the implementation of the reverse stock split at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five based on BioSante's capitalization at December 31, 2012 but prior to completion of the merger:

***BioSante Common Stock***

| Reverse Stock Split Ratio | BioSante Common Stock Issued and Outstanding | BioSante Common Stock Authorized and Reserved for Issuance | BioSante Common Stock Authorized and Unreserved for Issuance | Total Shares of BioSante Common Stock Authorized |
|---|---|---|---|---|
| Pre-split | 24,422,240 | 6,302,837 | 169,274,923 | 200,000,000 |
| 1-for-2 | 12,211,120 | 3,151,418 | 184,637,462 | 200,000,000 |
| 1-for-3 | 8,140,746 | 2,100,945 | 189,758,309 | 200,000,000 |
| 1-for-4 | 6,105,560 | 1,575,709 | 192,318,731 | 200,000,000 |
| 1-for-5 | 4,884,448 | 1,260,567 | 193,854,985 | 200,000,000 |

***BioSante Class C Special Stock***

| Reverse Stock Split Ratio | BioSante Class C Special Stock Issued and Outstanding | BioSante Class C Special Stock Authorized and Reserved for Issuance | BioSante Class C Special Stock Authorized and Unreserved for Issuance | Total Shares of BioSante Class C Special Stock Authorized |
|---|---|---|---|---|
| Pre-split | 65,211 | 0 | 4,622,473 | 4,687,684 |
| 1-for-2 | 32,605 | 0 | 4,655,079 | 4,687,684 |
| 1-for-3 | 21,737 | 0 | 4,665,947 | 4,687,684 |
| 1-for-4 | 16,302 | 0 | 4,671,382 | 4,687,684 |
| 1-for-5 | 13,042 | 0 | 4,674,642 | 4,687,684 |

Table of Contents

In addition, if approved and implemented, other possible effects of the reverse stock split include the following, all of which have been considered by the BioSante board of directors in approving the reverse stock split amendment:

- It is anticipated that the reduction in outstanding shares of BioSante common stock will result in an increase in the per share price of BioSante common stock. However, there is no assurance that such a result will occur. Similarly, there is no assurance that if the per share price of BioSante common stock increases as a result of the reverse stock split, such increase in the per share price will be permanent, which will be dependent on several factors.

- One of the purposes for the proposed reverse stock split is to comply with the initial listing requirements for The NASDAQ Global Market and The NASDAQ Capital Market so that the shares of BioSante common stock issued in the merger will be listed on one of such markets. However, there can be no assurance that the reverse stock split alone will guarantee the initial or continual listing of BioSante common stock on The NASDAQ Global Market or The NASDAQ Capital Market. The listing of the shares of BioSante common stock issued pursuant to the merger on The NASDAQ Global Market or The NASDAQ Capital Market is a condition to ANI's obligation to complete the merger. If the shares of BioSante common stock issued pursuant to the merger are not listed on The NASDAQ Global Market or The NASDAQ Capital Market, ANI may decide not to complete the merger.

- The reverse stock split could be viewed negatively by the market and, consequently, could lead to a decrease in BioSante's overall market capitalization. It is often the case that the reverse-split adjusted stock price and market capitalization of companies that effect a reverse stock split decline. Should the per share price of BioSante common stock decline after implementation of the reverse stock split, the percentage decline may be greater than would occur in the absence of the reverse stock split.

- The anticipated resulting increase in per share price of BioSante common stock due to the reverse stock split is expected to encourage greater interest in BioSante common stock by brokers and investors and possibly promote greater liquidity for BioSante stockholders. However, there is no assurance that such greater interest will occur.

- Since the reverse stock split will decrease the number of shares held by BioSante stockholders, the reverse stock split may increase the number of BioSante stockholders who hold less than a "round lot," or 100 shares. Typically, the transaction costs to stockholders selling "odd lots" are higher on a per share basis. Consequently, the reverse stock split could increase the transaction costs to existing BioSante stockholders in the event they wish to sell all or a portion of their shares.

BioSante common stock is currently registered under Section 12(b) of the Exchange Act, and BioSante is subject to the periodic reporting and other requirements of the Exchange Act. The reverse stock split will not affect the registration of BioSante common stock under the Exchange Act nor affect BioSante continuing to be subject to the periodic reporting requirements of the Exchange Act. The reverse stock split is not intended as, and will not have the effect of, a "going private transaction" covered by Rule 13e-3 under the Exchange Act. If the reverse stock split is implemented, and the combined company's initial listing application with The NASDAQ Global Market is approved, BioSante common stock will continue to be listed on The NASDAQ Global Market under the symbol "BPAX" (although NASDAQ likely will add the letter "D" to the end of the trading symbol for a period of 20 trading days to indicate that the reverse stock split has occurred). It is expected that following the merger, the combined company will change its name to "ANI Pharmaceuticals, Inc." and that its trading symbol will be changed. ANI has reserved the ticker symbol "ANIP" for this purpose.

Upon completion of the merger, each share of ANI capital stock will be converted into the right to receive that number of shares of BioSante common stock equal to the applicable exchange ratio. As

Table of Contents

of January 15, 2013, the last practicable date before the printing of this joint proxy statement/prospectus, 24,422,240 shares of BioSante common stock were outstanding and 2,375,312 shares of ANI series D preferred stock were outstanding and it is anticipated that an additional 321,737 shares of ANI series D preferred stock will be issued to ANI's executive officers and an additional ANI employee immediately prior to the merger, assuming BioSante's net cash is $18.0 million and an exchange ratio of 10.3502 for each share of ANI series D preferred stock and an exchange ratio of zero for each share of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock. The exchange ratios depend upon the reverse stock split ratio. If the merger had been completed as of December 31, 2012, assuming a reverse stock split ratio of one-for-two, each share of ANI series D preferred stock would have converted into and been exchanged for the right to receive 5.1751 shares of BioSante common stock and each share of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock would not have been entitled to receive any payment and would have been cancelled in connection with the merger, which would have resulted in an aggregate issuance of 14.0 million shares of BioSante common stock. If the merger had been completed as of December 31, 2012, assuming a reverse stock split ratio of one-for-five, each share of ANI series D preferred stock would have converted into and been exchanged for the right to receive 2.0700 shares of BioSante common stock and each share of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock would have been cancelled in connection with the merger, which would have resulted in an aggregate issuance of 5.6 million shares of BioSante common stock.

***Procedures for Effecting the Reverse Stock Split and Filing the Reverse Stock Split Amendment***

If the BioSante stockholders approve the reverse stock split amendment and BioSante and ANI subsequently determines that it is in the best interests of BioSante and its stockholders to effect a reverse stock split, BioSante and ANI, in their sole discretion, at any time prior to completion of the merger, will determine the ratio of the reverse stock split to be implemented. BioSante and ANI believe that BioSante stockholder approval of four potential exchange ratios (rather than a single exchange ratio) is in the best interests of BioSante and its stockholders because it provides BioSante and ANI with the flexibility to achieve the desired results of the reverse stock split and because it is not possible to predict market conditions at the time the reverse stock split would be implemented. The ratio to be selected by BioSante and ANI will be either one-for-two, one-for-three, one-for-four or one-for-five and the numbers in the ratio will consist only of whole numbers. The decision of BioSante and ANI as to whether and when to effect the reverse stock split, and the decision of BioSante and ANI regarding the final split ratio will be based, in part, on existing and expected trading prices for BioSante common stock, the combined company's ability to meet the initial listing requirements of The NASDAQ Global Market, and prevailing general market and economic conditions. BioSante and ANI intend to select a reverse split ratio that they believe would be most likely to achieve the anticipated benefits of the reverse stock split as described above.

After BioSante and ANI determine to effect a reverse stock split and have determined the split ratio, BioSante and ANI will determine the effective date of the reverse stock split and will announce publicly such information. Any such split will become effective upon the filing of the reverse stock split amendment with the Secretary of State of the State of Delaware or such later date as indicated in the reverse stock split amendment. It is currently anticipated that the reverse stock split would be effective on the closing date of the merger, prior to the effectiveness of the merger.

***Fractional Shares***

No fractional shares of BioSante common stock or BioSante class C special stock would be issued as a result of the reverse stock split, if any. Each holder of BioSante common stock at the effective time of the reverse stock split, if any, who otherwise would be entitled to a fractional share will, in lieu thereof,

Table of Contents

be entitled receive a cash payment equal to: (1) the fractional share amount multiplied by (2) the product of (a) the closing sale price of a share of BioSante common stock as reported on The NASDAQ Global Market or other principal market of BioSante common stock, as applicable, on the effective date of the reverse stock split and (b) the reverse stock split ratio, as determined by BioSante and ANI. Each holder of BioSante class C special stock at the effective time of the reverse stock split, if any, who otherwise would be entitled to a fractional share will, in lieu thereof, be entitled receive a cash payment equal to the cash payment that a holder of BioSante common stock would receive minus $15.00. Except for the right to receive the cash payment in lieu of fractional shares, BioSante stockholders will not have any voting, dividend or other rights with respect to the fractional shares they otherwise would be entitled to receive.

BioSante stockholders should be aware that, under the escheat laws of the various jurisdictions where stockholders reside, where BioSante is domiciled, and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the effective date of the reverse stock split may be required to be paid to the designated agent for each such jurisdiction, unless correspondence has been received by BioSante or the exchange agent concerning ownership of such funds within the time permitted in such jurisdiction. Thereafter, BioSante stockholders otherwise entitled to receive such funds will have to seek to obtain them directly from the state to which they were paid.

***Exchange of Pre-Reverse Stock Split Shares with Post-Reverse Stock Split Shares***

If the BioSante stockholders approve and BioSante and ANI implement a reverse stock split, BioSante's transfer agent will act as exchange agent for purposes of implementing the exchange of pre-reverse stock split shares of BioSante common stock for post-reverse stock split shares of BioSante common stock, and BioSante will act as exchange agent for purposes of implementing the exchange of pre-reverse stock split shares of BioSante class C special stock for post-reverse stock split shares of BioSante class C special stock.

*Registered Book Entry Stockholder.* Holders of BioSante common stock holding all of their shares electronically in book-entry form with BioSante's transfer agent do not need to take any action (the exchange will be automatic) to receive post-reverse stock split shares.

*Registered Certificated Stockholder.* Some of the holders of BioSante common stock hold their shares in certificate form or a combination of certificate and book-entry form and all of the holders of BioSante class C special stock hold their shares in certificate form. If any of your shares of BioSante common stock are held in certificate form, you will receive a transmittal letter from BioSante's transfer agent as soon as practicable after the effective date of the reverse stock split. The letter of transmittal will contain instructions on how to surrender your certificate(s) representing your pre-reverse stock split shares to the transfer agent. Upon receipt of your pre-reverse stock split certificate(s), you will be issued the appropriate number of shares of BioSante common stock electronically in book-entry form under the Direct Registration System (DRS). No new shares in book-entry form will be reflected until you surrender your outstanding pre-reverse stock split certificate(s), together with the properly completed and executed letter of transmittal, to BioSante's transfer agent. At any time after receipt of your DRS statement, you may request a stock certificate representing your ownership interest. Holders of BioSante class C special stock will receive a transmittal letter from BioSante as soon as practicable after the effective date of the reverse stock split. The letter of transmittal will contain instructions on how to surrender your certificate(s) representing your pre-reverse stock split shares to BioSante and upon receipt of your pre-reverse stock split certificate(s), you will be issued the appropriate number of shares of BioSante class C special stock in certificate form.

**BIOSANTE STOCKHOLDERS SHOULD NOT DESTROY ANY STOCK CERTIFICATES AND SHOULD NOT SUBMIT ANY CERTIFICATES UNTIL REQUESTED TO DO SO.**

Table of Contents

***Accounting Matters***

The reverse stock split is not expected to affect stockholders' accumulated deficit on BioSante's balance sheet. However, because the par value of BioSante common stock and BioSante class C special stock will remain unchanged on the effective date of the reverse stock split, the components that make up stockholders' accumulated deficit will change by offsetting amounts. The stated common stock and BioSante class C special stock components will be reduced, and the additional paid-in capital component will be increased by the amount by which the stated common stock and BioSante class C special stock component is reduced. The per share net loss and net book value of BioSante common stock and BioSante class C special stock will be increased because there will be fewer shares of BioSante common stock and BioSante class C special stock outstanding. Net loss per share amounts in prior periods will be restated to reflect the reverse stock split. BioSante does not anticipate that any other accounting consequences would arise as result of the reverse stock split.

***Potential Anti-Takeover Effect; Possible Dilution***

Because the reverse stock split would increase the number of authorized but unissued shares of BioSante common stock and BioSante class C special stock available for issuance, the reverse stock split could be construed as having an anti-takeover effect, since BioSante could use the increased available shares to frustrate persons seeking to effect a takeover or otherwise gain control of BioSante. For example, BioSante could use the additional authorized but unissued shares to resist or frustrate a third-party transaction providing an above-market premium that is favored by a majority of the BioSante stockholders. The reverse stock split proposal is not being proposed in response to any effort of which BioSante is aware to accumulate shares of BioSante common stock or obtain control of BioSante, other than as contemplated by the merger agreement, nor is it part of a plan by management to recommend a series of similar amendments to the BioSante stockholders.

In addition to the increased number of shares of BioSante common stock and BioSante class C special stock that would be available for issuance as a result of the reverse stock split, other provisions of BioSante's certificate of incorporation and bylaws could delay or prevent a merger, tender offer or proxy contest to take control of BioSante. Specifically, BioSante's certificate of incorporation and bylaws contain provisions which:

- authorize the issuance of "blank check" preferred stock, which is preferred stock that can be created and issued by the BioSante board of directors without prior stockholder approval, with rights senior to BioSante common stock or BioSante class C special stock;
- prohibit BioSante stockholders to call a special meeting; and
- prohibit cumulative voting for directors of BioSante.

BioSante's bylaws require advance written notice to BioSante of any stockholder-proposed business or of a stockholder's intention to make a nomination for director at an annual meeting of stockholders and limit the business that may be conducted at any special meeting of stockholders to business brought by the BioSante board of directors.

The holders of BioSante common stock and BioSante class C special stock do not have preemptive rights to subscribe for additional securities that may be issued by BioSante, which means that current BioSante stockholders do not have a prior right to purchase any additional shares from time to time issued by BioSante. Accordingly, if the BioSante board of directors elects to issue additional shares of BioSante common stock or BioSante class C special stock, such issuance could have a dilutive effect on the earnings (if any) per share, voting power and equity ownership of current BioSante stockholders.

Table of Contents

***Material U.S. Federal Income Tax Consequences of the Reverse Stock Split***

The following discussion describes the anticipated material U.S. federal income tax consequences to "U.S. holders" of BioSante capital stock relating to the reverse stock split. For purposes of this discussion, a "U.S. holder" is an owner of BioSante capital stock who is (i) a citizen or individual resident of the U.S., including an individual who is resident in the U.S. by reason of a physical presence here during the year or by virtue of lawful permanent residence; (ii) a corporation or other entity treated as a corporation which is created or organized under the laws of the U.S., any state thereof or the District of Columbia; (iii) an estate, the income of which is subject to U.S. federal income tax without regard to its source; or (iv) a trust if (A) a court within the U.S. is able to exercise primary supervision over the administration of the trust, and one or more U.S. persons have the authority to control all substantial decisions of the trust or (B) the trust was in existence on August 20, 1996, and has a valid election in effect under applicable Regulations to be treated as a domestic trust for U.S. federal income tax purposes. A holder of BioSante capital stock that is not a U.S. holder is urged to consult his, her or its own tax advisor regarding the U.S. federal income tax consequences of the reverse stock split.

This discussion is based upon the current provisions of the existing Treasury Regulations promulgated under the Internal Revenue Code of 1986, as amended (Code), and current administration rulings and court decisions, all as currently in effect and all of which are subject to change or differing interpretations, possibly with retroactive effect. BioSante has not obtained, and does not intend to obtain, a ruling from the IRS or an opinion of legal or tax counsel with respect to the tax consequences of the reverse stock split. The following discussion is for information purposes only and is not intended as tax or legal advice.

This discussion assumes that a U.S. holder holds BioSante capital stock as a capital asset within the meaning of Code Section 1221. This discussion does not address all of the tax consequences that may be relevant to a particular stockholder or to stockholders that are subject to special treatment under U.S. federal income tax laws including, but not limited to, financial institutions, tax-exempt organizations, insurance companies, regulated investment companies, persons that are broker-dealers, traders in securities who elect the mark-to-market method of accounting for their securities, or stockholders holding their shares of BioSante capital stock as part of a "straddle," "hedge," "conversion transaction," or other integrated transaction. This discussion also does not address the tax consequences to BioSante, or to BioSante stockholders that own five percent or more of BioSante capital stock, are affiliates of BioSante, or are not U.S. holders. In addition, this discussion does not address other U.S. federal taxes (such as gift or estate taxes or alternative minimum taxes), the tax consequences of the reverse stock split under state, local or foreign tax laws or certain tax reporting requirements that may be applicable with respect to the reverse stock split. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of the tax consequences set forth below.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) is a stockholder of BioSante, the tax treatment of a partner in the partnership, or any equity owner of such other entity will generally depend upon the status of the person and the activities of the partnership or other entity treated as a partnership for U.S. federal income tax purposes.

*Tax Consequences of the Reverse Stock Split Generally*

BioSante believes that the reverse stock split will qualify as a "reorganization" under Section 368(a)(1)(E) of the Code. Accordingly, provided that the fair market value of the post-reverse stock split shares is equal to the fair market value of the pre-reverse stock split shares surrendered in the reverse stock split:

A U.S. holder will not recognize any gain or loss as a result of the reverse stock split (except to the extent of cash received in lieu of a fractional share).

Table of Contents

A U.S. holder's aggregate tax basis in his, her or its post-reverse stock split shares will be equal to the aggregate tax basis in the pre-reverse stock split shares exchanged therefor, reduced by the amount of the adjusted basis of any pre-reverse stock split shares exchanged for such post-reverse stock split shares that is allocated to any fractional share for which cash is received.

A U.S. holder's holding period for the post-reverse stock split shares will include the period during which such stockholder held the pre-reverse stock split shares surrendered in the reverse stock split.

*Cash Received Instead of a Fractional Share*

A U.S. holder who receives cash instead of a fractional share of post-reverse stock split shares will be treated as having received the fractional share of post-reverse stock split shares pursuant to the reverse stock split and then as having exchanged the fractional share of post-reverse stock split shares for cash in a redemption by BioSante. In general, this deemed redemption will be treated as a sale or exchange, provided the redemption is not essentially equivalent to a dividend as discussed below. Gain or loss generally will be recognized based on the difference between the amount of cash received and the portion of the U.S. holder's adjusted tax basis of the pre-reverse stock split shares exchanged in the reverse stock split which is allocable to such fractional share. Such gain or loss generally will be long-term capital gain or loss if the U.S. holder's holding period for such pre-reverse stock split shares is more than one year as of the effective date of the reverse stock split, and otherwise will be short-term capital gain or loss. The deductibility of capital losses is subject to limitations.

The receipt of cash is "not essentially equivalent to a dividend" if the reduction in a U.S. holder's proportionate interest in BioSante resulting from the reverse stock split (taking into account for this purpose shares of BioSante common stock and BioSante class C special stock which such holder is considered to own under certain attribution rules) is considered a "meaningful reduction" given such U.S. holder's particular facts and circumstances. The IRS has ruled that a small reduction by a minority stockholder whose relative stock interest is minimal and who exercises no control over the affairs of a corporation can satisfy this test. If the receipt of cash in lieu of a fractional share is not treated as capital gain or loss under the test just described, it will be treated first as ordinary dividend income to the extent of a U.S. holder's ratable share of BioSante's current and accumulated earnings and profits, then as a tax-free return of capital to the extent of the portion of the U.S. holder's adjusted tax basis of the pre-reverse stock split shares which is allocable to such fractional share, and any remaining amount will be treated as capital gain.

*Information Reporting and Backup Withholding*

Cash payments received by a U.S. holder of BioSante capital stock pursuant to the reverse stock split are subject to information reporting, and may be subject to backup withholding at the applicable rate specified by the IRS (currently at a rate of 28 percent) if the holder fails to provide a valid taxpayer identification number and comply with certain certification procedures or otherwise establish an exemption from backup withholding. Backup withholding is not an additional U.S. federal income tax. Rather, the U.S. federal income tax liability of the person subject to backup withholding will be reduced by the amount of the tax withheld. If backup withholding results in an overpayment of taxes, a refund may be obtained provided that the required information is timely furnished to the IRS.

***No Appraisal Rights***

No appraisal rights are available under the Delaware General Corporation Law or under BioSante's certificate of incorporation or bylaws to any BioSante stockholder who dissents from the proposal to approve the amendment to BioSante's certificate of incorporation to effect the reverse stock split.

Table of Contents

***Discretion to Implement the Reverse Stock Split***

If the proposed reverse stock split is approved by the BioSante stockholders, BioSante and ANI, in their discretion, at any time prior to completion of the merger, may determine to implement the reverse stock split. Notwithstanding the approval of the form of the reverse stock split amendment, BioSante and ANI, in their discretion, may determine not to implement the reverse stock split.

***Vote Required; Recommendation of BioSante Board of Directors***

The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, having voting power outstanding on the record date for the BioSante special meeting is required for approval of BioSante Proposal No. 2.

A failure to submit a proxy card or vote at the BioSante special meeting, or an abstention or "broker non-vote" will have the same effect as a vote against the approval of BioSante Proposal No. 2.

**The BioSante board of directors unanimously recommends that BioSante stockholders vote "FOR" BioSante Proposal No. 2 to approve the amendment to BioSante's certificate of incorporation to effect a reverse split of the issued and outstanding shares of BioSante common stock and BioSante class C special stock at the discretion of the BioSante board of directors at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five.**

Table of Contents

**BioSante Proposal No. 3 Approval of Amendment to BioSante's Certificate of Incorporation to Change Corporate Name**

***General***

At the BioSante special meeting, BioSante stockholders will be asked to approve an amendment to BioSante's certificate of incorporation to change the name of the corporation from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc." immediately following completion of the merger. The full text of the form of proposed amendment is attached to this joint proxy statement/prospectus as Annex J.

The primary reason for the corporate name change is that ANI's senior management believes this will allow for recognition of the combined company's business following completion of the merger. ANI's senior management believes that the current name will no longer accurately reflect the business of the combined company and the mission of the combined company subsequent to the completion of the merger.

Insofar as the proposed new corporate name will reflect the combined company's business following completion of the merger, the proposed name change and the amendment to BioSante's certificate of incorporation, even if approved by the BioSante stockholders at the BioSante special meeting, will only be filed with the office of the Secretary of State of the State of Delaware and, therefore become effective, if the merger is completed.

***Vote Required; Recommendation of BioSante Board of Directors***

The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, having voting power outstanding on the record date for the BioSante special meeting is required for approval of BioSante Proposal No. 3.

A failure to submit a proxy card or vote at the BioSante special meeting, or an abstention or "broker non-vote" will have the same effect as a vote against the approval of BioSante Proposal No. 3.

**The BioSante board of directors unanimously recommends that BioSante stockholders vote "FOR" BioSante Proposal No. 3 to approve the amendment to BioSante's certificate of incorporation to change the name of the corporation from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc." immediately following completion of the merger.**

Table of Contents

**BioSante Proposal No. 4 Advisory Vote on Golden Parachute Compensation**

***General***

As required by Section 14A of the Exchange Act and the SEC's rules thereunder, BioSante is asking its stockholders to cast an advisory (non-binding) vote on the compensation that may be payable to its named executive officers under existing agreements in connection with the merger, as described in this joint proxy statement/prospectus under "The Merger Interests of BioSante's Directors and Officers in Connection with the Merger Golden Parachute Compensation," including in the associated narrative discussion. In accordance with these requirements, BioSante is asking its stockholders to vote on the adoption of the following resolution:

"RESOLVED, that the compensation that may be payable to BioSante's named executive officers in connection with the merger, as disclosed in the table captioned "Golden Parachute Compensation" beginning on page 147 of this joint proxy statement/prospectus under "The Merger Interests of BioSante's Directors and Officers in Connection with the Merger Golden Parachute Compensation," including the associated narrative discussion, and the agreements or understandings pursuant to which such compensation may be payable, are hereby APPROVED."

The vote on the compensation payable in connection with the merger is a vote separate and apart from the votes on the other BioSante proposals described in this joint proxy statement/prospectus. BioSante stockholders may vote to approve this proposal and vote not to approve another proposal, or may vote against this proposal and vote to approve some or all of the other proposals.

Because the vote on this BioSante Proposal No. 4 is advisory in nature only, it will not be binding on BioSante. Accordingly, because BioSante is obligated contractually to pay the compensation covered by this proposal, such compensation will be payable, subject only to the applicable conditions, if the merger is approved and regardless of the outcome of the advisory vote.

***Vote Required; Recommendation of BioSante Board of Directors***

The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, present in person or represented by proxy at the BioSante special meeting is required for approval of BioSante Proposal No. 4.

A failure to submit a proxy card or vote at the BioSante special meeting or a "broker non-vote" will have no effect on the outcome of BioSante Proposal No. 4. For purposes of the vote on this BioSante Proposal No. 4, an abstention will have the same effect as a vote "AGAINST" such proposal.

**The BioSante board of directors unanimously recommends that BioSante stockholders vote "FOR" BioSante Proposal No. 4 to approve the compensation that may be payable to BioSante's named executive officers in connection with the merger, as disclosed in the table captioned "Golden Parachute Compensation" beginning on page 147 of this joint proxy statement/prospectus under "The Merger Interests of BioSante's Directors and Officers in Connection with the Merger Golden Parachute Compensation," including the associated narrative discussion, and the agreements or understandings pursuant to which such compensation may be payable.**

Table of Contents

**BioSante Proposal No. 5 Approval of Possible Adjournment of the BioSante Special Meeting**

***General***

BioSante is asking its stockholders to consider and vote upon a proposal to approve one or more adjournments of the BioSante special meeting, if necessary or appropriate, including adjournments to permit further solicitation of proxies in favor of approval of BioSante Proposals No. 1, 2 and/or 3.

If the number of shares of BioSante capital stock present in person or represented by proxy at the BioSante special meeting voting in favor of BioSante Proposal No. 1, BioSante Proposal No. 2 or BioSante Proposal No. 3 is insufficient to approve one or more of such proposals at the time of the BioSante special meeting, then BioSante may move to adjourn the BioSante special meeting in order to enable the BioSante board of directors to solicit additional proxies in respect of the applicable proposal. In that event, BioSante stockholders will be asked to vote only upon the adjournment proposal, BioSante Proposal No. 5, and not on any other proposal.

In this proposal, BioSante is asking its stockholders to authorize the holder of any proxy solicited by the BioSante board of directors to vote in favor of granting discretionary authority to the proxy or attorney-in-fact to adjourn the BioSante special meeting one or more times for the purpose of soliciting additional proxies. If BioSante stockholders approve this BioSante Proposal No. 5, BioSante could adjourn the BioSante special meeting and any adjourned session of the BioSante special meeting and use the additional time to solicit additional proxies, including the solicitation of proxies from BioSante stockholders that previously have returned properly executed proxies or authorized a proxy by using the Internet or telephone. Among other things, approval of BioSante Proposal No. 5 could mean that, even if BioSante has received proxies representing a sufficient number of votes against the approval of BioSante Proposals No. 1, BioSante Proposal No. 2 or BioSante Proposal No. 3 that such proposal would be defeated, BioSante could adjourn the BioSante special meeting without a vote on such proposal and seek to obtain sufficient votes in favor of such proposal to obtain approval of that proposal.

BioSante currently does not intend to propose adjournment at the BioSante special meeting if there are sufficient votes to approve BioSante Proposals No. 1, 2 and 3.

***Vote Required; Recommendation of BioSante Board of Directors***

The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, present in person or represented by proxy at the BioSante special meeting is required for approval of BioSante Proposal No. 5.

A failure to submit a proxy card or vote at the BioSante special meeting or a "broker non-vote" will have no effect on the outcome of BioSante Proposal No. 5. For purposes of the vote on this BioSante Proposal No. 5, an abstention will have the same effect as a vote "AGAINST" such proposal.

**The BioSante board of directors unanimously recommends that BioSante stockholders vote "FOR" BioSante Proposal No. 5 to adjourn the special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of BioSante Proposals No. 1, 2 and 3.**

Table of Contents

## THE SPECIAL MEETING OF ANI STOCKHOLDERS

### General

This joint proxy statement/prospectus is being furnished to stockholders of ANI on or about January 25, 2013. ANI is sending this joint proxy statement/prospectus to its stockholders in connection with the solicitation of proxies by the ANI board of directors for use at the ANI special meeting and any adjournments or postponements of the special meeting.

### Date, Time and Place

The special meeting of ANI stockholders will be held at 9:00 a.m., local time, on Friday, March 15, 2013, at the offices of MVP Capital Partners located at 259 N. Radnor-Chester Road, Suite 130, Radnor, Pennsylvania 19087.

### Purposes of the ANI Special Meeting

The purposes of the ANI special meeting are to consider and act upon the following matters:

1. To consider and to vote upon a proposal to adopt the merger agreement, a copy of which is attached as Annex A to this joint proxy statement/prospectus, and the transactions contemplated thereby, including the merger.

2. To consider and to vote upon a proposal to approve an adjournment of the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of ANI Proposal No. 1.

ANI stockholders also will consider and act on any other matters as may properly come before the ANI special meeting or any adjournment or postponement thereof, including any procedural matters incident to the conduct of the special meeting.

### Recommendations of the ANI Board of Directors

The ANI board of directors has determined and believes that the merger agreement and the transactions contemplated thereby, including the merger, is advisable, fair to, and in the best interests of ANI and its stockholders and has unanimously approved such proposal. The ANI board of directors recommends unanimously that ANI stockholders vote "**FOR**" ANI Proposal No. 1 to approve the merger agreement and the transactions contemplated thereby, including the merger.

The ANI board of directors recommends unanimously that ANI stockholders vote "**FOR**" ANI Proposal No. 2 to adjourn the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of ANI Proposal No. 1.

### Record Date and Voting Power

The close of business on January 17, 2013 has been fixed as the ANI record date for the determination of ANI stockholders entitled to notice of, and to vote at, the ANI special meeting or any adjournments or postponements of the ANI special meeting. Only holders of record of ANI capital stock at the close of business on the ANI record date are entitled to notice of, and to vote at, the ANI special meeting. At the close of business on the record date, ANI had 2,375,312 shares of ANI series D preferred stock, 34,810 shares of ANI series C preferred stock, 78,491 shares of ANI series B preferred stock, 102,774 shares of ANI series A preferred stock and 23,613 shares of ANI common stock outstanding and entitled to vote. Each share of ANI series D preferred stock, ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock entitles the holder thereof to one vote on each matter submitted for stockholder approval. See "Principal

Table of Contents

Stockholders of ANI" for information regarding persons known to management of ANI to be the beneficial owners of more than five percent of the outstanding shares of ANI capital stock.

**Voting and Revocation of Proxies**

The proxy accompanying this joint proxy statement/prospectus is solicited on behalf of the ANI board of directors for use at the ANI special meeting.

If you are a stockholder of record of ANI as of the applicable record date referred to above, you may vote in person at the ANI special meeting or vote by proxy using the enclosed proxy card. Whether or not you plan to attend the ANI special meeting, ANI urges you to vote by proxy to ensure your vote is counted. You still may attend the ANI special meeting and vote in person if you already have voted by proxy. ANI stockholders of record as of the close of business on January 17, 2013 may submit their proxies by marking, signing and dating the enclosed proxy card and returning it in the postage-paid envelope provided or returning it pursuant to the instructions provided in the proxy card.

All properly executed proxies that are not revoked will be voted at the ANI special meeting and at any adjournments or postponements of the ANI special meeting in accordance with the instructions contained in the proxy. If a holder of ANI capital stock executes and returns a proxy and does not specify otherwise, the shares represented by that proxy will be voted "**FOR**" ANI Proposal No. 1 to approve the merger agreement and the transactions contemplated thereby, including the merger; "**FOR**" ANI Proposal No. 2 to adjourn the ANI special meeting, if necessary, if a quorum is present, to solicit additional proxies if there are not sufficient votes in favor of ANI Proposal No. 1 in accordance with the recommendation of the ANI board of directors.

Any ANI stockholder of record voting by proxy, other than those stockholders who have executed a voting agreement and irrevocable proxy, has the right to revoke the proxy at any time before the polls close at the ANI special meeting by sending a written notice stating that it would like to revoke its proxy to the Secretary of ANI, by providing a duly executed proxy card bearing a later date than the proxy being revoked or by attending the ANI special meeting and voting in person. Attendance alone at the ANI special meeting will not revoke a proxy.

**Quorum and Required Vote**

The presence at the ANI special meeting, in person or by proxy, of the holders of a majority of the voting power of the issued and outstanding shares of ANI capital stock entitled to vote will constitute a quorum for the transaction of business at the ANI special meeting. In general, shares of ANI capital stock represented by a properly signed and returned proxy card will be counted as shares present and entitled to vote at the ANI special meeting for purposes of determining a quorum. Shares represented by proxies marked "Abstain" or "Withheld" are counted in determining whether a quorum is present. If a quorum is not present at the ANI special meeting, ANI expects that the ANI special meeting will be adjourned or postponed to solicit additional proxies.

A description of the vote required to approve each proposal being submitted to a vote of ANI stockholders is included with the description of each proposal. For ANI Proposal No. 1, a failure to vote by proxy or in person at the ANI special meeting, or an abstention or vote withheld for such proposal, will have the same effect as a vote against the approval of such proposal. For ANI Proposal No. 2, a failure to submit a proxy card or vote at the ANI special meeting, or an abstention or vote withheld will have no effect on the outcome of such proposal.

In connection with the execution of the merger agreement, Meridian Venture Partners II, L.P., Argentum Capital Partners II, L.P. and four funds affiliated with First Analysis Corp., who in the aggregate held approximately 85 percent of the shares of the outstanding ANI capital stock, calculated on an as-converted basis, and approximately 86 percent of the outstanding shares of the ANI series D

Table of Contents

preferred stock, as of October 3, 2012 entered into a voting agreement with BioSante, pursuant to which they agreed to vote their shares of ANI capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement.

As of the record date for the ANI special meeting, the shares of ANI capital stock owned by all of ANI's directors, executive officers and affiliated entities constituted approximately 92 percent of the outstanding shares of ANI capital stock, on an as-converted basis, and approximately 94 percent of the outstanding shares of the ANI series D preferred stock on that date.

**Solicitation of Proxies**

In addition to solicitation by mail, the directors, officers, employees and agents of ANI may solicit proxies from ANI stockholders by personal interview, telephone, telegram or other electronic means. ANI will bear the costs of the solicitation of proxies by ANI from ANI's stockholders. Arrangements also will be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of ANI capital stock for the forwarding of solicitation materials to the beneficial owners of ANI capital stock. ANI will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials.

**Other Matters**

As of the date of this joint proxy statement/prospectus, the ANI board of directors does not know of any business to be represented at the ANI special meeting other than as set forth in the notice accompanying this joint proxy statement/prospectus. If any other matters should properly come before the ANI special meeting, or any adjournment or postponement of the ANI special meeting it is intended that the shares represented by proxies will be voted with respect to such matters in accordance with the judgment of the person voting the proxies.

Table of Contents

## MATTERS BEING SUBMITTED TO A VOTE OF ANI STOCKHOLDERS

### ANI Proposal No. 1 Adoption of Agreement and Plan of Merger and the Transactions Contemplated Thereby, Including the Merger

***General***

At the ANI special meeting, ANI stockholders will be asked to adopt the merger agreement, a copy of which is attached as Annex A to this joint proxy statement/prospectus, and the transactions contemplated thereby, including the merger.

If the merger is completed, ANI will be merged with and into BioSante, with BioSante surviving the merger.

Pursuant to the terms of the merger agreement, upon completion of the merger, ANI stockholders will have the right to receive, for each share of ANI capital stock they hold, that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. Following completion of the merger, the current ANI stockholders are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current BioSante stockholders are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. If the merger had been completed on January 17, 2013, the record date for the BioSante special meeting, an aggregate of 27.9 million shares of BioSante common stock would have been issuable to ANI stockholders upon completion of the merger, assuming BioSante's net cash is $18.0 million as of the determination date.

The terms of, reasons for and other aspects of the merger agreement and the merger are described in detail in the other sections of this joint proxy statement/prospectus. The full text of the merger agreement is attached as Annex A to this joint proxy statement/prospectus.

***Vote Required; Recommendation of ANI Board of Directors***

The affirmative vote of holders of a majority of the shares of ANI capital stock entitled to vote, calculated on an as-converted basis and voting together as a single class, and 65 percent of the shares of ANI series D preferred stock entitled to vote, in each case outstanding on the record date for the ANI special meeting, is required for approval of ANI Proposal No. 1.

A failure to submit a proxy card or vote at the ANI special meeting, or an abstention will have the same effect as a vote against the approval of ANI Proposal No. 1.

**The ANI board of directors unanimously recommends that ANI stockholders vote "FOR" ANI Proposal No. 1 to adopt the agreement and plan of merger and the transactions contemplated thereby, including the merger.**

Table of Contents

**ANI Proposal No. 2 Approval of Possible Adjournment of the ANI Special Meeting**

***General***

ANI is asking its stockholders to consider and vote upon a proposal to approve one or more adjournments of the ANI special meeting, if necessary or appropriate, including adjournments to permit further solicitation of proxies in favor of approval of ANI Proposal No. 1.

If the number of shares of ANI capital stock present in person or represented by proxy at the ANI special meeting voting in favor of ANI Proposal No. 1 is insufficient to approve such proposal at the time of the ANI special meeting, then ANI may move to adjourn the ANI special meeting in order to enable the ANI board of directors to solicit additional proxies in respect of the applicable proposal. In that event, ANI stockholders will be asked to vote only upon the adjournment proposal, ANI Proposal No. 2, and not on any other proposal.

In this proposal, ANI is asking its stockholders to authorize the holder of any proxy solicited by the ANI board of directors to vote in favor of granting discretionary authority to the proxy or attorney-in-fact to adjourn the ANI special meeting one or more times for the purpose of soliciting additional proxies. If ANI stockholders approve this ANI Proposal No. 2, ANI could adjourn the ANI special meeting and any adjourned session of the ANI special meeting and use the additional time to solicit additional proxies, including the solicitation of proxies from ANI stockholders that previously have returned properly executed proxies. Among other things, approval of ANI Proposal No. 2 could mean that, even if ANI has received proxies representing a sufficient number of votes against the approval of ANI Proposal No. 1 that such proposal would be defeated, ANI could adjourn the ANI special meeting without a vote on such proposal and seek to obtain sufficient votes in favor of such proposal to obtain approval of that proposal.

ANI currently does not intend to propose adjournment at the ANI special meeting if there are sufficient votes to approve ANI Proposal No. 1.

***Vote Required; Recommendation of ANI Board of Directors***

The affirmative vote of holders of a majority of the shares of ANI capital stock entitled to vote, calculated on an as-converted basis, present in person or represented by proxy and voting together as a single class is required for approval of ANI Proposal No. 2.

A failure to submit a proxy card or vote at the ANI special meeting will have no effect on the outcome of ANI Proposal No. 2. For purposes of the vote on ANI Proposal No. 2, an abstention will have the same effect as a vote "AGAINST" such proposal.

**The ANI board of directors unanimously recommends that ANI stockholders vote "FOR" ANI Proposal No. 2 to adjourn the special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of ANI Proposal No. 1.**

Table of Contents

## THE MERGER

*This section and the section entitled "The Merger Agreement" describe the material aspects of the merger, including the merger agreement. While BioSante and ANI believe that this description covers the material terms of the merger and the merger agreement, it may not contain all of the information that is important to you. You should read carefully this entire joint proxy statement/prospectus for a more complete understanding of the merger and the merger agreement, including the attached Annexes, and the other documents to which you are referred herein. See "Where You Can Find More Information."*

### General

The merger agreement provides that, at the effective time, ANI will be merged with and into BioSante, with BioSante surviving the merger.

Pursuant to the terms of the merger agreement, upon completion of the merger, ANI stockholders will have the right to receive, for each share of ANI capital stock they hold, that number of shares of BioSante common stock equal to the applicable exchange ratio, as such ratio is calculated pursuant to the terms of the merger agreement, such that immediately following completion of the merger, the current stockholders of ANI are expected to own approximately 53 percent of the outstanding capital stock of the combined company and current stockholders of BioSante are expected to own approximately 47 percent of the outstanding capital stock of the combined company, assuming BioSante's net cash as of the determination date is $18.0 million.

BioSante stockholders will continue to own their existing shares of BioSante common stock or BioSante class C special stock after the merger. Each share of BioSante common stock will represent one share of common stock in the combined company, and each share of BioSante class C special stock will represent one share of class C special stock in the combined company, subject to adjustment for any reverse stock split effective immediately prior to the merger.

The closing of the merger will take place as promptly as practicable after the day on which the last of the conditions to the merger set forth in the merger agreement has been satisfied or waived (if permissible), unless BioSante and ANI agree to a different date. However, because the merger is subject to a number of conditions, neither BioSante nor ANI can predict exactly when the closing will occur or if it will occur at all. See "The Merger Agreement  Conditions to Completion of the Merger" for a more complete description of the conditions that must be satisfied or, if permissible, waived before closing.

### Background of the Merger

As a part of its corporate strategy, BioSante over the past several years actively has sought and implemented strategic alternatives with respect to its products and its company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies.

In 2008, BioSante engaged a financial advisor to assist BioSante in exploring a possible exclusive license of LibiGel to a third party or a possible sale of BioSante. During 2008, BioSante's then financial advisor contacted approximately 100 public and private companies regarding their interest in licensing LibiGel or acquiring BioSante. Approximately 10 of these companies received management presentations from BioSante and/or performed limited due diligence on BioSante. However, almost all of these companies indicated that they were not interested in licensing LibiGel or acquiring BioSante. Of the companies that indicated an interest, none of them submitted a formal bid. BioSante's management, nonetheless, continued to pursue the companies that indicated informally an interest in licensing LibiGel or acquiring BioSante and other third parties that were subsequently identified by BioSante as possible candidates for a possible business combination, license transaction or other

Table of Contents

transaction with BioSante. However, no transaction to license LibiGel or acquire BioSante was ever negotiated or completed.

In October 2009, BioSante acquired Cell Genesys, Inc., a company that was focused on the development and commercialization of novel biological therapies for patients with cancer. Although the primary purpose of BioSante's acquisition of Cell Genesys was to acquire Cell Genesys's cash to use to fund BioSante's LibiGel clinical development program, BioSante also acquired Cell Genesys's rights to its GVAX cancer vaccine portfolio.

Subsequent to BioSante's acquisition of Cell Genesys, BioSante continued its development of LibiGel, including its two Phase III efficacy trials and its Phase III cardiovascular events and breast cancer safety study. BioSante also facilitated further studies and commercialization of its GVAX cancer vaccine portfolio in order to bring important cancer therapies to patients in need and maximize the value of the GVAX cancer vaccine portfolio to the BioSante stockholders. BioSante was successful in coordinating the further development of the GVAX cancer vaccine portfolio, including vaccines for the treatment of several different cancers including melanoma, leukemia, pancreatic, breast and prostate cancer, and obtaining FDA orphan drug designations for four of these vaccines to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma. Currently, there are 17 Phase I and Phase II clinical studies involving BioSante's GVAX cancer vaccines ongoing.

In an attempt to monetize the GVAX cancer vaccine portfolio, in July 2010, BioSante engaged a consulting and advisory firm that specializes in transactions in the biopharmaceutical and life sciences industries to assist BioSante in exploring strategic alternatives with respect to the GVAX cancer vaccine portfolio. BioSante's management and this consulting and advisory firm contacted over 80 companies to determine their interest in licensing some or all of BioSante's GVAX cancer vaccine portfolio. Through management's efforts, BioSante was successful in implementing licensing transactions during 2011 with Aduro BioTech, Inc. and The John P. Hussman Foundation covering certain aspects of the GVAX cancer vaccine portfolio. BioSante retains rights to substantially all of the GVAX cancer vaccine portfolio, other than those licensed to Aduro BioTech, Inc. and The John P. Hussman Foundation.

In 2010, BioSante again engaged a management consulting company to assist BioSante in exploring a possible exclusive license of LibiGel to a third party. During 2010 and 2011, BioSante's then advisor contacted over 60 public and private companies regarding their interest in the further development and marketing of LibiGel. Approximately 10 of these companies received management presentations from BioSante and/or performed limited due diligence on BioSante regarding LibiGel. Several of these companies expressed interest in a licensing transaction and potential terms were discussed with at least one of these companies. However, based on the passage of time and the then approaching completion of the LibiGel efficacy trials, all of these companies determined that they would wait until BioSante's receipt of the results from its LibiGel Phase III efficacy trials. Although some companies indicated that they may be interested in LibiGel after BioSante's receipt of the results from its LibiGel Phase III efficacy trials, none of these companies or any other companies indicated any such interest after BioSante's announcement of the results from the LibiGel Phase III efficacy trials in December 2011.

In December 2011, BioSante announced the results from its two LibiGel Phase III efficacy trials, which showed that the trials did not meet the co-primary or secondary endpoints. Although LibiGel performed as predicted, increasing satisfying sexual events and sexual desire and decreasing distress associated with low desire, the placebo response in the two efficacy trials was greater than expected, and LibiGel's results were not shown to be statistically different from use of placebo.

Subsequent to BioSante's announcement of the results from its two LibiGel Phase III efficacy trials, BioSante implemented several operating expense reduction measures, explored potential new product development projects through in-licensing and mergers and acquisitions, and analyzed further the data from the LibiGel Phase III efficacy trials in an attempt to understand whether to continue to allocate resources to the development of LibiGel and the LibiGel Phase III safety study.

Table of Contents

In January 2012, in order to reduce its operating expenses and conserve cash, BioSante implemented several cost-saving measures, including reducing substantially the number of its independent contractors, resulting in a 25 percent total reduction in BioSante's personnel.

In February 2012, in order to reduce its then outstanding debt of approximately $20.8 million in aggregate principal amount, and ongoing interest obligations, BioSante issued an aggregate of 1,868,055 shares of BioSante common stock in exchange for the cancellation of $9.0 million in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013 and the related accrued and unpaid interest of $79,024. After these securities exchange transactions, BioSante had $11.8 million in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013 outstanding.

From mid-December 2011 through May 2012, BioSante's management contacted over 50 public and private companies regarding their interest in a possible strategic transaction with BioSante, including in-licensing transactions and other business combinations or transactions. Of these companies, 12 engaged in management presentations with BioSante and/or limited due diligence investigations with BioSante, and approximately 10 of these companies entered into confidentiality agreements with BioSante, including the companies referred to as Company A, Company B and Company C in this section.

At the same time, from mid-December 2011 through May 2012, BioSante's management continued to analyze further the data from its LibiGel Phase III efficacy trials, consulted with key opinion leaders in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA in an attempt to understand whether to continue to allocate resources to the development of LibiGel and the LibiGel Phase III safety study. In addition, during such time period, BioSante's management also explored other alternative potential uses for its LibiGel Phase III safety study data.

On May 30, 2012, the BioSante board of directors held a regular meeting at BioSante's corporate offices in Lincolnshire, Illinois. At this meeting, the BioSante board of directors discussed whether it would be in the best interest of BioSante and its stockholders for BioSante to continue to allocate its resources to the development of LibiGel or allocate its resources to other biopharmaceutical product areas through in-licensing or acquisitions, or combine with or be acquired by a public or private company. After careful consideration of these strategic alternatives, the BioSante board of directors decided to proceed with a plan to continue the development of LibiGel, including continuing the then ongoing LibiGel Phase III safety study and initiating two new LibiGel Phase III efficacy trials. The BioSante board of directors determined that while such a plan was not without risk, it represented the best alternative then available to BioSante and its stockholders. However, the BioSante board of directors also directed BioSante's management to continue its pursuit to seek strategic alternatives and to keep the BioSante board of directors apprised of the status of such efforts so that the BioSante board of directors could revisit from time-to-time as appropriate its decision to continue the development of LibiGel.

On June 11, 2012, BioSante announced its plan to initiate two new LibiGel Phase III efficacy trials. BioSante subsequently continued to develop a protocol for the two new efficacy trials and to seek an FDA Special Protocol Assessment (SPA) agreement covering aspects of the two new efficacy trials.

On June 12, 2012, the day after BioSante announced its plan to initiate two new LibiGel Phase III efficacy trials, BioSante received an unsolicited indication of interest from a private specialty pharmaceutical company referred to as Company A to engage in a stock-for-stock transaction pursuant to which 50 percent of the surviving entity would be owned by the BioSante stockholders and the remaining 50 percent of which would be owned by Company A stockholders. The indication of interest contemplated that the surviving entity would be managed by Company A's management and would complete development of and submit new drug applications for two of Company A's drug candidates, and, based on statements in the indication of interest, would not pursue any further development of LibiGel.

Table of Contents

On June 18, 2012, the BioSante board of directors held a special meeting to discuss the receipt of the indication of interest from Company A, to engage possible financial advisors to assist BioSante and the BioSante board of directors in evaluating a response to the indication of interest from Company A and other strategic alternatives that may be available for BioSante, and BioSante's recently announced plan to initiate two new LibiGel Phase III efficacy trials. A representative of BioSante's legal counsel, Oppenheimer Wolff & Donnelly LLP (OWD) summarized the fiduciary duties and responsibilities of the BioSante board of directors both generally and specifically in considering an all-stock transaction of the type proposed by Company A. After extensive discussion, it was the consensus of the BioSante board of directors that although the board remained committed to BioSante's current business plan and strategy, including the plan to initiate two new LibiGel Phase III efficacy trials, the board also was committed to increasing stockholder value for the BioSante stockholders and thus remained open minded as to other strategic alternatives that would increase stockholder value and be in the best interests of the BioSante stockholders. The BioSante board of directors directed BioSante's management to request from Company A additional information, including its business plan and strategy, historical and projected financial information, and valuation information, in order to enable the BioSante board of directors to review and analyze the proposal.

Subsequent to the BioSante board of directors meeting on June 18, 2012, BioSante's president and chief executive officer, Stephen M. Simes, responded to Company A's June 12, 2012 indication of interest requesting additional information from Company A.

On June 20, 2012, the president and chief executive officer of Company A requested a meeting with Mr. Simes, and BioSante's senior vice president, finance, chief financial officer and secretary, Phillip B. Donenberg, to discuss Company A's indication of interest, BioSante's corporate strategy and general aspects of a possible transaction between the two companies.

On June 21, 2012, BioSante's management reiterated to Company A BioSante's need for additional information from Company A in order to enable BioSante to review and analyze Company A's offer.

On June 27, 2012, the president and chief executive officer of Company A responded that prior to responding to BioSante's information request, he would like to meet with BioSante's management to discuss Company A's indication of interest.

On July 3, 2012, the president and chief executive officer of Company A visited BioSante's corporate offices in Lincolnshire, Illinois and met with Mr. Simes and Mr. Donenberg. The parties discussed Company A's corporate strategy, BioSante's corporate strategy, Company A's indication of interest and general aspects of a possible transaction between the two companies. Subsequent to July 3, 2012, BioSante commenced a due diligence investigation of Company A, including its proposed products, regulatory matters and intellectual property, and gave access to Company A and its advisors to BioSante's electronic data room, which contained legal, regulatory, financial and other documents relating to BioSante and its business. Also subsequent to July 3, 2012, BioSante's management and Company A's management discussed on several occasions in person and via telephone the status of each other's respective due diligence investigations, the material terms of a possible transaction between the two parties and the status and timing of a possible transaction between the two parties.

On July 9, 2012, BioSante received a non-binding draft term sheet from a public biopharmaceutical company referred to as Company B proposing a stock-for-stock transaction pursuant to which the exchange ratio would be based on BioSante's market capitalization immediately prior to the signing of a definitive agreement. Under the term sheet, 30 percent of the Company B shares to be issued to the BioSante stockholders in connection with the transaction would be held back and offset against BioSante's transaction expenses, the remaining principal amount of BioSante's convertible senior notes and certain other costs and expenses, and the completion of the transaction would be conditioned upon BioSante having a specified minimum net cash as of closing. The term sheet also provided for

Table of Contents

contingent value rights that would entitle the BioSante stockholders to 75 percent of any fees received by Company B from the sale or license of LibiGel and certain milestone payments with respect to products in BioSante's GVAX cancer vaccine portfolio. The term sheet contemplated that Company B's management team would manage the surviving entity and the surviving entity would focus primarily on the further development and commercialization of Company B's products and technologies.

From July 10, 2012 to July 12, 2012, Mr. Simes and Mr. Donenberg attended the annual JMP Securities 7th Annual Healthcare Conference in New York. During the conference, Mr. Simes and Mr. Donenberg met with five investment banking firms which focused on the biopharmaceutical industry and that BioSante had worked with in the past regarding their interest in acting as a financial advisor for BioSante and assisting BioSante in responding to the indication of interest from Company A and the term sheet from Company B and in raising additional financing to fund the two new LibiGel efficacy trials. In addition, during the conference, Mr. Simes and Mr. Donenberg met with three institutional investors to discuss their interest in a possible equity investment in BioSante to fund the two new LibiGel Phase III efficacy trials.

Subsequent to BioSante's announcement of the two new LibiGel Phase III efficacy trials, the trading price of BioSante common stock decreased significantly from a closing sale price of $2.58 per share as of June 8, 2012 to a closing sale price of $2.01 as of July 12, 2012, a decrease of over 20 percent.

In part, as a result of the significant decrease in the trading price of BioSante common stock since the public announcement of the two new LibiGel Phase III efficacy trials, the input from the five investment banking firms and three institutional investors regarding BioSante's ability to raise the additional financing required to fund the two new LibiGel Phase III efficacy trials and the likely terms of such financing, the Listing Rules of The NASDAQ Global Stock Market which limit the ability of NASDAQ listed companies to raise additional financing in discounted equity offerings, the volatility of the stock market in general and the uncertainty of the capital markets environment to raise additional financing, BioSante's management began to recognize the significant risks and uncertainties involved in raising the substantial additional financing that would be required to fund the two new LibiGel efficacy trials. BioSante's management estimated that the two new LibiGel Phase III efficacy trials would cost approximately $15 to $18 million each, or a combined $30 to $36 million spread over 18 months.

On July 16, 2012, the BioSante board of directors held a special meeting for management to update the board with respect to BioSante's business, including the LibiGel clinical development program, and discuss strategic alternatives. At the meeting, BioSante's management presented financial scenarios of BioSante as an ongoing independent publicly traded company, assuming the continuation of the LibiGel Phase III safety study and the initiation of the two new LibiGel Phase III efficacy trials, but no other clinical development, licensing revenues or equity financings, and assuming a conclusion of the LibiGel Phase III safety study, a decision not to pursue the two new LibiGel Phase III efficacy trials, no other clinical development, licensing revenues or equity financings and certain restructuring activities to downsize BioSante's organization. BioSante's management described analyst and investor response to BioSante's June 2012 announcement of the two new LibiGel Phase III efficacy trials based on management's several meetings with investment banking firms and investors and the significant decrease in the trading price of BioSante common stock since the announcement. BioSante's management informed the board that raising the substantial additional financing required to fund the new LibiGel Phase III efficacy trials would be challenging in light of investor reaction to BioSante's announcement of the new LibiGel Phase III efficacy trials, BioSante's then current stock price and NASDAQ's limitations on discounted offerings. After extensive discussion, the BioSante board of directors authorized BioSante's management to continue to explore whether there were any strategic alternatives available to BioSante that likely would increase stockholder value more than BioSante's current business plan and strategy. In so directing BioSante's management, the BioSante board of directors recognized that since no cash buyers had emerged over the last five years during BioSante's

Table of Contents

efforts to seek strategic alternatives, a cash buyer was unlikely to emerge at this time and thus directed BioSante's management not to expend significant time and resources in pursuing a cash sale of BioSante and to focus on those companies that previously had expressed an interest in a potential business combination with BioSante or otherwise would be likely to be interested in a potential business combination with BioSante.

On July 18, 2012, Mr. Simes contacted the president and chief executive officer of Company B and informed him that BioSante was undertaking a process to evaluate strategic alternatives for BioSante and that he would discuss Company B's term sheet with the BioSante board of directors.

On July 19, 2012, Mr. Simes, Mr. Donenberg, Michael C. Snabes, M.D., Ph.D., BioSante's Senior Vice President of Medical Affairs, Joanne Zborowski, BioSante's Vice President of Clinical Development, and Jeff Winkelman, Ph.D., BioSante's Vice President of Intellectual Property and Contracts, met with representatives of another private biotechnology company referred to as Company C. At this meeting, the parties discussed each other's businesses and the possible terms of a potential transaction between the two companies.

On July 19, 2012, BioSante and ANI entered into a mutual confidentiality agreement in order to allow the parties to explore and evaluate a possible transaction and conduct initial due diligence.

On July 23, 2012, ANI sent an exploratory initial indication of interest letter to BioSante that proposed an acquisition of 100 percent of the equity securities of BioSante for total consideration of up to 50 percent of the equity securities of the combined company and additional contingent cash payments of 66 percent of any net cash payments received in connection with BioSante's LibiGel program, up to an aggregate of $40 million.

On July 26, 2012, BioSante received a written non-binding initial term sheet from Company C proposing a stock-for-stock transaction pursuant to which BioSante as the surviving company would be owned 51 percent by Company C stockholders and 49 percent by the BioSante stockholders, but would be managed by Company C's management team and focus primarily on Company C's business. The term sheet also provided for contingent value rights that would entitle the BioSante stockholders to 75 percent of any fees received by Company C from the sale or license of LibiGel for a period of two years from the closing date. The term sheet indicated that the transaction would be conditioned upon BioSante having a specified minimum net cash as of closing of the transaction.

On July 31, 2012, BioSante received a written non-binding letter of intent from Company A proposing a stock-for-stock merger transaction pursuant to which BioSante as the surviving entity would be owned 50 to 60 percent by the Company A stockholders and 40 to 50 percent by the BioSante stockholders, with the exact ownership percentages determined based on BioSante's net cash as of closing. The letter of intent indicated that the board of directors of the surviving entity would be comprised of three members selected by Company A, three members selected by BioSante and one member selected by both Company A and BioSante. The letter of intent contemplated that the surviving entity would focus on Company A's business and terminate all clinical development activities relating to LibiGel. The letter of intent contemplated that BioSante's management team would manage the merged company. The letter of intent stated that it would be valid only if executed by BioSante by August 9, 2012.

Table of Contents

During July 2012, in order to reduce further the outstanding principal amount of its convertible senior notes and ongoing interest obligations, BioSante issued an aggregate of 1,784,070 shares of BioSante common stock in exchange for the cancellation of $3.5 million in aggregate principal amount of its convertible senior notes and the related accrued and unpaid interest of $20,686. After these securities exchange transactions, BioSante had $8.3 million in aggregate principal amount of its convertible senior notes outstanding.

On August 3, 2012, Mr. Simes and Mr. Donenberg of BioSante met with Arthur S. Pryzbyl, ANI's president and chief executive officer, and Charlotte C. Arnold, ANI's vice president and chief financial officer, and representatives of Oppenheimer & Co. Inc. by telephone to discuss further a potential transaction between BioSante and ANI. Each of ANI's and BioSante's management team gave a corporate presentation on such call.

On August 7, 2012, the BioSante board of directors held a special meeting for management to update the board with respect to BioSante's business, including the LibiGel clinical development program, and discuss strategic alternatives. At the meeting, BioSante's management presented updated and revised financial scenarios of BioSante as an ongoing independent publicly traded company, assuming the continuation of the LibiGel Phase III safety study and the two new LibiGel Phase III efficacy trials, but no other clinical development, licensing revenues or equity financings, and assuming a conclusion of the LibiGel Phase III safety study, a decision not to pursue the two new LibiGel Phase III efficacy trials, no other clinical development, licensing revenues or equity financings and certain restructuring activities to downsize BioSante's organization. BioSante's management summarized for the board the four indications of interest that BioSante had received to date and the possibility that BioSante may receive additional indications of interest based on discussions between BioSante's management and other parties. BioSante's management described the companies that had submitted indications of interest, their businesses, the status of negotiations with each of the companies, and, at a high level, the likely terms of a possible transaction with BioSante. The BioSante board of directors authorized management to continue to explore whether there were any strategic alternatives available to BioSante that likely would increase stockholder value more than BioSante's current business plan and strategy. BioSante's management also informed the board regarding the various investment banking firms with whom it had met and the material terms of an engagement if BioSante were to engage such firms. The BioSante board of directors authorized BioSante's management to enter into an engagement letter with Oppenheimer & Co. Inc., pursuant to which Oppenheimer & Co. Inc. would act as exclusive financial advisor to BioSante in connection with a possible strategic transaction. The BioSante board of directors selected Oppenheimer & Co. Inc. based on its familiarity with BioSante's business and the biopharmaceutical industry in general, its ability to access companies potentially interested in a transaction with BioSante and the financial terms of the engagement. The BioSante board of directors authorized BioSante's management to direct Oppenheimer & Co. Inc. to solicit indications of interest regarding a possible business combination transaction with BioSante and to focus those efforts on companies in the biopharmaceutical industry with a commercial or near-commercial stage product or products in development that coincide with BioSante's products in development.

On August 8, 2012, BioSante formally engaged the investment banking firm, Oppenheimer & Co. Inc., in connection with BioSante's evaluation of alternatives.

On August 8, 2012, the president and chief executive officer of Company A contacted Mr. Simes and indicated that Company A was no longer interested in pursuing a stock-for-stock transaction with BioSante primarily because of BioSante's refusal prior to such time to engage in exclusive negotiations with Company A regarding the transaction proposed by Company A in its July 31, 2012 letter of intent.

On August 8, 2012, a representative of Oppenheimer & Co. Inc., on behalf of BioSante, contacted Company B and indicated that BioSante was conducting a formal process to seek strategic alternatives and would keep Company B informed as the process continued.

Table of Contents

On August 8, 2012, BioSante received a written indication of interest from a public biotechnology company referred to as Company D to engage in a possible business transaction. Prior to proposing the material terms of such a transaction, Company D insisted that BioSante enter into a written confidentiality agreement and that the parties commence a due diligence review of each other's operations, assets, liabilities, books, records, facilities and capital structure. On August 14, 2012, BioSante and Company D entered into a written confidentiality agreement and subsequently commenced their respective due diligence investigations. In furtherance of Company D's due diligence of BioSante, BioSante gave access to BioSante's electronic data room to Company D and its advisors. Based on conversations between representatives of BioSante and of Oppenheimer & Co. Inc. and representatives of Company D, Company D contemplated a stock-for-stock merger transaction pursuant to which the BioSante stockholders would own up to 50 percent of the parent or surviving entity.

On August 8, 2012, ANI's management and legal advisors were granted access to BioSante's electronic data room and immediately commenced a due diligence review of BioSante and its business.

On August 16, 2012, BioSante entered into a placement agent agreement with Rodman & Renshaw, LLC, pursuant to which Rodman & Renshaw, LLC agreed to use its reasonable best efforts to arrange for the sale of shares of BioSante common stock and warrants to purchase shares of BioSante common stock in a registered direct public offering. Later on August 16, 2012, BioSante and a certain institutional investor entered into a securities purchase agreement, pursuant to which BioSante agreed to sell 2,359,932 shares of its common stock and warrants to purchase a total of 1,179,966 shares of its common stock to such investor for gross proceeds of $3.475 million. The common stock and warrants were sold in units, with each unit consisting of one share of BioSante common stock and a warrant to purchase 0.50 of a share of BioSante common stock. The purchase price per unit was $1.4725. On August 20, 2012, BioSante completed the offering.

On August 22, 2012, BioSante received a revised non-binding written letter of intent from Company B proposing a reverse triangular stock-for-stock merger pursuant to which BioSante would be the surviving entity and a wholly owned subsidiary of Company B and the exchange ratio used to determine the number of Company B shares to be issued to the BioSante stockholders would be based on BioSante's market capitalization immediately prior to the signing of the definitive agreement. Under the letter of intent, 30 percent of the Company B shares to be issued to the BioSante stockholders in connection with the transaction would be held back and offset against BioSante's transaction expenses, the remaining principal amount of BioSante's convertible senior notes and certain other costs and expenses, and completion of the transaction would be conditioned upon BioSante having a specified minimum net cash as of closing. Unlike the initial term sheet provided by Company B to BioSante on July 9, 2012, the letter of intent did not contemplate the issuance of contingent value rights to the BioSante stockholders. The letter of intent contemplated that Company B's management team would manage the surviving entity going forward and the surviving entity would focus primarily on the further development and commercialization of Company B's products and technologies.

On August 24, 2012, BioSante and a public pharmaceutical oncology company referred to as Company E entered into a mutual confidentiality agreement. Shortly thereafter, BioSante gave access to BioSante's electronic data room to Company E and its advisors. On August 27, 2012 BioSante received from Company E a written non-binding term sheet describing the general terms of a proposed business combination transaction between BioSante and Company E. The term sheet contemplated a reverse triangular stock-for-stock merger pursuant to which Company E would be the surviving entity and the number of Company E shares to be issued to the BioSante stockholders would be based on BioSante's market capitalization at the time of the execution of the definitive merger agreement. The term sheet indicated that the transaction would be conditioned upon BioSante having a specified minimum amount of net cash at closing. Subsequent to August 27, 2012, representatives of BioSante and Company E conducted due diligence on each other and met in person and via telephone and discussed the general terms of a proposed business combination transaction between the two parties.

Table of Contents

During July and August 2012, in addition to the various companies previously mentioned BioSante conducted limited due diligence on a private oncology company and another private pharmaceutical company to decide whether to engage in more formal discussions regarding a potential business combination transaction with such companies. After BioSante's due diligence investigation of the two companies, BioSante's management decided that neither of the two companies would be a good fit for BioSante largely due to the fact that both companies' businesses were at too early a stage of development and would require significant additional investment for the foreseeable future.

On August 27, 2012, the BioSante board of directors held a special meeting for management to update the board with respect to BioSante's business, including the LibiGel clinical development program, and discuss strategic alternatives. With respect to the LibiGel clinical development program, the BioSante board of directors determined that in light of the independent Data Monitoring Committee's most recent unblinded review of the LibiGel safety study adequate safety data of LibiGel use in menopausal women had been obtained and determined to conclude the safety study. BioSante's management and representatives of Oppenheimer & Co. Inc. summarized for the board management's review and assessment of BioSante's alternatives, including a review of whether it would be in the best interest of BioSante and its stockholders for BioSante to continue as an independent company and continue to allocate its resources to the development of LibiGel or allocate its resources to other biopharmaceutical product areas through in-licensing or acquisitions, combine with or be acquired by a public or private company, sell BioSante's assets or liquidate BioSante. After an extensive discussion on the potential alternatives and the various companies that had submitted indications of interest and remained interested in a transaction with BioSante, it was the consensus of the BioSante board of directors that a combination of BioSante and ANI would create more value for the BioSante stockholders in the long-term than BioSante could create as an independent, stand-alone company, given the anticipated costs, timing and risks associated with continuing the development of LibiGel and other BioSante products in development and/or in-licensing or acquiring additional technologies or product candidates, and the uncertain capital markets, which BioSante historically had relied upon to raise additional financing to fund its product development efforts. In addition, the BioSante board of directors concluded that a potential transaction with ANI was superior to a liquidation of BioSante since ANI's proposal represented a premium to BioSante's estimated cash available to distribute to the BioSante stockholders and also included considerable upside through a continued equity investment in the combined business. The BioSante board of directors directed management to proceed with negotiations with ANI since ANI's proposal appeared to offer the most attractive terms for a transaction with BioSante out of the indications of interest that had been received by BioSante and such a transaction with ANI would give the BioSante stockholders an opportunity to participate in the potential future value of the combined company, including future potential value from ANI's established contract manufacturing operations, niche generic prescription products and products in development, as well as give the BioSante stockholders the right to potentially receive certain future cash payments in the event of a subsequent sale, transfer, license or similar transaction relating to BioSante's LibiGel program. In addition to ANI, the BioSante board of directors also directed management to explore further a potential transaction with Company B, Company D and Company E since discussions with those companies had not matured as quickly as with ANI.

On August 31, 2012, a representative of Oppenheimer & Co. Inc. sent to ANI's management a draft merger agreement and a due diligence request for purposes of assisting BioSante in performing a due diligence investigation of ANI.

On August 31, 2012, ANI's management communicated to Oppenheimer & Co. Inc. that ANI was not interested in spending significant resources on a potential transaction without an exclusivity letter and sent a draft exclusivity letter to BioSante's management.

On September 4, 2012, the representative of Oppenheimer & Co. Inc. informed ANI's management that BioSante would not grant exclusivity to ANI prior to September 14, 2012, the date of

Table of Contents

the next regular meeting of the BioSante board of directors, and that in the meantime, the parties should continue to perform their respective due diligence investigations of each other in order to move the transaction forward and enable BioSante's management to present a proposed transaction with ANI to the BioSante board of directors at its meeting on September 14, 2012.

On September 5, 2012, ANI's management sent to Oppenheimer & Co. Inc. and BioSante's management a draft non-binding letter of intent pursuant to which ANI proposed a merger with BioSante following which the holders of ANI capital stock and in-the-money dilutive securities would hold 55 percent of the issued and outstanding common stock of the combined company and the holders of BioSante common stock and in-the-money dilutive securities would hold 45 percent of the issued and outstanding common stock of the combined company. The letter of intent contemplated contingent cash payments to the BioSante stockholders of 65 percent of any net cash proceeds received for BioSante's LibiGel program, up to a maximum of $40 million in the aggregate. The letter of intent contemplated that the executive officers of ANI would be the executive officers of the combined company and that the board of directors of the combined company would consist of seven individuals, one of whom would be the combined company's chief executive officer, four of whom would be designated by ANI and two of whom would be designated by BioSante. The letter of intent also contained other provisions, including a minimum net cash closing requirement for BioSante, a net cash definition, termination right and fee provisions and a 15-day exclusivity provision

Between September 5, 2012 and September 14, 2012, representatives of BioSante and ANI exchanged drafts of the letter of intent and negotiated the terms and conditions of the letter of intent, including the post-merger ownership percentages, potential adjustments to the post-merger ownership percentages, the minimum net cash closing requirement for BioSante, the net cash definition, the composition of the board of directors of the combined company, termination right and fee provisions and the term of the exclusivity provision.

On September 13, 2012, Mr. Pryzbyl and Ms. Arnold and a representative of ANI's outside legal counsel, SNR Denton US LLP (Dentons) met with Mr. Simes and Mr. Donenberg of BioSante and a representative of OWD at BioSante's corporate offices in Lincolnshire, Illinois to engage in further negotiations and discussions regarding the letter of intent and conduct due diligence. By the end of the day on September 13th, the parties had negotiated the terms of the letter of intent, subject to the final approval of the letter of intent by the parties' respective boards of directors.

On September 14, 2012, a regular meeting of the BioSante board of directors took place at BioSante's corporate offices in Lincolnshire, Illinois. At the meeting, BioSante's management updated the board as to BioSante's business, including the status of the LibiGel clinical development program, and strategic alternatives. The representative of Oppenheimer & Co. Inc. described the process that Oppenheimer & Co. Inc. had engaged in since August 2012 to respond to companies that previously had indicated an interest in a possible strategic transaction with BioSante and to reach out to other companies that may have an interest in a strategic transaction with BioSante. The representative of Oppenheimer & Co. Inc. summarized the six indications of interest received by BioSante, and noted the other three parties that had engaged in discussions regarding a possible strategic business combination transaction with BioSante. The representative of Oppenheimer & Co. Inc. also discussed the potential terms of a transaction with each of these parties as evident by their respective indications of interest and, in some cases, subsequent conversations between representatives of Oppenheimer & Co. Inc. and such companies. The representative of Oppenheimer & Co. Inc. described the management teams, businesses, prospects, operating results and financial position of three of the companies with whom Oppenheimer & Co. Inc. and BioSante's management considered to be the most likely parties to a transaction with BioSante, and in much greater detail, the management team, business, prospects, operating results of ANI. BioSante's management summarized the material terms of the proposed non-binding letter of intent with ANI. After an extensive discussion, the BioSante

Table of Contents

board of directors authorized BioSante's management to enter into the non-binding letter of intent with ANI, on substantially the terms as described to the board at the meeting.

After the meeting of the BioSante board of directors, on September 14, 2012, and after further negotiation regarding the circumstances under which a termination of the merger agreement would give rise to the payment of a termination fee by BioSante, the letter of intent was executed by BioSante and ANI. Pursuant to the terms of the letter of intent, BioSante and ANI agreed to negotiate exclusively with one another until September 28, 2012, unless either party earlier notified the other of its decision to terminate discussions.

From September 14, 2012 to October 3, 2012, BioSante's and ANI's respective managements performed additional due diligence. During such period, several telephone conference calls were held between BioSante's management and advisors and ANI's management and advisors to discuss various aspects of their respective due diligence investigations.

On September 19, 2012, ANI's legal counsel sent BioSante's legal counsel a mark-up of the draft merger agreement.

On September 20, 2012, representatives of OWD and Dentons held a telephone conference call to discuss the terms of the merger agreement, including in particular the definition of net cash, various adjustments to net cash and the effect of potential future payments to BioSante on the determination of net cash for purposes of the merger agreement, certain representations and warranties, and certain covenants, including the non-solicitation covenant, the employee benefit covenant and the ability of BioSante and ANI to take certain actions during the period after the execution of the merger agreement and prior to the closing of the merger, and closing conditions.

Between September 20, 2012 and September 28, 2012, representatives from OWD and Dentons exchanged drafts of the merger agreement, contingent value rights agreement, form of voting agreements and form of lock-up agreement and continued to negotiate the terms and conditions of the merger agreement, the contingent value rights agreement and the other ancillary agreements.

On September 28, 2012, representatives of BioSante, ANI, OWD and Dentons held a telephone conference call to discuss the remaining open business terms of the merger agreement, including the definition of net cash, various adjustments to net cash and the effect of potential future payments to BioSante on the determination of net cash for purposes of the merger agreement, the ability of BioSante and ANI to enter into certain agreements during the period after the execution of the merger agreement and the closing of the merger, and certain conditions to the obligation of ANI to close the merger. The parties also discussed the remaining open business terms of the contingent value rights agreement. After such call, although BioSante and ANI did not enter into a written amendment to their letter of intent extending the exclusivity provision beyond September 28, 2012, the parties and their advisors committed to negotiate and finalize the merger agreement, the contingent value rights agreement and the other related ancillary agreements as soon as reasonably practicable.

Between September 28, 2012 and October 3, 2012, representatives from OWD and Dentons continued to exchange drafts of the merger agreement, the contingent value rights agreement and the other related ancillary agreements and negotiate the terms and conditions of such agreements.

On October 3, 2012, the BioSante board of directors held a special meeting to consider the proposed transaction with ANI. A representative of OWD reviewed with the BioSante board of directors its fiduciary duties applicable to the proposed transaction. A representative of OWD summarized the principal deal terms focusing, in particular, on changes to those terms since the meeting held by the BioSante board of directors on September 14, 2012 and the letter of intent executed on that date. A draft of the merger agreement and the contingent value rights agreement, a memorandum describing the principal terms of the transaction documents and proposed resolutions were provided to the members of the BioSante board of directors in advance of the meeting. Also at

Table of Contents

this meeting, Oppenheimer & Co. Inc. reviewed with the BioSante board of directors its financial analyses and rendered to the BioSante board of directors an oral opinion, which was confirmed by delivery of a written opinion dated October 3, 2012, to the effect that, as of that date and based on and subject to the matters described in the opinion, the exchange ratios provided in the merger agreement were fair, from a financial point of view, to BioSante. A representative of OWD summarized the proposed resolutions for the BioSante board of directors. After an extensive discussion and consideration of the financial and legal aspects of the proposed transaction and the other matters described under " BioSante Reasons for the Merger" beginning on page 128 of this joint proxy statement/prospectus, the directors unanimously determined that the merger and the other transactions contemplated thereby were fair to, and in the best interests of, BioSante and its stockholders. The directors voted unanimously to approve and adopt all of the resolutions, including the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger, the approval of the contingent value rights agreement and other related ancillary agreements and the approval of the amendments to BioSante's certificate of incorporation to effect a reverse split of BioSante common stock and BioSante class C special stock in the discretion of BioSante and ANI at a ratio of either one-to-two, one-to-three, one-to-four or one-to-five and to change the corporate name of BioSante to "ANI Pharmaceuticals, Inc."

On October 3, 2012, the ANI board of directors held a special meeting to consider the proposed transaction with BioSante. A representative of Dentons summarized the principal deal terms focusing, in particular, on changes to the terms since the letter of intent was executed on September 14, 2012. A draft of the merger agreement and the contingent value rights agreements were provided to the members of the ANI board of directors in advance of the meeting. After an extensive discussion and consideration of the financial and legal aspects of the proposed transaction and the other matters described under " ANI Reasons for the Merger" beginning on page 132 of this joint proxy statement/prospectus, the directors voted unanimously to approve the merger agreement and the transactions contemplated thereby, including the merger, and related matters.

During the evening of October 3, 2012, all of BioSante's directors and officers entered into voting agreements with ANI to vote in favor of the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger, and the approval of the amendments to BioSante's certificate of incorporation. In addition, certain stockholders of ANI entered into a voting agreement with BioSante pursuant to which they agreed to vote in favor of the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger, and one of ANI's stockholders, Meridian Venture Partners II, L.P., agreed in its voting agreement with BioSante to vote in favor of the election of the two directors designated by BioSante at the first annual meeting of stockholders of the combined company following completion of the merger.

Also during the evening of October 3, 2012, representatives of ANI and Dentons and BioSante and OWD finalized the merger agreement, and BioSante and ANI entered into the merger agreement.

On October 4, 2012, BioSante and ANI issued a joint news release announcing the proposed merger of ANI and BioSante.

On November 13, 2012, BioSante and ANI entered into an amendment to the merger agreement to change the date upon which the parties must agree to the amount of the current class action and shareholder derivative litigation reserve for purposes of the net cash definition from November 15, 2012 to November 30, 2012. BioSante and ANI subsequently agreed upon zero as the amount of the current class action and shareholder derivative litigation reserve for purposes of the net cash definition.

Table of Contents

**BioSante Reasons for the Merger**

In evaluating the merger, the BioSante board of directors consulted with BioSante's management and legal, financial and other advisors and, in reaching its decision to approve the merger and enter into the merger agreement, the BioSante board of directors considered a number of factors, including the following material factors which the BioSante board of directors viewed as generally supporting its decision to approve the merger and the merger agreement.

The consideration of BioSante's anticipated near- and long-term operations and performance on an independent, stand-alone basis, the substantial additional financing that would be needed to sustain such operations assuming BioSante continued its LibiGel clinical development program or in-licensed or acquired additional technologies or product candidates, and the risk that such substantial additional financing could not be obtained on terms favorable to BioSante, or at all, in light of a volatile economy, uncertain capital markets and limitations on BioSante's ability to effect equity offerings.

The consideration of other strategic alternatives to the proposed merger with ANI, including other merger transactions with other companies, continuing to operate BioSante on an independent, stand-alone basis, in-licensing or acquiring additional technologies or product candidates and undertaking a liquidation of BioSante, and the belief that the proposed merger with ANI would permit the BioSante stockholders with a greater potential opportunity to realize a return on their investment than any other alternative reasonably available to BioSante and the BioSante stockholders.

The belief that the combination of BioSante's and ANI's businesses would create more value for the BioSante stockholders in the long-term than BioSante could create as an independent, stand-alone company, given the anticipated costs, timing and risks associated with continuing the development of LibiGel and other BioSante products in development and/or in-licensing or acquiring additional technologies or product candidates, the uncertain capital markets, which BioSante historically has relied upon to raise additional financing to fund its product development efforts, and limitations on BioSante's ability to effect equity offerings.

Historical and current information concerning ANI's business, financial performance, financial condition, operations and management and the results of a due diligence investigation of ANI conducted by BioSante's management and advisors.

The opportunity for the BioSante stockholders to participate in the potential future value of the combined company, including potential future value from ANI's established contract manufacturing operations, niche generic prescription products and products in development.

The fact that the cash resources of the combined company expected to be available at the closing of the merger would provide the combined company sufficient capital to execute its near-term business strategy, obtain regulatory approvals for several of its products in development and maintain its projected business operations beyond 2013.

BioSante's ability, under the terms of the merger agreement, to issue CVRs to the holders of BioSante common stock prior to completion of the merger, which would give such BioSante stockholders the right to potentially receive certain cash payments in the event BioSante receives net cash payments during the ten-year period after the distribution of the rights as a result of the sale, transfer, license or similar transaction relating to BioSante's LibiGel program, subject to the terms and conditions contained in the CVR agreement.

The significant costs of liquidating BioSante, the operational challenges of maintaining a liquidating trust to administer any royalty and other future payments BioSante expects to receive from Teva, the licensee of BioSante's male testosterone gel, and may receive from other

Table of Contents

licensees of BioSante's products and technologies, the likelihood that BioSante would not be able to distribute immediately all of its remaining cash to the BioSante stockholders in the event of a liquidation and dissolution of the company, given the fact that BioSante would need to set aside a reserve to pay, and make provisions for, existing and future contingent and potential claims and liabilities, and the likelihood that any amount ultimately distributed to the BioSante stockholders would be minimal.

Historical and current information concerning BioSante's business, financial performance, financial condition, operations and management, including financial projections of BioSante under various scenarios and its short- and long-term strategic objectives and the risks associated therewith.

Historical and current financial market conditions and stock prices and historical stock prices and trading volumes of BioSante common stock.

The exchange ratios in the merger, which are subject to adjustment for changes in BioSante's net cash, and are intended to result in the BioSante stockholders holding approximately 47 percent of the outstanding shares of the combined company after the merger, assuming BioSante's net cash as of the determination date is $18.0 million.

The fact that the exchange ratios will not fluctuate based upon changes in the price of BioSante common stock or the value of ANI capital stock prior to completion of the merger, which protects the BioSante stockholders from any materially negative trends in the price of BioSante common stock and any materially positive trends in the value of ANI capital stock.

The all-stock nature of the merger and the intent that the merger be tax-free to the BioSante stockholders.

The terms and conditions of the merger agreement, including without limitation the following:

- The structure of the merger and the level of certainty as to the percentage of the total shares of common stock of the combined company that current BioSante and ANI stockholders will own after the merger provided by the exchange ratios which may be adjusted based on BioSante's net cash as of the determination date, but will not be adjusted to reflect changes in the market value of BioSante common stock or ANI common stock, and the determination that the relative percentage ownership of the combined company by the BioSante and ANI stockholders was consistent with BioSante's perceived valuation of each company at the time the BioSante board of directors approved the merger agreement.

- The provisions in the merger agreement that limit the ability of BioSante to solicit and respond to offers for alternative transactions, but which allow BioSante to respond to a bona fide acquisition proposal that the BioSante board of directors determines is or is reasonably likely to lead to a superior proposal, subject to certain restrictions imposed by the merger agreement, which such provisions the BioSante board of directors believes are reasonable under the circumstances.

- The requirement to hold a special meeting of BioSante stockholders to vote on the merger agreement even if the BioSante board of directors subsequently changes its recommendation, but the ability of the BioSante board of directors, in accordance with its fiduciary duties, to withdraw, modify or amend its recommendation that the BioSante stockholders vote in favor the adoption of the merger agreement and the transactions contemplated thereby, including the merger, which such provisions the BioSante board of directors believes are reasonable under the circumstances.

Table of Contents

The relatively limited nature of the closing conditions, the net cash closing condition and the inclusion of an exchange ratio adjustment for certain changes in BioSante's net cash rather than requiring a higher net cash closing condition requirement.

The ability of BioSante to effect other transactions with respect to its products in development during the pendency of the merger with ANI.

The conditions under which the merger agreement may be terminated by either party and the conclusion of the BioSante board of directors that the potential termination fee of $1.0 million or the reimbursement of certain transaction expenses incurred in connection with the merger of up to $500,000, payable by BioSante to ANI and the potential termination fee of $750,000 payable by ANI to BioSante and the circumstances when such fee or expense reimbursement may be payable or received by BioSante, are reasonable.

The restrictions on the ability of certain ANI stockholders to freely trade the shares of BioSante common stock that they receive in connection with the merger for a period of 180 days following completion of the merger.

The belief that the parties' respective representations, warranties and covenants, and conditions to their respective obligations, are reasonable under the circumstances.

The voting agreements entered into by certain stockholders of ANI representing approximately 90 percent of the outstanding shares of ANI common stock, on an as-converted basis, and 86 percent of the outstanding ANI series D preferred stock as of October 3, 2012, pursuant to which such stockholders agreed, solely in their capacity as stockholders, to vote all of their shares of ANI capital stock in favor of adoption of the merger agreement and against any alternative acquisition proposal.

The fact that two directors of BioSante will continue as directors of the combined company after the merger.

Oppenheimer & Co.'s opinion, and its financial presentation, dated October 3, 2012, to the BioSante board of directors as to the fairness, from a financial point of view and as of the date of the opinion, to BioSante of the exchange ratios, as described more fully below under the caption "Opinion of Oppenheimer & Co. Inc."

The BioSante board of directors weighed the factors described above which the BioSante board of directors viewed generally as supporting its decision to approve the merger and the merger agreement against a number of other factors identified in its deliberations weighing negatively against the merger, including without limitation the following material factors:

The fact that the shares of BioSante common stock to be issued in the merger will represent approximately 53 percent of the outstanding common stock of the combined company immediately after completion of the merger, assuming BioSante's net cash as of the determination date is $18.0 million, thus causing existing BioSante stockholders to experience immediate and significant dilution in their equity interests and voting power of BioSante upon completion of the merger.

The fact that, while BioSante expects the merger to be completed, there can be no assurance that all conditions to the parties' obligations to complete the merger, including BioSante obtaining stockholder approval of the merger and related merger proposals and BioSante's net cash being at least $17.0 million (as calculated and as adjusted pursuant to the terms of the merger agreement) as of the closing date of the merger, will be satisfied within the time frames contemplated by the merger agreement, especially since some of the conditions are outside the control of BioSante, and, as a result, the merger may not be completed.

Table of Contents

The amount of time required to complete the merger and the possibility that the merger may not be completed and the potential adverse consequences to BioSante if the merger is not completed, including the potential adverse effect on the reputation of BioSante, the potential to depress the values offered by others to BioSante in a business combination or other alternative transaction and the ability of BioSante to obtain financing in the future.

The possibility that the merger might be unduly delayed and the potential of such a delay to reduce or eliminate the expected benefits of the transaction, especially since a delay would cause BioSante's net cash to decrease thereby potentially resulting in a decrease in the percentage ownership of the BioSante stockholders in the combined company after the merger.

The possible negative effect of the public announcement of the merger on BioSante's stock price and the possible volatility in BioSante common stock that may occur during the pendency of the merger.

The possibility that the anticipated benefits of the merger may not be realized or that they may be lower than expected.

The risk that the per share value of the consideration to be paid in the merger to the ANI stockholders could increase significantly from the value prior to the announcement of the merger agreement because the exchange ratios will not be adjusted for changes in the market price of BioSante common stock or the value ANI capital stock.

The risk that sales of substantial amounts of BioSante common stock immediately after the closing of the merger and after the lapsing of lock-up restrictions 180 days after completion of the merger could adversely affect the market price of BioSante common stock.

The substantial charges to be incurred in connection with the merger, including transaction expenses that would be incurred whether or not the merger is completed, and change of control and severance payments to BioSante executive officers triggered by the closing of the transaction.

The risk of diverting the attention of BioSante's management from other strategic priorities to implement the merger and make arrangements for the integration of each company's operations and infrastructure following the merger.

The risk that ANI's revenue forecasts are not attained at the level or within the timeframe expected.

The risks, challenges and costs associated with successfully integrating two companies, with separate operations and locations.

The potential loss of key ANI employees critical to the ongoing success of the combined company's business.

The requirement under the merger agreement that BioSante call and hold a vote of the BioSante stockholders to approve the merger and related proposals, even in circumstances where the BioSante board of directors has withdrawn or adversely changed its recommendation to the BioSante stockholders with respect to such proposals in response to a superior proposal.

The ability of the ANI stockholders and management to significantly influence the combined company's business following completion of the merger.

The restrictions on the conduct of BioSante's business prior to completion of the merger, which require BioSante to carry on its business in the ordinary course and consistent with past practice, subject to specific additional restrictions, which may delay or prevent BioSante from pursuing

Table of Contents

business opportunities that otherwise would be in its best interests as an independent, stand-alone company.

The requirement that BioSante receive approval from The NASDAQ Global Market for the re-listing of BioSante common stock in connection with the merger based on The NASDAQ Global Market's initial listing requirements.

The risk of stockholder lawsuits that may be filed against BioSante and/or the BioSante board of directors in connection with the merger agreement.

The substantial transaction costs and expenses that have been incurred to date and are expected to be incurred in connection with the merger.

The provisions of the merger agreement that require BioSante to reimburse ANI for certain transaction expenses incurred in connection with the merger in the amount of up to $500,000 and pay a $1.0 million fee if the merger agreement is terminated by BioSante or ANI due to specified reasons.

The other risks of the type and nature described under "Risk Factors" and the matters described under "Cautionary Statement Regarding Forward-Looking Statements."

After consideration of these factors, the BioSante board of directors determined that these risks could be mitigated or managed by BioSante or ANI or by the combined company following the merger, were reasonably acceptable under the circumstances or, in light of the anticipated benefits, the risks were unlikely to have a materially adverse impact on the merger or on the combined company following the merger, and that, overall, these risks were significantly outweighed by the potential benefits of the merger.

Although this discussion of the information and factors considered by the BioSante board of directors is believed to include the material factors considered by the BioSante board of directors, it is not intended to be exhaustive and may not include all of the factors considered by the BioSante board of directors. In reaching its determination to approve the merger and approve and adopt the merger agreement, the BioSante board of directors did not find it useful and did not attempt to quantify or assign any relative or specific weights to the various factors that it considered in reaching its determination that the merger and the merger agreement are advisable and fair to and in the best interests of BioSante and its stockholders. Rather, the BioSante board of directors based its position and determination on the totality of the information presented to and factors considered by it. In addition, individual members of the BioSante board of directors may have given differing weights to different factors.

In considering the determination by the BioSante board of directors that the merger and the merger agreement are advisable and fair to and in the best interests of BioSante and its stockholders, you should be aware that certain BioSante directors and officers have arrangements that may cause them to have interests in the transaction that are different from, in addition to, or may conflict with the interests of the BioSante stockholders generally. See " Interests of BioSante's Directors and Officers in the Merger."

**ANI Reasons for the Merger**

In addition to its ongoing discussions and negotiations with the BioSante board of directors, the ANI board of directors discussed the potential merger with members of its management team, as well as its legal, financial and other advisors. The ANI board of directors also considered a number of

Table of Contents

factors which it believed supported its decision to approve the merger and the merger agreement, including, without limitation, the following:

That the existing BioSante product lines fit well within the ANI platform of hormone-based products.

That ANI would be able to leverage its knowledge of the hormone-based products market to further the existing BioSante product lines.

The fact that the remaining cash resources expected to be available at the closing of the merger would provide the combined company with enough capital to enable it to meet its operational needs beyond 2013.

The belief that the combination of the two businesses will result in accelerated growth and more value for the ANI stockholders than the ANI business could create on its own, given the combination of the product lines of the two companies, ANI's need for additional capital and the well-capitalized balance sheet that the combined company will have after completion of the merger.

The belief that potential future license and other royalty fees due to BioSante for its FDA-approved male testosterone gel and other products could generate significant future cash flow for the combined company.

The belief that the combined company will have access to a greater number of capital market opportunities as a public company than ANI would have as a privately held company.

That the exchange ratios in the merger will result in the ANI stockholders owning approximately 53 percent of the outstanding shares of common stock of the combined company following completion of the merger, assuming BioSante's net cash as of the determination date is $18.0 million.

The tax-free nature of the combination of ANI and BioSante in the merger.

The terms and conditions of the merger agreement, including, without limitation, the following:

The relatively limited number of closing conditions.

The ability of ANI to effect certain other transactions prior to completion of the merger.

The termination provisions and the potential for ANI to receive a termination fee of $1.0 million or the reimbursement of up to $500,000 of transaction expenses in the event of a termination by BioSante for certain specified reasons.

The reasonable nature of the representations and warranties of ANI and BioSante in the merger agreement.

The fact that the board of directors of the combined company will initially be controlled by persons appointed by ANI.

The ANI board of directors also considered certain factors that generally weighed against the merger, including, without limitation, the following:

The significant costs of concluding the LibiGel safety study and the risk that if such costs exceeded the estimates of BioSante's management, BioSante would not meet the $17.0 million net cash threshold closing condition.

The significant costs associated with the merger and the possibility that the merger will not close, with no certainty that any or all of such costs will be reimbursed by BioSante.

Table of Contents

The restrictions on the ability of certain of the ANI stockholders to freely trade their shares of BioSante common stock for a period of 180 days following completion of the merger.

The possibility that the merger may not result in the benefits the ANI board of directors expects or that such benefits could be lower than anticipated.

The risk that the per share value of the shares of BioSante common stock being issued in the merger to the ANI stockholders could be higher than the trading price of the combined company's common stock following completion of the merger.

The risk that the remaining BioSante products do not achieve the revenue currently anticipated by the ANI board of directors.

The risks, challenges and significant costs associated with integrating two companies with separate operations and locations.

The potential loss of key ANI employees critical to the performance of the combined company following completion of the merger.

The restrictions on the operation of the ANI business prior to completion of the merger, which generally require ANI to operate in the ordinary course, consistent with its past practice, which may restrict ANI from taking certain actions that the ANI board of directors otherwise believes to be in the best interest of the ANI stockholders.

The risk that ANI may be named in stockholder suits filed against BioSante in connection with the merger agreement.

The provision in the merger agreement that requires ANI to pay BioSante a $750,000 termination fee if the merger agreement is terminated by BioSante due to specified reasons.

Certain other risks of the type and nature described under "Risk Factors."

After considering all of the information, risks and concerns set forth above, the ANI board of directors determined that each of them was manageable or could otherwise be mitigated by ANI, BioSante or the combined company following the merger and that taken as a whole, such risks and concerns were reasonably acceptable when the benefits of the merger also were considered. Overall, the ANI board of directors did not believe that the risks outweighed the significant potential benefits of the merger.

In reaching its determination to approve the merger and approve and adopt the merger agreement, the ANI board of directors did not find it useful and did not attempt to quantify or assign any relative or specific weights to the various factors that it considered in reaching its determination that the merger and the merger agreement are advisable and fair to and in the best interests of ANI and its stockholders. Rather, the ANI board of directors based its position and determination on the totality of the information presented to and factors considered by it. In addition, individual members of the ANI board of directors may have given differing weights to different factors.

In considering the determination by the ANI board of directors that the merger and the merger agreement are advisable and fair to and in the best interests of ANI and its stockholders, you should be aware that certain ANI directors and officers have arrangements that may cause them to have interests in the transaction that are different from, in addition to, or may conflict with the interests of the ANI stockholders generally. See " Interests of ANI's Directors and Officers in the Merger."

**Opinion of Oppenheimer & Co. Inc.**

On August 8, 2012, BioSante engaged Oppenheimer & Co. Inc. (Oppenheimer & Co.) as its financial advisor in connection with the merger. In connection with this engagement, the BioSante

Table of Contents

board of directors requested that Oppenheimer & Co. evaluate the fairness, from a financial point of view, to BioSante of the exchange ratios, as provided in and as calculated pursuant to the terms of the merger agreement. On October 3, 2012, at a meeting of the BioSante board of directors held to evaluate the merger, Oppenheimer & Co. rendered to the BioSante board of directors an oral opinion, confirmed by delivery of a written opinion dated October 3, 2012, to the effect that, as of that date and based on and subject to the matters described in its opinion, the exchange ratios were fair, from a financial point of view, to BioSante.

The full text of Oppenheimer & Co.'s written opinion, dated October 3, 2012, which describes the assumptions made, procedures followed, matters considered and limitations on the review undertaken, is attached to this proxy statement/prospectus as Annex G and is incorporated by reference in its entirety. **Oppenheimer & Co.'s opinion was provided for the use of the BioSante board of directors (in its capacity as such) in connection with its evaluation of the exchange ratios from a financial point of view and did not address any other terms, aspects or implications of the merger, including, without limitation, the form or structure of the merger or any term, aspect or implication of any voting agreements or other agreement, arrangement or understanding entered into in connection with the merger or otherwise. Oppenheimer & Co. expressed no view as to, and its opinion did not address, the underlying business decision of BioSante to proceed with or effect the merger or the relative merits of the merger as compared to any alternative business strategies that might exist for BioSante or the effect of any other transaction in which BioSante might engage. Oppenheimer & Co.'s opinion does not constitute a recommendation to any BioSante or ANI stockholder as to how such stockholder should vote or act with respect to any matters relating to the merger or otherwise.** This summary of Oppenheimer & Co.'s opinion is qualified in its entirety by reference to the full text of its opinion.

In arriving at its opinion, Oppenheimer & Co.:

- reviewed the draft, dated October 2, 2012, of the merger agreement;
- reviewed publicly available financial statements of BioSante for the fiscal years ended December 31, 2010 and 2011, and unaudited financial statements of BioSante for the six months ended June 30, 2012;
- reviewed audited financial statements of ANI for the fiscal years ended December 31, 2010 and 2011, and unaudited financial statements of ANI for the eight months ended August 31, 2012, and other relevant financial and operating data furnished to Oppenheimer & Co. by ANI;
- reviewed financial forecasts and estimates relating to BioSante prepared by the management of BioSante;
- reviewed financial forecasts and estimates relating to ANI prepared by the management of ANI;
- held discussions with the senior managements of BioSante and ANI with respect to the businesses and prospects of BioSante and ANI, respectively;
- reviewed the historical market prices and trading volumes of BioSante common stock;
- reviewed and analyzed certain publicly available financial data for companies Oppenheimer & Co. deemed relevant in evaluating ANI;
- analyzed the estimated present value of the future cash flows of ANI based on financial forecasts and estimates prepared by the management of ANI;
- reviewed other public information concerning BioSante; and

performed such other analyses, reviewed such other information and considered such other factors as Oppenheimer & Co. deemed appropriate.

Table of Contents

In rendering its opinion, Oppenheimer & Co. relied upon and assumed, without independent verification or investigation, the accuracy and completeness of all of the financial and other information publicly available or provided to or discussed with Oppenheimer & Co. by BioSante and ANI and their respective employees, representatives and affiliates or otherwise reviewed by Oppenheimer & Co. With respect to the financial forecasts and estimates relating to BioSante and ANI utilized in Oppenheimer & Co.'s analyses, at the direction of the respective management and with BioSante's consent, Oppenheimer & Co. assumed, without independent verification or investigation, that such forecasts and estimates were reasonably prepared on bases reflecting the best available information, estimates and judgments of the respective managements of BioSante and ANI as to the future financial condition and operating results of BioSante and ANI and the other matters covered thereby and that the financial results reflected in such forecasts and estimates would be achieved at the times and in the amounts projected. Oppenheimer & Co. also assumed, at BioSante's direction, the final terms of the merger agreement would not vary materially from those set forth in the draft reviewed by Oppenheimer & Co. Oppenheimer & Co. further assumed, with BioSante's consent, that the merger would qualify for federal income tax purposes as a reorganization under Section 368(a) of the Internal Revenue Code of 1986, as amended. Oppenheimer & Co. also assumed, with the consent of BioSante, that the merger would be consummated in accordance with its terms without waiver, modification or amendment of any material term, condition or agreement and in compliance with all applicable laws and other requirements and that, in the course of obtaining the necessary regulatory or third party approvals, consents and releases with respect to the merger, no delay, limitation, restriction or condition would be imposed that would have an adverse effect on BioSante or the contemplated benefits of the merger.

Oppenheimer & Co. is not a legal, tax, regulatory or accounting advisor and relied on the assessments made by BioSante and its advisors with respect to such issues. The opinion of Oppenheimer & Co. did not constitute a solvency opinion or a fair value opinion, and Oppenheimer & Co. did not evaluate the solvency or fair value of BioSante under any federal or state laws relating to bankruptcy, insolvency or similar matters. Oppenheimer & Co. neither made nor obtained any independent evaluations or appraisals of the assets or liabilities (contingent or otherwise) of BioSante or ANI. Oppenheimer & Co. expressed no view as to, and its opinion did not address, any terms or other aspects or implications of the merger (other than the exchange ratios to the extent expressly specified in its opinion) or any aspect or implication of any other agreement, arrangement or understanding entered into in connection with the merger or otherwise, including, without limitation, the fairness of the amount or nature of the compensation resulting from the merger to any individual officers, directors or employees of BioSante, or class of such persons, relative to the exchange ratios. Oppenheimer & Co. also expressed no view as to, and its opinion did not address, the issuance by BioSante of a distribution to the holders of BioSante common stock prior to the consummation of the merger consisting of contingent value rights with respect to certain payments arising from the sale, transfer, license or a similar transaction relating to BioSante's LibiGel program in accordance with the terms of a form of contingent value rights agreement in the form agreed to by BioSante and ANI.

The opinion of Oppenheimer & Co. was based on the information available to it and general economic, financial and stock market conditions and circumstances as they existed and could be evaluated by Oppenheimer & Co. on the date of delivery of such opinion. Although subsequent developments may affect its opinion, Oppenheimer & Co. does not have any obligation to update, revise or reaffirm its opinion, provided that Oppenheimer & Co. has agreed to deliver one update of its opinion, subject to certain conditions.

This summary is not a complete description of Oppenheimer & Co.'s opinion or the financial analyses performed and factors considered by Oppenheimer & Co. in connection with its opinion, but is a description of their material terms. The preparation of a financial opinion is a complex analytical process involving various determinations as to the most appropriate and relevant methods of financial

Table of Contents

analysis and the application of those methods to the particular circumstances and, therefore, a financial opinion is not readily susceptible to summary description. Oppenheimer & Co. arrived at its ultimate opinion based on the results of all analyses undertaken by it and assessed as a whole, and did not draw, in isolation, conclusions from or with regard to any one factor or method of analysis for purposes of its opinion. In addition, Oppenheimer & Co. may have given various analyses and factors more or less weight than other analyses and factors, and may have deemed various assumptions more or less probable than other assumptions. As a result, the ranges of valuations resulting from any particular analysis described below should not be taken to be Oppenheimer & Co.'s view of the actual value of ANI or BioSante. Accordingly, Oppenheimer & Co. believes that its analyses and this summary must be considered as a whole and that selecting portions of its analyses and factors or focusing on information presented in tabular format, without considering all analyses and factors or the narrative description of the analyses, could create a misleading or incomplete view of the processes underlying Oppenheimer & Co.'s analyses and opinion.

In performing its analyses, Oppenheimer & Co. considered industry performance, general business, economic, market and financial conditions and other matters existing as of the date of its opinion, many of which are beyond ANI's control. No company or business used in the analyses is identical to ANI, and an evaluation of the results of those analyses is not entirely mathematical. Rather, the analyses involve complex considerations and judgments concerning financial and operating characteristics and other factors that could affect the acquisition, public trading or other values of the companies or business segments analyzed.

The assumptions and estimates contained in Oppenheimer & Co.'s analyses and the ranges of valuations resulting from any particular analysis are not necessarily indicative of actual values or future results, which may be significantly more or less favorable than those suggested by its analyses. In addition, analyses relating to the value of businesses or securities do not purport to be appraisals or to reflect the prices at which businesses or securities actually may be sold or acquired. Accordingly, the assumptions and estimates used in, and the results derived from, Oppenheimer & Co.'s analyses are inherently subject to substantial uncertainty.

Oppenheimer & Co. was not requested to, and it did not, recommend the specific consideration payable in the merger. The type and amount of consideration payable in the merger was determined through negotiation between BioSante and ANI and was approved by the BioSante board of directors. Oppenheimer & Co. provided advice to BioSante during these negotiations. Oppenheimer & Co. did not, however, recommend any specific consideration to BioSante or the BioSante board of directors or that any specific consideration constituted the only appropriate consideration for the merger. The decision to enter into the merger agreement was solely that of the BioSante board of directors. Oppenheimer & Co.'s opinion and financial analysis were only one of many factors considered by the BioSante board of directors in its evaluation of the merger and should not be viewed as determinative of the views of the BioSante board of directors or management with respect to the merger or the exchange ratios or of whether the BioSante board of directors would have been willing to agree to different consideration.

The following is a summary of the material financial analyses reviewed with the BioSante board of directors in connection with Oppenheimer & Co.'s opinion dated October 3, 2012. **The financial analyses summarized below include information presented in tabular format. In order to fully understand Oppenheimer & Co.'s financial analyses, the tables must be read together with the text of each summary. The tables alone do not constitute a complete description of the financial analyses. Considering the data in the tables below without considering the full narrative description of the financial analyses, including the methodologies and assumptions underlying the analyses, could create a misleading or incomplete view of Oppenheimer & Co.'s financial analyses.**

Table of Contents

***Implied Equity Value of ANI Based on BioSante's Share Price***

Based on BioSante fully diluted shares outstanding and value of equity implied from the five-day volume-weighted average share price of BioSante common stock of $1.87 as of October 1, 2012, and the 47 percent equity ownership percentage of the combined company to be held by BioSante's equity holders, Oppenheimer & Co. calculated an implied value of the equity of the combined company and an implied value of the equity of ANI of $54 million.

***Implied Equity Value of ANI Based on BioSante's Net Cash and Other Assets***

Based on dividing BioSante's estimated net cash and other assets of $39 million to $43 million at the closing of the merger by the 47 percent equity ownership percentage of the combined company to be held by BioSante's equity holders, Oppenheimer & Co. calculated an implied value of the equity of the combined company and an implied value of the equity of ANI in the range of $44 million to $49 million.

***Valuation of Net Cash and Other Assets of BioSante***

Net cash and other assets of BioSante range was calculated based on the sum of four following components, each based on information provided by BioSante's management: (i) estimated net cash at the time of closing of the merger of $18 million, (ii) estimated value range of $1.8 million to $3.6 million for BioSante's 10.9 percent equity investment in Ceregene, Inc., (iii) the present value of the estimated free cash flows with respect to BioSante's male testosterone gel, and (iv) the estimated value range of $1.0 million to $2.0 million for BioSante's GVAX assets.

Oppenheimer & Co. performed a discounted cash flow analysis of BioSante's male testosterone gel by calculating the estimated present value of the after-tax free cash flows that the product was forecasted to generate during fiscal years ending December 31, 2012 through 2019 based on internal estimates of BioSante's management. The cash flows were then discounted to present value as of September 30, 2012 using discount rates ranging from 16.9 percent to 18.9 percent, reflecting estimates of BioSante's weighted average cost of capital calculated using the capital asset pricing model and assuming that the selected companies' average capital structure represents the optimal capital structure. This analysis indicated an implied valuation range for BioSante's male testosterone gel of approximately $18 million to $20 million.

***ANI Comparable Company Analysis***

Oppenheimer & Co. performed a comparable company analysis, which attempts to provide a range of implied aggregate values for ANI's equity and the combined company's net cash at the closing of the merger, which is referred to as the implied pro forma equity value for ANI, by comparing it to similar companies. Oppenheimer & Co. reviewed financial information of ANI and the following eight selected publicly-held specialty pharmaceutical companies:

Mylan Inc.

Watson Pharmaceuticals Inc.

Perrigo Co.

Hospira Inc.

Akorn Inc.

Impax Laboratories Inc.

Hi-Tech Pharmacal Co. Inc.

Lannett Co. Inc.

Table of Contents

All multiples were based on closing stock prices on October 1, 2012. Estimated financial data for the selected companies were based on public filings, information available through FactSet, and publicly available equity research analyst estimates. Estimated financial data for ANI were based on ANI management projections.

For each of the selected companies, Oppenheimer & Co. calculated the following:

Equity Value, which is defined as market capitalization on a fully-diluted basis.

Enterprise Value, which is defined as market capitalization on a fully-diluted basis plus debt and preferred equity, less cash, adjusted for in-the-money options, warrants and convertible debt.

Enterprise Value/Revenue 2015E, which is defined as the ratio of Enterprise Value to calendar year 2015 estimated revenue, as adjusted to reflect calendar year-end and pro-forma adjustments for acquisitions.

Enterprise Value/EBITDA 2015E, which is defined as the ratio of Enterprise Value to calendar year 2015 estimated earnings before interest, taxes, depreciation and amortization, referred to as EBITDA, as adjusted to reflect calendar year-end and pro-forma adjustments for acquisitions.

Based on the analysis of the relevant metrics for each of the selected companies, Oppenheimer & Co. selected representative ranges of financial multiples of the selected companies and applied these ranges of multiples to determine the implied equity value of ANI. The median revenue multiple observed for the selected companies for estimated calendar year 2015 was 2.0x and the median EBITDA multiple observed for the selected companies for estimated calendar year 2015 was 7.1x. The selected ranges represent plus and minus 15 percent around each applicable median multiple. Financial data for the selected companies were based on publicly available research analyst estimates, public filings and other publicly available information. Financial data for ANI were based on information provided by the managements of ANI and BioSante. Based on the combined company's expected capitalization as a result of the merger, Oppenheimer & Co. calculated the estimated implied equity value of ANI as of October 1, 2012 as follows:

| Financial Statistic | Selected Company Representative Multiple Range | Implied Pro Forma Equity Value of ANI ($ millions) |
|---|---|---|
| 2015E Revenue | 1.7x - 2.3x | $82.2 - $112.4 |
| 2015E EBITDA | 6.0x - 8.2x | $67.1 - $92.0 |

Oppenheimer & Co. noted that based on BioSante's fully diluted value of equity implied from the five-day volume-weighted average share price of BioSante common stock of $1.87 as of October 1, 2012, the implied value of the equity of ANI is $54 million and based on BioSante's estimated net cash and other assets at the closing of the merger, the implied value of the equity of ANI is in the range of $44 million to $49 million.

Although the foregoing companies were compared to ANI for purposes of this analysis, Oppenheimer & Co. noted that no company used in the comparable companies analysis is identical to ANI because of differences between the private company/public company nature, business mix, markets served, operations, and other characteristics of ANI and the selected companies. In evaluating the selected companies, Oppenheimer & Co. relied on publicly available research analyst estimates, which estimates are based in part on judgments and assumptions with regard to industry performance, general business, economic, market and financial conditions, and other matters, many of which are beyond the control of ANI, such as the impact of competition on the business of ANI, as well as on the industry generally, industry growth, and the absence of any adverse material change in the financial condition and prospects of ANI or the industry or in the markets generally.

Table of Contents

***ANI Discounted Cash Flow Analysis***

Oppenheimer & Co. performed a discounted cash flow analysis of ANI by calculating the estimated present value of the standalone unlevered, after-tax free cash flows that ANI was forecasted to generate during fiscal years ending December 31, 2012 through 2020 based on internal estimates of ANI's management. Oppenheimer & Co. calculated terminal values for BioSante by applying a range of perpetuity growth rates to BioSante's fiscal year 2020 estimated free cash flow of 2 percent to 4 percent and a range of discount rates of 16.9 percent to 18.9 percent. The cash flows and terminal values were then discounted to present value as of September 30, 2012 using discount rates ranging from 16.9 percent to 18.9 percent, reflecting estimates of ANI's weighted average cost of capital calculated using the capital asset pricing model and assuming that the selected companies' average capital structure represents the optimal capital structure. This analysis indicated an implied equity valuation range for ANI of approximately $99 million to $136 million.

Oppenheimer & Co. noted that based on BioSante's fully diluted value of equity implied from the five-day volume-weighted average share price of BioSante common stock of $1.87 as of October 1, 2012, the implied value of the equity of ANI is $54 million and based on BioSante's estimated net cash and other assets at the closing of the merger, the implied value of the equity of ANI is in the range of $44 million to $49 million.

***Miscellaneous***

In connection with the review by the BioSante board of directors of the merger and the issuance of shares of BioSante common stock to ANI stockholders, Oppenheimer & Co. performed a variety of financial and comparative analyses for purposes of rendering its opinion. Oppenheimer & Co. conducted the analyses described above solely as part of its analysis of the fairness of the exchange ratios pursuant to the merger agreement from a financial point of view to BioSante and in connection with the delivery of its opinion dated October 3, 2012 to the BioSante board of directors. These analyses do not purport to be appraisals or to reflect the prices at which shares of BioSante common stock might naturally trade. The foregoing summary describes the material analyses performed by Oppenheimer & Co. but does not purport to be a complete description of the analyses performed by Oppenheimer & Co.

BioSante selected Oppenheimer & Co. to act as its financial advisor in connection with the merger based on Oppenheimer & Co.'s reputation and experience. Oppenheimer & Co. is an internationally recognized investment banking firm and, as a part of its investment banking business, is regularly engaged in valuations of businesses and securities in connection with acquisitions and mergers, underwritings, secondary distributions of securities, private placements and valuations for other purposes. In the ordinary course of business, Oppenheimer & Co. and its affiliates may actively trade securities of BioSante for Oppenheimer & Co.'s and its affiliates' own accounts and for the accounts of customers and, accordingly, at any time may hold a long or short position in such securities. In addition, a senior member of the Oppenheimer & Co. investment banking team assisting BioSante in connection with the merger currently owns approximately 1,400 shares of BioSante common stock, which were acquired in 2009.

BioSante has agreed to pay Oppenheimer & Co. for its financial advisory services in connection with the merger a customary fee, $500,000 of which was payable upon delivery of Oppenheimer & Co.'s opinion and $100,000 of which is contingent upon consummation of the merger. BioSante also has agreed to reimburse Oppenheimer & Co. for its expenses, including fees and expenses of its legal counsel, and to indemnify Oppenheimer & Co. and related parties against liabilities, including liabilities under the federal securities laws, relating to, or arising out of, its engagement. In the two years prior to the date hereof, Oppenheimer & Co. has provided financial advisory services for BioSante unrelated to the merger and has received fees in the aggregate amount of $100,000 from BioSante in connection

Table of Contents

with certain of such services. During the same period, Oppenheimer & Co. provided certain private placement and/or arranger services for ANI unrelated to the merger; however, the related transaction was not consummated and Oppenheimer & Co. did not receive any compensation therefor. Oppenheimer & Co. also may seek to provide financial advisory services to BioSante in the future and expects to receive fees for the rendering of these services.

The issuance of Oppenheimer & Co.'s opinion was approved by an authorized committee of Oppenheimer & Co. Oppenheimer & Co. has consented to the use of its written opinion in this joint proxy statement/prospectus and such consent is an exhibit to the registration statement of which this joint proxy statement/prospectus is a part.

**Certain Financial Forecasts of ANI Used in Connection with the Merger**

ANI does not, as a matter of course, publicly disclose long-term forecasts or internal projections as to future performance, earnings or other results, and ANI is particularly concerned with making such forecasts and projections due to the unpredictability of the underlying assumptions and estimates. In connection with its due diligence process and evaluation of the merger, ANI's management prepared financial forecasts regarding certain items of its projected operating results, including ANI's forecasted revenues and EBITDA for its 2012 through 2020 fiscal years. ANI's financial forecasts were not prepared with a view toward public disclosure. However, ANI has included below a summary of its financial forecasts to provide its stockholders and investors access to certain non-public information that was furnished to third parties in connection with the merger.

ANI's financial forecasts included assumptions with respect to general business, economic, competitive, regulatory, market and financial conditions, and other future events, as well as matters specific to ANI's business, such as the following, all of which are difficult to predict and many of which are beyond ANI's control:

- the time required to obtain FDA approval for ANDAs;
- the number of competitors, including authorized generics, for ANI's products;
- the prices at which ANI will be able to sell its products;
- the impact of new therapies on the sale of ANI's products;
- changes affecting ANI's contract manufacturing customers; and
- changes in the cost or availability of ANI's raw materials.

ANI's financial forecasts also assume the following:

- ANI will be able to continue to market all of its existing products, including its unapproved pharmaceutical products Opium Tincture and Esterified Estrogen with Methyltestosterone;
- ANI will be able to continue to contract manufacture, and earn royalties on, a group of unapproved pharmaceutical products marketed by its contract manufacturing customer;
- ANI will be able to obtain the raw materials necessary to support the ongoing commercial sales of its existing products, and the development, launch and commercial sales of its pipeline products, including obtaining a sufficient quota from the Drug Enforcement Administration to purchase raw materials to support the production and sales of its existing and future narcotic

products;

increases in the cost of raw materials for existing or pipeline products will not have a material negative effect on ANI's business;

Table of Contents

ANI will be able to develop and obtain FDA approval of and commercialize the products in its pipeline on a timely basis;

recent trends in unit sales and pricing for each of ANI's pipeline products are a reasonable basis for forecasting total market size upon product launch;

the number of competitors for ANI's existing products will remain stable;

ANI's expectations regarding the number of potential competitors for each of its pipeline products are reasonable.

ANI's financial forecasts presented below were provided to Oppenheimer & Co. Inc. in connection with its financial analysis of the exchange ratios. In addition, ANI's financial forecasts also were provided to BioSante by Oppenheimer & Co. Inc. and reviewed with the BioSante board of directors and were utilized by BioSante in connection with its financial analysis of the exchange ratios.

The inclusion of ANI's financial forecasts in this joint proxy statement/prospectus should not be regarded as an indication that ANI or the ANI board of directors considered, or now considers, these forecasts to be material to the ANI or BioSante stockholders or necessarily indicative of actual future results. You should not place undue reliance on the unaudited financial forecasts of ANI contained in this joint proxy statement/prospectus. Please read the information set forth below under the heading "Important Information About ANI's Financial Forecasts."

The following table presents the financial forecasts of ANI that were provided by ANI to Oppenheimer & Co. Inc.

| | | | | Projected | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **($ in millions)** | **2012E** | **2013E** | **2014E** | **2015E** | **2016E** | **2017E** | **2018E** | **2019E** | **2020E** |
| Revenue | $ 19.9 | $ 20.3 | $ 26.0 | $ 49.8 | $ 106.4 | $ 143.6 | $ 171.3 | $ 178.5 | $ 181.1 |
| EBITDA | 1.9 | (2.0) | (2.3) | 11.7 | 35.6 | 51.6 | 62.2 | 65.1 | 66.3 |

***Important Information About ANI's Financial Forecasts***

While ANI's financial forecasts were prepared in good faith, no assurance can be made regarding future events. The estimates and assumptions underlying ANI's financial forecasts involve judgments with respect to, among other things, future economic, competitive, regulatory and financial market conditions and future business decisions that may not be realized and that are inherently subject to significant business, economic, competitive and regulatory uncertainties and contingencies, including, among others, the risks and uncertainties described under the sections entitled "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" beginning on pages 38 and 91, respectively, all of which are difficult to predict and many of which are beyond the control of ANI and/or BioSante and will be beyond the control of the combined company. There can be no assurance that the underlying assumptions will prove to be accurate or that the forecasted results will be realized, and actual results likely will differ, and may differ materially, from those reflected in ANI's financial forecasts, whether or not the merger is completed.

ANI's financial forecasts summarized in this section were prepared solely for internal use by ANI. This prospective financial information was not prepared with a view toward compliance with published guidelines of the SEC or the guidelines established by the American Institute of Certified Public Accountants for preparation and presentation of prospective financial information. ANI's management believes the forecasts were prepared in good faith and on a reasonable basis based on the best information available to ANI's management at the time of their preparation. ANI's financial forecasts, however, are not fact and should not be relied upon as being necessarily indicative of actual future results, and readers of this joint proxy statement/prospectus are cautioned not to place undue reliance

Table of Contents

on this information. None of ANI's financial forecasts reflects any synergies or costs related to or that may arise from the merger.

The prospective financial information of ANI included in this section has been prepared by, and is the responsibility of, ANI's management. ANI's independent registered public accounting firm has neither examined, compiled nor performed any procedures with respect to the accompanying ANI prospective financial information and, accordingly, does not express an opinion or any other form of assurance with respect thereto. The report of ANI's independent registered public accounting firm included in this joint proxy statement/prospectus relates to the historical financial information of ANI. It does not extend to the prospective financial information of ANI and should not be read to do so.

By including in this joint proxy statement/prospectus a summary of ANI's financial forecasts, neither ANI nor any of its representatives has made or makes any representation to any person regarding the ultimate performance of ANI compared to the information contained in ANI's financial forecasts. ANI has made no representation to BioSante, in the merger agreement or otherwise, concerning ANI's financial forecasts. ANI's financial forecasts summarized in this section were prepared during the periods described above and have not been updated to reflect any changes since the date of this joint proxy statement/prospectus or any actual results of operations of ANI, as set forth under the section entitled "Selected Historical Financial Data of ANI" beginning on page 31. Neither ANI, BioSante nor, after completion of the merger, the combined company undertakes any obligation, except as required by law, to update or otherwise revise ANI's financial forecasts to reflect circumstances existing since their preparation or to reflect the occurrence of unanticipated events, even in the event that any or all of the underlying assumptions are shown to be in error, or to reflect changes in general economic or industry conditions.

The foregoing summary of ANI's financial forecasts is not included in this joint proxy statement/prospectus in order to induce any ANI stockholder to vote in favor of ANI Proposal No. 1 to approve and adopt the merger agreement and the transactions contemplated thereby, including the merger, or any other proposals to be voted on at the ANI special meeting or any BioSante stockholder to vote in favor of BioSante Proposal No. 1 to approve and adopt the merger agreement and the transactions contemplated thereby, including the merger and the issuance of BioSante common stock in connection with the merger, or any other proposals to be voted on at the BioSante special meeting.

**Interests of BioSante's Directors and Officers in the Merger**

In considering the recommendation of the BioSante board of directors to BioSante stockholders to vote in favor of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, and the other matters to be acted upon by BioSante stockholders at the BioSante special meeting, BioSante stockholders should be aware that members of the BioSante board of directors and BioSante's officers have interests in the merger that may be different from, in addition to, or may conflict with the interests of BioSante stockholders. These interests relate to or arise from, among other things:

- The fact that Fred Holubow and Ross Mangano, each of whom are current directors of BioSante, will continue to serve on the board of directors of the combined company following completion of the merger and will receive cash and equity compensation in connection with such service as described in more detail below and under "Management of the Combined Company After the Merger  Director Compensation."

- Severance benefits to which each of Stephen M. Simes, Phillip B. Donenberg and Michael C. Snabes, M.D., Ph.D. will become entitled in connection with the completion of the merger, as described in more detail below.

Table of Contents

The accelerated vesting of all BioSante stock options held by the directors and executive officers of BioSante upon completion of the merger as described in more detail below.

The right to continued indemnification and insurance coverage for directors and executive officers of BioSante following completion of the merger, pursuant to the terms of the merger agreement, as described in more detail below.

The BioSante board of directors was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, and to recommend that BioSante stockholders approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, and related matters. Other than full disclosure of these potential conflicts of interest, the BioSante board of directors did not take any other steps to alleviate such potential conflicts of interest since it did not consider such potential conflicts of interest to be material in connection with its decision to approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock.

***Ownership Interests***

As of January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, directors and executive officers of BioSante, together with their respective affiliates, beneficially owned and were entitled to vote 472,335 shares of BioSante common stock and 16,666 shares of BioSante class C special stock, or approximately 1.9 percent of the shares of BioSante common stock and 25.6 percent of the shares of BioSante class C special stock outstanding on that date. Assuming the merger had been completed as of such date, all directors and executive officers of BioSante, together with their respective affiliates, would beneficially own, in the aggregate, less than one percent of the outstanding shares of common stock of the combined company and 25.6 percent of the outstanding shares of BioSante class C special stock of the combined company.

For a more complete discussion of the ownership interests of the directors and executive officers of BioSante, see the sections entitled "Principal Stockholders of BioSante" and "Principal Stockholders of the Combined Company."

***Continuing Directors***

Following completion of the merger, Fred Holubow and Ross Mangano are expected to receive cash and equity compensation in accordance with BioSante's equity compensation policies for non-employee directors. Currently, BioSante provides an annual cash retainer of $25,000 for non-employee board members, pays each non-employee director $2,000 for board meetings attended in person, $1,000 for each board meeting attended by telephone and for each board committee meeting attended in person or by telephone, grants options on an annual basis and enters into indemnification agreements with each director, although these policies are subject to change at any time.

***Employment Letter Agreements and Severance and Change in Control Agreements***

Upon completion of the merger and the anticipated termination of their employment on the date following completion of the merger, Mr. Simes, Mr. Donenberg and Dr. Snabes will be entitled to receive certain severance payments and other benefits or payments, as applicable, each as more fully described below. BioSante has adopted a rabbi trust to hold funds to pay the severance amounts owed to Mr. Simes and Mr. Donenberg that are subject to the six-month suspension rule under Section 409A of the Internal Revenue Code of 1986.

Table of Contents

*Stephen M. Simes.* In January 1998, BioSante entered into an employment letter agreement with Stephen M. Simes. BioSante and Mr. Simes amended the agreement in July 2008 to ensure compliance with regulations on non-qualified deferred compensation severance benefits as mandated by Code Section 409A and to make certain changes to the change in control provisions. The agreement has not been amended since July 2008.

As a result of the anticipated termination of his employment immediately after completion of the merger, Mr. Simes will be entitled to receive:

- a severance payment, which would be paid in one lump sum equal to the sum of: (1) two times his annual base salary, plus (2) his most recent annual bonus, plus (3) his maximum annual bonus (100 percent of base salary) for the year in which the change in control occurs;

- substantially the same health, dental, life and disability insurance benefits he received prior to his termination for a period of up to 24 months and reimbursement for any costs incurred in securing such continuation coverage that are in excess of costs that would have been incurred by Mr. Simes immediately prior to his termination date to obtain such coverage; and

- provision of outplacement services up to a maximum amount of $30,000.

*Phillip B. Donenberg.* In June 1998, BioSante entered into an employment letter agreement with Phillip B. Donenberg. BioSante and Mr. Donenberg amended the agreement in July 2008 to ensure compliance with regulations on non-qualified deferred compensation severance benefits as mandated by Section 409A of the Internal Revenue Code of 1986 and to make certain changes to the change in control provisions. The agreement has not been amended since July 2008.

As a result of the anticipated termination of his employment immediately after completion of the merger, Mr. Donenberg will be entitled to receive:

- a severance payment, which would be paid in one lump sum equal to, the sum of: (1) one and one-half times his annual base salary, plus (2) his maximum annual bonus (100 percent of base salary) for the year in which the change in control occurs;

- substantially the same health, dental, life and disability insurance benefits he received prior to his termination for a period of up to 18 months and reimbursement for any costs incurred in securing such continuation coverage that are in excess of costs that would have been incurred by Mr. Donenberg immediately prior to his termination date to obtain such coverage; and

- provision of outplacement services up to a maximum amount of $30,000.

*Michael C. Snabes, M.D., Ph.D.* In July 2008, BioSante entered into a change of control and severance agreement with Michael C. Snabes, M.D., Ph.D. However, if Dr. Snabes is terminated without cause or upon a change in control, he will be entitled to certain payments and benefits under the BioSante Pharmaceuticals, Inc. Officer Severance Policy since the severance policy provides for greater severance benefits than Dr. Snabes is currently entitled to receive under his current agreement with BioSante.

As a result of the anticipated termination of his employment immediately after completion of the merger, Dr. Snabes will be entitled to receive:

- a severance payment, which would be paid in one lump sum equal to the sum of: (1) one times his annual base salary, plus (2) 100 percent of his target annual incentive bonus for the year in which the change in control occurs.

- substantially the same health, dental, life and disability insurance benefits he received prior to his termination for a period of up to 12 months and reimbursement for any costs incurred in

145

Table of Contents

securing such continuation coverage that are in excess of costs that would have been incurred by Dr. Snabes immediately prior to his termination date to obtain such coverage; and

provision of outplacement services up to a maximum amount of $15,000.

***Accelerated Vesting of Stock Options***

The terms of the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan and the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan provide that upon the occurrence of certain corporate transactions, including the merger, the vesting of any stock options outstanding under such plans will be accelerated in full at the effective time of such corporate transaction. As a result, the outstanding unvested stock options held by directors and executive officers of BioSante will vest immediately and become exercisable in full upon completion of the merger. However, if the trading price of BioSante common stock does not trade above the respective per share exercise prices of the options held by such individuals during the terms of the respective options, then no BioSante directors or executive officers will receive any benefit as a result of the option acceleration. As of December 31, 2012, the closing sale price of BioSante common stock was $1.23 per share, as reported by The NASDAQ Global Market. In addition, since it is anticipated that the employment or other service of all of the directors and officers named below (except Mr. Holubow and Mr. Mangano) will terminate effective as of completion of the merger, all of the options held by such individuals will terminate, if unexercised, three months (one year, in the case of Mr. Simes and Mr. Donenberg) after completion of the merger. These options likely will terminate unexercised in three months (or one year, in the case of Mr. Simes and Mr. Donenberg) after completion of the merger in light of the fact that the exercise prices range from $4.08 to $220.92 per share.

The table below sets forth, as of December 31, 2012, information with respect to BioSante stock options held by each of the directors and executive officers of BioSante:

| Name | Aggregate Number of Shares of BioSante Common Stock Underlying Options | Aggregate Number of Shares of BioSante Common Stock Underlying Vested Options | Aggregate Number of Shares of BioSante Common Stock Underlying Unvested Options | Per Share Exercise Prices | Aggregate Option Acceleration Value |
|---|---|---|---|---|---|
| Stephen M. Simes | 396,109 | 173,192 | 222,917 | $4.11 - 23.97 | $ 0 |
| Louis W. Sullivan, M.D. | 33,331 | 27,498 | 5,833 | 4.08 - 26.43 | 0 |
| Fred Holubow | 28,329 | 24,163 | 4,166 | 4.08 - 26.43 | 0 |
| Ross Mangano | 28,329 | 24,163 | 4,166 | 4.08 - 26.43 | 0 |
| John T. Potts, Jr., M.D. | 12,498 | 7,707 | 4,791 | 4.08 - 11.88 | 0 |
| Edward C. Rosenow III, M.D. | 28,329 | 24,163 | 4,166 | 4.08 - 26.43 | 0 |
| Stephen A. Sherwin, M.D. | 32,221 | 27,430 | 4,791 | 4.08 - 220.92 | 0 |
| Phillip B. Donenberg | 180,274 | 93,468 | 86,806 | 4.11 - 23.97 | 0 |
| Michael C. Snabes, M.D., Ph.D. | 84,998 | 41,109 | 43,889 | 4.11 - 26.58 | 0 |

***Indemnification and Insurance***

The merger agreement provides that the combined company will continue to indemnify and hold harmless each present and former director or officer of BioSante, with respect to acts or omissions occurring or alleged to have occurred at or prior to completion of the merger, to the fullest extent permitted under applicable law and BioSante's certificate of incorporation or bylaws. The merger agreement also provides that the combined company will honor all indemnification agreements in place with each present and former director or officer of BioSante.

Table of Contents

The merger agreement also provides that, prior to completion of the merger, BioSante will purchase and maintain for a period of six years following completion of the merger, a directors' and officers' liability "tail" insurance policy covering the present and former directors and officers of BioSante for events occurring prior to completion of the merger. Such policy must contain terms no less favorable than the policies maintained by BioSante prior to completion of the merger.

***Golden Parachute Compensation***

The following table sets forth the information required by Item 402(t) of Regulation S-K, which requires disclosure of information about compensation for each "named executive officer" of BioSante that is based on or otherwise relates to the merger. This compensation is referred to as "golden parachute" compensation. The "golden parachute" compensation payable to BioSante's named executive officers is subject to a non-binding advisory vote of BioSante stockholders, as described under "Matters Being Submitted to a Vote of BioSante Stockholders BioSante Proposal No. 4 Advisory Vote on Golden Parachute Compensation" beginning on page 109. Assuming that the merger is completed on January 15, 2013 and the named executive officers are terminated on such date, the executives would receive approximately the amounts set forth in the table below.

In order for BioSante's executives to receive the payments or benefits set forth in the table below as a result of the merger, there must be a termination event, such as a termination by the combined company for any reason other than for cause or a termination by the executive for good reason. For Mr. Simes and Mr. Donenberg, such termination event must occur either within the period beginning on the date of the merger and ending on the last day of the first full calendar month following the second year anniversary date of the merger or prior to the merger if the termination of employment was either a condition of the merger or was at the request or insistence of a person related to the merger. Dr. Snabes has the ability to terminate his employment for good reason if such termination occurs on the date of the merger and ending on the 12 month anniversary of the date of the merger. For purposes of the change in control provisions for Mr. Simes and Mr. Donenberg, the definition of "good reason" is broader than outside the context of change in control and includes: (1) BioSante's failure to obtain from any successor the assent to assume the employment letter agreements; (2) any purported termination by BioSante of the executive's employment that is not properly effected; (3) a requirement that the executive be based at any office or location that is more than 30 miles further from the office or location thereof immediately preceding the change in control; and (4) any termination by the executive of his employment for any reason during the 13th month after the completion of the change in control. For Dr. Snabes, the definition of "good reason" includes: (1) a material diminution in his authority, duties or responsibilities; (2) a material diminution in his base compensation; (3) a material diminution in the authority, duties or responsibilities of the supervisor to whom he reports; (4) a material change in the geographic location at which the company requires him to be based as compared to the location where he was previously based; and (5) any other action or inaction that constitutes a material breach by us under his agreement.

| Name | Cash(1) | Perquisites/ Benefits(2) | Total |
|---|---|---|---|
| Stephen M. Simes | $ 1,490,100 | $ 87,949 | $ 1,578,049 |
| Phillip B. Donenberg | 770,000 | 74,156 | 844,156 |
| Michael C. Snabes, M.D., Ph.D. | 526,400 | 44,972 | 571,372 |

(1) Represents a severance payment under the executive's employment agreement or, in the case of Dr. Snabes, the BioSante Pharmaceuticals, Inc. Officer Severance Policy, which would be paid in one lump sum equal to, in the case of Mr. Simes, the sum of: (a) two times his annual base salary, plus (b) his most recent annual bonus, plus (c) his maximum annual bonus (100 percent of base salary) for the year in which the change in control

Table of Contents

occurs, in the case of Mr. Donenberg, the sum of: (a) 1 1/2 times his annual base salary, plus (b) his maximum annual bonus (100 percent of base salary) for the year in which the change in control occurs, and in the case of Dr. Snabes, the sum of: (a) one times his annual base salary, plus (b) 100 percent of his target annual incentive bonus for the year in which the change in control occurs. All such benefits are "double trigger" and would only be paid upon completion of the merger and the termination of the executive officer's employment following completion of the merger.

(2)

The amounts above include the estimated value of, in the case of Mr. Simes and Mr. Donenberg, substantially the same health, dental, life and disability insurance benefits the executive received prior to his termination for a period of up to 24 months for Mr. Simes, 18 months for Mr. Donenberg, and in the case of Dr. Snabes, 12 months following the termination date, and reimbursement for any costs incurred in securing such continuation coverage that are in excess of costs that would have been incurred by the executive officer immediately prior to his termination date to obtain such coverage. The value of such benefits is estimated to be the following: Mr. Simes, $57,949; Mr. Donenberg, $44,156 and Mr. Snabes, $29,972. In addition, the above amounts include the provision of outplacement services up to a maximum amount of $30,000 in the case of Mr. Simes and Mr. Donenberg and $15,000 in the case of Dr. Snabes. All such benefits are "double trigger" and would only be paid upon completion of the merger and the termination of the executive officer's employment following completion of the merger.

**Interests of ANI's Directors and Officers in the Merger**

In considering the recommendation of the ANI board of directors to ANI stockholders to vote in favor of the merger agreement and the transactions contemplated thereby, including the merger, and the other matters to be acted upon by the ANI stockholders at the ANI special meeting, ANI stockholders should be aware that members of the ANI board of directors and ANI's officers have interests in the merger that may be different from or in addition to, or may conflict with the interests of ANI stockholders. These interests relate to or arise from, among other things:

The fact that, Robert E. Brown Jr., Tracy L. Marshbanks, Ph.D., Thomas A. Penn, Arthur S. Przybyl and Robert Schrepfer, each of whom are current directors of ANI, also will continue to serve on the board of directors of the combined company following completion of the merger and such directors, with the exception of Mr. Przybyl, will receive cash and equity compensation for such services, as described in more detail under "Management of the Combined Company After the Merger Director Compensation."

The fact that Robert E. Brown, Jr., ANI's chairman of the board, will continue as chairman of the board of the combined company.

The fact that the executive officers of the combined company will be the current executive officers of ANI and such officers will receive compensation for such service as described in more detail under "Management of the Combined Company After the Merger Officer Compensation."

The fact that the executive officers of ANI will receive special transaction bonus payments upon closing of the merger ranging, for each officer, from approximately $707,705 to $3,309,410 (assuming BioSante net cash at closing is $18.0 million) payable in shares of ANI series D preferred stock, which shares will convert into shares of BioSante common stock in the merger, as described in more detail under "Management of the Combined Company Following the Merger Certain Relationships and Related Transactions."

Table of Contents

The fact that MVP Capital and HVC, two firms affiliated with three of ANI's directors, will receive fees of approximately $350,000 and $40,000, respectively, upon closing of the merger. This is in addition to unpaid amounts due under existing monitoring arrangements with ANI, which will terminate at closing and which are expected not to exceed $120,000 for MVP Capital and $30,000 for HVC, assuming a closing on or before March 31, 2013.

The right to continued indemnification and insurance coverage for directors and executive officers of ANI following completion of the merger, pursuant to the terms of the merger agreement.

None of ANI's directors or officers has any other interests in the merger that may be different from, or in addition to, the interests of ANI stockholders. The ANI board of directors was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the merger agreement and the transactions contemplated thereby, including the merger, and to recommend that ANI stockholders approve the merger agreement and the transactions contemplated thereby, including the merger. Other than full disclosure of these potential conflicts of interest, the ANI board of directors did not take any other steps to alleviate such potential conflicts of interest since it did not consider such potential conflicts of interest to be material in connection with its decision to approve the merger agreement and the transactions contemplated thereby, including the merger.

***Ownership Interests***

As of January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, directors and executive officers of ANI, together with their respective affiliates, beneficially owned and were entitled to vote 28,239 shares of ANI common stock (including warrants to purchase common stock) and 1,902,877 shares of ANI preferred stock, or approximately 68.6 percent of the shares of ANI common stock (including warrants to purchase common stock) and 73.4 percent of the shares of ANI preferred stock outstanding on that date. Assuming the merger had been completed as of such date, all directors and executive officers of ANI, together with their respective affiliates, would beneficially own, in the aggregate, approximately 36.0 percent of the outstanding shares of common stock of the combined company.

For a more complete discussion of the ownership interests of the directors and executive officers of ANI, see the sections entitled "ANI Security Ownership of Certain Beneficial Owners and Management" and "Security Ownership of Certain Beneficial Owners and Management of the Combined Company Following the Merger."

***Employment Arrangements with Certain Executive Officers of ANI***

Following completion of the merger, the current executive officers of ANI are expected to be the executive officers of the combined company. The employment arrangements between ANI and such executive officers are expected to remain in place and the terms of such arrangements will be assumed by the combined company. For a discussion of the employment arrangements between ANI and the executive officers of ANI that are expected to become executive officers of the combined company see the section entitled "Management of the Combined Company Following the Merger  Executive Compensation."

***Transaction Bonus Agreements and Related Arrangements***

Pursuant to transaction bonus agreements between ANI and certain of its executive officers, such officers are entitled to receive a bonus based on the net proceeds to the ANI stockholders from the consummation of a "change of control" transaction. The agreements acknowledge that the merger between BioSante and ANI qualifies as a change of control. The net proceeds of the merger are calculated as the product of (a) the average closing sale price of the BioSante common stock for the

Table of Contents

five trading days prior to the announcement of a signed merger agreement with ANI (which announcement occurred on October 4, 2012) and (b) the aggregate number of shares of BioSante common stock to be issued to the ANI stockholders in the merger.

In connection with the payment of the transaction bonuses to the executive officers of ANI, ANI is required to withhold from such payments amounts sufficient to pay the executives' required tax withholding obligations. ANI and its executive officers expect to enter into arrangements to fund the payment of such withholdings. The transaction bonus agreements and tax withholding arrangements are described in further detail in the section entitled "Management of the Combined Company Following the Merger  Executive Compensation  Transaction Bonus Agreements and Related Arrangements."

***Indemnification and Insurance***

The merger agreement provides that the combined company will continue to indemnify and hold harmless each present and former director, officer, or employee of ANI, with respect to acts or omissions occurring or alleged to have occurred at or prior to completion of the merger, including advancing expenses, to the fullest extent allowed by applicable law. In addition, all rights to indemnification with respect to acts or omissions occurring at or prior to completion of the merger existing in favor of each present and former director, officer, or employee of ANI as provided in ANI's certificate of incorporation, ANI's bylaws, or indemnification agreements will remain in effect.

The merger agreement also provides that, prior to completion of the merger, ANI will purchase and maintain for a period of six years following completion of the merger, a directors' and officers' liability "tail" insurance policy covering the directors and officers of ANI for events occurring prior to completion of the merger. Such policy must contain terms no less favorable than the policies maintained by ANI prior to completion of the merger.

**Regulatory Approvals**

Neither BioSante nor ANI is required to make any filings or 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, BioSante must comply with applicable federal and state securities laws in connection with the issuance of shares of BioSante common stock in the merger, including the filing with the SEC of the registration statement of which this joint proxy statement/prospectus is a part. In addition, BioSante must comply with applicable rules of The NASDAQ Stock Market which, as described below, require the preparation and approval of an initial listing application in connection with the transaction.

**NASDAQ Listing of BioSante Common Stock**

BioSante common stock currently is listed on The NASDAQ Global Market under the symbol "BPAX". BioSante has agreed to use its reasonable best efforts to cause the shares of BioSante common stock issuable in connection with the merger to be approved, at or prior to completion of the merger, for listing (subject to notice of issuance) on The NASDAQ Global Market, and the listing of the shares of BioSante common stock issuable pursuant to the merger agreement is a condition to ANI's obligation to complete the merger.

As of the date of the mailing of this joint proxy statement/prospectus, BioSante has filed an initial listing application for The NASDAQ Global Market in connection with the merger. If such application is approved, BioSante anticipates that its common stock will be listed on The NASDAQ Global Market following completion of the merger under the trading symbol "BPAX". It is expected that following the merger, the combined company will change its name to "ANI Pharmaceuticals, Inc." and that its trading symbol will be changed. ANI has reserved the ticker symbol "ANIP" for this purpose.

Table of Contents

**Restrictions on Sales of BioSante Common Stock Received by ANI Stockholders in the Merger**

Pursuant to the merger agreement, the chief executive officer and chief financial officer of ANI and certain stockholders of ANI have agreed to enter into lock-up agreements with BioSante pursuant to which the shares of BioSante common stock received by ANI stockholders in the merger may not be sold, transferred or encumbered for a 180-day period following completion of the merger, except in limited circumstances.

In addition, shares of BioSante common stock received by ANI stockholders who become affiliates of BioSante for purposes of Rule 144 under the Securities Act may be resold by them only in transactions permitted by Rule 144, or as otherwise permitted under the Securities Act. Persons who may be deemed affiliates of BioSante generally include individuals or entities that control, are controlled by or are under common control with BioSante and may include officers and directors as well as principal stockholders of BioSante. Each director and executive officer of ANI who will serve as a director or executive officer of BioSante following completion of the merger will be deemed an affiliate of BioSante for purposes of Rule 144.

**Material U.S. Federal Income Tax Consequences of the Merger**

BioSante and ANI intend the merger to qualify as a "reorganization" within the meaning of Section 368(a) of the Code and have agreed to use reasonable best efforts to structure the merger to qualify as a reorganization and not to take any action that would prevent the merger from qualifying as a reorganization under Section 368(a) of the Code. For a more complete discussion of the material U.S. federal income tax consequences of the merger, see the section entitled "Material U.S. Federal Income Tax Consequences of the Merger." It is a condition to the completion of the merger that BioSante obtain from Oppenheimer Wolff & Donnelly LLP, and ANI obtain from SNR Denton US LLP, an opinion that the merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Code.

**Anticipated Accounting Treatment**

Under U.S. GAAP, the merger will be accounted for as a "reverse acquisition" pursuant to which ANI will be considered the acquiring entity for accounting purposes. As such, ANI will allocate the total purchase consideration to BioSante's tangible and identifiable intangible assets and liabilities based on their relative fair values at the date of the completion of the merger. ANI's historical results of operations will replace BioSante's historical results of operations for all periods prior to the merger; after completion of the merger, the results of operations of both companies will be included in BioSante's financial statements.

BioSante will account for the merger using the acquisition method of accounting under U.S. GAAP. Accounting Standards Codification 805 "*Business Combinations*," referred to as "ASC 805," provides guidance for determining the accounting acquiror in a business combination when equity interests are exchanged between two entities. ASC 805 provides that in a business combination effected through an exchange of equity interests, such as the merger, the entity that issues the equity interests is generally the acquiring entity. Commonly, the acquiring entity is the larger entity. However, the facts and circumstances surrounding a business combination sometimes indicate that a smaller entity acquires a larger one. ASC 805 further provides that in identifying the acquiring entity in a combination effected through an exchange of equity interests, all pertinent facts and circumstances must be considered, including the relative voting rights of the stockholders of the constituent companies in the combined entity, the composition of the board of directors and senior management of the combined company and the terms of the exchange of equity securities in the business combination, including payment of any premium.

Table of Contents

Based on the relative voting interests of BioSante and ANI in the combined company whereby the ANI stockholders will have majority voting interest, that the board of directors of the combined entity will be composed of five former-ANI board members and two former-BioSante directors and that the chief executive officer and chief financial officer of the combined entity will be the former chief executive officer and former chief financial officer of ANI, ANI is considered to be the acquiror of BioSante for accounting purposes. This means that the total purchase price will be allocated to BioSante's tangible and identifiable intangible assets and liabilities based on their estimated relative fair market values at the date of the completion of the merger. Final valuations of property, plant and equipment, and intangible and other assets have not yet been completed as management is still reviewing the existence, characteristics and useful lives of BioSante's intangible assets. The completion of the valuation work could result in significantly different amortization expenses and balance sheet classifications. After completion of the merger, the results of operations of both companies will be included in the financial statements of BioSante. For further discussion of the accounting treatment, see "Unaudited Pro Forma Condensed Combined Financial Information."

**Appraisal Rights**

***BioSante***

If the merger is completed, BioSante stockholders are not entitled to appraisal rights under Section 262 of the Delaware General Corporation Law (DGCL).

***ANI***

If the merger is completed, ANI stockholders who have not waived such rights are entitled to appraisal rights under Section 262 of the DGCL, referred to as Section 262, provided that they comply with the conditions established by Section 262.

This section is intended to provide a brief summary of the material provisions of the Delaware statutory procedures that a stockholder must follow in order to seek and perfect appraisal rights. However, this summary is not a complete statement of all applicable requirements, and it is qualified in its entirety by reference to the text of the relevant provisions of Delaware law, which are attached to this joint proxy statement/prospectus as Annex H. The following summary does not constitute any legal or other advice, nor does it constitute a recommendation that ANI stockholders exercise their appraisal rights under Section 262. Failure to follow precisely any of the statutory procedures set forth in Annex H may result in a termination or waiver of appraisal rights.

A record holder of shares of ANI capital stock who makes the demand described below with respect to such shares, who continuously holds such shares through the effective time of the merger, who submits a written demand for appraisal to ANI in compliance with the statutory requirements of Section 262, and who does not submit a proxy or vote in favor of the ANI Proposal No. 1 or consent thereto in writing will be entitled to an appraisal by the Delaware Court of Chancery of the fair value of his, her or its shares of ANI capital stock in lieu of the consideration that such stockholder would otherwise be entitled to receive pursuant to the merger agreement. All references in this summary of appraisal rights to a "stockholder" or "holders of shares of ANI capital stock" are to the record holder or holders of shares of ANI capital stock.

Under Section 262, because the merger agreement is to be submitted for adoption at the ANI special meeting, not fewer than 20 days prior to the meeting, ANI must notify each of the holders of its stock for whom appraisal rights are available that such appraisal rights are available and include in such notice a copy of Section 262. This joint proxy statement/prospectus shall constitute such notice to the record holders of ANI capital stock and a copy of Section 262 is attached to this joint proxy statement/prospectus as Annex H.

Table of Contents

ANI stockholders who desire to exercise their appraisal rights must satisfy all of the conditions of Section 262. Those conditions include the following:

ANI stockholders electing to exercise appraisal rights must not submit a proxy or vote "for" the ANI Proposal No. 1. Submitting a proxy or voting "for" the ANI Proposal No. 1 will result in the waiver of appraisal rights. Also, because a submitted proxy not marked "against" or "abstain" will be voted "for" the ANI Proposal No. 1, the submission of a proxy not marked "against" or "abstain" will result in the waiver of appraisal rights.

A written demand for appraisal of shares of ANI capital stock must be delivered to ANI before the taking of the vote on the ANI Proposal No. 1 at the ANI special meeting. The written demand for appraisal should specify the ANI stockholder's name and mailing address, and that such stockholder is thereby demanding appraisal of his, her or its shares of ANI capital stock. The written demand for appraisal of shares of ANI capital stock is in addition to and separate from a vote against the ANI Proposal No. 1 or an abstention from such vote. Failure to return your proxy, voting against, or abstaining from voting on, the ANI Proposal No. 1 will not satisfy your obligation to make a written demand for appraisal. Failure to make a written demand for appraisal prior to the taking of the vote on the ANI Proposal No. 1 at the ANI special meeting will constitute a waiver of appraisal rights.

A demand for appraisal must be executed by or for the ANI stockholder of record, fully and correctly, as such stockholder's name appears on the stock certificate. If the shares are owned of record in a fiduciary capacity, such as by a trustee, guardian or custodian, this demand must be executed by or for the fiduciary. If the shares of ANI capital stock are owned by or for more than one person, as in a joint tenancy or tenancy in common, such demand must be executed by or for all joint owners. An authorized agent, including an agent for two or more joint owners, may execute the demand for appraisal for an ANI stockholder of record. However, the agent must identify such record holder and expressly disclose the fact that, in exercising the demand, he is acting as agent for such record holder. A person having a beneficial interest in ANI capital stock held of record in the name of another person, such as a broker or nominee, must act promptly to cause the record holder to follow the steps summarized below in a timely manner to perfect appraisal rights on behalf of the beneficial owners.

An ANI stockholder who elects to exercise appraisal rights should mail or deliver his, her or its written demand to ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc., 210 Main Street West, Baudette, Minnesota 56623, Attention: Corporate Treasurer.

Within 10 days after the effective time of the merger, ANI must provide notice of the effective time of the merger to all ANI stockholders who have complied with Section 262 and have not voted in favor of the ANI Proposal No. 1.

Within 120 days after the effective time of the merger, either ANI or any ANI stockholder who has complied with the required conditions of Section 262 may file a petition in the Delaware Court of Chancery, with a copy served on ANI in the case of a petition filed by an ANI stockholder, demanding a determination of the fair value of the shares of ANI capital stock held by all ANI stockholders seeking to exercise appraisal rights. There is no present intent on the part of ANI to file an appraisal petition, and ANI stockholders seeking to exercise appraisal rights should not assume that ANI will file such a petition or that ANI will initiate any negotiations with respect to the fair value of such shares. Accordingly, ANI stockholders who desire to have their shares of ANI capital stock appraised should initiate any petitions necessary for the perfection of their appraisal rights within the time periods and in the manner prescribed in Section 262. Failure to file a petition for appraisal within the time period specified in Section 262 could result in a loss of appraisal rights.

Within 120 days after the effective time of the merger, any ANI stockholder who has satisfied the requirements of Section 262 will be entitled, upon written request, to receive from ANI a statement setting forth the aggregate number of shares of ANI common stock and ANI preferred stock not voting

Table of Contents

in favor of the ANI Proposal No. 1 and with respect to which demands for appraisal were received by ANI and the aggregate number of holders of such shares. Such statement must be mailed within 10 days after the ANI stockholder's request has been received by ANI or within 10 days after the expiration of the period for the delivery of demands as described above, whichever is later.

If a petition for an appraisal is timely filed and a copy thereof is served upon ANI, ANI will then be obligated, within 20 days after such service, to file in the office of the Register in Chancery (the Register) a duly verified list containing the names and addresses of all ANI stockholders who have demanded an appraisal of their shares of ANI capital stock and with whom agreements as to the value of such shares have not been reached. Upon notice to the ANI stockholders, as required by the Delaware Court of Chancery, at a hearing on such petition, the Delaware Court of Chancery will determine which ANI stockholders are entitled to appraisal rights. The Delaware Court of Chancery may require the ANI stockholders who have demanded an appraisal for their shares of ANI capital stock and who hold such stock represented by certificates to submit their certificates of stock to the Register for notation thereon of the pendency of the appraisal proceedings; and if any ANI stockholder fails to comply with such direction, the Delaware Court of Chancery may dismiss the proceedings as to such stockholder. Where proceedings are not dismissed, the Delaware Court of Chancery will appraise the shares of ANI capital stock owned by such stockholders, determining the fair value of such shares exclusive of any element of value arising from the accomplishment or expectation of the merger. When the fair value has been determined, the Delaware Court of Chancery will direct the payment of such value upon surrender by those stockholders of the certificates representing their shares of ANI capital stock. Unless the Delaware Court of Chancery in its discretion determines otherwise for good cause shown, interest from the effective time of the merger through the date of payment of the judgment shall be compounded quarterly and shall accrue at 5 percent over the Federal Reserve discount rate (including any surcharge) as established from time to time during the period between the effective time of the merger and the date of payment of the judgment.

Although the board of directors of ANI believes that the merger consideration is fair, no representation is made as to the outcome of the appraisal of fair value as would be determined by the Delaware Court of Chancery, and ANI stockholders should recognize that such an appraisal could result in a determination of a value higher or lower than, or the same as, the consideration they would receive pursuant to the merger agreement. Moreover, ANI does not anticipate offering more than the merger consideration to any ANI stockholder exercising appraisal rights and reserves the right to assert, in any appraisal proceeding, that, for purposes of Section 262, the "fair value" of a share of ANI capital stock is less than the merger consideration. In determining "fair value," the Delaware Court of Chancery is required to take into account all relevant factors. In *Weinberger v. UOP, Inc*., the Delaware Supreme Court discussed the factors that could be considered in determining fair value in an appraisal proceeding, stating that "proof of value by any techniques or methods which are generally considered acceptable in the financial community and otherwise admissible in court" should be considered and that "fair price obviously requires consideration of all relevant factors involving the value of a company." The Delaware Supreme Court has stated that in making this determination of fair value, the court must consider market value, asset value, dividends, earnings prospects, the nature of the enterprise and any other facts which could be ascertained as of the date of the merger which shed any light on the future prospects of the merged corporation. Section 262 provides that fair value is to be "exclusive of any element of value arising from the accomplishment or expectation of the merger." In *Cede & Co. v. Technicolor, Inc*., the Delaware Supreme Court stated that such exclusion is a "narrow exclusion that does not encompass known elements of value," but which rather applies only to the speculative elements of value arising from such accomplishment or expectation. In *Weinberger*, the Delaware Supreme Court also stated that "elements of future value, including the nature of the enterprise, which are known or susceptible of proof as of the date of the merger and not the product of speculation, may be considered." In addition, Delaware courts have decided that the statutory

Table of Contents

appraisal remedy, depending on factual circumstances, may or may not be a dissenting stockholder's exclusive remedy.

The cost of the appraisal proceeding, which does not include attorneys' or experts' fees, may be determined by the Delaware Court of Chancery and imposed upon the dissenting ANI stockholder(s) and/or ANI as the Delaware Court of Chancery deems equitable under the circumstances. Each dissenting ANI stockholder is responsible for his, her or its attorneys' and expert witness fees and expenses, although, upon application of a dissenting ANI stockholder, the Delaware Court of Chancery may order that all or a portion of the expenses incurred by any dissenting ANI stockholder in connection with the appraisal proceeding, including without limitation reasonable attorneys' fees and the fees and expenses of experts, be charged pro rata against the value of all shares of ANI capital stock entitled to appraisal.

Any ANI stockholder who has duly demanded appraisal in compliance with Section 262 will not, after the effective time of the merger, be entitled to vote for any purpose any shares of ANI capital stock subject to such demand or to receive payment of dividends or other distributions on such shares, except for dividends or distributions payable to ANI stockholders of record at a date prior to the effective time of the merger.

At any time within 60 days after the effective time of the merger, any ANI stockholder will have the right to withdraw his, her or its demand for appraisal and to accept the terms offered in the merger agreement. After this period, an ANI stockholder may withdraw his, her or its demand for appraisal and receive payment for his, her or its shares as provided in the merger agreement only with the consent of ANI. If no petition for appraisal is filed with the Delaware Court of Chancery within 120 days after the effective time of the merger, or if any ANI stockholder otherwise fails to perfect, successfully withdraws, or loses such holder's appraisal rights, then such stockholders' right to appraisal will cease and such stockholder's shares of ANI capital stock will be deemed to have been converted at the effective time of the merger into the right to receive the consideration that such ANI stockholder would otherwise be entitled to receive pursuant to the merger agreement. Inasmuch as ANI has no obligation to file such a petition, any ANI stockholder who desires a petition to be filed is advised to file it on a timely basis. Any ANI stockholder may withdraw such stockholder's demand for appraisal by delivering to ANI a written withdrawal of his, her or its demand for appraisal and acceptance of the merger consideration, except that (i) any such attempt to withdraw made more than 60 days after the effective time of the merger will require written approval of ANI and (ii) no appraisal proceeding in the Delaware Court of Chancery shall be dismissed as to any ANI stockholder who commenced or joined such proceeding as a named party without the approval of the Delaware Court of Chancery, and such approval may be conditioned upon such terms as the Delaware Court of Chancery deems just.

Failure by any ANI stockholder to comply fully with the procedures described above and set forth in Annex H to this joint proxy statement/prospectus may result in the loss of such stockholder's appraisal rights. In view of the complexity of exercising appraisal rights under Delaware law, any ANI stockholder considering exercising these rights should consult with legal counsel.

Table of Contents

## THE MERGER AGREEMENT

*BioSante and ANI entered into the merger agreement on October 3, 2012. The full text of this agreement is attached as Annex A to this joint proxy statement/prospectus and is incorporated by reference into this joint proxy statement/prospectus. BioSante and ANI urge you to read the merger agreement in its entirety for a more complete description of the terms and conditions of the merger and related matters.*

*The representations and warranties described below and included in the merger agreement were made by BioSante and ANI to each other as of specific dates. The assertions embodied in those representations and warranties were made solely for purposes of the merger agreement and may be subject to important qualifications and limitations agreed to by BioSante and ANI in connection with negotiating the terms of the merger agreement. Moreover, the representations and warranties may be subject to a contractual standard of materiality that may be different from what may be viewed as material to stockholders, or may have been used for the purpose of allocating risk between BioSante and ANI rather than establishing matters as facts. The merger agreement is described in this joint proxy statement/prospectus and included as Annex A only to provide you with information regarding the material terms and conditions of the merger agreement, and not to provide any other factual information regarding BioSante, ANI or their respective businesses. Accordingly, you should not rely on the representations and warranties in the merger agreement as characterizations of the actual state of facts about BioSante or ANI, and you should read the information provided elsewhere in this joint proxy statement/prospectus for information regarding BioSante, ANI and their respective businesses.*

### Structure of the Merger

Under the merger agreement, ANI will merge with and into BioSante, with BioSante surviving the merger. At the effective time of the merger, the name of the surviving company will be changed to ANI Pharmaceuticals, Inc., subject to approval of the BioSante stockholders of the amendment to BioSante's certificate of incorporation changing the company's name. The merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended.

### Completion of the Merger

The completion of the merger will occur at the time that the parties file the certificate of merger with the Secretary of State of the State of Delaware on the closing date of the merger or on such later date as BioSante and ANI may mutually agree (and set forth in the certificate of merger).

The closing of the merger will take place no later than the second business day after the satisfaction or waiver of the conditions to the completion of the merger contained in the merger agreement, other than the conditions which by their terms can be satisfied only as of the closing of the merger or on such other day as BioSante and ANI may mutually agree. For a more complete discussion of the conditions to the completion of the merger, see the section entitled "The Merger Agreement  Conditions to the Completion of the Merger." Because the completion of the merger is subject to the satisfaction of other conditions, BioSante and ANI cannot predict the exact time at which the merger will become effective and be completed, although it is anticipated to be completed during the first quarter of 2013.

### Merger Consideration and Adjustment

At the effective time of the merger, each outstanding share of capital stock of ANI will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. No fractional shares of BioSante common stock will be issued in connection with the merger. Instead, each ANI stockholder who otherwise would be entitled to receive

Table of Contents

a fractional share of BioSante common stock (after aggregating all fractional shares of BioSante common stock issuable to such holder) will be entitled to receive an amount in cash (rounded to the nearest whole cent), without interest, determined by multiplying such fraction of a share of BioSante common stock by the closing price of a share of BioSante common stock on The NASDAQ Global Market on the day on which the merger is completed.

Following the consummation of the transactions contemplated by the merger agreement, the current stockholders of ANI are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current stockholders of BioSante are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company, assuming BioSante's net cash as of the determination date is $18.0 million. BioSante will issue to the current stockholders of ANI the aggregate number of shares of BioSante common stock necessary for the current ANI stockholders to own 53 percent of the outstanding shares of common stock of the combined company, subject to adjustment based on BioSante's net cash, as discussed below.

The exchange ratio for each share of ANI capital stock will be determined based on the aggregate number of shares of BioSante common stock that BioSante issues in connection with the merger. The aggregate number of shares of BioSante common stock that BioSante issues in connection with the merger will be determined by multiplying 53 percent (subject to adjustment based on BioSante's net cash) multiplied by a fraction the numerator of which is the number of adjusted outstanding shares of BioSante common stock (as described below) and the denominator of which is 47 percent (subject to adjustment based on BioSante's net cash). The number of adjusted outstanding shares of BioSante common stock will be equal to the sum of the total number of shares of BioSante common stock outstanding immediately prior to the merger plus the product of .32 times the number of remaining shares of BioSante common stock that are issuable upon exercise of warrants to purchase an aggregate of 1,039,254 shares of BioSante common stock issued in or around August 2012. Pursuant to the terms of ANI's certificate of incorporation, before any amounts are paid to the holders of shares of any other series of ANI preferred stock or ANI common stock, the holders of shares of ANI series D preferred stock are entitled to receive an amount per share equal to $30.00 (subject to adjustment as provided in ANI's certificate of incorporation) plus all declared but unpaid dividends. As a result of such provisions, it is likely that holders of shares of other series of ANI preferred stock or ANI common stock will not receive any shares of BioSante common stock in connection with the merger. Assuming that only holders of ANI series D preferred stock will receive shares of BioSante common stock in connection with the merger, the exchange ratio for each share of ANI series D preferred stock will be determined by dividing the aggregate number of shares of BioSante common stock issued in connection with the merger by the aggregate number of shares of ANI series D preferred stock outstanding immediately prior to the merger.

For illustrative purposes only, if the merger had been completed on December 31, 2012, and assuming BioSante's net cash as of such date was $18.0 million, the exchange ratio (without giving effect to the proposed reverse stock split of BioSante common stock and BioSante class C special stock described elsewhere in this joint proxy statement/prospectus) for the ANI series D preferred stock (including shares that would have been issued to certain executive officers of ANI immediately prior to completion of the merger) would have been approximately 10.3502 shares of BioSante common stock for each share of ANI series D preferred stock and the exchange ratio (without giving effect to the proposed reverse stock split described elsewhere in this joint proxy statement/prospectus) for the ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock would have been zero. Therefore, if the merger had been completed on such date and you owned 1,000 shares of ANI series D preferred stock as of such date, you would have had the right to receive 10,350 shares of BioSante common stock in exchange for your shares of ANI series D preferred stock. If you owned 1,000 shares of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock or ANI common stock as of such date, you would have had the right to receive no

Table of Contents

shares of BioSante common stock for such shares of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock or ANI common stock.

The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger. For a more complete discussion of the determination of BioSante's net cash, see the section entitled "The Merger Agreement  Determination of BioSante's Net Cash." If BioSante has more than $18.0 million of net cash as of the determination date, then the percentage ownership of BioSante's current stockholders will be increased on a pro rata basis by 0.6 percent for each $1.0 million of net cash excess and if BioSante has less than $18.0 million of net cash as of the determination date, then the percentage ownership of BioSante's current stockholders will be decreased on a pro rata basis by 0.6 percent for each $1.0 million of net cash shortfall, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. In addition, one of the conditions to ANI's obligations to complete the merger is BioSante's net cash as of the closing date being no less than $17.0 million as calculated and as adjusted pursuant to the provisions of the merger agreement.

The following table illustrates the percentage ownership of the combined company by BioSante and ANI current stockholders assuming various amounts of net cash of BioSante as of the determination date.

| BioSante's Net Cash as of Determination Date Calculated Pursuant to Merger Agreement | BioSante Stockholder Ownership of Outstanding Shares of Combined Company | ANI Stockholder Ownership of Outstanding Shares of Combined Company |
|---|---|---|
| $23.0 million or more | 49.9% | 50.1% |
| 22.0 million | 49.4% | 50.6% |
| 21.0 million | 48.8% | 51.2% |
| 20.0 million | 48.2% | 51.8% |
| 19.0 million | 47.6% | 52.4% |
| 18.0 million | 47.0% | 53.0% |
| 17.0 million | 46.4% | 53.6% |

The items that will constitute BioSante's net cash balance at the determination date are subject to numerous factors, many of which are outside of BioSante's control. BioSante will issue a news release after the final determination of the exchange ratios announcing the final exchange ratios and BioSante's net cash balance at the determination date. If BioSante's net cash at the closing date is less than $17.0 million (as calculated and adjusted pursuant to the terms of the merger agreement), based on the manner of calculating net cash pursuant to the merger agreement, BioSante would be unable to satisfy a closing condition for the merger, and ANI could elect to terminate the merger agreement or waive the condition.

**Determination of BioSante's Net Cash**

For purposes of determining the exchange ratios, BioSante's net cash will be calculated as of the date that is 14 days prior to the date of the BioSante special meeting as set forth in this joint proxy statement/prospectus, subject to extension for an adjournment of such meeting. For purposes of determining whether BioSante has satisfied the condition to closing that BioSante have no less than $17.0 million in net cash as of the closing date (as calculated and as adjusted pursuant to the terms of the merger agreement), BioSante's net cash will be calculated shortly before the closing date of the merger. The closing of the merger could be delayed if BioSante and ANI are not able agree upon the

Table of Contents

amount of BioSante's net cash as of the determination date prior to the BioSante special meeting or as of the closing date.

Under the merger agreement, BioSante's "net cash" is defined as the amount of its cash and cash equivalents minus the aggregate amount of the following liabilities:

- accounts payable, accrued compensation (including accrued paid time off, vacation time, bonuses and payments in respect of benefit plans) and other accrued expenses, including certain amounts payable to BioSante employees as a result of the termination of their employment before or within 30 days after the merger or as a result of the merger constituting a change in control under their employment agreements, including severance costs and continuing insurance coverage;

- indebtedness for borrowed money;

- all remaining lease payments under BioSante's lease for its executive offices;

- all out-of-pocket costs in connection with the merger agreement and the transactions contemplated thereby;

- all remaining costs of BioSante's current LibiGel program, including the completion and/or conclusion of any clinical trials, safety studies or other research studies and the cost of keeping in effect any related product liability or similar insurance policies;

- a reserve yet to be determined by BioSante and ANI and currently expected to be approximately $0 to provide for any out-of-pocket costs associated with any then outstanding litigation of BioSante; and

- one-half of certain settlement payments.

**Treatment of ANI Stock Options and Warrants**

All options and warrants to purchase shares of ANI capital stock outstanding immediately prior to the effective time of the merger will terminate and will no longer be outstanding immediately after the merger, except for certain warrants which although not cancelled will not represent the right to acquire any equity or other interest in the combined company after the merger.

**Conditions to Completion of the Merger**

The obligations of each of BioSante and ANI to complete the merger are subject to the satisfaction or waiver (if permissible) at or before the effective time of the merger of the following conditions:

- the adoption by the requisite vote of BioSante stockholders of the merger agreement, including the merger and the issuance of BioSante common stock pursuant to the merger agreement, and approval by the requisite vote of BioSante stockholders of the amendments to BioSante's certificate of incorporation to change the company's corporate name and effect the reverse stock split;

- the adoption of the merger agreement, including the merger, by the requisite vote of ANI stockholders;

the absence of any legal prohibition to completing the merger;

the effectiveness of, and the absence of any stop order with respect to, the registration statement on Form S-4 of which this joint proxy statement/prospectus forms a part;

Table of Contents

the continued listing of BioSante common stock on The NASDAQ Global Market and the approval for listing on The NASDAQ Global Market or The NASDAQ Capital Market of the shares of BioSante common stock issuable in the merger; and

the receipt of legal opinions from BioSante's and ANI's outside counsel that the merger will qualify as a reorganization under Section 368(a) of the Internal Revenue Code of 1986, as amended.

In addition, each party's obligation to complete the merger is further subject to the satisfaction or waiver (if permissible) by that party of the following additional conditions:

the representations and warranties of the other party in the merger agreement being true and correct in all material respects, in each case as of the date of the merger agreement and as of the effective time of the merger, or, if such representations and warranties address matters as of a particular date, then as of that particular date;

the other party to the merger agreement having performed or complied with in all material respects all agreements and covenants required to be performed or complied with by it at or before the closing of the merger;

the other party having delivered a certificate signed by a duly authorized officer certifying to the satisfaction of such party of the above conditions in the merger agreement; and

no material adverse effect on the other party shall have occurred and be continuing since the date of the merger agreement.

In addition, the obligation of ANI to complete the merger is further subject to the satisfaction or waiver at or before the effective time of the merger of the following additional conditions:

BioSante's net cash as of the closing being no less than $17.0 million, as calculated and as adjusted as provided in the merger agreement; and

no new legal proceeding having been instituted against BioSante by any stockholder or holder of BioSante's convertible senior notes that has not been settled prior to the closing.

**No Solicitation**

Prior to the consummation of the merger or the termination of the merger agreement in accordance with its terms, BioSante and ANI each agreed that, except as described below, they and any of their subsidiaries will not, and will cause any of their respective officers, directors, employees and advisors retained by them or any of their subsidiaries not to, directly or indirectly:

solicit, initiate, encourage, facilitate or induce the making of any "acquisition proposal" of the type described below;

enter into, continue or otherwise participate in any discussions or negotiations regarding or otherwise facilitate or induce any effort or attempt to make or implement any acquisition proposal;

approve, endorse or recommend any acquisition proposal; or

agree, resolve or commit to do any of the foregoing.

An "acquisition proposal" is any proposal or offer in a single transaction or series of related transactions, other than pursuant to the merger agreement, with respect to either ANI or BioSante, respectively, involving: (i) any merger, consolidation, share exchange, business combination, issuance of securities, direct or indirect acquisition of securities, recapitalization, tender offer, exchange offer or other similar transaction pursuant to which a person or group of persons would own 15 percent or

Table of Contents

more of the voting power of any class of equity securities of such party; (ii) any issuance of securities representing 15 percent or more of the outstanding shares of any class of voting securities of such party; (iii) any sale, lease, exchange, transfer or other disposition of assets that constitute or represent 15 percent or more of the consolidated net revenue or fair market value of the assets of such party; or (iv) any liquidation or dissolution of such party.

However, prior to BioSante stockholder adoption of the merger agreement, BioSante is permitted to engage in discussions or negotiations with, and provide information to, any person in response to an unsolicited written acquisition proposal that is a "superior proposal" of the type described below or could reasonably be expected to lead to a superior proposal if:

- the BioSante board of directors determines, after receiving the advice of its advisors, that such acquisition proposal is a superior proposal or could reasonably be expected to lead to a superior proposal and that failing to take such action would be inconsistent with its fiduciary duties to the BioSante stockholders;

- the person or group of persons making the acquisition proposal enter into a confidentiality agreement with terms no less restrictive to such person as the terms of the confidentiality agreement between ANI and BioSante; and

- within one day of receipt of an acquisition proposal, BioSante advises ANI in writing of such receipt or any inquiry to request to enter into discussions with respect to an acquisition proposal, provides a summary of the material terms and conditions of such acquisition proposal, the identity of the person making such proposal, and copies of any acquisition proposal and other written materials provided in connection with such acquisition proposal.

In connection with a superior proposal, BioSante may make a change in its board recommendation of the merger and the amendments to BioSante's certificate of incorporation or terminate the merger agreement to enter into such superior proposal concurrent with or immediately following such termination, if:

- the BioSante board of directors determines, after receiving the advice of its advisors, that such acquisition proposal is a superior proposal and that failing to take such action would be inconsistent with its fiduciary duties to the BioSante stockholders; and

- prior to changing its board recommendation or terminating the merger agreement, BioSante gives ANI (i) at least three business days' notice of its intention to change its board recommendation or terminate the merger agreement and the material terms and conditions of such superior proposal, and (ii) the opportunity to negotiate with BioSante during such notice period in good faith to revise the terms and conditions of the merger agreement so that the superior proposal ceases to be a superior proposal.

A "superior proposal" is an bona fide written acquisition proposal, changing the references to 15 percent in the definition of "acquisition proposal" above to be references to 50 percent, which the BioSante board of directors determines, after receiving the advice of its advisors, to be reasonably likely to be consummated if accepted and to be more favorable to the BioSante stockholders from a financial point of view than the merger with ANI, after taking into account, among other factors the BioSante board of directors may deem relevant, the various legal, financial and regulatory aspects of the proposal, all the terms and conditions of the proposal and any changes to the terms of the merger agreement offered by ANI in response to such proposal.

The merger agreement also provides that the parties will keep each other reasonably informed of the status of any negotiations with respect to an acquisition proposal and will provide each other the identity of the person making the proposal and any non-public information provided to any other person in connection with an acquisition proposal.

Table of Contents

**Meetings of Stockholders; Change in Board Recommendation**

BioSante is obligated under the merger agreement to call and hold the BioSante special meeting for purposes of considering the adoption of the merger agreement, the issuance of BioSante common stock pursuant to the merger and the approval of the amendments to BioSante's certificate of incorporation. The BioSante board of directors has recommended the adoption of the merger agreement and the issuance of BioSante common stock pursuant to the merger and the approval of the amendments to BioSante's certificate of incorporation by the BioSante stockholders and has agreed that it will not change or publicly propose to change, in any manner adverse to ANI, the approval or recommendation by the BioSante board of directors of the merger agreement, the merger or the issuance of BioSante common stock pursuant to the merger or the amendments to BioSante's certificate of incorporation, or take any action inconsistent with its recommendation. However, the BioSante board of directors may make a change in its recommendation prior to the BioSante stockholder approval of the merger agreement and the issuance of BioSante common stock pursuant to the merger and the amendments to BioSante's certificate of incorporation under the circumstances described above under the heading "The Merger Agreement  No Solicitation."

Unless the merger agreement is otherwise terminated in accordance with its terms, even if the BioSante board of directors has made an adverse recommendation change regarding the merger and the issuance of the BioSante common stock pursuant to the merger and the amendments to BioSante's certificate of incorporation, those proposals must be submitted to the BioSante stockholders at a meeting of the BioSante stockholders called for such purpose.

ANI is obligated under the merger agreement to call and hold the ANI special meeting for purposes of considering the adoption of the merger agreement. The ANI board of directors has recommended the adoption of the merger agreement by the ANI stockholders and has agreed that it will not change or publicly propose to change, in any manner adverse to BioSante, the approval or recommendation by the ANI board of directors of the merger agreement or merger, or take any action inconsistent with its recommendation. However, the ANI board of directors may make a change in its recommendation prior to the ANI stockholder approval of the merger and the merger agreement, if:

- the BioSante board of directors has changed its recommendation of the approval of the merger agreement and the issuance of BioSante common stock pursuant to the merger and the amendments to BioSante's certificate of incorporation by the BioSante stockholders;
- BioSante has engaged in discussions or negotiations with, or provided information to, any person in response to a superior proposal; or
- ANI has terminated the merger agreement.

Unless the merger agreement is otherwise terminated in accordance with its terms or the BioSante board of directors changes its recommendation as described above, even if the ANI board of directors has made an adverse recommendation change regarding the merger, the proposal to adopt the merger agreement must be submitted to the ANI stockholders at a meeting of the ANI stockholders called for such purpose.

**Covenants; Conduct of Business Pending the Merger**

BioSante and ANI each agreed to certain restrictions on their respective businesses until the later of either the effective time of the merger or the date the merger agreement is terminated. In general, BioSante and ANI must conduct their operations in the ordinary course of business and use their reasonable best efforts to preserve intact their business and keep available the services of their officers and employees. Each of BioSante and ANI also agreed that, subject to certain limited exceptions

Table of Contents

described in the merger agreement, without the consent of the other party, it would not, during the period prior to the closing of the merger:

- enter into certain material contracts or terminate or amend any material contracts;
- adopt any new severance plan or grant any severance or termination payments to any officer or director, except in accordance with existing agreements or policies;
- declare dividends or split, combine or reclassify its shares of capital stock;
- amend its certificate of incorporation or bylaws;
- sell or pledge any assets other than immaterial assets;
- incur any indebtedness for borrowed money;
- adopt or amend any employee benefit plan, enter into any employment contract, pay any special bonus to or increase the salaries or wages of any director or employee;
- pay or discharge any material claim or obligation;
- acquire or dispose of any material amount of assets or securities;
- fail to maintain any material intellectual property;
- change its accounting policies and procedures;
- make or change any material tax election, settle or compromise any material tax liability or engage in certain other activities with respect to taxes;
- issue or sell equity securities, options or other securities convertible into or exercisable for equity securities;
- enter into any agreement that would limit it from engaging or competing in any line of business;
- allow any material permit to lapse;
- make material capital expenditures;
- tax any action that would prevent the merger from qualifying as a reorganization under Section 368(a) of the Internal Revenue Code; or

agree or commit to do any of the foregoing.

In addition, BioSante agreed that it will, during the period prior to the closing of the merger, make all required filings with the SEC in a timely manner and take all such actions as may be necessary or advisable to effect a conclusion of its LibiGel product clinical trials and safety study in accordance with a budget agreed upon with ANI.

**Other Agreements**

Each of BioSante and ANI has agreed:

to use its reasonable best efforts to cause the registration statement of which this joint proxy statement/prospectus is a part to become effective as promptly as practicable;

to coordinate with the other in preparing and exchanging information and promptly provide the other with copies of all filings or submissions made in connection with the merger;

to use its reasonable best efforts to take all actions necessary, proper or advisable to complete the merger and to obtain all consents, approvals and authorizations necessary to complete the merger;

Table of Contents

to use its reasonably best efforts to structure the merger to qualify as a reorganization under Section 368 of the Internal Revenue Code; and

to consult with each other about any public statement either will make concerning the merger, subject to certain exceptions.

BioSante and ANI also agreed that:

BioSante will promptly prepare and submit to The NASDAQ Stock Market a listing application covering the shares of BioSante common stock that ANI stockholders will be entitled to receive pursuant to the merger, and to use its reasonable best efforts to obtain approval for the listing of such shares prior to the effective time of the merger.

The combined company will continue to indemnify each of the directors and officers of BioSante and ANI to the fullest extent permitted under the Delaware General Corporation Law and, for a period of six years after the merger, and will maintain directors' and officers' liability insurance for BioSante's and ANI's directors and officers.

Immediately prior to the merger, BioSante will terminate all of its employees, including its officers, except for any employees as to whom ANI has delivered written notice that they should not be terminated, if any.

The directors and officers of the combined company will be as described under the heading "Management of the Combined Company Following the Merger."

**Termination**

The merger agreement may be terminated at any time before the completion of the merger, whether before or after the required stockholder approvals to complete the merger have been obtained as set forth below:

by mutual written consent of BioSante and ANI;

by BioSante or ANI, if the merger has not been completed by May 31, 2013, subject to extension to no later than July 31, 2013, based on the date of filing of the registration statement on Form S-4 of which this joint proxy statement/prospectus forms a part, except that a party whose material breach of the merger agreement resulted in the failure of the merger to occur by such date cannot seek termination for this reason;

by BioSante or ANI, if any applicable law irrevocably prohibits or makes the merger illegal or a governmental entity has issued a final and non-appealable order, decree or ruling or taken any other action that permanently restrains, enjoins or otherwise prohibits the merger, except that the right to terminate the merger agreement for this reason is not available to any party who has not used reasonable best efforts to cause such law or order to be lifted;

by BioSante or ANI, if ANI stockholders fail to adopt the merger agreement at the ANI special meeting or if BioSante stockholders fail to adopt the merger agreement, including the merger and the issuance of shares of BioSante common stock pursuant to the merger, and approve the amendments to BioSante's certificate of incorporation at the BioSante special meeting;

Table of Contents

by ANI, if either of the following occur, each a "BioSante triggering event":

BioSante fails to include in this joint proxy statement/prospectus the recommendation of the BioSante board of directors to the BioSante stockholders in favor of adoption of the merger agreement, including the merger and the issuance of shares of BioSante common stock in the merger, and approval of the amendments to BioSante's certificate of incorporation; or

prior to the BioSante special meeting the BioSante board of directors has withdrawn or made a change, or publicly proposed to withdraw or make a change, in its recommendation to the BioSante stockholders to adopt the merger agreement, including the issuance of shares of BioSante common stock in the merger, and to approve the amendments to BioSante's certificate of incorporation in a manner adverse to ANI;

by BioSante, if BioSante enters into a superior proposal in accordance with the terms of the merger agreement. For a more detailed description of BioSante's ability to terminate the merger agreement in connection with a superior proposal, see under the heading above "The Merger Agreement  No Solicitation"; or

by BioSante or ANI, if the other party has breached any of its representations, warranties, covenants or other agreements contained in the merger agreement or if any representation or warranty has become inaccurate, in either case such that the conditions to the closing of the merger would not be satisfied, provided that if such breach or inaccuracy is curable, then the merger agreement will not terminate pursuant to this provision as a result of a particular breach or inaccuracy until the expiration of a 30-day period after delivery of notice of such breach or inaccuracy if such breach has not been cured; or

by ANI, if after BioSante receives an acquisition proposal, BioSante has materially breached its obligations under the merger agreement with respect to the acquisition proposal.

**Termination Fees and Expenses**

BioSante must pay ANI up to $500,000 of ANI's fees and expenses incurred in connection with the merger if:

ANI terminates the merger agreement in accordance with the merger agreement because of a BioSante triggering event or an uncured BioSante breach of the merger agreement that causes the conditions to closing of the merger to not be satisfied; or

BioSante terminates the merger agreement because (i) ANI's stockholders fail to adopt the merger agreement, including the merger, at the ANI stockholder meeting or (ii) the BioSante board of directors changed its recommendation and terminates the merger agreement for the purpose of entering into a superior proposal.

In addition, BioSante must pay ANI a termination fee equal to $1.0 million, less the amount of any expenses already paid, if any one of the following occurs:

ANI terminates the merger agreement due to a BioSante triggering event or an uncured BioSante breach of the merger agreement that causes the conditions to closing of the merger to not be satisfied and within 12 months after the date of any such termination BioSante enters into a definitive agreement with respect to (and subsequently consummates) an acquisition proposal (changing the 15 percent amount referred to in the definition of "acquisition proposal" described above under the heading "The Merger Agreement  No Solicitation," to 30 percent for purposes of this provision);

BioSante terminates the merger agreement because the ANI stockholders did not adopt the merger agreement and within two months after the date of such termination BioSante enters

Table of Contents

into a definitive agreement with respect to (and subsequently consummates) an acquisition proposal (using the 30 percent amount described above); or

BioSante terminates the merger agreement because of a superior proposal in accordance with the merger agreement, as described under the heading above "The Merger Agreement  No Solicitation."

ANI must pay BioSante a termination fee of $750,000 if BioSante terminates the merger agreement because an uncured ANI breach of the merger agreement that causes the conditions to closing of the merger to not be satisfied.

These termination fees would be the exclusive remedy of the parties for any damages suffered as a result of the failure of the merger to be consummated.

**Representations and Warranties**

The merger agreement contains customary representations and warranties of ANI and BioSante related to, among other things:

due organization, good standing and qualification;

capitalization;

corporate authority to enter into the merger agreement and complete the merger;

required stockholder vote to approve the merger and related transactions;

absence of any breach of organizational documents, laws and agreements as a result of the merger;

required consents and filings with government entities;

compliance with applicable laws;

conformity of the financial statements with applicable accounting principles and that the financial statements fairly present, in all material respects, the consolidated financial positions of BioSante and ANI;

absence of undisclosed liabilities;

sufficiency of internal controls over financial reporting;

absence of material pending or threatened legal proceedings;

tax matters;

material contracts;

employee benefit plans;

ownership of subsidiaries;

absence of material changes or events since December 31, 2011;

approval and adoption of the merger agreement and related matters by the board of directors;

real property ownership and leases;

intellectual property;

regulatory compliance;

environmental matters;

Table of Contents

labor and employment matters;

insurance coverage;

information contained in this joint proxy statement/prospectus;

affiliate transactions; and

no finder's fees.

The merger agreement contains additional representations and warranties made of BioSante to ANI related to:

BioSante's compliance with applicable SEC requirements with respect to, and sufficiency of, documents filed with the SEC by BioSante;

the registration of BioSante's common stock under the Securities Exchange Act of 1934, as amended, and its listing on The NASDAQ Global Market; and

certain statements made by BioSante in news releases issued by it in respect of its LibiGel product.

The representations and warranties are, in many respects, qualified by materiality and knowledge, and will not survive the merger, but their accuracy forms the basis of one of the conditions to the obligations of BioSante and ANI to complete the merger.

**Amendments**

The merger agreement may be amended by the parties at any time, except that after the merger agreement has been adopted (and, in the case of BioSante, the issuance of BioSante common stock and amendments to its certificate of incorporation have been approved) by either the ANI stockholders or the BioSante stockholders, no amendment that by law requires further approval of the ANI stockholders or BioSante stockholders, as applicable, may be made without such further approval.

Table of Contents

## VOTING AND OTHER ANCILLARY AGREEMENTS

### ANI Voting Agreements

Concurrently and in connection with the execution of the merger agreement, Meridian Venture Partners II, L.P., Argentum Capital Partners II, L.P. and four funds affiliated with First Analysis Corp., who in the aggregate held approximately 85 percent of the shares of the outstanding ANI capital stock, calculated on an as-converted basis, and approximately 86 percent of the outstanding shares of the ANI series D preferred stock, as of October 3, 2012 entered into a voting agreement with BioSante, pursuant to which they agreed to vote their shares of ANI capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement. The form of ANI voting agreement is attached as Annex B to this joint proxy statement/prospectus and is incorporated by reference into this joint proxy statement/prospectus. BioSante and ANI urge you to read the form of ANI voting agreement carefully and in its entirety.

In addition, one of ANI's stockholders, Meridian Venture Partners II, L.P., has agreed in its voting agreement with BioSante to vote in favor of the election of the two directors designated by BioSante at the first annual meeting of stockholders of the combined company following completion of the merger. As of October 3, 2012, Meridian Venture Partners II, L.P. held approximately 57 percent of the outstanding shares of ANI capital stock, approximately 60 percent of the outstanding shares of ANI common stock on an as-converted basis and 58 percent of the outstanding shares of ANI series D preferred stock, and is expected to hold approximately 27 percent of the outstanding shares of capital stock of the combined company immediately after completion of the merger. The voting agreement between BioSante and Meridian Venture Partners II, L.P. is attached as Annex C to this joint proxy statement/prospectus and is incorporated by reference into this joint proxy statement/prospectus. BioSante and ANI urge you to read the voting agreement between BioSante and Meridian Venture Partners II, L.P. carefully and in its entirety.

The ANI voting agreements will terminate upon the earlier of the consummation of the merger or the termination of the merger agreement, except that, if the merger is completed, the obligation of Meridian Venture Partners II, L.P. to vote in favor of the two directors designated by BioSante under its voting agreement with BioSante will terminate upon the completion of the first annual meeting of stockholders of the combined company following completion of the merger. In addition, the ANI voting agreements will terminate if (1) the BioSante board of directors changes its recommendation that the BioSante stockholders vote in favor of the adoption of the merger agreement and the issuance of BioSante common stock pursuant to the merger and the approval of the amendments to BioSante's certificate of incorporation or (2) if BioSante has engaged in discussions or negotiations with, or provided information to, any person in response to a superior acquisition proposal.

### BioSante Voting Agreements

All of BioSante's directors and officers entered into voting agreements with ANI, pursuant to which each stockholder agreed to vote its shares of BioSante capital stock in favor of adoption of the merger agreement and the merger and the other transactions contemplated by the merger agreement, including the approval of the merger and the issuance of shares of BioSante common stock in the merger, and in favor of the two proposed amendments to BioSante's certificate of incorporation as described in this joint proxy statement/prospectus, and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transactions contemplated by the merger agreement. As of October 3, 2012, such BioSante stockholders collectively held approximately two percent of the outstanding shares of BioSante capital stock. The form of the BioSante voting agreement is attached as Annex D to this joint proxy statement/prospectus and is incorporated by

Table of Contents

reference into this joint proxy statement/prospectus. BioSante and ANI urge you to read the form of BioSante voting agreement carefully and in its entirety.

The BioSante voting agreements will terminate upon the earlier of the consummation of the merger or the termination of the merger agreement.

**Lock-Up Agreements**

Concurrently and in connection with the execution of the merger agreement, ANI's chief executive officer and chief financial officer, both of whom are entitled to receive shares of ANI series D preferred stock prior to completion of the merger as described under the heading "Interests of ANI's Directors and Officers in the Merger," and each of the ANI stockholders that entered into voting agreements with BioSante in connection with the execution of the merger agreement, entered into lock-up agreements with BioSante pursuant to which the shares of BioSante common stock received by those ANI stockholders in the merger may not be sold, transferred or encumbered for a 180-day period following completion of the merger, except in limited circumstances. The form of the lock-up agreement is attached as Annex E to this joint proxy statement/prospectus and is incorporated by reference into this joint proxy statement/prospectus.

Table of Contents

## CONTINGENT VALUE RIGHTS

### General

Under the terms of the merger agreement, BioSante has the right in its sole discretion to distribute and issue contingent value rights (CVRs), to holders of BioSante common stock as of immediately prior to completion of the merger. As of the date of this joint proxy statement/prospectus, BioSante plans to distribute and issue CVRs to holders of record of BioSante common stock as of March 15, 2013. BioSante expects that one CVR will be issued for each share of BioSante common stock outstanding as of the record date for the distribution of the CVRs. Since shares of BioSante class C special stock are not entitled to receive any distributions or dividends, holders of BioSante class C special stock will not be entitled to receive any CVRs, if CVRs are issued.

### Contingent Value Rights Agreement

BioSante plans to enter into a contingent value rights agreement with Computershare Inc., as rights agent, for the purpose of establishing the terms and conditions of the CVRs and the procedures by which payments, if any, will be made to the CVR holders. The form of the contingent value rights agreement is attached as Annex F to this joint proxy statement/prospectus and is incorporated by reference into this joint proxy statement/prospectus. BioSante and ANI urge you to read the form of the contingent value rights agreement carefully and in its entirety.

### Material Terms of the CVRs

The CVRs will not be certificated and will not be attached to the shares of BioSante common stock. The CVRs will be nontransferable, subject to certain limited exceptions as set forth in the contingent value rights agreement. The CVRs will not represent an equity or ownership interest in the combined company or otherwise, and CVR holders will have no voting or dividend rights. The rights of CVR holders will be limited to those rights expressly set forth in the contingent value rights agreement.

Pursuant to the contingent value rights agreement, CVR holders, under certain circumstances, may have rights to receive a portion of the net cash proceeds actually received by the combined company in connection with a LibiGel transaction. A "LibiGel transaction" for purposes of the contingent value rights agreement means a full or partial sale, license, transfer or other disposition entered into by the combined company with respect to the LibiGel assets. The "LibiGel assets" for purposes of the contingent value rights agreement mean the intellectual property rights and know-how and related assets, that currently are or have been used in the research, development and manufacture of BioSante's LibiGel product, a proprietary transdermal testosterone formulation subject to a license agreement with Antares Pharma Inc., including all BioSante generated regulatory filings, clinical and non-clinical safety, efficacy and pharmacokinetic data, compiled by or on behalf of BioSante in connection with the development of the LibiGel product.

Subject to the terms and conditions of the contingent value rights agreement, if the combined company consummates a LibiGel transaction within the 10-year period following completion of the merger, CVR holders will be entitled to receive cash payments equal to such holder's pro rata portion of 66 percent of the net cash proceeds actually received by the combined company in connection with such LibiGel transaction during the 10-year period following completion of the merger, up to an aggregate of $40.0 million. If the combined company does not consummate a LibiGel transaction during the 10-year period following completion of the merger, no cash payment will be payable to CVR holders.

Under the contingent value rights agreement, the combined company's only obligation will be to act in good faith in connection with: (1) any continued operation of, development of or investment in

Table of Contents

the LibiGel assets; (2) pursuing, negotiating or entering into one or more LibiGel transactions; and (3) the terms and conditions of any LibiGel transaction.

**Discretion of BioSante to Issue CVRs**

Although BioSante currently plans to enter into the contingent value rights agreement and issue CVRs to holders of BioSante common stock, there is no assurance that BioSante will distribute and issue the CVRs at all or based on the terms currently set forth in the form of contingent value rights agreement attached as Annex F to this joint proxy statement/prospectus. As of the date of this joint proxy statement/prospectus, BioSante has not entered into the contingent value rights agreement and it is possible that the BioSante board of directors may determine in its sole discretion not to issue the CVRs based on, among other things, the tax impact to the holders of BioSante common stock of the distribution and issuance of the CVRs. Furthermore, if BioSante and ANI agree, the terms of the contingent value rights agreement as currently contemplated may be changed prior to BioSante entering into the contingent value rights agreement.

Table of Contents

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE MERGER

The following discussion summarizes the material U.S. federal income tax consequences of the merger. This summary is based upon current provisions of the Code, existing Treasury Regulations promulgated thereunder and current administrative rulings and court decisions, all of which are subject to change and to differing interpretations, possibly with retroactive effect. Any change could alter the tax consequences to BioSante, ANI or ANI stockholders, as described in this summary. This summary is not binding on the IRS, and there can be no assurance that the IRS (or a court, in the event of an IRS challenge) will agree with the conclusions stated herein.

This discussion does not address all of the U.S. federal income tax consequences of the merger that may be relevant to ANI stockholders and BioSante stockholders in light of their particular circumstances and does not apply to stockholders that are subject to special treatment under U.S. federal income tax laws, including, without limitation:

- dealers, brokers and traders in securities;
- individuals who are not citizens or residents of the U.S., including U.S. expatriates;
- corporations (or other entities taxable as a corporation for U.S. federal income tax purposes) created or organized outside of the U.S.;
- tax-exempt entities;
- financial institutions, regulated investment companies, real estate investment trusts or insurance companies;
- partnerships, limited liability companies that are not treated as corporations for U.S. federal income tax purposes, subchapter S corporations and other pass-through entities and investors in such entities;
- an estate or trust;
- holders who are subject to the alternative minimum tax provisions of the Code;
- holders who acquired their shares in connection with stock option or stock purchase plans or in other compensatory transactions;
- holders who hold their shares through a pension plan or other qualified retirement plan;
- holders who hold their shares as part of an integrated investment such as a hedge or as part of a hedging, straddle or other risk reduction strategy;
- holders who do not hold their shares as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment will be a capital asset); or
- holders who have a functional currency other than the U.S. dollar.

In addition, the following discussion does not address:

- the tax consequences of the merger under any U.S. federal non-income tax laws or under state, local or foreign tax laws;
- the tax consequences of transactions effectuated before, after or at the same time as the merger, whether or not they are in connection with the merger;
- the tax consequences of the exchange of any ANI capital stock that constitutes "Section 306 stock" within the meaning of Section 306 of the Code;
- the tax consequences of the receipt of shares of BioSante common stock other than in exchange for shares of ANI capital stock;

Table of Contents

the tax consequences of the ownership or disposition of shares of BioSante common stock acquired in the merger; or

all of the tax implications of a failure of the merger to qualify as a "reorganization" within the meaning of Section 368(a) of the Code.

**Accordingly, ANI stockholders are advised and expected to consult their own tax advisors regarding the U.S. federal income tax consequences of the merger in light of their personal circumstances and the consequences of the merger under U.S. federal non-income tax laws and state, local and foreign tax laws.**

***U.S. Federal Income Tax Consequences of the Merger***

The merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Code. BioSante and ANI have agreed to use reasonable best efforts to structure the merger to qualify as a "reorganization" and not to take any action that would prevent the merger from qualifying as a reorganization under Section 368(a) of the Code. Further, as a condition to the completion of the merger, Oppenheimer Wolff & Donnelly LLP must render a tax opinion to BioSante that the merger will constitute a "reorganization" within the meaning of Section 368(a) of the Code and SNR Denton US LLP must render a tax opinion to ANI that the merger will constitute a "reorganization" within the meaning of Section 368(a) of the Code. Neither BioSante nor ANI presently intends to waive these conditions. The tax opinions discussed in this section will be conditioned upon certain assumptions and qualifications stated in the tax opinions and will be based on the truth, accuracy, and completeness, as of the completion of the merger, of certain representations and other statements made by each of BioSante and ANI, as applicable, in letters delivered to counsel rendering such opinions.

Neither BioSante nor ANI will request a ruling from the IRS regarding the tax consequences of the merger. The opinions of counsel do not bind the IRS or courts of law and thus do not prevent the IRS from asserting a contrary position, or a court from upholding any such assertion. In addition, if any of the representations or assumptions upon which the opinions are based are inconsistent with the actual facts, the tax consequences of the merger and the vitality of the opinions could be adversely affected.

It is expected that Oppenheimer Wolff & Donnelly LLP and SNR Denton US LLP, subject to the qualifications described above, will each deliver an opinion that the merger will be treated for U.S. federal income tax purposes as a "reorganization" within the meaning of Section 368(a) of the Code. Assuming that the merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Code, the following material U.S. federal income tax consequences should result:

BioSante, ANI and the BioSante stockholders generally will recognize no gain or loss solely as a result of the merger;

ANI stockholders, other than ANI stockholders who exercise appraisal rights (as discussed below), generally will recognize no gain or loss upon the receipt of BioSante common stock for their ANI capital stock, other than with respect to cash received in lieu of fractional shares of BioSante common stock (as discussed below);

the aggregate tax basis of the shares of BioSante common stock that are received by an ANI stockholder in the merger will be equal to the aggregate tax basis of the shares of ANI capital stock surrendered in exchange therefor, reduced by any amount allocable to a fractional share of BioSante common stock for which cash is received;

the holding period of the shares of BioSante common stock received by an ANI stockholder in connection with the merger will include the holding period of the shares of ANI capital stock surrendered in exchange therefor; and

Table of Contents

an ANI stockholder who receives cash instead of a fractional share of BioSante common stock generally will recognize a capital gain or loss in an amount equal to the difference, if any, between such stockholder's basis in the fractional share and the amount of cash received.

There will be no material U.S. federal income tax consequences of the merger for BioSante stockholders whether or not the merger qualifies as a "reorganization" within the meaning of Section 368(a) of the Code.

***Treatment of ANI Stockholders Who Exercise Appraisal Rights***

The discussion above does not apply to ANI stockholders who properly perfect appraisal rights with respect to such stockholder's shares of ANI capital stock. Generally, an ANI stockholder who perfects appraisal rights and receives cash in exchange for such stockholder's ANI capital stock will recognize capital gain or loss measured by the difference between the amount of cash received and such stockholder's adjusted tax basis in those shares. Such gain or loss will generally be long-term capital gain or loss, provided the shares of ANI capital stock were held for more than one year before the disposition of the shares. The deductibility of capital losses is subject to limitations.

***Information Reporting and Backup Withholding***

Generally, non-corporate ANI stockholders may be subject to information reporting and backup withholding (currently at a rate of 28 percent) with respect to cash received in lieu of a fractional share interest in BioSante common stock or cash received for perfecting appraisal rights. However, backup withholding will not apply to an ANI stockholder who furnishes a valid taxpayer identification number and complies with certain certification procedures or otherwise establishes an exemption from backup withholding. Backup withholding is not an additional U.S. federal income tax. Any amounts so withheld will be allowed as a refund or credit against the ANI stockholder's U.S. federal income tax liability (if any), provided that the ANI stockholder timely furnishes the required information to the IRS.

**The foregoing summary of material U.S. federal income tax consequences is not intended to be a complete analysis or description of all potential U.S. federal income tax consequences of the merger. In addition, the summary does not address tax consequences that may vary with, or are contingent on, individual circumstances. Moreover, the summary does not address any U.S. federal non-income tax or any foreign, state or local tax consequences of the merger, nor any tax consequences of any transaction other than the merger. Accordingly, each ANI stockholder is strongly urged to consult his, her or its own tax advisor to determine the particular federal, state, local, or foreign income or other tax consequences of the merger to such ANI stockholder.**

Table of Contents

## BIOSANTE'S BUSINESS

### Overview

BioSante is a specialty pharmaceutical company focused on developing products for female sexual health and oncology.

BioSante's products, either approved or in clinical development, include:

LibiGel once daily transdermal testosterone gel in Phase III development for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD).

Male testosterone gel once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc. (Teva).

GVAX cancer vaccines a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers.

The Pill-Plus (triple component contraceptive) once daily use of various combinations of estrogens, progestogens and androgens in Phase II development.

Elestrin once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of hot flashes associated with menopause and marketed in the U.S. by Meda Pharmaceuticals, Inc. (Meda Pharmaceuticals), BioSante's licensee.

BioSante's corporate strategy is to develop high value medically-needed pharmaceutical products. As a part of BioSante's corporate strategy, BioSante seeks to implement strategic alternatives with respect to its products and its company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. Therefore, as a matter of course, from time to time, BioSante may engage in discussions with third parties regarding the licensure, sale or acquisition of its products and technologies, with the goal of maximizing stockholder value.

BioSante's lead product in development is LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. For the past several years, BioSante has focused its efforts on two Phase III LibiGel efficacy trials and a LibiGel Phase III cardiovascular and breast cancer safety study. In December 2011, BioSante announced results from its two Phase III LibiGel efficacy trials, which showed that the trials did not meet the co-primary or secondary endpoints. Although LibiGel performed as predicted, increasing satisfying sexual events and sexual desire and decreasing distress associated with low desire, the placebo response in the two efficacy trials was greater than expected, and LibiGel's results were not shown to be statistically different from the placebo.

Beginning in December 2011, BioSante analyzed the data from its Phase III LibiGel efficacy trials, consulted with key opinion leaders in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA. As a result of this process, in June 2012 BioSante announced a plan to initiate two new LibiGel Phase III efficacy trials.

BioSante is in the process of developing a protocol for the two new efficacy trials and applying for an FDA Special Protocol Assessment (SPA) agreement covering aspects of the two new efficacy trials. BioSante expects that any potential new LibiGel Phase III efficacy trials would include the same FDA-required efficacy endpoints as its prior Phase III efficacy trials: an increase in the number of satisfying sexual events and sexual desire, and decreased distress associated with low desire. BioSante estimates that the cost of the two new LibiGel Phase III efficacy trials would be similar to the cost of the previous trials, approximately $15 to $18 million each, or a combined $30 to $36 million spread

Table of Contents

over approximately 18 months. No assurance can be provided that these cost estimates will be correct or that BioSante, if it decides to pursue the trials, will be able to obtain the necessary working capital to fund the trials. In addition, no assurance can be provided that BioSante will be able to design the two new efficacy trials to the FDA's satisfaction or to minimize sufficiently the placebo effect and meet the co-primary and secondary endpoints for the trials.

With respect to BioSante's LibiGel Phase III safety study, in September 2012, BioSante announced that the independent Data Monitoring Committee (DMC) completed its ninth unblinded review of the LibiGel Phase III cardiovascular events and breast cancer safety study and recommended that the LibiGel safety study should continue as per the FDA-agreed protocol, without modifications. Given this latest review during which no specific or general safety issues were raised, and after extensive consideration, BioSante announced in September 2012 the conclusion of the LibiGel Phase III safety study effective immediately. Prior to the initiation of the LibiGel safety study in 2008, the FDA had advised BioSante that subjects in the cardiovascular event and breast cancer safety study were required to have a minimum average exposure in the safety study of 12 months prior to submitting a LibiGel new drug application (NDA), and prior to a potential FDA approval of LibiGel. As of the date of the conclusion of the safety study, subjects had been in the study for an average time of 24.8 months; more than 3,200 subjects had been in the study for more than one year and over 1,850 subjects had been enrolled for more than two years. With this ninth unblinded review of the study by the DMC, and over 7,400 women-years of exposure, BioSante believes that adequate safety data of LibiGel use in menopausal women has been obtained.

Elestrin is BioSante's first FDA approved product and now is one of BioSante's two FDA approved products. Meda Pharmaceuticals, Inc. (which acquired Jazz Pharmaceuticals, Inc.'s women's health business and which in turn acquired Azur Pharma International II Limited (Azur), BioSante's prior licensee), is marketing Elestrin in the U.S. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur pursuant to which BioSante received $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to BioSante related to sales of Elestrin. BioSante maintains the right to receive up to $140 million in sales-based milestone payments from Meda Pharmaceuticals if Elestrin reaches certain predefined sales per calendar year; although, based on current sales levels, BioSante believes its receipt of such payments unlikely in the near term, if at all.

BioSante's male testosterone gel is its second FDA approved product. This product initially was developed by BioSante, and then licensed by BioSante to Teva for late stage clinical development. Teva submitted an NDA to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been disclosed publicly. No launch date for this product has been announced by Teva.

BioSante's GVAX cancer vaccines, which are designed to stimulate a patient's immune system to fight effectively the patient's own cancer, are in development for the treatment of several different types of cancer including melanoma, leukemia, pancreatic, breast and prostate cancer. Four of these vaccines to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma have been granted FDA orphan drug designation. Currently, there are 17 Phase I and Phase II clinical studies involving BioSante's GVAX cancer vaccines ongoing. The studies are being funded by various sources, including certain foundations and BioSante's licensees. BioSante's objective with respect to its GVAX cancer vaccines is to help facilitate further studies and commercialization in order to bring important cancer therapies to patients in need and to maximize the value of BioSante's GVAX cancer vaccine portfolio to its stockholders. This objective includes monetizing the entire

Table of Contents

portfolio or seeking additional licensees to fund, develop and eventually commercialize the cancer vaccines. BioSante currently is negotiating the terms of a potential transation with an unidentified third party pursunt to which, if completed, BioSante would sell all of its assets related to its GVAX cancer vaccine portfolio in exchange for a $1.0 million up front cash payment plus the potential for future royalty, milestone and sublicense payments.

**BioSante's Primary Product Portfolio**

**Description of BioSante's Female Sexual Health, Menopause, Contraception and Male Hypogonadism Products**

***Overview.*** BioSante's products for female sexual health, menopause, contraception and male hypogonadism include its gel formulations of estradiol or testosterone and combinations of estrogen, progestogen and androgen.

BioSante's gel products are designed to be quickly absorbed through the skin after application on the upper arm for the women's products, delivering the active component to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue and to dry in under one to two minutes. BioSante believes its gel products have a number of benefits over competitive products, including the following:

- BioSante's transdermal gels can be spread over areas of skin where they dry rapidly and decrease the chance for skin irritation versus transdermal patches;
- BioSante's transdermal gels have been shown to be well absorbed, thus allowing effective therapeutic levels to reach the systemic circulation;
- transdermal gels may allow for better dose adjustment than either transdermal patches or oral tablets or capsules; and
- transdermal gels may be more appealing to patients since they are less conspicuous than transdermal patches, which may be aesthetically unattractive.

BioSante licenses the technology underlying LibiGel and Elestrin, but not its male testosterone gel, from Antares Pharma, Inc. (Antares). BioSante's male testosterone gel was developed by BioSante and

Table of Contents

licensed to Teva. BioSante licenses the technology underlying The Pill Plus from Wake Forest University Health Sciences and Cedars-Sinai Medical Center.

***LibiGel.*** BioSante's lead product in development is LibiGel, a once daily transdermal testosterone gel designed to treat FSD, specifically HSDD in postmenopausal women.

Although generally thought of as being limited to men, testosterone also is important to women and its deficiency has been found to cause low libido or sex drive. Studies have shown that testosterone therapy in women can boost sexual desire, sexual activity and pleasure, increase bone density, raise energy levels and improve mood. According to a study published in the *Journal of the American Medical Association*, 43 percent of American women between the ages of 18 to 59, or about 40 million women, experience some degree of impaired sexual function. Among the more than 1,400 women surveyed, 32 percent lacked interest in sex (low sexual desire). Furthermore, according to a study published in the *New England Journal of Medicine*, 43 percent of American women between the ages of 57 to 85 experience low sexual desire. Importantly, according to IMS data, approximately two million testosterone prescriptions were written off-label for women in the U.S. in 2010. In addition, according to independent primary market research, approximately two million additional prescriptions of compounded testosterone were written for women in the U.S. in 2010. Female sexual dysfunction is defined as a consistent lack of sexual desire, arousal or pleasure. The majority of women with FSD are postmenopausal, experiencing symptoms due to hormonal changes that occur with aging or following surgical menopause.

Although treatment with LibiGel in BioSante's Phase II clinical trial significantly increased satisfying sexual events in surgically menopausal women suffering from FSD, the Phase III efficacy trials did not meet the co-primary endpoints of increase in satisfying sexual events or increase in sexual desire or the secondary endpoint of decrease in sexual distress. The Phase II trial results showed LibiGel significantly increased the number of satisfying sexual events by 238 percent versus baseline; this increase also was significant versus placebo. In this trial, the effective dose of LibiGel produced testosterone blood levels within the normal range for pre-menopausal women and had a safety profile similar to that observed in the placebo group. In addition, no serious adverse events and no discontinuations due to adverse events occurred in any subject receiving LibiGel. The Phase II clinical trial was a double-blind, placebo-controlled trial, in surgically menopausal women distressed by their low sexual desire and activity.

The Phase III safety and efficacy trials were randomized, double-blind, placebo-controlled, multi-center trials of a total of 1,172 menopausal women, exposed to LibiGel or placebo for six months. Subjects in the first trial, called BLOOM-1, who were treated with LibiGel showed an increase of 1.47 days with a satisfying sexual event compared to baseline, while those receiving placebo gel showed an increase of 1.26 days with a satisfying sexual event compared to baseline. The difference between these increases demonstrated a p value of 0.463. (The smaller the p value, the stronger the statistical significance. A p-value of .05 or less is typically used to represent statistical significance of trial results.) In BLOOM 1, there was an increase in the total number of satisfying sexual events of 3.87 from baseline (an increase of 83 percent) in the LibiGel group and in the placebo group there was an increase of 3.52 satisfying sexual events from baseline (an increase of 65 percent) for a p value of 0.698. Subjects in BLOOM-2 who were treated with LibiGel showed an increase of 1.0 day with a satisfying sexual event compared to baseline, while those receiving placebo gel showed an increase of 1.28 days with a satisfying sexual event compared to baseline. The difference between these increases demonstrated a p value of 0.214. Subjects in BLOOM-1 showed an increase in mean sexual desire of 0.03 over placebo, a p value of 0.672, while subjects in BLOOM-2 demonstrated an increase in mean sexual desire of 0.03 compared to placebo, a p value of 0.48. Subjects in both trials demonstrated a decrease in sexual distress when treated with LibiGel (p=0.569 and p=0.26) compared to baseline.

Table of Contents

As seen in previous pharmacokinetic data, the LibiGel groups in both Phase III efficacy trials showed an increase in free testosterone levels compared to baseline and placebo. In BLOOM-1, mean free testosterone at baseline was approximately 1.19 picograms per milliliter (pg/ml) and 1.10 pg/ml in the placebo and LibiGel groups, respectively. In month six of the trial, free testosterone levels were approximately 1.35 pg/ml and 4.01 pg/ml in the placebo and LibiGel groups, respectively. In BLOOM-2, mean free testosterone at baseline was approximately 1.06 pg/ml and 1.19 pg/ml in the placebo and LibiGel group, respectively. In month six of the trial, free testosterone levels were approximately 1.09 pg/ml and 3.70 pg/ml in the placebo and LibiGel groups, respectively.

Results of the two Phase III efficacy trials were announced on December 14, 2011. Subsequently, BioSante continued to analyze the data from the Phase III LibiGel efficacy trials, consulted with key opinion leaders in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA. As a result of this process, in June 2012 BioSante announced a plan to initiate two new LibiGel Phase III efficacy trials.

In September 2012, BioSante announced that the independent DMC completed its ninth unblinded review of the LibiGel Phase III cardiovascular events and breast cancer safety study and recommended that the LibiGel safety study should continue as per the FDA-agreed protocol, without modifications. At the time of the DMC review, there were 53 adjudicated CV events, with a lower than anticipated event rate of approximately 0.72 percent. In the same population of subjects, there were 27 breast cancers reported, a rate of approximately 0.37 percent, which is in line with the expected rate based on the ages of the subjects enrolled in the study. Given this latest review during which no specific or general safety issues were raised, and after extensive consideration, BioSante announced in September 2012 the conclusion of the LibiGel Phase III safety study effective immediately. Prior to the initiation of the LibiGel safety study in 2008, the FDA had advised BioSante that subjects in the safety study were required to have a minimum average exposure in the safety study of 12 months prior to submitting a LibiGel new drug application (NDA), and prior to a potential FDA approval of LibiGel. As of the date of the conclusion of the safety study, subjects had been in the study for an average time of 24.8 months; more than 3,200 subjects had been in the study for more than one year and over 1,850 subjects had been enrolled for more than two years. With this ninth positive unblinded review of the study by the DMC, and over 7,400 women-years of exposure, BioSante believes that adequate safety data of LibiGel use in menopausal women has been obtained. BioSante remains blinded as to whether the CV events and breast cancers are experienced by subjects in the LibiGel arm or the placebo arm of the study.

BioSante is continuing to develop a protocol for the two new LibiGel efficacy trials and will seek an FDA Special Protocol Assessment (SPA) agreement covering aspects of the two new efficacy trials.

***Male Testosterone Gel.*** BioSante's once daily transdermal testosterone gel indicated for the treatment of hypogonadism, or testosterone deficiency, in men is BioSante's second FDA approved product.

Testosterone deficiency in men is known as hypogonadism. Low levels of testosterone may result in lethargy, depression, decreased sex drive, impotence, low sperm count and increased irritability. Men with severe and prolonged reduction of testosterone also may experience loss of body hair, reduced muscle mass, osteoporosis and bone fractures due to osteoporosis. Testosterone therapy has been shown to restore levels of testosterone with minimal side effects.

There are currently several products on the market for the treatment of low testosterone levels in men. As opposed to estrogen therapy products, oral administration of testosterone is currently not possible as the hormone is, for the most part, rendered inactive in the liver making it difficult to achieve adequate levels of the compound in the bloodstream. Current methods of administration include testosterone injections, patches and gels. Testosterone injections require large needles, are often painful and not effective for maintaining adequate testosterone blood levels throughout the day.

Table of Contents

Delivery of testosterone through transdermal patches was developed primarily to promote the therapeutic effects of testosterone therapy without the often painful side effects associated with testosterone injections. Transdermal patches, however, similar to estrogen patches, have a physical presence, can fall off and can result in skin irritation. Testosterone gel formulated products for men are designed to deliver testosterone without the pain of injections and the physical presence, skin irritation and discomfort associated with transdermal patches. BioSante is aware of four gel testosterone products for men currently on the market in the United States.

Unlike LibiGel and Elestrin, BioSante's male testosterone gel was developed by BioSante and therefore BioSante has no royalty or milestone obligations to any other party. BioSante's male testosterone gel is subject to a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. Under the development and license agreement, Teva has agreed to market the male testosterone gel for the U.S. market and is responsible for any and all manufacturing and marketing associated with the product. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva, which was paid to BioSante in December 2002, and an obligation by Teva to pay BioSante certain milestones and royalties on sales of the product in exchange for rights to develop and market the product, as described in more detail below. Teva is entitled to deduct the amount of any legal expenses incurred by Teva in connection with associated patent litigation against Teva from the net sales of the product. The term of the development and license agreement will expire 10 years from the date on which Teva makes its first commercial sale of the male testosterone gel to an unrelated third party in an arms-length transaction in the United States. The parties may terminate the development and license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party. BioSante may terminate the agreement if Teva files a petition in bankruptcy, enters into an arrangement with its creditors or makes an assignment for the benefit of creditors or a receiver or trustee is appointed or if Teva suffers or permits the entry of an order adjudicating it to be bankrupt or insolvent. Teva may terminate the agreement if Teva determines that the continued development and/or marketing of the male testosterone gel is no longer commercially viable.

In October 2012, BioSante and Teva entered into an amendment to the development and license pursuant to which Teva made a $1.0 million payment to BioSante upon the signing of the amendment and agreed to make the following milestone based payments to BioSante: (1) $500,000 if the FDA authorizes marketing of the licensed male testosterone gel as an "AB-rated" equivalent to AndroGel®; (2) $750,000 upon the earlier to occur of (a) December 31, 2012 and (b) five business days after Teva's submission to the FDA of a final report regarding a "washing" clinical study required by the FDA; and (3) $500,000 upon the earlier to occur of (a) December 31, 2013 and (b) five business days after Teva's commencement of commercial manufacture of the licensed product for sale in the United States. In addition, Teva has agreed to pay BioSante $4.0 million in the event Teva is the sole marketer in the United States of a generic 1% testosterone gel AB-rated to AndroGel® for at least 180 days immediately following the launch date of the licensed product in the United States. The royalty rate to be paid by Teva to BioSante under the agreement is five percent of net sales; provided, however, that during the period of time that Teva markets the licensed product and is the sole marketer of a generic 1% testosterone gel that is AB-rated to AndroGel® in the United States, the royalty rate will be seven and one half percent of net sales. Additionally, pursuant to the terms of the October 2012 amendment, the parties agreed to release each other from certain liabilities.

Teva submitted an NDA to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been disclosed publicly. No launch date for this product has been announced by Teva.

Table of Contents

***The Pill-Plus.*** The Pill-Plus is based on three issued U.S. patents claiming triple component therapy via any route of administration (the combination use of estrogen plus progestogen plus androgen, e.g. testosterone). The Pill-Plus adds a third component, an androgen, to the normal two component (estrogen and progestogen) oral contraceptive to prevent testosterone deficiency which can result from the estrogen and progestogen components and which often leads to a decrease in sexual desire, sexual activity and mood changes. In a completed Phase II double-blind randomized clinical trial, the addition of an oral androgen resulted in restoration of testosterone levels to the normal and physiological range for healthy women. Paradoxically, many women who use oral contraceptives have reduced sexual desire, arousabilty and activity due to the estrogen and progestogen in normal oral contraceptives. The Pill-Plus is designed to avoid or to improve the symptoms of female sexual dysfunction in oral contraceptive users.

BioSante has an exclusive license from Wake Forest University Health Sciences (formerly known as Wake Forest University) and Cedars-Sinai Medical Center for the three issued U.S. patents for triple component contraception. The financial terms of the license include an upfront payment, regulatory milestone payments, maintenance payments and royalty payments by BioSante if a product incorporating the licensed technology gets approved and subsequently is marketed.

The Pill-Plus is subject to a sublicense agreement with Pantarhei Bioscience B.V. (Pantarhei), a Netherlands-based pharmaceutical company. Pantarhei is responsible under the agreement for all expenses to develop and market the product. BioSante may receive certain development and regulatory milestones for the first product developed under the license. In addition, BioSante will receive royalty payments on any sales of the product in the U.S., if and when approved and marketed. If the product is sublicensed by Pantarhei to another company, BioSante will receive a percentage of any and all payments received by Pantarhei for the sublicense from a third party. BioSante has retained all rights under its licensed patents to the transdermal delivery of triple component contraceptives.

***Elestrin.*** Elestrin is BioSante's first FDA approved product. Elestrin is a once daily transdermal gel that delivers estrogen without the skin irritation associated with, and the physical presence of, transdermal patches, and to avoid the effects of oral estrogen. Elestrin contains estradiol versus conjugated equine estrogen contained in the most commonly prescribed oral estrogen.

Elestrin is indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause. Elestrin is administered using a metered dose applicator. Two doses of Elestrin were approved by the FDA.

Meda Pharmaceuticals Inc. is marketing Elestrin in the U.S. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur (which was acquired by Jazz Pharmaceuticals, Inc. which subsequently sold its women's health business to Meda Pharmaceuticals) pursuant to which BioSante received $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to BioSante related to sales of Elestrin. BioSante maintains the right to receive up to $140 million in sales-based milestone payments from Meda Pharmaceuticals if Elestrin reaches certain predefined sales per calendar year, although based on current sales levels, BioSante believes its receipt of such payments unlikely in the near term, if at all.

Elestrin also is subject to an exclusive agreement with Valeant Pharmaceuticals International, Inc. (which acquired PharmaSwiss SA) for the marketing of Elestrin in Israel. Valeant Pharmaceuticals will be responsible for regulatory and marketing activities in Israel. Israeli authorities have approved Elestrin, but the product has not been launched.

***Other Products.*** Marketing rights to BioSante's gel products in Canada are subject to an agreement with Paladin Labs Inc. In exchange for the sublicense, Paladin agreed to make an initial investment in BioSante's company, make future milestone payments and pay royalties on sales of the

Table of Contents

products in Canada. The milestone payments are required to be in the form of a series of equity investments by Paladin in BioSante's common stock at a 10 percent premium to the market price of its stock at the time the equity investment is made. No recent investments have been made and none are expected in the foreseeable future.

**Description of BioSante's GVAX Cancer Vaccines and Other Technologies**

***GVAX Cancer Vaccine Technology.*** BioSante's GVAX cancer vaccines are designed to stimulate the patient's immune system to effectively fight cancer. BioSante's cancer vaccines are comprised of tumor cells that are genetically modified to secrete an immune-stimulating cytokine known as granulocyte-macrophage colony-stimulating factor (GM-CSF), and are then irradiated for safety. Since BioSante's cancer vaccines consist of whole tumor cells, the cancer patient's immune system can be activated against multiple tumor cell components, or antigens, potentially resulting in greater clinical benefit than if the vaccine consisted of only a single tumor cell component. Additionally, the secretion of GM-CSF by the modified tumor cells can enhance greatly the immune response by recruiting and activating dendritic cells at the injection site, a critical step in the optimal response by the immune system to any immunotherapy product. The antitumor immune response which occurs throughout the body following administration of BioSante's cancer vaccine potentially can result in the destruction of tumor cells that persist or recur following surgery, radiation therapy or chemotherapy treatment.

BioSante's cancer vaccines can be administered conveniently in an outpatient setting as an injection into the skin, a site where immune cells, including in particular dendritic cells, can be optimally accessed and activated. These cancer vaccines are being tested primarily as non patient-specific, or allogeneic, vaccines. BioSante's GVAX cancer vaccines are in development for the treatment of several different types of cancer including melanoma, leukemia, pancreatic, breast and prostate cancer. Four of these vaccines to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma have been granted FDA orphan drug designation. Currently, there are 17 Phase I and Phase II clinical studies involving BioSante's GVAX cancer vaccines ongoing. The studies are being funded by various sources, including certain foundations and BioSante's licensees.

In March 2011, BioSante licensed aspects of its GVAX pancreas cancer vaccine and GVAX prostate cancer vaccine to Aduro BioTech, Inc., a clinical-stage immunotherapy company, solely for use in combination with Aduro's proprietary vaccine platform based on Listeria monocytogenes (Lm). Under the agreement, BioSante is entitled to receive milestone and royalty payments upon the commercialization of combination cancer vaccines using its GVAX cancer vaccine technology in combination with Aduro's vaccines.

In July 2011, BioSante announced an exclusive worldwide license of its melanoma vaccine to The John P. Hussman Foundation (Hussman Foundation), in exchange for its receipt of an upfront license fee, milestone payments, royalties on any sales and a percentage of any sublicense fees. Additionally, the Hussman Foundation has committed up to approximately $11 million in GVAX melanoma vaccine Phase I and Phase II clinical development funding.

BioSante's objective with respect to its GVAX cancer vaccines is to help facilitate further studies and commercialization in order to bring important cancer therapies to patients in need and to maximize the value of BioSante's GVAX cancer vaccine portfolio to the BioSante stockholders. This objective includes monetizing the entire portfolio or seeking additional licensees to fund, develop and eventually commercialize the cancer vaccines. BioSante currently is negotiating the terms of a potential transation with an unidentified third party pursunt to which, if completed, BioSante would sell all of its assets related to its GVAX cancer vaccine portfolio in exchange for a $1.0 million up front cash payment plus the potential for future royalty, milestone and sublicense payments.

***Oncolytic Virus Technology.*** In November 2010, BioSante entered into an assignment and technology transfer agreement with Cold Genesys, Inc. pursuant to which BioSante sold to Cold

Table of Contents

Genesys exclusive, worldwide rights to develop and commercialize its oncolytic virus technology. The oncolytic virus technology uses replication-competent adenoviruses derived from Adenovirus type 5, a common "cold" virus that replicate in and selectively kill tumor cells. The replication of the virus is controlled by replacing the promoter of a gene required for replication with a promoter that is preferentially expressed only in tumor cells. Furthermore, the virus may optionally include a gene encoding a cytokine, which enhances immune stimulation to the tumor, thereby providing a dual mechanism of action for killing targeted cancer cells by direct cell lysis as well as via cellular and humoral immune responses to the tumor. The oncolytic virus technology includes CG0070, a replication-competent adenovirus that has completed a Phase I clinical trial for treatment of superficial bladder cancer. In exchange for the technology, BioSante received an initial 19.9 percent ownership position in Cold Genesys and a $95,000 upfront cash payment and is eligible to receive future milestone and royalty payments.

**Sales and Marketing**

BioSante currently has no sales and marketing personnel to sell any of its products on a commercial basis. Under BioSante's license agreements, its licensees have agreed to market the products covered by the agreements in certain countries. For example, under BioSante's license agreement with Meda Pharmaceuticals, Meda Pharmaceuticals has agreed to use commercially reasonable efforts to manufacture, market, sell and distribute Elestrin for commercial sale and distribution throughout the United States, and under BioSante's agreement with Teva, Teva has agreed to use commercially reasonable efforts to market its male testosterone gel in the United States. If and when BioSante is ready to launch commercially a product not covered by its license agreements, BioSante will either contract with or hire qualified sales and marketing personnel or seek a joint marketing partner or licensee to assist BioSante with this function.

**Research and Product Development**

BioSante historically has spent a significant amount of its financial resources on product development activities, with the largest portion being spent on clinical studies for LibiGel. BioSante spent approximately $44.2 million in 2011, $39.7 million in 2010 and $13.7 million in 2009 on research and product development activities. BioSante spent an average of approximately $3.7 million per month on its research and product development activities during 2011, the substantial majority of which was spent on its LibiGel Phase III clinical studies. BioSante incurred expenses of $14.5 million on research and development activities during the nine months ended September 30, 2012, the substantial majority of which was spent on its LibiGel Phase III cardiovascular events and breast cancer study, and which is a 61 percent decrease compared to the same period in 2011, primarily as a result of the conclusion of BioSante's prior two LibiGel Phase III efficacy trials at the end of 2011. BioSante anticipates that its research and development expenses for 2013 will consist primarily of expenses associated with the conclusion of the safety study and the planning for the two new LibiGel Phase III efficacy trials.

**Manufacturing**

BioSante does not have any facilities suitable for manufacturing on a commercial scale basis any of its products nor does it have any experience in volume manufacturing. BioSante currently uses third-party current Good Manufacturing Practices (cGMP), manufacturers to manufacture its products in development in accordance with FDA and other appropriate regulations.

**Patents, Licenses and Proprietary Rights**

BioSante's success depends and will continue to depend in part upon its ability to maintain its exclusive licenses, to obtain and maintain patent protection for its products and processes, to preserve its proprietary information, trademarks and trade secrets and to operate without infringing the

Table of Contents

proprietary rights of third parties. BioSante's policy is to attempt to protect its technology by, among other things, filing patent applications or obtaining license rights for technology that BioSante considers important to the development of its business.

***Gel Products.*** BioSante licensed the technology underlying LibiGel and Elestrin, but not its male testosterone gel, from Antares Pharma, Inc. Under the agreement, Antares granted BioSante an exclusive license to certain patents and patent applications covering these gel products, including rights to sublicense, in order to develop and market the products in certain territories, including the U.S., Canada, New Zealand, South Africa, Israel, Mexico, China (including Hong Kong) and Indonesia. BioSante is the exclusive licensee in certain territories for issued U.S. patents for these products and additional patent applications have been filed for this licensed technology in the U.S. and several foreign jurisdictions. Under the agreement, BioSante is required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products BioSante or its sub-licensees sell incorporating the in-licensed technology. Specifically, BioSante is obligated to pay Antares 25 percent of all upfront and milestone payments related to a license and a 4.5 percent royalty on net sales of product by BioSante or a licensee.

BioSante and Antares may terminate the license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party or if the other party goes into liquidation or bankruptcy or makes an assignment for the benefit of creditors or a receiver is appointed. Antares may terminate the agreement with respect to certain products or territories if BioSante does not continue development, seeking regulatory approval or marketing of such products in the covered territories. BioSante may terminate the agreement with respect to certain products or territories if, for technical, scientific or regulatory reasons, it is not likely that the product will gain required regulatory approvals in a territory, if regulatory approvals in a territory are not obtained or if BioSante determines that it is not economically viable to continue development or marketing of a product in a territory.

The patents covering the formulations used in these gel products are expected to expire in 2022, although with respect to LibiGel, a new U.S. patent covering the "method of use" of LibiGel for treating FSD and HSDD was issued, which will expire in December 2028. In addition, BioSante has other patents pending, which, if issued, may expire later than 2028. BioSante's male testosterone gel was developed by BioSante and not covered under the Antares license.

***GVAX Cancer Vaccine Technology.*** BioSante owns development and commercialization rights to its GVAX cancer vaccine technology as a result of its merger with Cell Genesys in October 2009. The patent estate covering BioSante's cancer vaccine technology is licensed exclusively to BioSante from Johns Hopkins University and The Whitehead Institute for Biomedical Research. In addition, BioSante owns several patents and patent applications that build upon its in-licensed technology, and provides for significant additional patent term.

BioSante's cancer vaccine patent estate broadly covers its cancer vaccine products and pipeline. The cancer vaccine patent estate includes 17 patent families, comprising over 50 issued US and foreign patents, directed to various aspects of BioSante's cancer vaccine technology. The patents expire between 2012 and 2026.

Under the various agreements, BioSante is required to pay Johns Hopkins University and The Whitehead Institute for Biomedical Research certain development and regulatory milestone payments and royalties based on net sales of any products BioSante or its sub-licensees sell incorporating the in-licensed technology. BioSante currently is negotiating the terms of a potential transation with an unidentified third party pursunt to which, if completed, BioSante would sell all of its assets related to its GVAX cancer vaccine portfolio in exchange for a $1.0 million up front cash payment plus the potential for future royalty, milestone and sublicense payments.

Table of Contents

***The Pill Plus.*** BioSante licensed the technology underlying its triple component contraceptives, or The Pill Plus, from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license include regulatory milestone payments, maintenance payments and royalty payments by BioSante if a product incorporating the licensed technology gets approved and subsequently is marketed. The patents covering the technology underlying The Pill Plus expire in 2016.

***Trademarks and Trademark Applications/Registrations.*** BioSante owns trademark registrations in the U.S. and/or in certain foreign jurisdictions for several marks, including BIOSANTE® and LIBIGEL®. In addition, BioSante has filed trademark applications for several other marks including ELESTRIN (pursuant to a license agreement regarding Elestrin, the Elestrin trademark in the U.S. is now owned by Meda Pharmaceuticals). In addition, BioSante owns common law rights to several trademarks, including BIOSANTE®, LIBIGEL®, GVAX , THE PILL-PLUS and ELESTRIN . For those trademarks for which registration has been sought, registrations have issued for some of those trademarks in certain jurisdictions and others currently are in the application/prosecution phase.

***Confidentiality and Assignment of Inventions Agreements.*** BioSante requires its employees, consultants and advisors having access to its confidential information to execute confidentiality agreements upon commencement of their employment or consulting relationships with BioSante. These agreements generally provide that all confidential information BioSante develops or makes known to the individual during the course of the individual's employment or consulting relationship with BioSante must be kept confidential by the individual and not disclosed to any third parties. BioSante also requires all of its employees and consultants who perform research and development for BioSante to execute agreements that generally provide that all inventions and works-for-hire conceived by these individuals during their employment by BioSante will be BioSante's property.

**Competition**

There is intense competition in the biopharmaceutical industry. Potential competitors in the United States are numerous and include major pharmaceutical and specialized biotechnology companies, universities and other institutions. In general, competition in the pharmaceutical industry can be divided into four categories: (1) corporations with large research and developmental departments that develop and market products in many therapeutic areas; (2) companies that have moderate research and development capabilities and focus their product strategy on a small number of therapeutic areas; (3) small companies with limited development capabilities and only a few product offerings; and (4) university and other research institutions. Many of BioSante's competitors have longer operating histories, greater name recognition, substantially greater financial resources and larger research and development staffs than BioSante does, as well as substantially greater experience than BioSante in developing products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. A significant amount of research is carried out at academic and government institutions. These institutions are aware of the commercial value of their findings and are aggressive in pursuing patent protection and negotiating licensing arrangements to collect royalties for use of technology that they have developed.

There are several firms currently marketing or developing products that may be competitive with BioSante's gel products. They include Upsher-Smith Laboratories, Inc., Noven Pharmaceuticals, Inc. (a subsidiary of Hisamitsu Pharmaceutical Co., Inc.), Auxilium Pharmaceuticals, Inc., Ascend Therapeutics, Inc., Watson Pharmaceuticals, Inc. and Abbott Laboratories. Competitor products include oral tablets, transdermal patches, a spray and gels. BioSante expects its FDA-approved products, Elestrin and its male testosterone gel, and its other products, if and when approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability and patent position and potentially on cost. In addition, the first product to reach the market in a therapeutic or preventative area is often at a significant competitive advantage relative to later entrants in the market and may result in certain marketing exclusivity as per federal legislation. Acceptance by physicians and other health care providers, including managed care groups, also is critical to the success of a product versus competitor products.

Table of Contents

With regard to BioSante's GVAX cancer vaccine technology and other related technologies, BioSante faces substantial competition in the development of products for cancer and other diseases. This competition from other manufacturers is expected to continue in both U.S. and international markets. Cancer vaccines are evolving areas in the biotechnology industry and are expected to undergo many changes in the coming years as a result of technological advances. BioSante currently is aware of a number of groups that are developing cancer vaccines including early-stage and established biotechnology companies, pharmaceutical companies, academic institutions, government agencies and research institutions. Examples in the cancer vaccine area include Dendreon Corporation, which has an FDA approved vaccine for prostate cancer.

**Governmental Regulation**

Pharmaceutical companies are subject to extensive regulation by national, state and local agencies in countries in which they do business. Pharmaceutical products intended for therapeutic use in humans are governed by extensive FDA regulations in the United States and by comparable regulations in foreign countries. Any products developed by BioSante will require FDA approvals in the United States and comparable approvals in foreign markets before they can be marketed.

The U.S. Federal Food, Drug, and Cosmetic Act (FDCA) and other federal and state statutes and regulations govern or influence, among other things, the development, testing, manufacture, safety, labeling, storage, recordkeeping, approval, advertising, promotion, sale, import, export and distribution of pharmaceutical products in the United States. Pharmaceutical manufacturers also are subject to certain record-keeping and reporting requirements, establishment registration and product listing, and FDA inspections.

Manufacturers of controlled substances also must comply with the federal Controlled Substances Act of 1970 (CSA) and regulations promulgated by the U.S. Drug Enforcement Administration (DEA), as well as similar state and local regulatory requirements for manufacturing, distributing, testing, importing, exporting and handling controlled substances.

Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunction, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, and criminal prosecution.

Product development and approval within the FDA regulatory framework take a number of years, involve the expenditure of substantial resources, and are uncertain. Many products ultimately do not reach the market because they are not found to be safe or effective or cannot meet the FDA's other regulatory requirements. After a product is approved, the FDA may revoke or suspend the product approval if compliance with post-market regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-market studies or evidence of safety concerns. Further, the current regulatory framework may change and additional regulatory or approval requirements may arise at any stage of BioSante's product development that may affect approval, delay the submission or review of an application or require additional expenditures by BioSante. BioSante may not be able to obtain necessary regulatory clearances or approvals on a timely basis, if at all, for any of its products under development. Delays in receipt or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on BioSante's business.

Table of Contents

***New Product Development and Approval.*** All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, product testing, manufacturing processes, manufacturing facilities, packaging, labeling, quality control, and evidence of safety and effectiveness for intended uses. For a generic drug product, instead of safety and effectiveness data, an application must demonstrate that the proposed product is the same as the branded drug in several key characteristics. There are two types of applications used for obtaining FDA approval of new non-biological drug products, other than a generic product:

An NDA, sometimes referred to as a "full NDA," generally is submitted when approval is sought to market a drug with active ingredients that have not been previously approved by the FDA. Full NDAs typically are submitted for newly developed branded products and, in certain instances, an applicant submits an NDA or NDA supplement for a change to one of its previously approved products, such as a new dosage form, a new delivery system or a new indication.

Another form of an NDA is the "505(b)(2) NDA," which typically is used to seek FDA approval of products that share characteristics (often, the active ingredient(s)) with a previously approved product of another company, but contain modifications to, or differences from, the approved product that preclude submission of an abbreviated new drug application. A 505(b)(2) NDA is required where at least some of the information required for approval does not come from studies conducted by or for the applicant or for which the applicant has obtained a right of reference. Usually, this means the application relies on the FDA's previous approval of a similar product or reference listed drug, or published data in scientific literature that are not the applicant's.

The process by which a product, other than a generic product, is approved for marketing in the United States can take from three to more than 10 years, and generally involves the following:

laboratory and preclinical tests;

submission of an Investigational New Drug (IND) application, which must become effective before clinical studies may begin;

adequate and well-controlled human clinical studies to establish the safety and efficacy of the proposed product for its intended use;

submission of a full NDA or 505(b)(2) NDA containing, to the extent required, the results of the preclinical tests and clinical studies establishing the safety and efficacy of the proposed product for its intended use, as well as extensive data addressing matters such as manufacturing and quality assurance;

scale-up to commercial manufacturing;

satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities; and

FDA approval of the application.

To the extent that a 505(b)(2) NDA applicant can rely on a previously approved application or published literature, it may not be required to conduct some or all laboratory and preclinical tests or human clinical studies.

***Pre-Clinical Studies and Clinical Trials.*** Typically, preclinical studies are conducted in the laboratory and in animals to gain preliminary information on a product's uses and physiological effects and harmful effects, if any, and to identify any potential safety problems that would preclude testing in humans. The results of these studies, together with the general investigative plan, protocols for specific human studies and other information, are submitted to the FDA as part of the IND application. The FDA regulations do not, by their terms, require FDA approval of an IND. Rather, they allow a clinical

187

Table of Contents

investigation to commence if the FDA does not notify the sponsor to the contrary within 30 days of receipt of the IND. As a practical matter, however, FDA approval is often sought before a company commences clinical investigations. That approval may come within 30 days of IND receipt but may involve substantial delays if the FDA requests additional information. BioSante's submission of an IND, or those of its collaboration partners, may not result in FDA authorization to commence a clinical trial.

A separate submission to an existing IND also must be made for each successive clinical trial conducted during product development. Depending on its significance, the FDA also must approve changes to an existing IND. Further, an independent institutional review board (IRB) for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. Alternatively, a central IRB may be used instead of individual IRBs. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice requirements and regulations for informed consent.

The sponsor of a drug product typically conducts human clinical trials in three sequential phases, but the phases may overlap or not all phases may be necessary. The initial phase of clinical testing, which is known as Phase I, is conducted to evaluate the metabolism, uses and physiological effects of the experimental product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of possible effectiveness. Phase I studies can also evaluate various routes, dosages and schedules of product administration. These studies generally involve a small number of healthy volunteer subjects, but may be conducted in people with the disease the product is intended to treat. The total number of subjects is generally in the range of 20 to 80. A demonstration of therapeutic benefit is not required in order to complete Phase I trials successfully. If acceptable product safety is demonstrated, Phase II trials may be initiated.

Phase II trials are designed to evaluate the effectiveness of the product in the treatment of a given disease and involve people with the disease under study. These trials often are well controlled, closely monitored studies involving a relatively small number of subjects, usually no more than several hundred. The optimal routes, dosages and schedules of administration are determined in these studies. If Phase II trials are completed successfully, Phase III trials are often commenced, although Phase III trials are not always required.

Phase III trials are expanded, controlled trials that are performed after preliminary evidence of the effectiveness of the experimental product has been obtained. These trials are intended to gather the additional information about safety and effectiveness that is needed to evaluate the overall risk/benefit relationship of the experimental product and provide the substantial evidence of effectiveness and the evidence of safety necessary for product approval. Phase III trials are usually conducted with several hundred to several thousand subjects.

A clinical trial may combine the elements of more than one phase and typically two or more Phase III studies are required. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the trial will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. In addition, a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The FDA closely monitors the progress of the phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based on the data accumulated and its assessment of the risk/benefit ratio to patients. It is not possible to estimate with any certainty the time required to complete Phase I, II and III studies with respect to a given product.

Success in early-stage clinical trials does not necessarily assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative

Table of Contents

interpretations that could delay, limit or even prevent regulatory approval. Regulations require the posting of certain details about active clinical trials on government (i.e., www.clinicaltrials.gov) or independent websites, and subsequently a limited posting of the results of those trials. This helps prospective patients find out about trials they may wish to enroll in, but also provides some competitive intelligence to other companies working in the field. Failure to post the trial or its results in a timely manner can result in civil penalties and the rejection of the drug application.

***New Drug Applications.*** The results of the product development, including preclinical studies, clinical studies, and product formulation and manufacturing information, are then submitted to the FDA as part of the NDA.

The FDA reviews each submitted application before accepting it for filing, and may refuse to file the application if it does not appear to meet the minimal standards for filing. If the FDA refuses to file an application and requests additional information, the application must be resubmitted with the requested information. Once the submission is accepted for filing, the FDA begins an in-depth review of the application to determine, among other things, whether a product is safe and effective for its intended use. As part of this review, the FDA may refer the application to an appropriate FDA-advisory committee of outside experts, typically a panel of clinicians, for review, evaluation and a recommendation. Under the policies agreed to by the FDA under the Prescription Drug User Fee Act (PDUFA), the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months of the PDUFA goal date. Following its review of an NDA, the FDA invariably raises questions or requests additional information. The NDA approval process can, accordingly, be very lengthy, and there is no assurance that the FDA will ultimately approve an NDA.

Acceptance for filing of an application does not assure FDA approval for marketing. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the submitted data, which could delay, limit, or prevent regulatory approval. If it concludes that the application does not satisfy the regulatory criteria for approval, the FDA typically issues a "complete response" letter communicating the agency's decision not to approve the application and outlining the deficiencies in the submission. The complete response letter may request additional information, including additional preclinical testing or clinical trials. Even if such information and data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If the FDA approves the application, the agency may require post-marketing studies, also known as Phase IV studies, as a condition to approval. These studies may involve continued testing of a product and development of data, including clinical data, about the product's effects in various populations and any side effects associated with long-term use. After approval, the FDA also may require post-marketing studies or clinical trials if new safety information develops.

The FDA also may conclude that as part of the NDA or the 505(b)(2) NDA, the sponsor must develop a risk evaluation and mitigation strategy (REMS) to ensure that the benefits of the drug outweigh the risks. A REMS may have different components, including 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.

***Special Protocol Assessments.*** The special protocol assessment process generally involves FDA evaluation of a proposed Phase III clinical trial protocol and a commitment from the FDA that the design and analysis of the trial are adequate to support approval of an NDA, if the trial is performed according to the SPA and meets its endpoints. The FDA's guidance on the SPA process indicates that SPAs are designed to evaluate individual clinical trial protocols primarily in response to specific questions posed by the sponsors. In practice, the sponsor of a product candidate may request an SPA

Table of Contents

for proposed Phase III trial objectives, designs, clinical endpoints and analyses. A request for an SPA is submitted in the form of a separate amendment to an IND, and the FDA's evaluation generally will be completed within a 45-day review period under applicable PDUFA goals, provided that the trials have been the subject of discussion at an end-of-Phase II and pre-Phase III meeting with the FDA, or in other limited cases.

If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. While the FDA's guidance on SPAs states that documented SPAs should be considered binding on the review division, the FDA has the latitude to change its assessment if certain exceptions apply. Exceptions include identification of a substantial scientific issue essential to safety or efficacy testing that later comes to light, a sponsor's failure to follow the protocol agreed upon, or the FDA's reliance on data, assumptions or information that are determined to be wrong.

***The Hatch-Waxman Act.*** The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act (Hatch-Waxman), established an abbreviated process for obtaining FDA approval for generic versions of approved branded drug products. In addition to establishing a shorter, less expensive pathway for approval of generic drugs, Hatch-Waxman provides incentives for the development of new branded products and innovations to approved products by means of marketing exclusivities and extension of patent rights. Under the Hatch-Waxman Act, newly-approved drugs and new conditions of use may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five years of marketing exclusivity if the product's active ingredient is a new chemical entity not previously approved. The Hatch-Waxman Act provides three years of marketing exclusivity for the approval of new and supplemental NDAs for, among other things, new indications, dosages or strengths of a drug containing a previously approved active ingredient, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. This three-year marketing exclusivity period protects against the approval of abbreviated new drug applications and 505(b)(2) NDAs for the innovation that required clinical data; it does not prohibit the FDA from accepting or approving abbreviated new drug application or 505(b)(2) applications for other products containing the same active ingredient. The five- and three-year marketing exclusivity periods apply equally to patented and non-patented drug products. It is under this provision that BioSante received three years marketing exclusivity for Elestrin.

***Orphan Drug Exclusivity.*** The Orphan Drug Act was enacted by Congress to provide financial incentives for the development of drugs for rare conditions (affecting less than 200,000 individuals per year) in the United States. The orphan designation is granted for a combination of a drug entity and an indication and therefore it can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs may be exempt from application fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50 percent of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment.

***Other Regulatory Requirements.*** Regulations continue to apply to pharmaceutical products after FDA approval occurs. Post-marketing safety surveillance is required in order to continue to market an approved product. The FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products.

All facilities and manufacturing techniques used to manufacture products for clinical use or sale in the United States must be operated in conformity with "current good manufacturing practice"

Table of Contents

regulations, commonly referred to as "cGMP" regulations, which govern the production of pharmaceutical products. BioSante currently does not have any manufacturing capability.

The FDA regulates and monitors all promotion advertising and of prescription drugs after approval. All promotion must be consistent with the conditions of approval and submitted to the agency. Failure to adhere to FDA promotional requirements can result in enforcement letters, warning letters, changes to existing promotional material, and corrective notices to healthcare professionals. Promotion of a prescription drug for uses not approved by the FDA can have serious consequences and result in lawsuits by private parties, state governments and the federal government, significant civil and criminal penalties, and compliance agreements that require the company to change current practices and prevent unlawful activity in the future.

***U.S. Drug Enforcement Administration.*** The DEA regulates certain drug products containing controlled substances, such as testosterone, pursuant to the U.S. Controlled Substances Act. The CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

***Foreign Regulation.*** Products marketed outside of the United States are subject to regulatory approval requirements similar to those in the United States, although the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain European and other countries (i.e., Canada, Australia and Japan), the sales price of a product also must be approved. The pricing review period often begins after market approval is granted. BioSante intends to seek and utilize foreign partners to apply for foreign approvals of its products.

**Employees**

As of September 30, 2012, BioSante had 45 employees, including 33 in product development and 12 in management or administrative positions. None of BioSante's employees is covered by a collective bargaining agreement. BioSante also engages independent contractors from time to time on an as needed, project by project, basis.

**Properties**

BioSante's principal executive office is located in a leased facility in Lincolnshire, Illinois, where BioSante leases approximately 20,000 square feet of office space for approximately $20,000 per month. BioSante's lease for this space expires in February 2014. Management of BioSante's company considers its leased properties suitable and adequate for its current and foreseeable needs.

**Legal Proceedings**

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes naming BioSante and its President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that

Table of Contents

certain of BioSante's disclosures relating to the efficacy of LibiGel and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of BioSante's securities resulting in violations of Section 10(b) of the Securities Exchange Act of 1934, as amended, Rule 10b-5 and Section 20(a) of the Exchange Act. Although a substantially similar complaint was filed in the same court on February 21, 2012, such complaint was voluntarily dismissed by the plaintiff in April 2012. The plaintiff seeks to represent a class of persons who purchased BioSante's securities between February 12, 2010 and December 15, 2011, and seeks unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys' fees on behalf of such purchasers. BioSante believes the action is without merit and intends to defend the action vigorously. On November 6, 2012, the plaintiff filed a consolidated amended complaint. BioSante and Mr. Simes filed motions to dismiss the consolidated amended complaint on December 28, 2012.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of BioSante filed a shareholder derivative action in the United States District Court for the Northern District of Illinois under the caption Weinstein v. BioSante Pharmaceuticals, Inc. et al., naming BioSante's directors as defendants and BioSante as a nominal defendant. A substantially similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits generally related to the same events that are the subject of the class action litigation described above. The complaints allege breaches of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment as causes of action occurring from at least February 2010 through December 2011. The complaints seek unspecified damages, punitive damages, costs and disbursements and unspecified reform and improvements in BioSante's corporate governance and internal control procedures. On September 24, 2012, the District Court consolidated the two cases before it and on November 20, 2012 plaintiffs filed their consolidated amended complaint. On January 11, 2013, the defendants filed a motion to dismiss this complaint. On November 27, 2012, the plaintiff in the action pending in Illinois state court filed an amended complaint. On January 11, 2013, the defendants filed a motion to dismiss this complaint.

The lawsuits are in their early stages; and, therefore, BioSante is unable to predict the outcome of the lawsuits and the possible loss or range of loss, if any, associated with their resolution or any potential effect the lawsuits may have on BioSante's operations. Depending on the outcome or resolution of these lawsuits, they could have a material effect on BioSante's operations, including its financial condition, results of operations, or cash flows.

BioSante is not involved in any other legal actions, however, from time to time may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time.

**Available Information**

BioSante is a Delaware corporation that was initially formed as a corporation organized under the laws of the Province of Ontario in 1996. BioSante's principal executive offices are located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069. BioSante's telephone number is (847) 478-0500, and its Internet web site address is www.biosantepharma.com. The information contained on BioSante's web site or connected to its web site is not incorporated by reference into and should not be considered part of this joint proxy statement/prospectus.

BioSante makes available, free of charge and through its Internet web site, its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after BioSante electronically files such material with, or furnishes it to, the SEC. BioSante also makes available, free of charge and through its Internet web site, to any stockholder who requests, its corporate governance guidelines, the charters of its board committees and its Code of Conduct and Ethics. Requests for copies can be directed to Investor Relations at (847) 478-0500, extension 120, or by e-mail at info@biosantepharma.com.

Table of Contents

## BIOSANTE'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of financial condition and results of operations together with the "Selected Historical Financial Data of BioSante" section of this joint proxy statement/prospectus and BioSante's financial statements and the related notes included in this joint proxy statement/prospectus. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. BioSante's actual results could differ materially from those anticipated by the forward-looking statements due to important factors including, but not limited to, those set forth in the "Risk Factors Risks Related to BioSante" section of this joint proxy statement/prospectus.*

### Business Overview

BioSante is a specialty pharmaceutical company focused on developing products for female sexual health and oncology.

BioSante's products, either approved or in clinical development, include:

LibiGel once daily transdermal testosterone gel in Phase III development for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD).

Male testosterone gel once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc. (Teva).

GVAX cancer vaccines a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers.

The Pill-Plus (triple component contraceptive) once daily use of various combinations of estrogens, progestogens and androgens in Phase II development.

Elestrin once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of hot flashes associated with menopause and marketed in the U.S. by Meda Pharmaceuticals, Inc. (Meda Pharmaceuticals), BioSante's licensee.

BioSante's corporate strategy is to develop high value medically-needed pharmaceutical products. As a part of its corporate strategy, BioSante seeks to implement strategic alternatives with respect to its products and company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. Therefore, as a matter of course, from time to time, BioSante may engage in discussions with third parties regarding the licensure, sale or acquisition of its products and technologies or a merger or sale of our company, with the goal of maximizing stockholder value.

### Proposed Merger with ANI

#### *Agreement and Plan of Merger*

On October 3, 2012, BioSante entered into an agreement and plan of merger with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. The merger agreement provides that, subject to the terms and conditions set forth in the merger agreement, ANI will merge with and into BioSante, with BioSante continuing as the surviving company. At the effective time of the merger, each outstanding share of capital stock of ANI will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. All options, warrants

or

Table of Contents

other rights to purchase shares of capital stock of ANI, will be canceled at the effective time of the merger without any consideration in exchange, except for certain warrants which although not cancelled will not represent the right to acquire any equity or other interest in the combined company after the merger. No fractional shares of BioSante common stock will be issued in connection with the merger, and holders of ANI capital stock will be entitled to receive cash in lieu thereof. Following completion of the transactions contemplated by the merger agreement, the current ANI stockholders are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current BioSante stockholders are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company, assuming BioSante's net cash as of the determination date is $18.0 million. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of BioSante's "net cash," as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. The merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended.

The merger agreement provides that, immediately following the effective time of the merger, the board of directors of the combined company will consist of five former directors of ANI and two former directors of BioSante, and ANI's current executive officers are expected to serve as executive officers of the combined company. In connection with the merger, BioSante will seek to amend its certificate of incorporation to: (i) effect a reverse split of BioSante common stock at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five, as determined by BioSante and ANI, which is intended to ensure that the listing requirements of The NASDAQ Global Market or The NASDAQ Capital Market are satisfied; and (ii) change the name of the company to "ANI Pharmaceuticals, Inc." or another name as designated by ANI (together, the charter amendments).

Completion of the merger is subject to a number of conditions, including, but not limited to (i) the adoption and approval of the merger agreement and the transactions contemplated thereby by both the BioSante and ANI stockholders and the approval of the charter amendments by the BioSante stockholders; (ii) the effectiveness of a Form S-4 registration statement to be filed by BioSante with the Securities and Exchange Commission to register the shares of BioSante common stock to be issued in connection with the merger, which will contain a joint proxy statement/prospectus; (iii) approval for the listing of shares of BioSante common stock to be issued in the merger on The NASDAQ Global Market or The NASDAQ Capital Market; (iv) written opinions of counsel that the merger will qualify as a reorganization within the meaning of Section 368(a) of the Code; and (v) other customary closing conditions. In addition, the obligation of ANI to effect the merger is subject to a condition that BioSante's net cash, after deducting all remaining liabilities, as calculated and as adjusted pursuant to the terms of the merger agreement, be no less than $17.0 million immediately prior to the effective time of the merger. No fractional shares of BioSante common stock will be issued in connection with the reverse split and holders of BioSante common stock will be entitled to receive cash in lieu thereof.

Each of BioSante and ANI have made customary representations, warranties and covenants in the merger agreement, including among others, covenants that (i) each party will conduct its business in the ordinary course consistent with past practice during the interim period between the execution of the merger agreement and the consummation of the merger; (ii) each party will not engage in certain kinds of transactions or take certain actions during such period; (iii) ANI will convene and hold a meeting of its stockholders for the purpose of considering the adoption and approval of the merger agreement and the transactions contemplated thereby and the board of directors of ANI will recommend that the ANI stockholders adopt and approve the merger agreement, subject to certain exceptions; and (iv) BioSante will convene and hold a meeting of the BioSante stockholders for the purpose of considering the

Table of Contents

adoption and approval of the merger agreement and the transactions contemplated thereby and the approval of the charter amendments and the BioSante board of directors will recommend that the BioSante stockholders adopt and approve the merger agreement and approve the charter amendments, subject to certain exceptions. Each of BioSante and ANI also has agreed not to solicit proposals relating to alternative business combination transactions or enter into discussions or an agreement concerning any proposals for alternative business combination transactions, subject to exceptions for BioSante in the event of its receipt of a "superior proposal."

The merger agreement contains certain termination rights in favor of each of ANI and BioSante in certain circumstances. If the merger agreement is terminated due to certain triggering events specified in the merger agreement, BioSante will be required to pay ANI a termination fee of up to $1.0 million or ANI will be required to pay BioSante a termination fee of up to $750,000. The merger agreement also provides that under specified circumstances, BioSante may be required to reimburse ANI up to $500,000 for ANI's expenses in connection with the transaction. Any expenses paid by BioSante will be credited against the $1.0 million termination fee if the termination fee subsequently becomes payable by BioSante.

***Voting Agreements***

Concurrently and in connection with the execution of the merger agreement, certain ANI stockholders, who collectively held approximately 90 percent of the outstanding shares of ANI common stock on an as-converted basis and approximately 86 percent of the outstanding shares of ANI series D preferred stock as of October 3, 2012, entered into voting agreements with BioSante, pursuant to which each ANI stockholder agreed to vote its shares of ANI capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement. In addition, one of the ANI stockholders, who held approximately 57 percent of the outstanding shares of ANI capital stock as of October 3, 2012, has agreed to vote in favor of the election of the two directors designated by BioSante at the first annual meeting of BioSante stockholders following completion of the merger.

In addition, all of BioSante's directors and officers, who collectively held approximately two percent of the outstanding shares of BioSante capital stock as of October 3, 2012, entered into voting agreements with ANI, pursuant to which each BioSante stockholder agreed to vote its shares of BioSante capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and the charter amendments, and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement.

***Lock-Up Agreements***

Concurrently and in connection with the execution of the merger agreement, ANI's chief executive officer and chief financial officer and certain ANI stockholders, who collectively held approximately 85 percent of the outstanding shares of ANI common stock, on an as-converted basis, as of October 3, 2012, entered into lock-up agreements with BioSante, pursuant to which each ANI stockholder will be subject to a six-month lock-up on the sale of shares of BioSante common stock received in the merger.

***Contingent Value Rights Agreement***

BioSante has the right in its sole discretion to issue contingent value rights (each, a CVR and collectively, the CVRs) to holders of BioSante common stock as of immediately prior to completion of the merger. BioSante expects that one CVR will be issued for each share of BioSante common stock outstanding as of the record date to be set at a date prior to completion of the merger. However, the

Table of Contents

CVRs will not be certificated and will not be attached to the shares of BioSante common stock. Each CVR will be a non-transferable (subject to certain limited exceptions) right to potentially receive certain cash payments in the event BioSante receives net cash payments during the ten-year period after the distribution of the rights as a result of the sale, transfer, license or similar transaction relating to BioSante's LibiGel program, upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between BioSante and its transfer agent, as rights agent. The aggregate cash payments to be distributed to the holders of the CVRs, if any, will be equal to 66 percent of the net cash payments received by the combined company as a result of the sale, transfer, license or similar transaction relating to BioSante's LibiGel program, as determined pursuant to the CVR agreement, and will not exceed $40 million in the aggregate.

**Financial Overview**

BioSante's lead product in development is LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. For the past several years, BioSante has focused its efforts on two Phase III LibiGel efficacy trials and its LibiGel Phase III cardiovascular and breast cancer safety study. In December 2011, BioSante announced results from its two Phase III LibiGel efficacy trials, which showed that the trials did not meet the co-primary or secondary endpoints. Although LibiGel performed as predicted, increasing satisfying sexual events and sexual desire and decreasing distress associated with low desire, the placebo response in the two efficacy trials was greater than expected, and LibiGel's results were not shown to be statistically different from the placebo.

Beginning in December 2011, BioSante analyzed the data from its Phase III LibiGel efficacy trials, consulted with key opinion leaders in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA. As a result of this process, in June 2012 BioSante announced a plan to initiate two new LibiGel Phase III efficacy trials.

In September 2012, BioSante announced that the independent Data Monitoring Committee (DMC) completed its ninth unblinded review of the LibiGel Phase III cardiovascular events and breast cancer safety study and recommended that the LibiGel safety study should continue as per the FDA-agreed protocol, without modifications. At the time of the DMC review, there were 53 adjudicated CV events, with a lower than anticipated event rate of approximately 0.72 percent. In the same population of subjects, there were 27 breast cancers reported, a rate of approximately 0.37 percent, which is in line with the expected rate based on the ages of the subjects enrolled in the study. Given this latest review during which no specific or general safety issues were raised, and after extensive consideration, BioSante also announced in September 2012 the conclusion of the LibiGel Phase III safety study effective immediately. Prior to the initiation of the LibiGel safety study in 2008, the FDA advised BioSante that subjects in the cardiovascular event and breast cancer safety study were required to have a minimum average exposure in the safety study of 12 months prior to submitting a LibiGel new drug application (NDA), and prior to a potential FDA approval of LibiGel. As of the date of the conclusion of the safety study, subjects had been in the study for an average time of 24.5 months; more than 3,200 subjects had been in the study for more than one year and over 1,700 subjects had been enrolled for more than two years. With this ninth positive unblinded review of the study by the DMC, and over 7,400 women-years of exposure, BioSante believes that adequate safety data of LibiGel use in menopausal women has been obtained.

BioSante is continuing to develop a protocol for the two new LibiGel efficacy trials and will seek an FDA SPA agreement covering aspects of the two new efficacy trials.

Elestrin was BioSante's first FDA approved product and now is one of BioSante's two FDA approved products. Meda Pharmaceuticals, Inc. (which acquired Jazz Pharmaceuticals, Inc.'s women's health business and which in turn had acquired Azur Pharma International II Limited (Azur),

Table of Contents

BioSante's prior licensee), is marketing Elestrin in the U.S. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur pursuant to which BioSante received $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to BioSante related to sales of Elestrin. BioSante maintains the right to receive up to $140 million in sales-based milestone payments from Meda Pharmaceuticals if Elestrin reaches certain predefined sales per calendar year; although, based on current sales levels, BioSante believes its receipt of such payments unlikely in the near term, if at all.

BioSante's male testosterone gel is its second FDA approved product. This product initially was developed by BioSante, and then licensed by BioSante to Teva for late stage clinical development. Teva submitted an NDA to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been disclosed publicly. No launch date for this product has been announced by Teva.

Under BioSante's development and license agreement with Teva, Teva has agreed to market the male testosterone gel for the U.S. market and is responsible for any and all manufacturing and marketing associated with the product. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva, which was paid to BioSante in December 2002, and an obligation by Teva to pay BioSante certain milestones and royalties on sales of the product in exchange for rights to develop and market the product, as described in more detail below. Teva is entitled to deduct the amount of any legal expenses incurred by Teva in connection with associated patent litigation against Teva from the net sales of the product. The term of the development and license agreement will expire 10 years from the date on which Teva makes its first commercial sale of the male testosterone gel to an unrelated third party in an arms-length transaction in the United States. The parties may terminate the development and license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party. BioSante may terminate the agreement if Teva files a petition in bankruptcy, enters into an arrangement with its creditors or makes an assignment for the benefit of creditors or a receiver or trustee is appointed or if Teva suffers or permits the entry of an order adjudicating it to be bankrupt or insolvent. Teva may terminate the agreement if Teva determines that the continued development and/or marketing of the male testosterone gel is no longer commercially viable.

In October 2012, BioSante entered into an amendment to its agreement with Teva pursuant to which Teva made a $1.0 million payment to BioSante upon the signing of the amendment and agreed to make the following milestone based payments to BioSante: (1) $500,000 if the FDA authorizes marketing of the licensed male testosterone gel as an "AB-rated" equivalent to AndroGel®; (2) $750,000 upon the earlier to occur of (a) December 31, 2012 and (b) five business days after Teva's submission to the FDA of a final report regarding a "washing" clinical study required by the FDA; and (3) $500,000 upon the earlier to occur of (a) December 31, 2013 and (b) five business days after Teva's commencement of commercial manufacture of the licensed product for sale in the United States. In addition, Teva has agreed to pay BioSante $4.0 million in the event Teva is the sole marketer in the United States of a generic 1% testosterone gel AB-rated to AndroGel® for at least 180 days immediately following the launch date of the licensed product in the United States. The royalty rate to be paid by Teva to BioSante under the agreement is five percent of net sales; provided, however, that during the period of time that Teva markets the licensed product and is the sole marketer of a generic 1% testosterone gel that is AB-rated to AndroGel® in the United States, the royalty rate will be seven and one half percent of net sales. Additionally, pursuant to the terms of the October 2012 amendment, the parties agreed to release each other from certain liabilities.

Table of Contents

BioSante licenses the technology underlying certain of its gel products, including LibiGel and Elestrin, but not the male testosterone gel, from Antares Pharma, Inc. The patents covering the formulations used in the gel products covered under the license agreement are expected to expire in 2022, although with respect to LibiGel, a new U.S. patent covering the "method of use" of LibiGel for treating FSD and HSDD was issued, which will expire in December 2028. BioSante's license agreement with Antares requires BioSante to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products BioSante or its licensees sell incorporating the licensed technology. Specifically, BioSante is obligated to pay Antares 25 percent of all upfront and milestone payments related to a license and a 4.5 percent royalty on net sales of product by BioSante or a licensee. Since entering into the agreement and through September 30, 2012, BioSante has paid Antares an upfront payment of $1.0 million, an aggregate of $5.1 million in milestone payments and an aggregate of $100,000 in royalties. Aggregate potential milestone payments to be paid by BioSante to Antares under the agreement include 25 percent of the potential $140 million in sales-based milestone payments, or $35 million from Meda Pharmaceuticals if Elestrin reaches certain predefined sales per calendar year; although, based on current sales levels, BioSante believes its receipt of such payments unlikely in the near term, if at all.

The term of BioSante's license agreement with Antares will expire on a country-by-country and product-by-product basis when the royalties expire (at patent expiration), at which time BioSante will have a fully paid-up exclusive license regarding the applicable product in such country. BioSante and Antares may terminate the license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party or if the other party goes into liquidation or bankruptcy or makes an assignment for the benefit of creditors or a receiver is appointed. Antares may terminate the agreement with respect to certain products or territories if BioSante does not continue development, seeking regulatory approval or marketing of such products in the covered territories. BioSante may terminate the agreement with respect to certain products or territories if, for technical, scientific or regulatory reasons, it is not likely that the product will gain required regulatory approvals in a territory, if regulatory approvals in a territory are not obtained or if BioSante determines that it is not economically viable to continue development or marketing of a product in a territory.

BioSante licenses the technology underlying The Pill Plus from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license include regulatory milestone payments, maintenance payments and royalty payments by BioSante if a product incorporating the licensed technology gets approved and subsequently is marketed.

BioSante's GVAX cancer vaccines, which are designed to stimulate a patient's immune system to fight effectively the patient's own cancer, are in development for the treatment of several different types of cancer including melanoma, leukemia, pancreatic, breast and prostate cancer. Four of these vaccines  to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma  have been granted FDA orphan drug designation. Currently, there are 17 Phase I and Phase II clinical studies involving our GVAX cancer vaccines ongoing. The studies are being funded by various sources, including certain foundations and our licensees. BioSante's objective with respect to its GVAX cancer vaccines is to help facilitate further studies and commercialization in order to bring important cancer therapies to patients in need and to maximize the value of the GVAX cancer vaccine portfolio to the BioSante stockholders. This objective includes monetizing the entire portfolio or seeking additional licensees to fund, develop and eventually commercialize the cancer vaccines. BioSante currently is negotiating the terms of a potential transation with an unidentified third party pursunt to which, if completed, BioSante would sell all of its assets related to its GVAX cancer vaccine portfolio in exchange for a $1.0 million up front cash payment plus the potential for future royalty, milestone and sublicense payments.

Table of Contents

**Financial Overview**

Substantially all of BioSante's revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. BioSante's business operations to date have consisted primarily of licensing and research and development activities and if BioSante does not complete its proposed merger with ANI, BioSante would expect this to continue for the immediate future. To date, BioSante has used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from its 2009 merger with Cell Genesys, Inc., to fund its ongoing business operations and short-term liquidity needs.

As of September 30, 2012, BioSante had $38.0 million of cash and cash equivalents and had outstanding $8.3 million in aggregate principal amount of our 3.125% convertible senior notes due May 1, 2013. Absent the receipt of any additional licensing income or financing, BioSante expects its cash and cash equivalents balance to decrease as it continues to use cash to fund its operations. Assuming the proposed merger between BioSante and ANI is completed, BioSante expects its cash and cash equivalents as of September 30, 2012 to meet its liquidity requirements through at least its anticipated closing of the merger, including the requirement under the merger agreement to have at least $17 million of "net cash," as defined in the merger agreement, available upon the closing of the merger. If the proposed merger between BioSante and ANI is not completed, BioSante will need to reevaluate its strategic alternatives, which may include continuing as an independent, stand-alone business, a sale of the company, liquidation of the company or other strategic transaction. BioSante's liquidity position will be dependent upon the strategic alternative selected; however, assuming BioSante does not enter into another strategic transaction, and assuming BioSante decides not to commence the two new efficacy trials for LibiGel, BioSante expects its cash and cash equivalents as of September 30, 2012 will be sufficient to meet its liquidity requirements for at least the next three to five years. Additional financing would be required should BioSante decide to commence the two new efficacy trials for LibiGel. These estimates may prove incorrect or BioSante, nonetheless, may choose to raise additional financing earlier.

BioSante incurred expenses of $14.5 million on research and development activities during the nine months ended September 30, 2012, which is a 61 percent decrease compared to the same period in 2011, primarily as a result of the conclusion of the two LibiGel Phase III efficacy trials at the end of 2011. BioSante anticipates that its research and development expenses for the remainder of 2012 and 2013 will consist primarily of expenses associated with the conclusion of the safety study and continuing to develop a protocol for the two new LibiGel Phase III efficacy trials. BioSante currently expects to spend approximately $1.1 million per month on research and development activities during the remainder of 2012, which is based on the assumption that BioSante does not in-license additional products and technologies requiring additional development.

General and administrative expenses for the nine months ended September 30, 2012 increased 1.3 percent compared to the same period in 2011 due primarily to an increase in professional fees and other administrative expenses. BioSante's general and administrative expenses generally fluctuate from year-to-year and quarter-to-quarter depending upon the amount of non-cash, stock-based compensation expense and the amount of legal, public and investor relations, accounting, corporate governance and other general and administrative fees and expenses incurred.

BioSante recognized an income tax benefit based on the receipt of an income tax credit for the nine months ended September 30, 2012 of $121,791 compared to the recognition of no income tax benefit for the nine months ended September 30, 2011. The income tax benefit was a result of an election to accelerate research and development credits in lieu of receiving bonus depreciation on certain property under Section 168(k)(4) of the Internal Revenue Code of 1986, as amended.

BioSante recognized a net loss for the nine months ended September 30, 2012 of $23.7 million compared to a net loss of $45.0 million for the nine months ended September 30, 2011. This decrease

Table of Contents

was primarily a result of the conclusion of the prior two LibiGel Phase III efficacy trials at the end of 2011 and in September 2012 the conclusion of the LibiGel Phase III safety study, and was offset in part by an increase in the non-cash fair value adjustment relating to the cancellation of $12.5 million in aggregate principal amount of its convertible senior notes. BioSante recognized a net loss per share for the nine months ended September 30, 2012 of $1.14 compared to a net loss per share of $2.86 for the nine months ended September 30, 2011. This decrease in net loss per share was the result of the significantly higher weighted average number of shares outstanding, partially offset by the lower net loss described above.

**Results of Operations**

***Nine Months Ended September 30, 2012 Compared to Nine Months Ended September 30, 2011***

The following table sets forth BioSante's results of operations for the nine months ended September 30, 2012 and 2011.

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | **2012** | **2011** | **$ Change** | **% Change** |
| Revenue | $ 333,163 | $ 320,787 | $ 12,376 | 3.9% |
| Expenses | | | | |
| Research and development | 14,454,258 | 37,480,873 | (23,026,615) | (61.4)% |
| General and administrative | 5,327,711 | 5,257,853 | 69,858 | 1.3% |
| Other expense Convertible note fair value adjustment | (4,037,797) | (1,929,000) | 2,108,797 | 109.3% |
| Other expense Interest expense | (283,348) | (516,000) | (232,652) | (45.1)% |
| Other income Interest income | 5,300 | 6,472 | (1,172) | (18.1)% |
| Income tax benefit | 121,791 | | 121,791 | 100.0% |
| Net loss | $ (23,730,408) | $ (44,959,682) | $ (21,229,274) | (47.2)% |
| Net loss per common share (basic and diluted) | $ (1.14) | $ (2.86) | $ 1.72 | (60.1)% |
| Weighted average number of common shares and common equivalent shares outstanding | 20,841,417 | 15,744,738 | 5,096,679 | 32.4% |

The only revenue recognized during the nine months ended September 30, 2012 consisted of royalty revenue from Jazz Pharmaceuticals for Elestrin sales, which royalty revenue is offset by BioSante's corresponding obligation to pay Antares royalties representing the same amount. BioSante's corresponding obligation to pay Antares a portion of the royalties received, which equaled $333,163 during the nine months ended September 30, 2012 and $220,787 during the nine months ended September 30, 2011, is recorded within general and administrative expenses in BioSante's condensed statements of operations. In addition, during the nine months ended September 30, 2011, BioSante recognized an additional $100,000 in revenue from its receipt of an upfront non-refundable licensing fee from The John P. Hussman Foundation.

Research and development expenses for the nine months ended September 30, 2012 decreased 61 percent compared to the nine months ended September 30, 2011 primarily as a result of the completion of BioSante's two LibiGel Phase III efficacy trials at the end of 2011 and the conclusion of the safety study in September 2012.

General and administrative expenses for the nine months ended September 30, 2012 increased 1.3 percent compared to the nine months ended September 30, 2011 primarily as a result of an increase in professional fees and other administrative expenses.

The fair value adjustment on BioSante's convertible senior notes for the nine months ended September 30, 2012 was $4.0 million compared to $1.9 million for the nine months ended

Table of Contents

September 30, 2011. The increase in the expense for the nine months ended September 30, 2012 was primarily as a result of $3,157,151 non-cash fair value adjustment (expense) recorded upon cancellation of $12.5 million in aggregate principal amount of BioSante's convertible senior notes in February and July 2012. The convertible fair value adjustment for the nine months ended September 30, 2011 increased the recorded liability and corresponding expense by $1,929,000 and included the 2011 and 2013 Notes.

Interest expense was $283,348 and $516,000 for the nine months ended September 30, 2012 and 2011, respectively, as a result of BioSante's convertible senior notes. Interest expense decreased during the most recent current year period as a result of the repayment of BioSante's 3.125% convertible senior notes due November 1, 2011 during the fourth quarter of 2011 and the cancellation of $12.5 million in aggregate principal amount of BioSante's 3.125% convertible senior notes due May 1, 2013, including accrued and unpaid interest, during the first and third quarter of 2012 in exchange for the issuance of 3,652,125 shares of BioSante common stock.

Interest income decreased $1,172 for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 as a result of lower cash balances and lower average interest rates during the nine months ended September 30, 2012.

BioSante recognized an income tax benefit based on the receipt of an income tax credit for the nine months ended September 30, 2012 of $121,791 compared to the recognition of no income tax benefit for the nine months ended September 30, 2011. The income tax benefit was a result of an election to accelerate research and development credits in lieu of receiving bonus depreciation on certain property under Section 168(k)(4) of the Internal Revenue Code of 1986, as amended.

***Years Ended December 31, 2011, 2010 and 2009***

The following table sets forth, for the periods indicated, BioSante's results of operations.

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2011** | **2010** | **2009** |
| Revenue | $ 435,160 | $ 2,474,237 | $ 1,258,054 |
| Expenses | | | |
| Research and development | 44,182,260 | 39,705,502 | 13,680,573 |
| General and administrative | 6,981,490 | 5,940,360 | 5,373,945 |
| Acquired in-process research and development | | | 9,000,000 |
| Excess consideration paid over fair value | | | 20,192,194 |
| Licensing expense | 50,000 | 268,750 | 299,616 |
| Total expenses | 51,361,990 | 46,082,598 | 48,683,608 |
| Other (expense) income Convertible note fair value adjustment | (23,427) | (1,870,916) | 33,163 |
| Other expense Investment impairment charge | | (286,000) | |
| Other expense Interest expense | (681,573) | (688,083) | 147,025 |
| Other income | 15,000 | 244,479 | |
| Other income Interest income | 8,326 | 12,665 | 11,648 |
| Net loss | $ (51,608,504) | $ (46,196,216) | $ (47,527,768) |
| Net loss per common share (basic and diluted) | $ (3.15) | $ (4.21) | $ (8.40) |
| Weighted average number of common shares and common equivalent shares outstanding | 16,397,618 | 10,985,291 | 5,658,609 |

Table of Contents

***Year Ended December 31, 2011 Compared to Year Ended December 31, 2010***

Revenue decreased $2.0 million, or 82.4 percent in 2011 compared to 2010, primarily as a result of the recognition of royalty revenue during 2010 resulting primarily from the receipt of $2.3 million in non-refundable upfront payments from Azur, partially offset by BioSante's receipt during 2011 of $100,000 in a non-refundable upfront licensing fee from the Hussman Foundation relating to an exclusive worldwide license of BioSante's melanoma vaccine. The $2.3 million payment from Azur in 2010 was in exchange for the elimination of all remaining future royalty payments that BioSante is not required to pay Antares under a separate agreement and certain future milestone payments due BioSante under the terms of the original license, as permitted by the amendment to BioSante's license agreement signed in December 2009. The only other revenue recognized during 2011 consisted of royalty revenue from Jazz Pharmaceuticals for Elestrin sales, which royalty revenue is offset by a corresponding obligation of BioSante to pay Antares royalties representing the same amount.

Research and development expenses for 2011 increased 11.3 percent compared to 2010 primarily as a result of the conduct of the three LibiGel Phase III clinical studies, particularly the safety study.

General and administrative expenses for 2011 increased 17.5 percent compared to 2010 primarily as a result of an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses during 2011.

The fair value adjustment on BioSante's convertible senior notes for 2011 was $23,427 compared to $1.9 million for 2010 as the fair value of the debt did not change significantly between December 31, 2010 and 2011.

Interest expense for 2011 was $681,573 compared to $688,083 for 2010. BioSante expects interest expense to decrease in 2012 compared to 2011 as a result of the repayment of $1.2 million in aggregate principal amount of BioSante's 3.125% convertible senior notes due November 1, 2011 and the cancellation of $9.0 million in aggregate principal amount of BioSante's 3.125% convertible senior notes previously due May 1, 2013, which were exchanged for shares of common stock as previously discussed.

During 2010, BioSante recorded an investment impairment loss of $286,000 based on BioSante's determination that an other-than-temporary loss had occurred with respect to BioSante's investment in Ceregene, Inc. based on a third-party investment in Ceregene in 2010.

***Year Ended December 31, 2010 Compared to Year Ended December 31, 2009***

Revenue increased $1.2 million in 2010 compared to 2009 primarily as a result of an increase in royalty and licensing revenue during 2010 compared to 2009. Of the $2.3 million in royalty revenue during 2010, $2.2 million resulted from BioSante's receipt of non-refundable upfront payments from Jazz Pharmaceuticals as a result of the December 2009 amendment to BioSante's license agreement. Pursuant to a separate agreement with Antares and related to the December 2009 amendment, BioSante paid Antares an aggregate of $268,750 in February 2010. In addition, during 2010, BioSante recorded royalty revenue of $152,228 and a corresponding amount of royalty expense, which is recorded within general and administrative expenses in BioSante's statements of operations, to reflect the Antares portion of the Elestrin royalty revenues, which revenues were not eliminated as a result of the December 2009 Jazz Pharmaceuticals license amendment. In October 2010, BioSante received $244,479, the maximum per project, after LibiGel qualified for a grant under the Qualifying Therapeutic Discovery Project Program which was created in March 2010 as part of the Patient Protection and Affordability Care Act.

Research and development expenses increased 190 percent in 2010 compared to 2009 primarily as a result of the conduct of the three LibiGel Phase III clinical studies.

Table of Contents

General and administrative expenses increased 11 percent in 2010 compared to 2009 primarily as a result of an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses in 2010.

BioSante recognized total additional non-cash expenses of $29.2 million in 2009 related to its merger with Cell Genesys, consisting of $9.0 million related to the write-off of acquired in-process research and development, and $20.2 million related to transaction related expenses and additional charges related to the excess of merger consideration over fair values of the net assets acquired. No similar expense was recognized in 2010.

BioSante recognized licensing expense of $268,750 related to its payment to Antares as a result of the December 2009 Jazz Pharmaceuticals license amendment compared to licensing expense of $299,616 in 2009 as a result of expenses associated with the Jazz Pharmaceuticals licensing agreement and the termination of BioSante's prior licensing agreement for Elestrin.

The fair value adjustment on BioSante's convertible senior notes to increase the recorded liability and corresponding expense was $1.9 million in 2010 compared to a fair value adjustment to decrease the recorded liability and corresponding expense of $33,163 in 2009.

BioSante recorded an investment impairment charge of $286,000 in 2010 based on its determination that an other-than-temporary impairment had occurred with respect to its investment in Ceregene, Inc. based on a third-party investment in Ceregene in 2010. No similar investment impairment charge was recognized in 2009.

Interest expense increased $541,058, or 368 percent, in 2010 compared to 2009 as a result of BioSante's convertible senior notes, which BioSante assumed during the fourth quarter of 2009.

Interest income increased $1,017, or 9 percent, in 2010 compared to 2009 primarily as a result of higher cash balances and cash being in a U.S. Treasury portfolio for a portion of 2010 compared to cash being in a non-interest bearing checking account for the majority of 2009.

**Liquidity and Capital Resources**

***Working Capital***

Since its inception, BioSante has incurred significant operating losses resulting in an accumulated deficit of $241.0 million as of September 30, 2012. To date, BioSante has used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from its 2009 merger with Cell Genesys, to fund its ongoing business operations and short-term liquidity needs.

As of September 30, 2012, BioSante had $38.0 million of cash and cash equivalents and $8.3 million in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013 outstanding. Absent the receipt of any additional licensing income or financing, BioSante expects its cash and cash equivalents balance to decrease as it continues to use cash to fund its operations. Assuming the proposed merger between BioSante and ANI is completed during the first quarter of 2013, BioSante expects its cash and cash equivalents as of September 30, 2012 to meet its liquidity requirements through at least the anticipated closing of the merger, including the requirement under the merger agreement to have at least $17 million of "net cash" as defined in the merger agreement available upon closing of the merger. If the proposed merger between BioSante and ANI is not completed, BioSante will need to reevaluate its strategic alternatives, which may include continuing as an independent, stand-alone company, a sale of the company, liquidation of the company or other strategic transaction. BioSante's liquidity position will be dependent upon the strategic alternative selected; however, assuming BioSante does not enter into another strategic transaction, and assuming BioSante decides not to commence the two new efficacy trials for LibiGel, BioSante expects its cash and cash equivalents as of September 30, 2012 will be sufficient to meet its liquidity requirements for at

Table of Contents

least the next three to five years. Substantial additional financing would be required should BioSante decide to commence the two new efficacy trials for LibiGel. These estimates may prove incorrect or BioSante, nonetheless, may choose to raise additional financing earlier.

BioSante's future capital requirements will depend upon numerous factors, including:

- the timing, cost and successful completion of the proposed merger between BioSante and ANI;
- the progress, timing, cost and results of BioSante's clinical development programs, including in particular the conclusion of the LibiGel Phase III safety study, and if BioSante has not completed the proposed merger between BioSante and ANI, beginning in mid-2013, the two new LibiGel Phase III efficacy trials if BioSante decides to commence such trials, and if BioSante in-license additional new products that require further development;
- the cost, timing and outcome of regulatory actions with respect to BioSante's products;
- the success, progress, timing and costs of BioSante's business development efforts to implement business collaborations, licenses and other business combinations or transactions, and BioSante's efforts to evaluate various strategic alternatives available with respect to its products and company.
- BioSante's ability to obtain value from its current products and technologies and its ability to out-license its products and technologies to third parties for development and commercialization and the terms of such out-licenses;
- BioSante's ability to acquire or in-license additional new products and technologies and the costs and expenses of such acquisitions or licenses;
- the timing and amount of any royalties, milestone or other payments BioSante may receive from or be obligated to pay to current and potential licensors, licensees and other third parties;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights;
- the emergence of competing products and technologies, and other adverse market developments;
- the perceived, potential and actual commercial success of BioSante's products;
- the outstanding principal amount of BioSante's 3.125% convertible senior notes due May 1, 2013 that are scheduled to mature and become due and payable on May 1, 2013 and BioSante's ability to avoid a "fundamental change" or an "event of default" under the indenture governing such notes, which may cause such notes to become due and payable prior to their maturity date on May 1, 2013;
- BioSante's operating expenses; and
- the resolution of BioSante's pending purported class action and shareholder derivative litigation and any amount BioSante may be required to pay in excess of its directors' and officers' liability insurance.

BioSante does not have any existing credit facilities under which it could borrow funds. In the event that BioSante would require additional working capital to fund future operations, it could seek to acquire such funds through additional equity or debt financing arrangements. If BioSante raises additional funds by issuing equity securities, its stockholders may experience dilution. Debt financing, if available, may involve covenants restricting BioSante's operations or its ability to incur additional debt. There is no assurance that any financing transaction will be available on terms acceptable to BioSante, or at all. As an alternative to raising additional financing, BioSante may choose to license one or more of its products or technologies to a third party who may finance a portion or all of the continued

Table of Contents

development and, if approved, commercialization of that licensed product, or sell certain assets or rights under its existing license agreements. In addition, from time to time, BioSante may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of BioSante, in open market purchases, privately negotiated transactions and/or a tender offer. In February 2012, BioSante issued an aggregate of 1,868,055 shares of its common stock to one of the holders of its convertible senior notes in exchange for the cancellation of $9.0 million in aggregate principal amount of such notes, including accrued and unpaid interest of $79,024, and in July 2012, BioSante issued an aggregate of 1,784,070 shares of its common stock to two of the holders of BioSante's convertible senior notes in exchange for the cancellation of $3.5 million in aggregate principal amount of such notes and accrued and unpaid interest of $20,686. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the trading price and volume of BioSante common stock, the willingness of the note holders to sell, exchange or restructure their notes, BioSante's available cash and cash equivalents, its liquidity requirements, regulatory limitations, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the BioSante stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of existing BioSante stockholders and/or decrease BioSante's cash balance. A significant decrease in BioSante's cash balance, together with an inability to raise additional financing when needed, may impair BioSante's ability to execute strategic alternatives or leave it without sufficient cash remaining for operations.

BioSante is subject to pending purported class action and shareholder derivative litigation, which litigation is described elsewhere in this joint proxy statement/prospectus. Such litigation could divert management's attention, harm BioSante's business and/or reputation and result in significant liabilities, as well as harm BioSante's ability to raise additional financing and execute certain strategic alternatives.

BioSante can provide no assurance that additional financing, if needed, will be available on terms favorable to BioSante, or at all. This is particularly true if investors are not confident in the success of the proposed merger between BioSante and ANI, BioSante's LibiGel development program, the future value of BioSante and/or economic and market conditions deteriorate. If BioSante does not complete the proposed merger between BioSante and ANI and if adequate funds are not available or are not available on acceptable terms when BioSante needs them, BioSante may need to reduce its operating costs further or it may be forced to explore other strategic alternatives, such as other business combination transactions or winding down its operations and liquidating the company. In such case, BioSante stockholders could lose some or all of their investment.

***Uses of Cash and Cash Flow***

*Nine Months Ended September 30, 2012 Compared to Nine Months Ended September 30, 2011*

Net cash used in operating activities was $22.1 million for the nine months ended September 30, 2012 compared to net cash used in operating activities of $36.9 million for the nine months ended September 30, 2011. Net cash used in operating activities for the nine months ended September 30, 2012 was primarily the result of the net loss for that period which was lower compared to the prior year period due to lower clinical trial related expenses primarily as a result of the completion of BioSante's two LibiGel Phase III efficacy trials at the end of 2011 and the conclusion of the safety study in September 2012. Net cash used in operating activities for the nine months ended September 30, 2011 was primarily the result of the net loss for that period.

Net cash used in investing activities was $536,697 for the nine months ended September 30, 2012 compared to net cash used in investing activities of $645,603 for the nine months ended September 30, 2011. Net cash used in investing activities for each of the nine months ended September 30, 2012 and 2011 was due primarily to the purchase of fixed assets.

Table of Contents

Net cash provided by financing activities was $3.5 million for the nine months ended September 30, 2012 compared to net cash provided by financing activities of $69 million for the nine months ended September 30, 2011. Net cash provided by financing activities for the nine months ended September 30, 2012 was the result of BioSante's August 2012 registered direct offering, which resulted in net proceeds of $3.3 million, after deduction of placement agent fees and offering expenses. Net cash provided by financing activities for the nine months ended September 30, 2011 was the result of BioSante's August 2011 underwritten public offering and March 2011 registered direct offering, which resulted in net proceeds of $45.1 million and $23.9 million, respectively, after deduction of underwriting discounts and commissions or placement agent fees and offering expenses.

*Years Ended December 31, 2011, 2010 and 2009*

Net cash used in operating activities was $47.9 million for the year ended December 31, 2011 compared to net cash used in operating activities of $40.1 million for the year ended December 31, 2010 and net cash used in operating activities of $18.4 million for the year ended December 31, 2009. Net cash used in operating activities for 2011 was primarily the result of the net loss for that period which was higher compared to 2010 due to higher LibiGel Phase III clinical study related expenses, partially offset by a decrease in prepaid expenses and other assets and an increase in accounts payable and accrued liabilities and the non-cash mark-to-market expense for BioSante's convertible senior notes. Net cash used in operating activities for 2010 was primarily the result of the net loss for that period, which was slightly higher compared to the prior year period due primarily to higher LibiGel Phase III clinical study related expenses, partially offset by an increase in accounts payable and accrued liabilities and a decrease in prepaid expenses and other assets. Net cash used in operating activities for 2009 was primarily the result of the net loss for that period. Technology and transaction related expenses and charges of $29.2 million were incurred as a result of BioSante's merger with Cell Genesys in 2009 but did not result in an operating cash payment by BioSante as it issued shares of its common stock as consideration for the transaction and cash payments for transaction costs were classified as a financing activity based on the nature of the transaction.

Net cash used in investing activities was $719,925 for the year ended December 31, 2011 compared to net cash provided by investing activities of $60,366 for the year ended December 31, 2010 and net cash provided by investing activities of $2.9 million for the year ended December 31, 2009. The increase in net cash used in investing activities for 2011 compared to 2010 was due to a significant increase in the purchase of fixed assets, including in particular machinery, computers and furniture. The machinery purchased during 2011 relates to new BioSante-owned machinery for LibiGel product manufacturing at its contract manufacturer and the increased amounts spent on computers and furniture during 2011 was due primarily to its increased number of personnel compared to 2010. Net cash used in investing activities for 2011 and 2010 was primarily for the purchase of capital assets.

Net cash provided by financing activities was $67.7 million for the year ended December 31, 2011 compared to $48.5 million for the year ended December 31, 2010 and $33.7 million for the year ended December 31, 2009. Net cash provided by financing activities in 2011 resulted from the net proceeds to BioSante, after deducting placement agent fees, underwriters' discounts, commissions and other offering expenses, from the completion of BioSante's March 2011 registered direct offering and August 2011 underwritten public offering, partially offset by the repayment of the 3.125% convertible senior notes due November 1, 2011 of $1.2 million. Net cash provided by financing activities in 2010 resulted from the net proceeds to BioSante, after deducting placement agent fees and offering expenses, from the completion of BioSante's March, June and December 2010 registered direct offerings. Net cash provided by financing activities for 2009 resulted from a combination of recognizing $24.7 million in cash acquired as a result of BioSante's merger with Cell Genesys and $11.4 million in net proceeds to BioSante, after deducting placement agent fees and offering expenses, from the completion of

Table of Contents

BioSante's August 2009 registered direct offering, partially offset by $2.4 million in cash paid for Cell Genesys acquisition-related costs.

***3.125% Convertible Senior Notes Due May 1, 2013***

As a result of BioSante's merger with Cell Genesys in 2009, BioSante assumed $1.2 million in aggregate principal amount of 3.125% convertible senior notes due November 1, 2011 and $20.8 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 issued by Cell Genesys. Prior to the November 1, 2011 maturity date, BioSante repaid in its entirety the outstanding aggregate principal amount of the 2011 Notes and all accrued and unpaid interest thereon through such date. During the nine months ended September 30, 2012, BioSante issued an aggregate of approximately 3.7 million shares of BioSante common stock to holders of the 3.125% convertible senior notes due May 1, 2013 in exchange for cancellation of $12.5 million in aggregate principal amount of such notes, including accrued and unpaid interest.

Contractual interest payments on the convertible senior notes are due on May 1 and November 1 of each year through maturity. Annual interest on the remaining convertible senior notes is approximately $259,000.

The remaining outstanding convertible senior notes are convertible into an aggregate of approximately 370,871 shares of BioSante common stock at a conversion price of $22.32 per share, subject to adjustments for stock dividends, stock splits and other similar events. The convertible senior notes are general, unsecured obligations of BioSante, ranking equally with all of BioSante's existing and future unsubordinated, unsecured indebtedness and senior in right of payment to any subordinated indebtedness, but are effectively subordinated to all of BioSante's existing and future secured indebtedness to the extent of the value of the related collateral, and structurally subordinated to all existing and future liabilities and other indebtedness of any subsidiaries of BioSante. The convertible senior notes are subject to repurchase by BioSante at each holder's option, if a fundamental change (as defined in the indenture) occurs, at a repurchase price equal to 100 percent of the principal amount of the convertible senior notes, plus accrued and unpaid interest on the repurchase date and are subject to redemption for cash by BioSante, in whole or in part, at a redemption price equal to 100 percent of the principal amount of such notes plus accrued and unpaid interest to the redemption date, if the closing price of BioSante common stock has exceeded 150 percent of the conversion price then in effect with respect to such notes for at least 20 trading days in any period of 30 consecutive trading days ending on the trading day prior to the mailing of the notice of redemption. As of September 30, 2012, the convertible senior notes were not eligible for redemption. The indenture governing the convertible senior notes, as supplemented by the supplemental indenture, does not contain any financial covenants and does not restrict us from paying dividends, incurring additional debt or issuing or repurchasing other securities of BioSante. In addition, the indenture, as supplemented by the supplemental indenture, does not protect the holders of the convertible senior notes in the event of a highly leveraged transaction or a fundamental change of BioSante except in certain circumstances specified in the indenture.

In addition, from time to time, BioSante may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of BioSante, in open market purchases, privately negotiated transactions and/or a tender offer. The amounts involved may be material. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, BioSante's available cash and cash equivalents, its liquidity requirements, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the BioSante stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of the existing BioSante stockholders and/or decrease BioSante's cash balance. A

Table of Contents

significant decrease in BioSante's cash balance may impair its ability to execute strategic alternatives or leave it without sufficient cash remaining for operations.

BioSante has elected to record the convertible senior notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which otherwise would require specialized valuation, bifurcation and recognition. Accordingly, BioSante has adjusted the carrying value of the convertible senior notes to their fair value as of September 30, 2012, with changes in the fair value of the convertible senior notes occurring since December 31, 2011 reflected in convertible note fair value adjustment in BioSante's statement of operations for the nine months ended September 30, 2012. The fair value of the convertible senior notes are based on Level 2 inputs according to the fair value hierarchy required under GAAP, which means fair value of the convertible senior notes is based on observable prices that are based on inputs not quoted on active markets, but corroborated by market data. The aggregate recorded fair value of the convertible senior notes of $7.6 million as of September 30, 2011 differs from their total stated principal amount of $8.3 million as of September 30, 2012 by $0.7 million. The aggregate recorded fair value of the convertible senior notes of $17.3 million as of December 31, 2011 differs from their total stated principal amount of $20.8 million as of such date by $3.5 million.

***Commitments and Contractual Obligations***

BioSante did not have any material commitments for capital expenditures as of September 30, 2012. BioSante has a purchase obligation relating to a gel packaging machine of $40,608. This obligation is due upon the shipment, assembly and calibration of the machine at a location designated by BioSante. In light of the proposed merger between BioSante and ANI, BioSante is evaluating the future plans for this gel packaging machine. BioSante also have several financial commitments, including its convertible senior notes, product development milestone payments to the licensors of certain of its products, payments under its license agreements with Johns Hopkins University and Wake Forest University Health Sciences, as well as minimum annual lease payments.

The following table summarizes the timing of these future contractual obligations and commitments as of September 30, 2012:

| | | Payments Due by Period | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 Year | 1 - 3 Years | 3 - 5 Years | More than 5 Years |
| Convertible senior notes | $ 8,277,850 | $ 8,277,850 | $ 0 | $ 0 | $ 0 |
| Interest payment obligations related to convertible senior notes | 150,898 | 150,898 | 0 | 0 | 0 |
| Operating lease | 350,413 | 246,119 | 104,295 | 0 | 0 |
| Commitments under license agreements with Johns Hopkins University | 320,000 | 45,000 | 135,000 | 90,000 | 50,000 |
| Commitments under license agreement with Massachusetts Institute of Technology | 100,000 | 50,000 | 50,000 | 0 | 0 |
| Commitments under license agreement with University of California | 300,000 | 20,000 | 60,000 | 40,000 | 180,000 |
| Commitments under license agreement with Wake Forest | 360,000 | 80,000 | 200,000 | 80,000 | 40,000 |
| Total contractual cash obligations | $ 9,859,162 | $ 8,869,867 | $ 549,295 | $ 210,000 | $ 230,000 |

Table of Contents

***Off-Balance Sheet Arrangements***

BioSante does not have any off-balance sheet arrangements that have or reasonably are likely to have a material effect on BioSante's financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. As a result, BioSante is not exposed materially to any financing, liquidity, market or credit risk that could arise if BioSante had engaged in these arrangements.

**Critical Accounting Policies**

BioSante's significant accounting policies are described in Note 2 to its financial statements for the year ended December 31, 2011, included in this joint proxy statement/prospectus. The discussion and analysis of BioSante's financial statements and results of operations are based upon BioSante's financial statements, which have been prepared in accordance with GAAP. The preparation of BioSante's financial statements requires management to make estimates and judgments that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The SEC has defined a company's most critical accounting policies as those that are most important to the portrayal of its financial condition and results of operations, and which requires BioSante to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, BioSante has identified the critical accounting policy described below. Although BioSante believes that its estimates and assumptions are reasonable, they are based upon information available when they are made. Actual results may differ significantly from these estimates under different assumptions or conditions.

***Accounting for Convertible Senior Notes Assumed in Connection with the Cell Genesys Acquisition***

On October 14, 2009, BioSante completed a legal merger with Cell Genesys, as a result of which BioSante acquired all of the assets and liabilities of Cell Genesys. Concurrently with the merger, the common stock of Cell Genesys was converted into common stock of BioSante, and Cell Genesys ceased to exist. The primary reason BioSante merged with Cell Genesys was BioSante's need at that time for additional funding to continue its Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for BioSante to access capital prior to and at the time the merger agreement was entered into by BioSante and Cell Genesys in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been BioSante's primary method for raising additional financing. BioSante has accounted for this transaction with Cell Genesys under GAAP as an acquisition of the net assets of Cell Genesys, whereby BioSante has recorded the individual assets and liabilities of Cell Genesys as of the completion of the merger based on their estimated fair values. As Cell Genesys had ceased operations, the acquisition was not considered to be a business combination, and the allocation of the purchase price did not result in recognition of goodwill. As a result of this treatment, during the fourth quarter of 2009, BioSante recognized a non-cash expense of approximately $20.2 million representing the excess of the consideration and costs of the transaction over the fair value of assets and liabilities received.

BioSante assumed $22.0 million in aggregate principal amount of convertible senior notes in connection with the Cell Genesys acquisition, including $1.2 million in aggregate principal amount of 3.125% convertible senior notes due November 1, 2011, which were repaid prior to the November 1, 2011 maturity date, and $20.8 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013, which were outstanding as of December 31, 2011. As of September 30, 2012, $8.3 million in aggregate principal amount of convertible senior notes remained outstanding following the exchange transactions previously discussed.

BioSante elected to apply the fair value option to the debt at the time of the acquisition, with recognition of subsequent changes in the fair value of the convertible senior notes recognized in

Table of Contents

BioSante's statements of operations immediately. As a result of this election, BioSante periodically must estimate the fair value of its convertible senior notes, which requires BioSante to make certain judgments and estimates about appropriate discount rates, BioSante's creditworthiness, and assumptions regarding potential conversion of the notes. BioSante believes that its estimates and assumptions are reasonable; however, changes in these estimates and assumptions could result in significant differences in the carrying value of the convertible senior notes. The most sensitive of these assumptions is the discount rate used in the fair value estimate, which was 18.5 percent at December 31, 2011, and is based on the median yield to maturity of Ca and Caa3 rated debt instruments as of December 31, 2011. A one percentage point increase or decrease in the discount rate would cause the recorded value of the convertible senior notes to decrease or increase by approximately $191,000 and $194,000, respectively.

**Recently Issued Accounting Pronouncements**

BioSante does not expect the adoption of any recent accounting pronouncements to have a material effect on its financial position, results of operations or cash flows.

**Quantitative and Qualitative Disclosures About Market Risk**

BioSante is exposed to interest rate sensitivity on its cash equivalents in money market funds and its outstanding fixed rate debt. The objective of BioSante's investment activities is to preserve principal, while at the same time maximizing yields without significantly increasing risk. To achieve this objective, BioSante invests in highly liquid U.S. Treasury money market funds. BioSante's investments in U.S. Treasury money market funds are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, BioSante invests in short-term securities and its goal is to maintain an average maturity of less than one year. As of the date of this proxy statement/prospectus, all of BioSante's cash equivalents are only invested in a U.S. Treasury money market fund and a certificate of deposit.

The following table provides information about BioSante's financial instruments that are sensitive to changes in interest rates.

**Interest Rate Sensitivity**
**Principal Amount by Expected Maturity and Average Interest Rate**

| As of September 30, 2012 | 2012 | 2013 | Total | Fair Value September 30, 2012 |
|---|---|---|---|---|
| Total cash equivalents | $ 36,957,469 | | | $ 36,957,469 |
| Average interest rate | 0.04% | | | |
| Fixed interest rate convertible senior notes | | $ 8,277,850 | $ 8,277,850 | $ 7,593,216 |
| Average interest rate | 3.125% | 3.125% | 3.125% | |

| As of December 31, 2011 | 2012 | 2013 | Total | Fair Value December 31, 2011 |
|---|---|---|---|---|
| Total cash equivalents | $ 55,465,507 | | | $ 55,465,507 |
| Average interest rate | 0.02% | | | |
| Fixed interest rate convertible senior notes | | $ 20,782,000 | $ 20,782,000 | $ 17,336,760 |
| Average interest rate | 3.125% | 3.125% | 3.125% | |

Table of Contents

## ANI'S BUSINESS

### Overview

ANI is a fully integrated specialty pharmaceutical company developing, manufacturing and marketing branded and generic prescription pharmaceuticals. In two facilities with combined manufacturing, packaging and laboratory capacity totaling 173,000 square feet, ANI manufactures oral solid dose products, as well as liquids and topicals, including narcotics and those that must be manufactured in a fully contained environment due to their potency and/or toxicity. ANI also performs contract manufacturing for other pharmaceutical companies. ANI's targeted areas of product development include narcotics, anti-cancers and hormones (potent compounds) and extended release niche generic prescription product opportunities.

ANI was organized as a Delaware corporation in March 2004 and is headquartered in Baudette, Minnesota. The address of ANI's main office is 210 Main Street West, Baudette, Minnesota, 56623, and the telephone number is (218) 634-3500.

ANI acquired its two facilities in May 2007 from Solvay Pharmaceuticals, Inc. (Solvay). Solvay in turn had acquired the facilities in 1986 through its purchase of Atlanta-based Reid-Rowell, Inc., after which the facilities served as Solvay's sole U.S.-based manufacturing facilities for hormone, steroid and other prescription products.

In March 2009, ANI's leadership transitioned from founding management to a new team focused initially on stabilizing the business and then developing and executing a strategy based on ANI's prescription pharmaceutical manufacturing assets and capabilities. To that end, since the first quarter of 2009, ANI's new management team has:

Consolidated and relocated ANI's corporate offices to its facilities in Minnesota.

Successfully divested an over-the-counter pharmaceutical manufacturing operation in Gulfport, Mississippi in 2010 for $2.3 million. The net assets of the Gulfport operation had a carrying value of $5.8 million on the date of the sale, resulting in a loss of $3.7 million on disposal of the discontinued operation. The decision to sell the Gulfport operation was based on the historical underperformance and recurring losses at such operation and ANI's change in strategic direction to focus on the prescription pharmaceutical market.

Implemented cost reductions and early lease terminations yielding $3.0 million in annual savings.

Retired all third-party long-term debt and capital leases totaling $4.7 million.

Raised over $13.5 million in capital from existing investors.

Increased prescription product sales 40-fold through market share gains on established products, a product acquisition and new product launches.

Generated positive cash flow from operations.

Developed three new contract manufacturing customer relationships.

Established an external product development partnership to bolster the internal pipeline.

Filed three Abbreviated New Drug Applications (ANDAs) and developed a pipeline of eight additional ANDAs.

**Operations**

ANI's two facilities have highly specialized manufacturing capabilities as a result of capital investments by Solvay during its ownership. ANI's Baudette-based manufacturing and product development teams have successfully developed and manufactured liquid, powder and oral solid dose

Table of Contents

products, including those requiring containment. The plants have sufficient capacity, including analytical and stability laboratories, to expand production and substantially grow revenues. ANI can offer no assurances that it will in fact be successful in growing revenues, as multiple other factors, including those discussed in "Risk Factors  Risks Related to ANI" may impair its ability to do so.

In addition to laboratories that support all of the requirements of raw material, finished product and stability testing, ANI has a 1,000 square foot pilot laboratory offering liquid, suspension and solid dose development capabilities. This pilot laboratory offers a full range of analytical capabilities including method development, validation and de-formulation, and is licensed by the Drug Enforcement Administration (DEA). In addition, a separate development suite located within ANI's high-potency manufacturing facility offers additional capabilities for product development.

ANI has filed three ANDAs for products and has eight ANDAs in progress  three internal and five with development partner RiconPharma LLC (RiconPharma). RiconPharma, an experienced pharmaceutical development firm, shares in the development costs, which enables ANI to expand and diversify beyond its own suite of products. See "  Research and Development."

Over the previous ten years, ANI has had six general inspections by the Food and Drug Administration, resulting in two 483 observations, which are observations in which, in the investigator's judgment, the observed conditions or practices indicate that an FDA-regulated product may be in violation of FDA's requirements. In addition, ANI is regularly audited by its contract manufacturing customers, including but not limited to Abbott Laboratories, JDS/Noven, MEDA Pharmaceuticals and County Line Pharmaceuticals, LLC.

**Mission and Strategy**

ANI's mission is to use its manufacturing assets to develop and market niche generic pharmaceuticals, focusing on opportunities in pain management (narcotics), anti-cancer (oncolytics), women's health (hormones and steroids), as well as complex formulations including extended release and combination products.

ANI considers a variety of criteria in determining which products to develop, all of which influence the level of competition upon product launch. These criteria include:

***Formulation Difficulty.*** Potent, extended release, combination and low dosage products.

***Patent Status.*** Existing patent protection, if any, time remaining to patent expiration, and existing patent challenges.

***Market Size.*** Current and expected market size at launch based on forecasted price erosion upon conversion from branded to generic pricing.

***Profit Potential.*** Availability and cost of active pharmaceutical ingredients combined with forecasted market share.

***Manufacturing.*** Ability of ANI to manufacture in company-owned facilities.

***Competition.*** Existing and expected competitors.

**Government Regulation**

***Generic Pharmaceutical Products***

Prescription pharmaceutical products in the United States are generally marketed as either branded or generic drugs. Branded products are marketed under brand names through marketing programs that are designed to generate physician and consumer loyalty. Branded products are generally patent protected, which provides a period of market exclusivity during which time they are sold with

212

Table of Contents

little or no competition for the compound, although typically there are other products in the same therapeutic area. Additionally, branded products may benefit from additional periods of non-patent market exclusivity. Exclusivity ordinarily provides branded products with the ability to maintain their profitability for relatively long periods of time, and branded products typically continue to play a significant role in the market after the end of patent protection or other market exclusivities due to physician and consumer loyalties.

Generic pharmaceutical products are the chemical and therapeutic equivalents of reference branded drugs. A reference branded drug is an approved drug product listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, popularly known as the "Orange Book." The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) provides that generic drugs may enter the market after the approval of an ANDA, which requires that bioequivalence to a reference branded product be demonstrated, and the expiration, invalidation or circumvention of any patents on the corresponding reference branded drug, or the end of any other relevant market exclusivity periods related to the reference branded drug. Generic drugs are bioequivalent to their reference branded name counterparts. Bioequivalence compares the bioavailability of one drug product with that of the referenced drug product containing the same active ingredient. Bioavailability indicates the rate and extent to which the active ingredients or active moiety is absorbed from a drug product and becomes available at the site of action. When established, bioequivalence confirms the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Accordingly, generic products provide a safe, effective and cost-efficient alternative to users of these reference branded products. Growth in the generic pharmaceutical industry has been driven by the increased market acceptance of generic drugs, as well as the number of branded drugs for which patent terms and/or other market exclusivities have expired.

All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. Information to support the bioequivalence of generic drug products or the safety and effectiveness of new drug products for their intended use is also required to be submitted. There are generally two types of applications used for obtaining FDA approval of new products:

*New Drug Application* An NDA is filed when approval is sought to market a newly developed branded product and, in certain instances, for a new dosage form, a new delivery system or a new indication for a previously approved drug.

*Abbreviated New Drug Application* An ANDA is filed when approval is sought to market a generic equivalent of a drug product previously approved under an NDA and listed in the FDA's Orange Book or (following FDA approval of a petition) for a new dosage form, strength or route of administration for a drug previously approved under an NDA.

The ANDA development process is generally less time-consuming and less complex than the NDA development process. It typically does not require new preclinical and clinical studies, because it relies on the studies establishing safety and efficacy conducted for the reference branded drug previously approved through the NDA process. The ANDA process, however, typically requires one or more bioequivalence studies to show that the ANDA drug is bioequivalent to the previously approved referenced branded drug.

Generic products are generally introduced to the marketplace after the expiration of patent protection for the branded product and after the end of a period of non-patent market exclusivity. However, if an ANDA applicant files an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed in the Orange Book with respect to the

Table of Contents

reference branded drug product, that generic equivalent may be able to be marketed prior to the expiration of patent protection for the branded product. Such patent certification is commonly referred to as a Paragraph IV certification. If the holder of the NDA sues, claiming patent infringement, within 45 days of notification by the applicant, the FDA may not approve the ANDA until the earlier of the rendering of a court decision favorable to the ANDA applicant or the expiration of 30 months. An ANDA applicant that is first to file a Paragraph IV certification is eligible for a period of generic marketing exclusivity. This exclusivity, which under certain circumstances may be required to be shared with other applicable ANDA sponsors with Paragraph IV certifications, lasts for 180 days, during which the FDA cannot grant final approval to other ANDA sponsors holding applications for a generic equivalent to the same reference branded drug.

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent market exclusivity, during which the FDA cannot approve an application for a generic version product. If the reference drug is a new chemical entity, the FDA may not accept an ANDA for a generic product for up to five years following approval of the NDA for the new chemical entity. If it is not a new chemical entity, but the holder of the NDA conducted clinical trials essential to approval of the NDA or a supplement thereto, the FDA may not approve an ANDA for reference NDA product before the expiration of three years. Certain other periods of exclusivity may be available if the referenced drug is indicated for treatment of a rare disease or is studied for pediatric indications.

Prior Approval Supplements are required for approval of various types of changes to an approved ANDA, and these supplements may be under review for six months or more. In addition, certain types of changes may only be approved once new bioequivalence studies are conducted or other requirements are satisfied.

One requirement for FDA approval of NDAs and ANDAs is that ANI's manufacturing procedures and operations conform to FDA requirements and guidelines, generally referred to as cGMP. The requirements for FDA approval encompass all aspects of the production process, including validation and recordkeeping, the standards around which are continuously changing and evolving.

Facilities, procedures, operations and/or testing of products are subject to periodic inspection by the FDA, the DEA and other authorities. In addition, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether ANI's systems and processes are in compliance with cGMP and other FDA regulations. ANI's suppliers are subject to similar regulations and periodic inspections.

ANI has filed three ANDAs for products for which FDA approvals are expected beginning in 2014; however, ANI can offer no assurances that it in fact will be able to obtain such approvals. In addition, ANI has eight ANDAs in progress three internal and five with a development partner. ANI expects to file an ANDA for one of these products in 2012, and the remaining seven ANDAs in 2013, with approvals expected beginning in 2015; however, there can be no assurances that the filing of these ANDAs will not be delayed or abandoned and no assurances that approval will be obtained. Further, ANI's pipeline of future development candidates includes products in each area of strategic focus, i.e., pain management (narcotics), anti-cancer (oncolytics), women's health (hormones and steroids), as well as complex formulations including extended release and combination products.

***Generic Drug User Fee Amendment***

The Generic Drug User Fee Amendment of 2012 (GDUFA) to the FDA Safety and Innovation Act gives the FDA the authority to collect user fees from the generic pharmaceutical industry to fund reviews of generic drugs. GDUFA is designed to speed access to safe and effective generic drugs to the public. The law requires generic industry participants to pay user fees to supplement the costs of reviewing generic drug applications and inspecting facilities. The FDA believes these additional resources will enable it to reduce a current backlog of pending ANDA applications and cut the average

Table of Contents

time required to review generic drug applications for safety. For FDA's fiscal year 2013, the user fee rates are $51,520 for new ANDAs, $25,760 for Prior Approval Supplements, and $17,434 for each ANDA already on file at FDA. ANI also will have to pay a facility user fee, the amount of which has not yet been established by the FDA.

During 2012, ANI paid $68,954 for its two ANDAs on file at the FDA and $51,520 for a new ANDA filing.

***Unapproved Pharmaceutical Products***

Certain of ANI's generic products are marketed without approved NDAs or ANDAs, specifically, Esterified Estrogen with Methyltestosterone and Opium Tincture. During the nine months ended September 30, 2012 and 2011, combined net revenues for these products were $3.6 million and $2.2 million, respectively and during the years ended December 31, 2011 and 2010, combined net revenues for these products were $3.5 million and $95,000, respectively.

The FDA's policy with respect to the continued marketing of unapproved products is stated in the FDA's September 2011 Compliance Policy Guide, titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. ANI believes that so long as it complies with applicable manufacturing and labeling standards, it will not be targeted for enforcement under the FDA's current enforcement policy. There can be no assurance, however, that the FDA will continue this policy or not take a contrary position with any individual product or group of products.

In October 2012, ANI received a telephone call requesting a meeting with the FDA representatives from the Minneapolis district of the FDA to discuss continued manufacturing and distribution of Opium Tincture, which is an unapproved product. That meeting was held on October 25, 2012 by conference telephone call and included FDA representatives from the Office of Compliance at the Center for Drug Evaluation and Research (CDER). Discussions with CDER are continuing. If, as a result of such discussions or otherwise, the FDA were to make a determination that ANI could not continue to sell Opium Tincture as an unapproved product, ANI would be required to seek FDA approval for such product or withdraw such product from the market. If ANI determined to withdraw the product from the market, ANI's net revenues for generic pharmaceutical products would decline materially, and if ANI decided to seek FDA approval, it would face increased expenses and might need to suspend sales of the product until such approval is obtained, and there are no assurances that ANI would receive such approval.

In addition, one group of products that ANI manufactures on behalf of a contract customer, and based on the sale of which ANI receives royalties, is marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market, which could materially adversely affect ANI's contract manufacturing and royalty revenue. ANI's contract manufacturing revenue for this group of products for the nine months ended September 30, 2012 and 2011 was $775,000 and $1.1 million, respectively. ANI's royalties on the net sales of these products for the nine months ended September 30, 2012 and 2011 were $220,000 and $249,000, respectively. ANI's contract manufacturing revenue for the group of unapproved products for the years ended December 31, 2011 and 2010 was $1.3 million and $623,000, respectively. ANI's royalties on the net sales of these unapproved products for the years ended December 31, 2011 and 2010 were $320,000 and $118,000, respectively.

Table of Contents

See also "Risk Factors  Risks Related to ANI  Certain of ANI's generic products are marketed without approved NDAs or ANDAs and ANI can offer no assurances that the FDA will not require ANI to seek approval for these products or withdraw them from the market. In either case, ANI's business, financial position, results of operations and cash flows could be materially adversely affected."

***Controlled Substances***

***U.S. Drug Enforcement Administration.*** The DEA regulates certain drug products containing controlled substances, such as opium, pursuant to the U.S. Controlled Substances Act (CSA). The CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

In addition, each year, ANI must submit a request to the DEA for a quota to purchase the amount of active pharmaceutical ingredient (opium) needed to manufacture Opium Tincture. Without an approved quota from DEA, ANI would not be able to purchase this ingredient from its supplier. As a result, ANI is dependent upon the DEA to approve, on an annual basis, a quota of active pharmaceutical ingredient that is sufficiently large to support the continued manufacture of Opium Tincture.

***Medicaid/Medicare***

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and branded pharmaceuticals effective January 1, 2010. The required rebate is currently 13 percent of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11 percent for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23 percent (up from 15 percent) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period. ANI believes that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

Under Part D of the Medicare Modernization Act, Medicare beneficiaries are eligible to obtain discounted prescription drug coverage from private sector providers. As a result, usage of pharmaceuticals has increased, which is a trend that ANI believes will continue to benefit the generic pharmaceutical industry. However, such potential sales increases may be offset by increased pricing pressures, due to the enhanced purchasing power of the private sector providers that are negotiating on behalf of Medicare beneficiaries.

Under the Patient Protection and Affordable Care Act, pharmaceutical companies are required to provide discounts to Medicare Part D beneficiaries for the cost of branded prescription drugs. Under the Medicare Coverage Gap Discount Program authorized by PPACA, any pharmaceutical product marketed under an NDA, regardless of whether the product is marketed as a "generic," is subject to the rebate. ANI's generic hydrocortisone enema and fluvoxamine maleate tablets, while marketed as "generics", are actually the subject of approved NDAs and, therefore, are subject to the rebate.

Table of Contents

**Research and Development**

ANI obtains new generic products through a combination of internal development and in partnership with other firms. Additionally, ANI licenses and co-develops products through arrangements with other companies.

To accelerate its product development pipeline, ANI entered into a relationship with RiconPharma. Under the parties' master product development and collaboration agreement from July 2011, ANI and RiconPharma have agreed to collaborate in a cost, asset and profit sharing arrangement for the development, manufacturing, regulatory approval and marketing of pharmaceutical products in the United States. The specific terms and conditions of each new product collaboration, including a description of the product, estimated cost of development and percentage allocation of costs and profits, are included in amending exhibits to the agreement. Unless otherwise set forth in the amending exhibit, RiconPharma is responsible for developing the products and ANI is responsible for manufacturing, sales, marketing and distribution of the products. The parties are jointly responsible for directing any bioequivalence studies. ANI is responsible for obtaining and maintaining all necessary regulatory approval, including the preparation of all ANDAs. Under the agreement and unless otherwise specified in the amending exhibit, the parties will own equally all the rights, title and interest in the products. To the extent permitted by applicable law, ANI will be identified on the product packaging as the manufacturer and labeler/distributor of the product. During the term of the agreement, both parties are prohibited from developing, manufacturing, selling or distributing any products that are identical or bioequivalent to products covered under the agreement. The master product development and collaboration agreement and any amending exhibit may be terminated as a result of uncured material breach upon 30 days' prior written notice, subject to a 30-day extension. The terminating party may not develop, manufacture, market, distribute or sale any covered product or a bioequivalent product for five years after termination. In addition, either party may terminate an amending exhibit upon 30 to 60 days' prior written notice.

During the years ended December 31, 2011 and 2010, ANI's research and development expenses were $799,302 and $84,762, respectively.

**Patents, Trademarks and Licenses**

ANI owns the trademark names for each of its branded products, Cortenema® and Reglan®. Generally, the branded pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. ANI does not own or license any patents associated with these products. Further, patent protection and market exclusivity for these products have long-since expired. Therefore, ANI considers the trademark names to be of material value and acts to protect these rights from infringement. However, ANI's business is not dependent upon any single trademark. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and may be renewed indefinitely.

In the branded pharmaceutical industry, the majority of an innovative product's commercial value is usually realized during the period in which the product has market exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there can often be very substantial and rapid declines in the branded product's sales. The rate of this decline varies by country and by therapeutic category; however, following patent expiration, branded products often continue to have market viability based upon the goodwill of the product name, which typically benefits from trademark protection. ANI believes that sales of its branded products have and will continue to benefit from the goodwill of the product name.

ANI has licensed the right to manufacture and market an authorized generic version, fluvoxamine maleate, of Luvox® IR from Jazz Pharmaceuticals, which in turn acquired the rights to Luvox® IR from Solvay Pharmaceuticals, Inc. This license is in addition to a manufacturing and supply agreement with

Table of Contents

Jazz Pharmaceuticals, under which ANI manufactures and supplies Jazz Pharmaceuticals' requirements for Luvox® IR. Under the license agreement, Jazz Pharmaceuticals transferred responsibility for the related NDA to ANI. The license agreement may be terminated by Jazz Pharmaceuticals if the Solvay license agreement is terminated, if ANI breaches or defaults in the performance or observance of any material provisions of the agreement or the related supply agreement and such breach or default is not cured within 60 days after written notice is received, in the case of voluntary or involuntary bankruptcy filings by/against ANI, if ANI does not make royalty payments when due, or in the event ANI receives an adverse finding letter from the FDA relating to the NDA and is either not able to cure or provide evidence of a reasonable plan to cure within 30 days of receipt by ANI of such adverse finding letter, among other events. ANI may terminate the agreement with the consent of Jazz Pharmaceuticals, such consent not to be unreasonably withheld.

**Customers**

ANI's products are sold by four major retail pharmacy chains, Walgreens, CVS, RiteAid and Wal-Mart, and are included in the source programs of four major national wholesalers, Cardinal, McKesson, AmerisourceBergen and Morris Dickson. In addition, ANI's customers include national mail order houses and group purchasing organizations.

Abbott Laboratories, formerly Solvay Pharmaceuticals, is one of ANI's largest ongoing contract manufacturing customers, the loss of whom would have a material adverse effect on ANI's business. For 2011 and 2010, sales to Abbott represented 15.6 percent and 41.6 percent of net revenues, respectively. The written agreement under which ANI performed contract manufacturing services for Abbott Laboratories expired in April 2012 and has not been renewed. ANI currently conducts its contract manufacturing services for Abbott Laboratories based on periodic individual purchase orders submitted by Abbott Laboratories to ANI, and there can be no assurances that Abbott Laboratories will continue submitting such orders and not choose another contract manufacturer for its products.

Consistent with industry practice, ANI maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. See "ANI's Management's Discussion and Analysis of Results of Operations and Financial Condition  Critical Accounting Policies and Estimates" for a discussion of several of ANI's revenue recognition provisions.

**Markets**

ANI's target markets have limited competition due to complexities in formulation, active pharmaceutical ingredient sourcing, material handling and manufacturing, and regulatory hurdles.

***Hormone and Steroidal Drugs***

The market for hormone and steroidal drugs includes hormone therapy to alleviate menopausal symptoms in women, contraceptives, testosterone replacement therapies for men, and therapies for treating hormone-sensitive and other cancers.

Hormone Therapy (HT) has been an accepted medical treatment for alleviating the symptoms of menopause since the 1930s, with formal FDA approval for that use granted in 1942. In the beginning, HT consisted of estrogen only, but has evolved to include combination therapies of estrogen, progesterone and androgens. In 2000, the FDA approved the use of estrogen for prevention of osteoporosis. ANI targets niche products in the HT and steroidal products market for several reasons:

- Hormone and steroid products are a core competency based on ANI's manufacturing and product development teams' long history of manufacturing these types of products; and

Table of Contents

The aging baby boom population, of which women represent a majority, is expected to support continued growth in the HT market.

***Oncolytics***

ANI is positioned to develop and manufacture niche oncolytic (anti-cancer) drugs due to the capabilities of the ANI's containment facility and its expertise in manufacturing segregation. In particular, ANI is targeting products subject to priority review by the FDA, those with no blocking patents, and those with no generic competition. In addition to one such product already under development, ANI has identified six additional priority review opportunities in oncolytics.

***Narcotics***

ANI's main manufacturing facility in Baudette, Minnesota is licensed by the DEA for the manufacture and distribution of Schedule II narcotics, i.e., drugs considered to have a high abuse risk but that also have safe and accepted medical uses in the United States. In addition to its existing pipeline of three ANDAs (and five additional ANDAs with a development partner), ANI has identified additional product development opportunities in this segment.

***Contract Manufacturing***

Contract manufacturers are experiencing significant growth as both branded and generic companies are outsourcing some or all of their production to contract manufacturing organizations (CMOs) for the following reasons:

Free-up internal resources to focus on core competencies in sales and marketing as well as research and development;

Utilize internal manufacturing operations for higher volume or more critical products;

Provide an alternative cGMP production site in the event of regulatory compliance issues at primary manufacturing site; and

Specialized equipment or unique intellectual property possessed by the CMO.

ANI considers contract manufacturing to be an important component of its ongoing business strategy. Given its highly specialized manufacturing capabilities, ANI is focused on attracting niche contract manufacturing opportunities that fill idle capacity and offer higher margins.

**Marketing and Distribution**

ANI's products are distributed through the following channels:

***Wholesalers.*** ANI has contracts with four major wholesalers in the United States: Cardinal, McKesson, AmerisourceBergen and Morris Dickson, as well as access to their respective retail source programs.

***Retail Market Chains.*** ANI conducts business with the four major retail chains in the United States, including Walgreens, CVS, RiteAid and Wal-Mart.

***Distributors and Mail Order Pharmacies.*** ANI has contracts with several major distributors and mail order pharmacies in the United States including Anda, ExpressScripts and Omnicare.

***Hospital Market.*** ANI has contracts with group purchasing organizations in the United States, such as Premiere, MedAssets, Minnesota Multi-State and the Federal Supply Schedule (FSS).

Table of Contents

**Competition**

The U.S. pharmaceutical industry is highly competitive. ANI's primary competitors include other generic companies (both major multinational and regional companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent and other statutory expirations.

The primary means of competition among generic companies are pricing and contract terms, service levels, and supplier reliability. To compete effectively, ANI establishes active working relationships with each of its customers, continually gathers important market information in order to respond successfully to requests for proposals, maintains sufficient inventories to assure high service levels, and works to reduce product costs by sourcing and qualifying alternative suppliers whenever possible and rebidding product components on a routine basis.

ANI's sales can be impacted by new studies that indicate that a competitor's product has greater efficacy for treating a disease or particular form of a disease than one of ANI's products. If competitors introduce new products and processes with therapeutic or cost advantages, ANI's products can be subject to progressive price reductions and/or decreased volume of sales.

Principal competitors for the types of drugs in which ANI transacts business are as follows:

***Hormones and Steroids.*** Competition for hormone and steroidal drugs is limited because of the small number of plants in the United States capable of safely manufacturing these high-potency compounds. Key generic participants in hormone and steroidal drugs include Amneal Pharmaceuticals, Creekwood Pharmaceuticals, Endo Pharmaceuticals, Glenmark Pharmaceuticals, Watson Pharmaceuticals and Teva Pharmaceuticals USA.

***Oncolytics.*** Competitors for oncolytic products include both top-tier generic pharmaceutical companies as well as niche players. Key market participants include Mylan, Par Pharmaceutical Companies, Sandoz, the generic pharmaceuticals division of Novartis AG, Watson Pharmaceuticals and Teva Pharmaceuticals USA.

***Narcotics.*** Although market share in narcotic products is concentrated among two principal companies, i.e., Purdue Pharma and Mallinckrodt, several other companies with material market share in specific product categories within narcotics include Endo Pharmaceuticals, Roxane Laboratories and Watson Pharmaceuticals.

**Product Liability**

Product liability litigation represents an inherent risk to firms in the pharmaceutical industry. ANI utilizes traditional third-party insurance policies with regard to its product liability claims. Such insurance coverage at any given time reflects market conditions, including cost and availability, existing at the time the policy is written, and the decision to obtain commercial insurance coverage or to self-insure varies accordingly.

In February 2009, the FDA mandated a "black box" warning for the drug metoclopramide, specifically highlighting the risks of patients developing tardive dyskinesia, a movement disorder, when taking metoclopramide for longer than 12 weeks. As a result, numerous state-level lawsuits were brought against pharmaceutical manufacturers, both branded and generic, who had ever manufactured and/or sold metoclopramide. Among the defendants is ANI, which manufactures the generic version and since 2011 has been manufacturing the branded version under the name Reglan®. The plaintiffs in these lawsuits claim to have incurred bodily injuries as a result of ingestion of metoclopramide or Reglan® prior to the FDA's black box warning requirement. The allegations involve a failure, based on various state-level consumer protection laws, to adequately warn patients and doctors about the risks of using metoclopramide for longer than 12 weeks as evidenced by the FDA's mandate to strengthen the

Table of Contents

labeled warning. ANI has been named and served in 79 separate complaints between December 2009 and November 2012, including three in Pennsylvania, nine in New Jersey, and 67 in California, covering 2,921 plaintiffs in total. In August 2012, ANI was dismissed with prejudice as a defendant in all of the cases brought in New Jersey.

As the state-level litigation progressed, the generic pharmaceutical defendants appealed to the US Supreme Court arguing that generic companies could not comply with state laws that required them to strengthen their labels because generic companies are prohibited by federal law from making any changes except those adopted by the brand or mandated by FDA for all manufacturers, e.g. federal pre-emption. The US Supreme Court decided in favor of the generic companies in June 2011 in what is known now as the Mensing decision. While many cases have since been dismissed by state courts, several judges, including in Pennsylvania and California, have allowed the plaintiffs to resubmit their complaints.

At the present time, ANI's management is unable to assess the likely outcome of the remaining cases. ANI's insurance company has assumed the defense of this matter. In addition, ANI's insurance company renewed ANI's product liability insurance on September 1, 2011 and 2012 with absolute exclusions for claims related to Reglan® and metoclopramide. ANI cannot provide assurances that the outcome of these matters will not have an adverse effect on its business, results of operations, financial condition and cash flow. Furthermore, like all pharmaceutical manufacturers, ANI in the future may be exposed to other product liability claims, which could harm its business, results of operations, financial condition and cash flow.

**Suppliers and Raw Materials**

ANI sources the raw materials for its products, including active pharmaceutical ingredients (API) from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers must usually be approved through a Prior Approval Supplement by the FDA. As the API typically comprises the majority of a product's manufactured cost, and qualifying an alternative is costly and time-consuming, API suppliers must be selected carefully based on quality, reliability of supply and long-term financial stability. ANI's principal API suppliers include Mallinckrodt, Symbiotech Pharmalab, Johnson Matthey and Pfizer Centersource.

In addition, each year, ANI must submit a request to the Drug Enforcement Agency (DEA) for a quota to purchase the amount of active pharmaceutical ingredient needed to manufacture Opium Tincture. Without an approved quota from DEA, ANI would not be able to purchase this ingredient from its supplier. As a result, ANI is dependent upon the DEA to approve, on an annual basis, a quota of active pharmaceutical ingredient that is sufficiently large to support the continued manufacture of Opium Tincture.

**Employees**

ANI's workforce includes 69 full-time employees, including 36 salaried employees, and a flexible direct labor pool of 18 experienced pharmaceutical manufacturing and packaging staff. Of the full-time employees, 44 are in selling, general and administrative, 20 in production and five in research and development.

Table of Contents

## ANI'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of financial condition and results of operations should be read together with ANI's financial statements and condensed financial statements and accompanying notes appearing elsewhere in this joint proxy statement/prospectus. This discussion contains forward-looking statements, based on current expectations and related to future events and ANI's future financial performance, that involve risks and uncertainties. ANI's actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under "Risk Factors Risks Related to ANI" and "Risk Factors Risks Related to the Combined Company" and elsewhere in this joint proxy statement/prospectus.*

### Overview

ANI is a fully integrated specialty branded and generic pharmaceutical company developing, manufacturing and marketing branded and generic prescription pharmaceuticals. In two facilities with combined manufacturing, packaging and laboratory capacity totaling 173,000 square feet, ANI manufactures oral solid dose products, as well as liquids and topicals, including narcotics and those that must be manufactured in a fully contained environment due to their potency and/or toxicity. ANI also performs contract manufacturing for other pharmaceutical companies.

ANI's established product portfolio consists of both branded and generic pharmaceuticals, including:

| Generic Products | Branded Products |
|---|---|
| Opium Tincture | Cortenema® |
| Fluvoxamine Maleate Tablets | Reglan® Tablets |
| Esterified Estrogen with Methyltestosterone Tablets | |
| Hydrocortisone Enema | |
| Metoclopramide Syrup | |

ANI's business strategy is to utilize its manufacturing assets to develop and market niche generic pharmaceuticals, focusing on products in pain management (narcotics), anti-cancer (oncolytics), women's health (hormones and steroids), as well as complex formulations, including extended release and combination products. These areas of focus reflect ANI's specialized manufacturing experience and capabilities and offer a large number of attractive niche generic product opportunities.

ANI considers a variety of criteria in determining which products to develop, all of which influence the level of competition upon product launch. These criteria include:

***Formulation Difficulty.*** Potent, extended release, combination and low dosage products.

***Patent Status.*** Existing patent protection, if any, time remaining to patent expiration, and existing patent challenges.

***Market Size.*** Current and expected market size at launch based on forecasted price erosion upon conversion from branded to generic pricing.

***Profit Potential.*** Availability and cost of active pharmaceutical ingredients combined with forecasted market share.

***Manufacturing.*** Ability of ANI to manufacture in company-owned facilities.

***Competition.*** Existing and expected competitors.

Table of Contents

**Recent Developments**

In October 2012, ANI entered into a definitive merger agreement with BioSante pursuant to which the companies are to merge in an all-stock transaction. Under the terms of the agreement, upon completion of the merger, BioSante will issue to ANI stockholders shares of BioSante common stock such that the ANI stockholders will own approximately 53 percent of the combined company's shares outstanding, and the BioSante stockholders will own approximately 47 percent, subject to adjustment as provided in the merger agreement. In addition, immediately prior to the merger, BioSante plans to distribute to its then current stockholders contingent value rights (CVR) providing payment rights arising from a future sale, transfer, license or similar transaction(s) involving BioSante's LibiGel® (female testosterone gel). Upon completion of the merger, the combined company will be renamed ANI Pharmaceuticals, Inc. and will operate under the leadership of ANI's management team. The board of directors of the combined company is expected to have two directors from BioSante and five directors from ANI. The merger, which is subject to normal closing conditions including approval of the stockholders of both BioSante and ANI, is expect to close during the first quarter of 2013. Completion of the merger is subject to the number of customary conditions, including, but not limited to, the approval of the merger agreement by the BioSante and ANI stockholders. If any of the conditions to the merger are not satisfied or, where waiver is permissible not waived, the merger will not be consummated. For further details, please refer to the sections entitled "The Merger" and "The Merger Agreement" in this joint proxy statement/prospectus.

**Critical Accounting Policies and the Use of Estimates**

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on ANI's financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of these financial statements requires ANI to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, ANI evaluates these estimates and assumptions, including those described below. ANI bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

Some of the estimates and assumptions ANI has to make under GAAP require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding ANI's business operations, financial condition and results of operations.

***Revenue Recognition***

Revenue is recognized for product sales upon shipment and when estimates of discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured and ANI has no further performance obligations. These estimates reduce gross revenues to net revenues in the statements of operations, or are presented as current liabilities or reductions in accounts receivable in the balance sheets.

***Accruals for Chargebacks, Returns and Other Allowances***

ANI's generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, product returns, administrative fees, and other rebates and prompt payment discounts. ANI accrues for these items at the time of sale based on the estimates and methodologies

Table of Contents

described below. In the aggregate, these gross-to-net accruals exceed 65 percent of generic and branded gross product sales and reduce gross revenues to net revenues in the statements of operations, or are presented as current liabilities or reductions in accounts receivable in the balance sheets. ANI continually monitors and re-evaluates the accruals as additional information becomes available, which includes, among other things, updates to trade inventory levels and customer product mix. ANI makes adjustments to the accruals at the end of each reporting period, to reflect any such updates to the relevant facts and circumstances.

*Chargebacks*

Chargebacks, primarily from wholesalers, are the most significant of ANI's accruals. Chargebacks result from arrangements ANI has with indirect customers establishing prices for products which the indirect customer purchases through a wholesaler. Alternatively, ANI may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, ANI provides a chargeback credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price, typically Wholesale Acquisition Cost (WAC).

Chargeback credits are calculated as follows:

Prior period chargebacks claimed by wholesalers are analyzed to determine the actual average selling price (ASP) for each product. This calculation is performed by product by wholesaler. ASPs can be affected by several factors such as:

a change in customer mix;

a change in negotiated terms with customers;

a change in product sales mix;

a change in the volume of off-contract purchases; and

changes in WAC.

As necessary, ANI adjusts ASPs based on anticipated changes in the factors above.

The difference between ASP and WAC is recorded at the same time ANI recognizes revenue from the product sale as a reduction in both gross revenues and accounts receivable.

To evaluate the adequacy of its chargeback accruals, ANI obtains on-hand inventory counts from the wholesalers. This inventory is multiplied by the chargeback amount, the difference between ASP and WAC, to arrive at total expected future chargebacks, which is then compared to the chargeback accruals. ANI continually monitors chargeback activity and adjusts ASPs when it believes that actual selling prices will differ from current ASPs.

*Returns*

Consistent with industry practice, ANI maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date until up to one year after its expiration date. ANI's product returns are settled through the issuance of a credit to the customer. ANI's estimate for returns is based upon its historical experience with actual returns. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future returns. ANI continually monitors its estimates for returns and makes adjustments when it believes that actual product returns may differ from the established accruals.

Table of Contents

*Administrative Fees and Other Rebates*

Administrative fees or rebates are offered to wholesalers, group purchasing organizations and indirect customers, consistent with pharmaceutical industry practice. ANI accrues for fees and rebates, by product by wholesaler, at the time of sale based on contracted rates and ASPs.

To evaluate the adequacy of its administrative fee accruals, ANI obtains on-hand inventory counts from the wholesalers. This inventory is multiplied by the ASPs to arrive at total expected future sales, which is then multiplied by contracted rates. The result is then compared to the administrative fee accruals. ANI continually monitors administrative fee activity and adjusts its accruals when it believes that actual administrative fees will differ from the accruals.

*Prompt Payment Discounts*

Sales discounts are granted for prompt payment. The reserve for sales discounts is based on invoices outstanding. ANI assumes based on past experience that 100 percent of available discounts will be taken.

The following table summarizes activity in the balance sheet for accruals and allowances for the nine months ended September 30, 2012 and fiscal years ended December 31, 2011 and 2010:

| | Accruals for Chargebacks, Returns and Other Allowances | | | |
|---|---|---|---|---|
| | Chargebacks | Returns | Administrative Fees and Other Rebates | Prompt Payment Discounts |
| Balance at December 31, 2009 | $ 439,176 | $ | $ | $ |
| Accruals/Adjustments | 1,975,853 | 80,067 | 114,727 | 25,000 |
| Credits Taken Against Reserve | (1,664,571) | | (55,125) | |
| Balance at December 31, 2010 | $ 750,458 | $ 80,067 | $ 59,602 | $ 25,000 |
| Accruals/Adjustments | 13,005,579 | 356,364 | 672,882 | 446,187 |
| Credits Taken Against Reserve | (10,075,199) | (184,386) | (494,289) | (304,748) |
| Balance at December 31, 2011 | $ 3,680,838 | $ 252,045 | $ 238,195 | $ 166,439 |
| Accruals/Adjustments | 15,996,550 | 486,844 | 925,488 | 522,812 |
| Credits Taken Against Reserve | (15,348,165) | (351,274) | (892,370) | (481,435) |
| Balance at September 30, 2012 | $ 4,329,223 | $ 387,615 | $ 271,313 | $ 207,816 |

***Accounts Receivable***

ANI extends credit to customers on an unsecured basis. ANI utilizes the allowance method to provide for doubtful accounts based on management's evaluation of the collectability of accounts receivable. ANI provides an allowance for doubtful accounts equal to the estimated uncollectible amounts. ANI's estimate is based on historical collection experience and a review of the current status of trade accounts receivable. ANI determines trade receivables to be delinquent when greater than 30 days past due. Receivables are written off when it is determined that amounts are uncollectible. ANI determined that no allowance for doubtful accounts was necessary as of September 30, 2012 or December 31, 2011 and 2010.

**Recently Issued Accounting Standards**

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-05, Presentation of Comprehensive Income. ASU 2011-05 revises the manner in which entities present comprehensive income in their financial statements. The new guidance removes the presentation options in Accounting Standards Codification 220 and requires entities to report

Table of Contents

components of comprehensive income in either (1) a continuous statement of comprehensive income or (2) two separate but consecutive statements. ASU 2011-05 did not change the items that must be reported in other comprehensive income. ANI adopted the provisions of ASU 2011-05 in the first quarter of 2012. As ANI's net loss is the same as comprehensive loss, ANI did not present a statement of comprehensive loss.

**General**

The following table sets forth, for all periods indicated, the percentage relationship that items in ANI's Statements of Operations bear to net revenues.

| | Nine Months Ended September 30, | | Years Ended December 31, | |
|---|---|---|---|---|
| | 2012 | 2011 | 2011 | 2010 |
| Net revenues | 100.0% | 100.0% | 100.0% | 100.0% |
| Operating expenses | | | | |
| Cost of sales (exclusive of depreciation and amortization) | 41.8% | 40.8% | 41.5% | 38.5% |
| Salaries and benefits | 23.4% | 27.1% | 26.5% | 49.4% |
| Freight | 1.6% | 1.5% | 1.5% | 1.5% |
| Research and development | 4.2% | 6.1% | 4.8% | 0.9% |
| Selling, general and administrative | 19.7% | 23.0% | 22.5% | 35.8% |
| Depreciation and amortization | 2.8% | 3.3% | 3.2% | 5.4% |
| Operating income (loss) from continuing operations | 6.5% | (1.8)% | 0.0% | (31.5)% |
| Interest expense | 8.2% | 13.4% | 13.6% | 13.1% |
| Other expense | 1.3% | 2.1% | 2.3% | 1.5% |
| Net loss from continuing operations | (3.0)% | (17.3)% | (15.9)% | (46.1)% |
| Gain (loss) on discontinued operation | 0.7% | 2.4% | 1.2% | (57.1)% |
| Net loss | (2.3)% | (14.9)% | (14.7)% | (103.2)% |

The following table summarizes ANI's results of operations for the nine months ended September 30, 2012 and 2011 and the years ended December 31, 2011 and 2010.

| | Nine Months Ended September 30, | | Years Ended December 31, | |
|---|---|---|---|---|
| | 2012 | 2011 | 2011 | 2010 |
| Net revenues | $ 15,049,619 | $ 11,954,985 | $ 16,514,579 | $ 8,974,818 |
| Operating expenses | | | | |
| Cost of sales (exclusive of depreciation and amortization) | 6,292,377 | 4,875,692 | 6,860,551 | 3,456,999 |
| Salaries and benefits | 3,516,427 | 3,245,637 | 4,352,250 | 4,425,012 |
| Freight | 242,814 | 178,499 | 253,394 | 137,837 |
| Research and development | 636,726 | 726,960 | 799,302 | 84,762 |
| Selling, general and administrative | 2,961,649 | 2,744,334 | 3,711,669 | 3,214,706 |
| Depreciation and amortization | 425,238 | 391,917 | 532,768 | 486,315 |
| Operating income (loss) from continuing operations | $ 974,388 | $ (208,054) | $ 4,645 | $ (2,830,813) |
| Interest expense | 1,239,137 | 1,597,156 | 2,253,794 | 1,179,431 |
| Other expense | 190,605 | 254,006 | 384,555 | 138,061 |
| Net loss from continuing operations | $ (455,354) | $ (2,059,216) | $ (2,633,704) | $ (4,148,305) |
| Gain (loss) on discontinued operation | 104,120 | 291,096 | 205,545 | (5,124,805) |

| | | | | |
|---|---|---|---|---|
| Net loss | $ (351,234) | $ (1,768,120) | $ (2,428,159) | $ (9,273,110) |

Table of Contents

**Results of Operations for the Nine Months Ended September 30, 2012 and 2011**

***Net Revenues***

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2012 | 2011 | Change | % Change |
| ANI generic pharmaceutical products | $ 7,401,002 | $ 4,974,433 | $ 2,426,569 | 48.8% |
| ANI branded pharmaceutical products | 1,320,480 | 599,582 | 720,898 | 120.2% |
| Contract manufacturing | 5,701,893 | 5,884,512 | (182,619) | (3.1)% |
| Contract services and other income | 626,244 | 496,458 | 129,786 | 26.1% |
| Total net revenues | $ 15,049,619 | $ 11,954,985 | $ 3,094,634 | 25.9% |

ANI has historically derived substantially all of its revenues from sales of generic and branded pharmaceutical products, contract manufacturing and contract services, which includes product development services for potential contract customers, laboratory services for existing contract customers where those services are billed separately from contract manufacturing and royalties on net sales of certain contract manufactured products. Revenue for the nine months ended September 30, 2012 was $15.0 million compared to $12.0 million for the nine months ended September 30, 2011.

Revenue for the nine months ended September 30, 2012 increased $3.1 million, or 25.9 percent, compared to revenue for the nine months ended September 30, 2011, primarily as a result of the following factors:

Net revenues for ANI generic pharmaceutical products were $7.4 million in the nine months ended September 30, 2012, an increase of 48.8 percent compared to $5.0 million for the same period in 2011. The primary reasons for the increase were significant market share gains on Opium Tincture, Fluvoxamine Maleate tablets, and Esterified Estrogen with Methyltestosterone tablets. For Fluvoxamine Maleate and Esterified Estrogen with Methyltestosterone, the market share gains resulted from winning primary positions on wholesaler source programs through competitive bidding processes. For Opium Tincture, ANI secured additional market share due to a decrease in competition. Additional competition ordinarily has a negative impact on the pricing and volume of the affected products and, conversely, reduced competition ordinarily has a positive impact. In addition to the decrease in competition, the cost of the active pharmaceutical ingredient for Opium Tincture increased on January 1, 2012. This increased cost was passed along to ANI's end customers through finished product price increases. Increased sales of Hydrocortisone enema, and Metoclopramide oral solution also contributed to the positive results. Partially offsetting these increases was a decrease in average pricing for Esterified Estrogen with Methyltestosterone tablets as a result of ANI matching lower pricing offered by a competitor to an established ANI customer. As described in further detail under "Business  Government Regulation  Unapproved Pharmaceutical Products," ANI markets Opium Tincture and Esterified Estrogen with Methyltestosterone without FDA-approved New Drug Applications (NDAs). The FDA has stated that it will follow a risk-based approach, on a case-by-case basis, in deciding whether to take enforcement action against unapproved products, and ANI believes that so long as it complies with applicable manufacturing and labeling standards, the FDA will not take enforcement action against it with respect to the marketing of Opium Tincture and Esterified Estrogen with Methyltestosterone. However, there can be no assurance that the FDA will continue its policy or not take a contrary position with respect to such products. If the FDA were to take a contrary position, ANI may be required to seek FDA approval for Opium Tincture, Esterified Estrogen with Methyltestosterone, or both, or withdraw those products from the market. ANI's combined net revenues for Opium Tincture and Esterified Estrogen with Methyltestosterone for the nine months ended September 30, 2012 and

Table of Contents

2011 were $3.6 million and $2.2 million, respectively. In addition, if ANI decided to seek FDA approval, it would face increased expenses. In October 2012, ANI received a telephone call requesting a meeting with the FDA representatives from the Minneapolis district of the FDA to discuss continued manufacturing and distribution of Opium Tincture, which is an unapproved product.

Net revenues for ANI branded pharmaceutical products were $1.3 million in the nine months ended September 30, 2012, an increase of 120.2 percent compared to approximately $600,000 for the same period in 2011. In mid-2011, ANI acquired and launched Reglan® tablets, which contributed to revenue for all nine months ended September, 2012 but only for three of the nine months in the prior year period. Increased sales for Cortenema® also contributed to the increase.

Contract manufacturing revenues were $5.7 million in the first nine months of 2012, a decrease of 3.1 percent from $5.9 million for the corresponding period in 2011, due to decreased orders from contract manufacturing customers during the 2012 period. Abbott Laboratories, formerly Solvay Pharmaceuticals, is one of ANI's largest ongoing contract manufacturing customers, the loss of whom would have a material adverse effect on ANI's business. For 2011 and 2010, sales to Abbott Laboratories represented 15.6 percent and 41.6 percent of net revenues, respectively. The written agreement under which ANI performed contract manufacturing services for Abbott Laboratories expired in April 2012 and has not been renewed. ANI currently conducts its contract manufacturing services for Abbott Laboratories based on periodic individual purchase orders submitted by Abbot Laboratories to ANI, and there can be no assurance that Abbott Laboratories will continue submitting such orders and not choose another contract manufacturer for its products. In addition, one group of products that ANI manufactures on behalf of a contract customer is marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. ANI's contract manufacturing revenue for the group of unapproved products for the nine months ended September 30, 2012 and 2011 was $775,000 and $1.1 million, respectively.

Contract services and other income were approximately $626,000 in the first nine months of 2012, an increase of 26.1 percent from approximately $496,000 for the corresponding period in 2011, due to increased fees charged to contract manufacturing customers during the period. ANI receives royalties on the net sales of a group of contract-manufactured products, which are marketed by the contract customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. ANI's royalties on the net sales of these unapproved products for the nine months ended September 30, 2012 and 2011 were $220,000 and $249,000, respectively.

***Cost of Sales (Exclusive of Depreciation and Amortization)***

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | **2012** | **2011** | **Change** | **% Change** |
| Cost of sales (exclusive of depreciation and amortization) | $ 6,292,377 | $ 4,875,692 | $ 1,416,685 | 29.1% |

Cost of sales consists of direct labor, including manufacturing and packaging, active pharmaceutical ingredients, excipients and packaging components. Cost of sales does not include depreciation and amortization expense, which is reported as a separate component of operating expenses on ANI's statements of operations.

Table of Contents

For the nine months ended September 30, 2012, cost of sales increased to $6.3 million from $4.9 million for the corresponding 2011 period, an increase of $1.4 million or 29.1 percent, primarily as a result of an increase in sales of ANI generic and branded pharmaceutical products. Cost of sales as a percentage of net revenues increased to 41.8 percent during the nine months ended September 30, 2012 from 40.8 percent for the corresponding 2011 period, primarily as a result of the following factors:

- The cost of the active pharmaceutical ingredient for Opium Tincture increased on January 1, 2012. This increased cost was partially passed along to ANI's end customers.

- The average selling price for Esterified Estrogen with Methyltestosterone tablets decreased as a result of ANI matching lower pricing offered by a competitor.

ANI sources the raw materials for its products, including active pharmaceutical ingredients (API), from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers usually must be approved by the FDA, which approval can take 18 months or longer. As a result, ANI is dependent upon its current vendors to supply reliably the API required for ongoing product manufacturing. During the nine months ended September 30, 2012, ANI purchased approximately 43 percent of total costs of sales from two suppliers. As of September 30, 2012, amounts payable to these suppliers totaled $159,705.

Each year, ANI must submit a request to the Drug Enforcement Agency (DEA) for a quota to purchase the amount of API needed to manufacture Opium Tincture. Without an approved quota from DEA, ANI would not be able to purchase API from its supplier. As a result, ANI is dependent upon the DEA to annually approve a sufficient quota of API to support the continued manufacture of Opium Tincture.

***Other Operating Expenses***

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | **2012** | **2011** | **Change** | **% Change** |
| Salaries and benefits | $ 3,516,427 | $ 3,245,637 | $ 270,790 | 8.3% |
| Freight | 242,814 | 178,499 | 64,315 | 36.0% |
| Research and development | 636,726 | 726,960 | (90,234) | (12.4)% |
| Selling, general and administrative | 2,961,649 | 2,744,334 | 217,315 | (7.9)% |
| Depreciation and amortization | 425,238 | 391,917 | 33,321 | 8.5% |
| Total other operating expenses | $ 7,782,854 | $ 7,287,347 | $ 495,507 | 6.8% |

Other operating expenses consist of salaries and benefits, outbound freight, research and development costs, selling, general and administrative expenses, and depreciation and amortization. ANI expects other operating expenses to continue to increase in the future due to anticipated hiring of additional employees to support the activities associated with being a public company, assuming ANI's pending merger with BioSante is completed and to support anticipated additional revenue growth, as well as from anticipated additional research and product development costs.

For the nine months ended September 30, 2012, other operating expenses increased to $7.8 million from $7.3 million for the corresponding 2011 period, an increase of approximately $496,000 or 6.8 percent, primarily as a result of the following factors:

- Salaries and benefits increased from $3.2 million to $3.5 million, as a result of hiring new employees combined with increases in benefit costs, particularly health insurance.

- Freight expense increased from approximately $178,000 to $243,000 due to higher sales.

Table of Contents

Research and development expenses decreased from approximately $727,000 to $637,000, due to timing differences in product development schedules between the periods.

Selling, general and administrative expenses increased from $2.7 million to $3.0 million as a result of expenses incurred relating to ANI's pending merger with BioSante, which were partially offset by decreases in promotional allowances. Promotional allowances during the 2011 prior period were higher as a result of the launches of Esterified Estrogen with Methyltestosterone tablets and Opium Tincture.

Depreciation and amortization expense increased from approximately $392,000 to $425,000 as a result of an increase in manufacturing equipment.

Other operating expenses as a percentage of net revenues decreased to 51.7 percent during the nine months ended September 30, 2012 from 61.0 percent for the corresponding 2011 period, primarily as a result of ANI controlling these costs while increasing net revenues by $3.1 million during the same period.

***Other Expenses***

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | **2012** | **2011** | **Change** | **% Change** |
| Interest expense | $ 1,239,137 | $ 1,597,156 | $ (358,019) | (22.4)% |
| Other expense | 190,605 | 254,006 | (63,401) | (25.0)% |
| Total other expenses | $ 1,429,742 | $ 1,851,162 | $ (421,420) | (22.8)% |

Other expenses consist of interest expense associated with ANI's revolving line of credit and secured subordinated convertible notes, and other non-operating expenses including monitoring and advisory fees totaling $200,000 annually to certain of ANI's investors. See "Management of the Combined Company Following the Merger-Certain Relationships and Related Transactions" for further details.

Interest expense decreased from $1.6 million to $1.2 million as a result of the conversion on June 6, 2012 of all of the outstanding subordinated debt to Series D convertible preferred stock.

Other expense decreased from approximately $254,000 to $191,000 as a result of higher costs, including forbearance fees, in the 2011 prior period related to ANI's then-existing line of credit. ANI expects other expense to decrease assuming the completion of its pending merger with BioSante, which will terminate the monitoring and advisory fee agreements. At the closing of the merger, however, approximately $540,000 will be payable under the monitoring and advisory fee agreements, which amounts cover the accrued portion of monitoring and advisory fees as well as approximately $390,000 for overall management, deal structuring, financial advisory and due diligence services in connection with the merger. See "Management of the Combined Company Following the Merger  Certain Relationships and Related Transactions" for further details.

***Gain on Discontinued Operation***

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | **2012** | **2011** | **Change** | **% Change** |
| Gain on discontinued operation | $ 104,120 | $ 291,096 | $ (186,976) | (64.2)% |

Table of Contents

Gain on discontinued operation consists of revenue and expenses associated with ANI's over-the-counter pharmaceutical products operation in Gulfport, Mississippi. This operation was sold in September 2010.

For the nine months ended September 30, 2012, gain on discontinued operation decreased to approximately $104,000 from $291,000 for the corresponding 2011 period, primarily as a result of a recovery of bad debt and increased settlement activity with suppliers in 2011.

**Results of Operations for the Years Ended December 31, 2011 and 2010**

***Net Revenues***

| | Years Ended December 31, | | | |
|---|---|---|---|---|
| | 2011 | 2010 | Change | % Change |
| ANI generic pharmaceutical products | $ 6,852,338 | $ 1,394,006 | $ 5,458,332 | 391.6% |
| ANI branded pharmaceutical products | 952,439 | 233,567 | 718,872 | 307.8% |
| Contract manufacturing | 7,945,704 | 6,443,272 | 1,502,432 | 23.3% |
| Contract services and other income | 764,098 | 903,973 | (139,875) | (15.5)% |
| Total net revenues | $ 16,514,579 | $ 8,974,818 | $ 7,539,761 | 84.0% |

Revenue for the year ended December 31, 2011 increased to $16.5 million from $9.0 million in 2010, an increase of $7.5 million or 84.0 percent, primarily as a result of the following factors:

Net revenues for ANI generic pharmaceutical products were $6.9 million in the year ended December 31, 2011, an increase of 391.6 percent compared to $1.4 million for the same period in 2010. The primary reasons for the increase were the launches of Esterified Estrogen with Methyltestosterone tablets and Opium Tincture during 2011 as well as market share gains on Fluvoxamine Maleate tablets and Hydrocortisone enema, partially offset by lower sales for Metoclopramide oral solution. Please refer to the description under "Results of Operations for the Nine Months Ended September 30, 2012 and 2011 Net Revenues" for material uncertainties relating to ANI's marketing of Opium Tincture and Esterified Estrogen with Methyltestosterone. ANI's combined net revenues for Opium Tincture and Esterified Estrogen with Methyltestosterone for the years ended December 31, 2011 and 2010 were $3.5 million and $95,000, respectively.

Net revenues for ANI branded pharmaceutical products were approximately $952,000 in the year ended December 31, 2011, an increase of 307.8 percent compared to approximately $234,000 for the same period in 2010. In mid-2011, ANI acquired and launched Reglan® tablets, which contributed to net revenues for the six months ended December 31, 2011, as further explained above under "Results of Operations for the Nine Months Ended September 30, 2012 and 2011 Net Revenues." Increased sales for Cortenema® also contributed to the increase.

Contract manufacturing revenues were $7.9 million in the year ended December 31, 2011, an increase of 23.3 percent from $6.4 million for the corresponding period in 2010, due to increased orders totaling $2.3 million from contract manufacturing customers, partially offset by a decrease in orders from a single contract manufacturing customer during the period. Please refer to the description under "Results of Operations for the Nine Months Ended September 30, 2012 and 2011 Net Revenues" for material uncertainties relating to contract manufacturing services provided for Abbott Laboratories as well as material uncertainties relating to revenue from one of ANI's customer's marketing of a group of unapproved products. ANI's contract manufacturing revenue for the group of unapproved products for the years ended December 31, 2011 and 2010 was $1.3 million and $623,000, respectively.

Table of Contents

Contract services and other income were approximately $764,000 in the year ended December 31, 2011, a decrease of 15.5 percent from approximately $904,000 for the corresponding period in 2010, due to decreased laboratory service fees charged to contract manufacturing customers during the period, partially offset by increased fees charged for contract product development. Please refer to the description under "Results of Operations for the Nine Months Ended September 30, 2012 and 2011 Net Revenues" for material uncertainties relating to one of ANI's customer's marketing of its group of unapproved products. ANI's royalties on the net sales of these unapproved products for the years ended December 31, 2011 and 2010 were $320,000 and $118,000, respectively.

***Cost of Sales (Exclusive of Depreciation and Amortization)***

| | Years Ended December 31, | | | |
|---|---|---|---|---|
| | 2011 | 2010 | Change | % Change |
| Cost of sales (exclusive of depreciation and amortization) | $ 6,860,551 | $ 3,456,999 | $ 3,403,552 | 98.5% |

For the year ended December 31, 2011, cost of sales increased to $6.9 million from $3.5 million in 2010, an increase of $3.4 million or 98.5 percent, primarily as a result of an increase in sales of ANI generic and branded pharmaceutical products. Cost of sales does not include depreciation and amortization expense, which is reported as a separate component of operating expenses on ANI's statements of operations.

Cost of sales as a percentage of net revenues increased to 41.5 percent during year ended December 31, 2011 from 38.5 percent for the corresponding 2010 period, primarily as a result of a higher percentage of net revenues comprised of ANI's generic pharmaceutical products, which generally produce lower margins than contract manufacturing. Please refer to " Results of Operations for the Nine Months Ended September 30, 2012 and 2011 Cost of Sales" for a description of material uncertainties faced by pharmaceutical manufacturers, including ANI, with respect to their suppliers.

***Other Operating Expenses***

| | Years Ended December 31, | | | |
|---|---|---|---|---|
| | 2011 | 2010 | Change | % Change |
| Salaries and benefits | $ 4,352,250 | $ 4,425,012 | $ (72,762) | (1.6)% |
| Freight | 253,394 | 137,837 | 115,557 | 83.8% |
| Research and development | 799,302 | 84,762 | 714,540 | 843.0% |
| Selling, general and administrative | 3,711,669 | 3,214,706 | 496,963 | 15.5% |
| Depreciation and amortization | 532,768 | 486,315 | 46,453 | 9.6% |
| Total other operating expenses | $ 9,649,383 | $ 8,348,632 | $ 1,300,751 | 15.6% |

For the year ended December 31, 2011, other operating expenses increased to $9.6 million from $8.3 million in 2010, an increase of $1.3 million or 15.6 percent, primarily as a result of the following factors:

Salaries and benefits decreased by approximately $73,000, primarily as a result of concluding in 2010 severance payments to a former employee.

Freight expense increased from approximately $138,000 to $253,000 due to higher sales.

Research and development expenses increased from approximately $85,000 to $799,000, due to the initiation of ANI's internal product development program during 2011.

Table of Contents

Selling, general and administrative expenses increased from $3.2 million to $3.7 million as a result of increases in maintenance expenses, promotional allowances and utility costs. Maintenance expenses increased due to ANI's greater production volumes during 2011 compared to 2010. Promotional allowances during 2011 were higher as a result of the launch of Esterified Estrogen with Methyltestosterone tablets and Opium Tincture during the period. Utility costs increased due to higher production volumes as well as significant rate hikes in March 2011 from ANI's electricity providers.

Depreciation and amortization expense increased from approximately $486,000 to $533,000 as a result of an increase in manufacturing equipment.

***Other Expenses***

| | Years Ended December 31, | | | |
|---|---|---|---|---|
| | **2011** | **2010** | **Change** | **% Change** |
| Interest expense | $ 2,253,794 | $ 1,179,431 | $ 1,074,363 | 91.1% |
| Other expense | 384,555 | 138,061 | 246,494 | 178.5% |
| Total other expenses | $ 2,638,349 | $ 1,317,492 | $ 1,320,857 | 100.3% |

For the year ended December 31, 2011, other expenses increased to $2.6 million from $1.3 million in 2010, an increase of $1.3 million or 100.3 percent, primarily as a result of the following factors:

Interest expense increased from $1.2 million to $2.3 million as a result of increases in the amount of secured subordinated convertible notes on ANI's balance sheet.

Other expense increased from approximately $138,000 to $384,000. In 2011, ANI entered into an agreement to pay monitoring and advisory fees totaling $200,000 annually to certain of ANI's investors. See "Management of the Combined Company Following the Merger  Certain Relationships and Related Transactions" for further details.

***Gain (Loss) on Discontinued Operation***

| | Years Ended December 31, | | | |
|---|---|---|---|---|
| | **2011** | **2010** | **Change** | **% Change** |
| Gain (loss) on discontinued operation | $ 205,545 | $ (5,124,805) | $ 5,330,350 | 104.0% |

For the year ended December 31, 2011, gain (loss) on discontinued operation was a gain of approximately $206,000 versus a loss of $5.1 million in 2010. Upon the sale in October 2010 of the Gulfport, Mississippi operation, ANI recognized a loss for the difference between the consideration received from the sale and the carrying value of the operation's net assets on the date of sale. The gain in 2011 resulted from a recovery of bad debt and increased settlement activity with suppliers.

Table of Contents

**Liquidity and Capital Resources**

The following table highlights selected liquidity and working capital information from ANI's balance sheets.

| | September 30, 2012 | December 31, 2011 | 2010 |
|---|---|---|---|
| Cash and cash equivalents | $ 148,331 | $ | $ |
| Accounts receivable, net | 5,622,997 | 5,104,568 | 1,689,203 |
| Inventories | 2,494,635 | 2,107,463 | 2,361,990 |
| Prepaid expenses | 402,335 | 224,618 | 978,408 |
| Total current assets | $ 8,668,298 | $ 7,436,649 | $ 5,029,601 |
| Accounts payable | $ 1,296,220 | $ 1,208,323 | $ 1,638,226 |
| Accrued expenses | 876,712 | 824,011 | 338,422 |
| Returned goods reserve | 387,615 | 252,045 | 80,067 |
| Borrowing under line of credit | 3,428,776 | 3,064,414 | 1,722,678 |
| Current maturities of long-term debt | | | 400,000 |
| Notes payable | | 300,000 | 275,000 |
| Current liabilities of discontinued operation | 378,565 | 512,275 | 1,500,693 |
| Total current liabilities | $ 6,367,888 | $ 6,161,068 | $ 5,955,086 |

At September 30, 2012, ANI had approximately $148,000 in cash, cash equivalents and short-term investments and unused availability under its line of credit of approximately $1.6 million. At December 31, 2011, ANI had zero cash, cash equivalents and short-term investments and approximately $36,000 of unused availability under its then-existing line of credit.

ANI's primary cash requirements are to fund operations, including research and development programs, and support general and administrative activities. ANI's future capital requirements will depend on many factors, including, but not limited to:

- proportions of net revenues comprised of contract manufacturing and sales of ANI generic and branded products;
- pricing and payment terms with customers;
- costs of raw materials and payment terms with suppliers;
- capital expenditures and equipment purchases to support product launches; and
- business and product acquisitions.

Consolidation among wholesale distributors, chain drug stores and group purchasing organizations has resulted in a smaller number of companies each controlling a larger share of pharmaceutical distribution channels. ANI's net revenues are concentrated among three customers representing 24 percent, 21 percent and 12 percent of net revenues, respectively, during the nine months ended September 30, 2012. As of September 30, 2012, accounts receivable from these three customers totaled $3.6 million, or approximately 64 percent of ANI's net accounts receivable. ANI's net revenues for those same three customers were 21 percent, 16 percent and 16 percent for the year ended December 31, 2011 and six percent, four percent and 42 percent for the year ended December 31, 2010. As of December 31, 2011 and 2010, accounts receivable from these three customers totaled $3.2 million or approximately 63 percent of net accounts receivable, and $840,000 or approximately 50 percent of net accounts receivable, respectively. As a result, negotiated payment terms with these customers have a material impact on ANI's liquidity and working capital.

234

Table of Contents

Two of ANI's generic pharmaceutical products, Opium Tincture and Fluvoxamine Maleate tablets, account for approximately 30 percent of ANI's net revenues. As a result, market pricing for these products, combined with the costs of raw materials and payment terms with suppliers, have a material impact on ANI's liquidity and working capital.

Other than during the nine months ended September 30, 2012, ANI has not generated positive cash flows from operations. To bridge the gap between revenues and operating and capital needs, ANI has relied on a variety of financing sources, including the issuance of equity securities and convertible notes and revolving lines of credit. Based on projected revenue and expenses for the next twelve months, ANI anticipates that current cash on hand and borrowing availability under its revolving line of credit will be sufficient to meet ongoing expenses and capital requirements at least through December 31, 2013, assuming the pending merger with BioSante is not completed. Assuming the merger is completed, ANI anticipates that its current resources, combined with the additional cash, expected future licensing revenues, and other assets of BioSante, will be sufficient to meet ongoing expenses and capital requirements at least through December 31, 2015. If ANI's assumptions underlying estimated revenue and expenses prove to be wrong or if its cash requirements change materially as a result of shifts in its business and strategy, ANI or the combined company, as the case may be, may require additional financing to fund operating and capital requirements, and may require such financing prior to the dates specified above.

The continuing global economic uncertainty, exacerbated by the European debt crisis and the "fiscal cliff" in the United States, has resulted in extreme volatility in the capital markets and is threatening to once again tighten the credit markets. As a result, there can be no assurance that future funding will be available to ANI on reasonably acceptable terms, or at all.

ANI has incurred cumulative net losses and expects to incur additional losses in conducting further research and development activities. ANI has relatively limited capital resources. ANI's plans with regard to these matters include raising additional capital through the issuance of equity securities, debt securities, or both, increasing net revenues through product acquisitions, new product launches, reducing manufacturing costs and completion of the planned merger with BioSante. Although ANI continues to pursue these plans, there is no assurance that sufficient future financing will be available on commercially reasonable terms or at all, that ANI will be able to generate sufficient revenue or that ANI will be able to lower its manufacturing costs. ANI's consolidated financial statements have been prepared on a basis that assumes that it will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. These statements do not include any adjustments that might result if the carrying amount of recorded assets and liabilities are not realized.

***Sources and Uses of Cash***

*Debt Financing*

ANI utilizes a revolving line of credit to finance its operations. Under the line of credit in place at December 31, 2011, ANI's borrowings were based on a percentage of eligible accounts receivable and inventory, up to a maximum of $3.5 million. Without considering the $3.5 million limit, but applying the applicable percentage to eligible accounts receivable and inventory, ANI could have borrowed up to $4.9 million at December 31, 2011. As a result of the loan limit restriction and other factors, on June 6, 2012, ANI refinanced its line of credit with a new lender, Alostar Bank of Commerce.

Under the new arrangement, ANI may borrow on a revolving basis, based on a percentage of eligible accounts receivable and inventory, up to a maximum of $5.0 million. The loan agreement bears interest daily at the greater of (i) LIBOR plus 5 percent or (ii) 6 percent. The line of credit is secured by substantially all of ANI's assets. The principal is repayable at the termination date, unless accelerated as a result of certain events of default. If ANI generates any proceeds from the collateral

Table of Contents

securing the line of credit, such proceeds must be paid to the lender up to the amount of any outstanding balance. Interest is due and payable on the first of every month and at the termination date, unless accelerated as a result of an event of default. In addition, a usage fee equal to 0.375 percent per annum of the unused amounts under the facility and a management fee equal to $18,000 per annum are assessed monthly. The revolving loan agreement expires in June 2015, but can be terminated early in the following circumstances: (a) automatically upon the commencement of insolvency proceedings by or against ANI, (b) at the option of the lender without notice upon any other event of default, and (c) at the option of ANI upon ten business days' prior written notice.

In the event of early termination, whether effected by ANI, the lender or automatically, ANI is obligated to pay an amount corresponding to a percentage of $5.0 million, with such percentage being: 3 percent if termination occurs in the first year, 2 percent if termination occurs in the second year and 1 percent if termination occurs after the second year but prior to the last day of the term.

The loan agreement contains customary representations, warranties and covenants.

ANI must maintain a minimum fixed charge coverage ratio of 1.1 to 1.0, calculated by dividing (a) (i) Earnings before Interest, Taxes, Depreciation and Amortization (EBITDA) less (ii) unfinanced capital expenditures, by (b) the sum of cash paid for (i) interest and (ii) monitoring and advisory fees (See "Management of the Combined Company Following the Merger  Certain Relationships and Related Transactions.") Also, ANI must generate at least $800,000 in EBITDA, measured on a trailing four-quarter basis. Restrictive covenants apply to, among other things, research and development expenditures, incurrence of additional indebtedness, prepayment of other indebtedness, additional liens, acquisitions, mergers or consolidations and sales of assets.

The representations, warranties and covenants contained in the loan agreement were made only for purposes of such agreement and as of a specific date or specific dates, were solely for the benefit of the parties to such agreement, and may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures exchanged between the parties in connection with the execution of the loan agreement.

Events of default under the agreement include, but are not limited to: (i) liquidation, bankruptcy or similar events; (ii) failure to pay any debts due on a timely basis; (iii) failure to observe any covenant or condition under the loan agreement, which failure, in most cases, is not cured within 30 days of written notice by lender; (iv) material misrepresentations; (v) ANI is restrained by court order from continuing to conduct all or any material part of ANI's business; (vi) certain money judgments are entered against ANI; and (vii) ANI challenges the validity or enforceability of the loan agreement in any proceeding. Remedies for events of default include acceleration of amounts owing under the loan agreement and taking immediate possession of, and selling, any collateral securing the loan.

As of September 30, 2012, approximately $3.4 million was outstanding under the loan agreement, at an effective interest rate of 6.0 percent. ANI was in compliance with all of the covenants under the loan agreement as of September 30, 2012 and expects to remain in compliance with such covenants during the remainder of 2012.

At September 30, 2012, ANI had approximately $148,000 in cash, cash equivalents and short-term investments and unused availability under its line of credit of approximately $1.6 million. At December 31, 2011, ANI had zero cash, cash equivalents and short-term investments and approximately $36,000 of unused availability under its then-existing line of credit.

*Equity Financing*

In 2009, ANI issued $2,502,814 of secured subordinated convertible notes, referred to as the 2009 convertible notes. The 2009 convertible notes, which bore interest at 10 percent per annum, were due

Table of Contents

on September 3, 2011. Interest on the 2009 convertible notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The 2009 convertible notes were secured by a second lien on substantially all of ANI's assets and included financial covenants and limitations on ANI's ability to enter into certain transactions while the 2009 convertible notes were outstanding.

In 2010, ANI issued $8,474,952 of secured subordinated convertible notes, referred to as the 2010 convertible notes. The 2010 convertible notes, which bore interest at 14 percent per annum, were due on September 3, 2011. Interest on the 2010 convertible notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The 2010 convertible notes were secured by a second lien on substantially all of ANI's assets and included financial covenants and limitations on ANI's ability to enter into certain transactions while the 2010 convertible notes were outstanding.

In 2011, ANI issued $2,694,295 of secured subordinated convertible notes, referred to as the 2011 convertible notes, and consolidated all of the outstanding 2009 and 2010 convertible notes into 2011 convertible notes, which are collectively referred to as the consolidated 2011 convertible notes. The consolidated 2011 convertible notes, which bore interest at 14 percent per annum, were due on December 31, 2012. Interest on the consolidated 2011 convertible notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The consolidated 2011 convertible notes were secured by a second lien on substantially all of ANI's assets and included financial covenants and limitations on ANI's ability to enter into certain transactions while the consolidated 2011 convertible notes were outstanding.

On June 6, 2012, the holders converted all of the outstanding 2011 convertible notes and accrued interest into shares of ANI series D preferred stock. As of September 30, 2012, no convertible notes remained outstanding.

***Net Cash Provided by (Used in) Operating Activities***

Net cash provided by operating activities was approximately $422,000 for the nine months ended September 30, 2012 compared to $1.9 million used in operating activities during the nine months ended September 30, 2011, an increase of $2.3 million between the periods. This increase was due to changes in current assets and current liabilities and changes in net loss. Increases in current assets and decreases in current liabilities (in each case a use of cash) for the nine months ended September 30, 2012 totaled $680,000 compared to $1.9 million for the nine months ended September 30, 2011, a decrease of approximately $1.2 million between the periods. Also, ANI's net loss from continuing operations, after adjusting for non-cash interest relating to convertible debt, decreased by $1.1 million between the periods.

Net cash used in operating activities was $3.1 million for the year ended December 31, 2011 compared to $2.9 million for the year ended December 31, 2010, an increase of approximately $193,000 between the periods. This increase was due to changes in current assets and current liabilities and changes in net loss. Increases in current assets and decreases in current liabilities (in each case a use of cash) in 2011 totaled $3.0 million compared to approximately $225,000 in 2010, an increase of $2.7 million between the periods. Offsetting this increase was a $2.5 million decrease in ANI's net loss from continuing operations, after adjusting for non-cash interest relating to convertible debt, between the periods.

***Net Cash Used in Investing Activities***

Net cash used in investing activities was approximately $77,000 for the nine months ended September 30, 2012, which related primarily to capital expenditures. Net cash used in investing

Table of Contents

activities was approximately $259,000 for the nine months ended September 30, 2011, which included capital expenditures and the acquisition in mid-2011 of Reglan® tablets.

Net cash used in investing activities was approximately $288,000 for the year ended December 31, 2011 compared to approximately $434,000 for the year ended December 31, 2010. Net cash used in investing activities decreased by approximately $146,000 primarily due to decreases in capital equipment purchases, partially offset by an increase related to the acquisition in mid-2011 of Reglan® tablets.

***Net Cash Provided by Financing Activities***

Net cash used in financing activities was approximately $196,000 for the nine months ended September 30, 2012, which included approximately $364,000 in increased borrowings under ANI's revolving line of credit, net of payment of debt issuance costs of approximately $261,000 and approximately $300,000 in note payable repayments. Net cash provided by financing activities was $2.2 million for the nine months ended September 30, 2011, which included approximately $950,000 in increased borrowings under ANI's revolving line of credit and $1.8 million from the issuance of convertible notes, net of approximately $575,000 in term loan repayments.

Net cash provided by financing activities was $3.4 million for the year ended December 31, 2011, which included $1.3 million in increased borrowings under ANI's revolving line of credit, $2.7 million from the issuance of convertible notes, and approximately $25,000 in notes payable issuances, net of approximately $633,000 in term loan repayments. Net cash provided by financing activities was $3.4 million for the year ended December 31, 2010, which included $8.5 million from the issuance of convertible notes and approximately $275,000 from the issuance of notes payable, net of $2.4 million in decreased borrowings under ANI's revolving line of credit and $3.0 million in term loan repayments.

**Off-Balance Sheet Arrangements**

As of September 30, 2012 and 2011, and December 31, 2011 and 2010, ANI did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

Table of Contents

**UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION**

The following unaudited pro forma condensed combined financial data is intended to show how the merger might have affected historical financial statements if the merger had been completed on January 1, 2011 for the purposes of the statements of operations and September 30, 2012 for the purposes of the balance sheet, and was prepared based on the historical financial results reported by BioSante and ANI. The following should be read in conjunction with the audited and unaudited historical financial statements of each of BioSante and ANI and the notes thereto beginning on pages F-1 and F-47, respectively, and the sections entitled "BioSante's Management's Discussion and Analysis of Financial Condition and Results of Operations" and "ANI's Management's Discussion and Analysis of Financial Condition and Results of Operations", and the other information contained in this joint proxy statement/prospectus. The following information does not give effect to the reverse stock split of BioSante common stock and BioSante class C special stock described in BioSante Proposal No. 2.

The merger will be accounted for as a reverse acquisition under the accounting rules for business combinations. Under the reverse acquisition method of accounting, ANI will be treated as the accounting acquiror and BioSante will be treated as the "acquired" company for financial reporting purposes because, immediately upon completion of the merger, ANI stockholders prior to the merger will hold a majority of the voting interest of the combined company. In addition, the seven member board of directors of the combined company will be comprised of five of the current members of the ANI board of directors; and therefore, ANI's current board of directors will possess majority control of the board of directors of the combined company. Members of the current management of ANI will be responsible for the management of the combined company and the majority of the combined company's activities will be activities related to ANI's current business.

The unaudited pro forma condensed combined financial statements were prepared in accordance with the regulations of the SEC. The pro forma adjustments reflecting the completion of the merger are based upon the reverse acquisition method of accounting in accordance with GAAP, and upon the assumptions set forth in the notes to the unaudited pro forma condensed combined financial statements.

The unaudited pro forma condensed combined balance sheet as of September 30, 2012 combines the historical balance sheets of BioSante and ANI as of September 30, 2012 and gives pro forma effect to the merger as if it had been completed on September 30, 2012.

The unaudited pro forma condensed combined statements of operations for the nine months ended September 30, 2012 combine the unaudited historical statements of operations of BioSante and ANI for their respective nine-month periods ended September 30, 2012 and gives pro forma effect to the merger as if it had been completed on January 1, 2011. The unaudited pro forma condensed combined statements of operations for the year ended December 31, 2011 combine the historical statements of operations of BioSante and ANI for their respective twelve months ended December 31, 2011 and gives pro forma effect to the merger as if it had been completed on January 1, 2011.

The historical financial data has been adjusted to give pro forma effect to events that are (i) directly attributable to the merger, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results. The pro forma adjustments are preliminary and based on management's estimates of the fair value and useful lives of the assets acquired and liabilities assumed and have been prepared to illustrate the estimated effect of the acquisition and certain other adjustments.

The unaudited pro forma condensed combined financial data is presented for illustrative purposes only and is not necessarily indicative of the financial condition or results of operations of future periods or the financial condition or results of operations that actually would have been realized had the

Table of Contents

entities been combined during the periods presented. In addition, as explained in more detail in the accompanying notes to the unaudited pro forma condensed combined financial statements, the preliminary acquisition-date fair value of the identifiable assets acquired and liabilities assumed reflected in the unaudited pro forma condensed combined financial statements is subject to adjustment and may vary from the actual amounts that will be recorded upon completion of the merger.

Table of Contents

**UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET**

| | As of September 30, 2012 | | | |
|---|---|---|---|---|
| | BioSante Historical | ANI Historical | Pro Forma Adjustments | Pro Forma Combined |
| | (in thousands) | | | |
| **ASSETS** | | | | |
| CURRENT ASSETS | | | | |
| Cash and cash equivalents | $ 38,049 | $ 148 | $ | $ 38,197 |
| Accounts receivable, net | | 5,623 | | 5,623 |
| Inventories, net | | 2,495 | | 2,495 |
| Prepaid expenses | 534 | 402 | | 936 |
| | **38,583** | **8,668** | | **47,251** |
| PROPERTY AND EQUIPMENT, NET | **1,185** | **4,793** | | **5,978** |
| OTHER ASSETS | | | | |
| Investments | 3,414 | | | 3,414 |
| Deposits | 30 | | | 30 |
| Intangible assets, net | | 98 | 19,535 (B) | 19,633 |
| | **$ 43,212** | **$ 13,559** | **19,535** | **76,306** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | | | |
| CURRENT LIABILITIES | | | | |
| Accounts payable | $ 2,005 | $ 1,296 | $ | $ 3,301 |
| Accrued compensation | 464 | | 3,900 (F) | 4,364 |
| Other accrued expenses | 752 | 877 | 2,800 (E) | 4,429 |
| Returned goods reserve | | 388 | | 388 |
| Borrowings under line of credit | | 3,429 | | 3,429 |
| Convertible senior notes | 7,593 | | | 7,593 |
| Interest due on convertible senior notes | 108 | | | 108 |
| Current liabilities of discontinued operations | | 378 | | 378 |
| TOTAL LIABILITIES | **10,922** | **6,368** | **6,700** | **23,990** |
| Redeemable convertible preferred stock | | **46,155** | **(46,155)**(D) | |
| STOCKHOLDERS' EQUITY | | | | |
| Capital stock | | | | |
| Issued and outstanding: | | | | |
| Class C common stock | | | | |
| Common stock | 273,260 | 2 | (2)(C) | |
| | | | 46,155 (D) | |
| | | | (225,951)(A) | |
| | | | 6,154 (K) | |
| Additional paid in capital | | 1,082 | (1,082)(C) | |
| | **273,260** | **1,084** | **(174,726)** | **99,618** |
| Accumulated deficit | (240,970) | (40,048) | 240,970 (A) | (47,302) |
| | | | (1,100)(E) | |
| | | | (6,154)(K) | |
| TOTAL STOCKHOLDERS' EQUITY | **32,290** | **(38,964)** | **58,990** | **52,316** |
| | **$ 43,212** | **$ 13,559** | **$ 19,535** | **$ 76,306** |

241

Table of Contents

**UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENTS OF OPERATIONS**

**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2012**

| | BioSante Historical | ANI Historical | Pro Forma Adjustments | Pro Forma Combined |
|---|---|---|---|---|
| | | (in thousands) | | |
| REVENUE | | | | |
| Licensing revenue | $ | $ | $ | $ |
| Royalty revenue | 333 | | | 333 |
| Product revenues | | 15,050 | | 15,050 |
| | **333** | **15,050** | | **15,383** |
| OPERATING EXPENSES | | | | |
| Cost of sales (excluding depreciation and amortization) | | 6,292 | | 6,292 |
| Salaries and benefits | 4,802 | 3,516 | | 8,318 |
| Freight | | 243 | | 243 |
| Research and development | 11,101 | 637 | | 11,738 |
| Selling, general and administrative | 3,879 | 2,962 | (514)(E) | 6,327 |
| Licensing expense | | | | |
| Depreciation and amortization | 88 | 425 | 1,832(G) | 2,345 |
| | **19,870** | **14,075** | **1,318** | **35,263** |
| OTHER | | | | |
| Convertible note fair value adjustment | (4,037) | | | (4,037) |
| Interest expense | (283) | (1,239) | | (1,522) |
| Other income (expense) | | (191) | | (191) |
| Interest income | 5 | | | 5 |
| NET LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAX BENEFIT | **(23,852)** | **(455)** | **(1,318)** | **(25,625)** |
| Income tax benefit | 122 | | (I) | 122 |
| NET LOSS FROM CONTINUING OPERATIONS | **(23,730)** | **(455)** | **(1,318)** | **(25,503)** |
| DISCONTNIUED OPERATIONS | | | | |
| Gain on discontinued operations | | 104 | | 104 |
| NET LOSS | **$ (23,730)** | **$ (351)** | **$ (1,318)** | **$ (25,399)** |
| NET LOSS FROM CONTINUING OPERATIONS | **$ (23,730)** | **$ (455)** | **$ (1,318)** | **$ (25,503)** |
| PREFERRED STOCK DIVIDENDS | | **(4,327)** | **4,327(J)** | |
| NET LOSS FROM CONTINUING OPERATIONS AVAILABLE TO COMMON SHAREHOLDERS | **$ (23,730)** | **$ (4,782)** | **$ 3,009** | **$ (25,503)** |
| BASIC AND DILUTED NET LOSS PER SHARE | **$ (1.14)** | | | **$ (0.52)** |
| WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING | **20,841** | | **27,915(H)** | **48,756** |

Table of Contents

**UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENTS OF OPERATIONS**

**FOR THE YEAR ENDED DECEMBER 31, 2011**

| | BioSante Historical | ANI Historical | Pro Forma Adjustments | Pro Forma Combined |
|---|---|---|---|---|
| | | (in thousands) | | |
| REVENUE | | | | |
| Licensing revenue | $ 100 | $ | $ | $ 100 |
| Royalty revenue | 335 | | | 335 |
| Product revenues | | 16,515 | | 16,515 |
| | **435** | **16,515** | | **16,950** |
| OPERATING EXPENSES | | | | |
| Cost of sales (excluding depreciation and amortization) | | 6,861 | | 6,861 |
| Salaries and benefits | 8,234 | 4,352 | | 12,586 |
| Freight | | 253 | | 253 |
| Research and development | 38,324 | 799 | | 39,123 |
| Selling, general and administrative | 4,606 | 3,712 | | 8,318 |
| Licensing expense | 50 | | | 50 |
| Depreciation and amortization | 148 | 533 | 2,442(G) | 3,123 |
| | **51,362** | **16,510** | **2,442** | **70,314** |
| OTHER | | | | |
| Convertible note fair value adjustment | (23) | | | (23) |
| Interest expense | (682) | (2,254) | | (2,936) |
| Other income (expense) | 15 | (385) | | (370) |
| Interest income | 8 | | | 8 |
| NET LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAX BENEFIT | **(51,609)** | **(2,634)** | **(2,442)** | **(56,685)** |
| Income tax benefit | | | (I) | |
| NET LOSS FROM CONTINUING OPERATIONS | **(51,609)** | **(2,634)** | **(2,442)** | **(56,685)** |
| DISCONTNIUED OPERATIONS | | | | |
| Gain on discontinued operations | | 206 | | 206 |
| NET LOSS | **$ (51,609)** | **$ (2,428)** | **$ (2,442)** | **$ (56,479)** |
| NET LOSS FROM CONTINUING OPERATIONS | **$ (51,609)** | **$ (2,634)** | **$ (2,442)** | **$ (56,685)** |
| PREFERRED STOCK DIVIDENDS | | **(2,280)** | **2,280(J)** | |
| NET LOSS FROM CONTINUING OPERATIONS AVAILABLE TO COMMON SHAREHOLDERS | **$ (51,609)** | **$ (4,914)** | **$ (162)** | **$ (56,685)** |
| BASIC AND DILUTED NET LOSS PER SHARE | **$ (3.15)** | | | **$ (1.28)** |
| WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING | **16,398** | | **27,915(H)** | **44,313** |

Table of Contents

**NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION**

**1. Description of Transaction and Basis of Presentation**

***Description of Transaction***

On October 3, 2012, BioSante entered into the merger agreement with ANI. Pursuant to the terms and subject to the conditions set forth in the merger agreement, ANI will be merged with and into BioSante, and BioSante will survive as the continuing entity.

At the effective time of the merger, each outstanding share of capital stock of ANI will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation, and all options, warrants or other rights to purchase shares of capital stock of ANI, will be canceled without consideration therefor, except for certain warrants which although not cancelled will not represent the right to acquire any equity or other interest in the combined company after the merger. No fractional shares of BioSante common stock will be issued in connection with the merger, and holders of ANI capital stock will be entitled to receive cash in lieu thereof.

Upon completion of the merger, ANI stockholders are expected to receive shares of BioSante common stock representing an aggregate of approximately 53 percent of the outstanding shares of common stock of the combined company. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger, and thus will not be determined until that time. If BioSante has more than $18.0 million of net cash as of the determination date, then the percentage ownership of the current BioSante stockholders will be increased on a pro rata basis by 0.6 percent for each $1.0 million of net cash excess, which would dilute further the ownership of the current ANI stockholders in the combined company. If BioSante has less than $18.0 million of net cash as of the determination date, then the percentage ownership of current BioSante stockholders will be decreased on a pro rata basis by 0.6 percent for each $1.0 million of net cash shortfall, which would dilute further the ownership of the current BioSante stockholders in the combined company. In no event, however, will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. In addition, one of the conditions to ANI's obligations to complete the merger is BioSante's net cash as of the closing date being no less than $17.0 million as calculated and as adjusted pursuant to the provisions of the merger agreement.

Pursuant to the terms of ANI's certificate of incorporation, (i) before any amounts are paid to the holders of shares of any other series of ANI preferred stock or ANI common stock, the holders of shares of ANI series D preferred stock are entitled to receive an amount per share equal to $30.00 plus all declared but unpaid dividends; (ii) before any amounts are paid to the holders of shares of ANI series B preferred stock, ANI series A preferred stock or ANI common stock, the holders of shares of ANI series C preferred stock are entitled to receive an amount per share equal to $110.00 plus all declared but unpaid dividends; (iii) before any amounts are paid to the holders of shares of ANI series A preferred stock or ANI common stock, the holders of shares of ANI series B preferred stock are entitled to receive an amount per share equal to $110.00 plus all declared but unpaid dividends; (iv) before any amounts are paid to the holders of shares of ANI common stock, the holders of shares of ANI series A preferred stock are entitled to receive an amount per share equal to $100.00 plus all declared but unpaid dividends; and (v) after payments have been made to all holders of ANI preferred

Table of Contents

**NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION (Continued)**

**1. Description of Transaction and Basis of Presentation (Continued)**

stock, the remaining assets of ANI will be distributed ratably to the holders of ANI common stock, including holders of ANI series C preferred stock, ANI series B preferred stock and ANI series A preferred stock who elect to convert into ANI common stock in lieu of receiving the stated dollar preference amounts described above, and ANI series D preferred stock. The stated value of each series of ANI preferred stock set forth above is subject to adjustment as provided in ANI's certificate of incorporation. The exchange ratios in the merger agreement reflect these preferential payments. As a result of such provisions, it is likely that holders of shares of ANI series A preferred stock, ANI series B preferred stock, ANI series C preferred stock or ANI common stock will not receive any shares of BioSante common stock in connection with the merger.

***Basis of Presentation***

The unaudited pro forma condensed combined financial statements were prepared in accordance with the regulations of the SEC and are intended to show how the merger might have affected the historical financial statements if the merger had been completed on January 1, 2011 for the purposes of the statements of operations and September 30, 2012 for the purposes of the balance sheet. The pro forma adjustments reflecting the completion of the merger are based upon the accounting rules for business combinations, specifically, the reverse acquisition method of accounting in accordance with GAAP, and upon the assumptions set forth herein. Based on the terms of the merger, ANI is deemed to be the accounting acquiror.

Under the reverse acquisition method of accounting, the identifiable assets acquired and liabilities assumed of BioSante will be recorded at the acquisition date fair values and added to those of ANI. The pro forma adjustments are preliminary and based on management's estimates of the fair value and useful lives of the assets acquired and liabilities assumed and have been prepared to illustrate the estimated effect of the acquisition. These estimates are based on the most recently available information. To the extent there are significant changes to the combined company's business following completion of the merger, the assumptions and estimates set forth in the unaudited pro forma condensed combined financial statements could change significantly. The allocation is dependent upon certain valuation and other studies that will not be completed until following the merger. Accordingly, the pro forma purchase price adjustments are subject to further adjustments as additional information becomes available and as additional analyses and final valuations are conducted following completion of the merger. There can be no assurances that these additional analyses and final valuations will not result in material changes to the estimates of fair value set forth below under Note 2.

The unaudited pro forma condensed combined balance sheet as of September 30, 2012 combines the historical balance sheets of BioSante and ANI as of September 30, 2012 and gives pro forma effect to the merger as if it had been completed on September 30, 2012.

The unaudited pro forma condensed combined statements of operations for the nine months ended September 30, 2012 combine the historical statements of operations of BioSante and ANI for their respective nine month periods ended September 30, 2012 and gives pro forma effect to the merger as if it had been completed on January 1, 2011. The unaudited pro forma condensed combined statements of operations for the year ended December 31, 2011 combine the historical statements of operations of BioSante and ANI for their respective year ended December 31, 2011 and gives pro forma effect to the merger as if it had been completed on January 1, 2011.

Table of Contents

**NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION (Continued)**

**1. Description of Transaction and Basis of Presentation (Continued)**

The unaudited pro forma condensed combined financial statements assume that BioSante's net cash, as defined in the merger agreement, will be $18.0 million as of the determination date and an exchange ratio of 10.3502 shares of BioSante common stock for each share of ANI series D preferred stock and an exchange ratio of zero shares of BioSante common stock for each share of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock. Such exchange ratios do not give any effect to the proposed reverse stock split of BioSante common stock and BioSante class C special stock described elsewhere in this joint proxy statement/prospectus but take into account shares of ANI series D preferred stock to be issued to certain of ANI's executive officers immediately prior to completion of the merger.

The exchange ratios, as such ratios are calculated pursuant to the formulas set forth in the merger agreement, are based on the number of shares of BioSante common stock and ANI capital stock outstanding as of immediately prior to completion of the merger, and in the case of BioSante, a certain percentage of the number of certain warrants to purchase shares of BioSante common stock outstanding as of such date, and will not be determined until that time. The exchange ratios will be adjusted upward or downward only as a result of changes to the outstanding capital stock of either or both of BioSante and ANI as of immediately prior to completion of the merger and changes to BioSante's net cash as of a determination date prior to completion of the merger. No adjustments to the exchange ratios will be made based on changes in the trading price of BioSante common stock or the value of ANI capital stock prior to completion of the merger. As a result, the value of the shares of BioSante common stock issued to ANI stockholders in connection with the merger could be substantially less or substantially more than the current market value of BioSante common stock. The following information does not give effect to the reverse stock split of BioSante common stock and BioSante class C special stock described in BioSante Proposal No. 2.

**2. Purchase Price**

A preliminary estimate of the purchase price is as follows (table in thousands):

| | | |
|---|---|---|
| Fair value of BioSante shares outstanding | $ | 46,158 |
| Estimated fair value of vested BioSante stock options | | 67 |
| Estimated purchase price | $ | 46,225 |

For pro forma purposes, the fair value of the BioSante common stock used in determining the purchase price was $1.89 per share based on the closing price of BioSante common stock on September 30, 2012. The fair value of the BioSante stock options was determined by using the Black-Scholes option pricing model with the following assumption: (i) stock price of $1.89, which is the value ascribed to the BioSante common stock in determining the purchase price, (ii) volatility of 90 percent; risk-free interest rate of 0.21 percent, and (iii) a weighted average expected life of 1.37 years. All outstanding BioSante options will fully vest upon completion of the merger. The combined company will expense all transaction costs as incurred.

Table of Contents

**NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION (Continued)**

**2. Purchase Price (Continued)**

The estimated acquired tangible and intangible assets and liabilities assumed based on their estimated fair values as of September 30, 2012 comprises (table in thousands):

| | |
|---|---|
| Cash and cash equivalents | $ 38,049 |
| Receivables and other current assets | 534 |
| Intangible assets | 19,535 |
| Other assets | 4,629 |
| Convertible senior notes, including interest | (7,701) |
| Other assumed liabilities | (8,821) |
| Total | $ 46,225 |

The allocation of the purchase price is preliminary. The final determination of the purchase price allocation will be based on the fair values of assets, including identifiable intangible assets, acquired, and the fair values of liabilities assumed as of the date that the merger is completed. BioSante and ANI believe that the historical values of BioSante's current assets and current liabilities, excluding the convertible senior notes, approximate their fair value based on the short term nature of such items. The convertible senior notes historically have been recorded at fair value; and accordingly, no adjustment to the historical recorded value of the convertible senior notes is necessary. BioSante and ANI believe that the historical value of BioSante's investments represents fair value based upon current information known to BioSante and ANI, and the valuation performed by BioSante in 2011 when an impairment charge was recorded on BioSante's investment in Ceregene. BioSante's property and equipment consists substantially of a new asset, not yet put into use; and therefore, its historical cost is deemed to be its fair value. The only identifiable intangible assets are BioSante's developed technology, which consists primarily of its intellectual property related to BioSante's male testosterone gel and the GVAX cancer vaccines. The estimated fair values of the assets acquired and liabilities assumed will remain preliminary until the combined company completes a valuation of significant identifiable intangible assets acquired and determines the fair values of other assets and liabilities acquired. Based on such valuation, any excess of the purchase price over the fair value of assets and liabilities acquired will be allocated to goodwill, although at this time, based on preliminary valuation estimates, BioSante and ANI do not believe there will be any goodwill resulting from the merger. The final determination of the fair values is expected to be completed as soon as practicable after completion of the merger. The final amounts could differ from the amounts presented in the unaudited pro forma condensed combined financial statements, because the amounts allocated will not be determined until the date of the merger.

**3. Pro Forma Adjustments**

The pro forma adjustments are as follows:

(A) Represents the elimination of BioSante's accumulated deficit and the adjustment to outstanding common stock to reflect the additional shares of BioSante common stock to be issued to ANI stockholders in the merger.

(B) Represents the estimated fair value of BioSante's identifiable intangible assets, representing developed technology, acquired in the merger. BioSante's developed technology consists primarily of its intellectual property related to BioSante's male testosterone gel and the GVAX cancer vaccines. The estimated fair value of the male testosterone gel represents the

Table of Contents

**NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION (Continued)**

**3. Pro Forma Adjustments (Continued)**

majority of the $19.5 million estimated fair value of the developed technology, with the GVAX cancer vaccines representing approximately $1.0 million of the total estimated fair value. These fair values estimates are based on a preliminary valuation that discounted the forecasted, estimated future net cash flows to be generated from the respective technologies. The final determination of the fair values is expected to be completed as soon as practicable after completion of the merger.

(C)

Represents the elimination of ANI's historical common stock equity accounts.

(D)

Represents the elimination and/or exchange of ANI preferred stock for BioSante common stock in connection with the merger. Pursuant to the terms of ANI's capital stock, only the ANI series D preferred stockholders are expected to receive shares of BioSante common stock in connection with the merger. See adjustment (H) below.

(E)

Reflects BioSante and ANI estimated transaction costs payable in cash that have not been incurred as of September 30, 2012. The amounts include $1.7 million of anticipated costs for BioSante and $1.1 million of anticipated costs for ANI. The $1.7 million of anticipated BioSante costs consist of $0.6 million investment banking firm transaction fees, $0.8 million in legal, accounting and filing fees and $0.3 million in insurance, which costs are included in assumed liabilities in allocating the purchase price. BioSante has also incurred $0.2 million of transaction costs, principally legal fees, through September 30, 2012. The $1.1 million of anticipated ANI costs consist of $0.4 million of advisory/monitoring fees and $0.7 million of legal and accounting fees. ANI has also incurred $0.3 million of transaction costs, principally legal fees, through September 30, 2012.

(F)

Represents the accrual $3.9 million of retention, change of control and severance obligations for certain employees of BioSante that will become due upon closing of the merger consisting of $3.8 million for change of control and severance and $0.1 million of retention.

(G)

Represents the amortization of BioSante's developed technology over an estimated useful life of eight years based on the weighted-average remaining life of the patents underlying such technology.

(H)

Represents the shares of BioSante common stock to be issued to holders of ANI series D preferred stock in connection with the merger at an assumed estimated exchange ratio of 10.3502. No fractional shares of BioSante common stock will be issued in connection with the merger and holders of ANI series D preferred stock will be entitled to receive cash in lieu thereof. Cash paid in lieu of fractional shares will be from existing cash balances which has not been reflected due to immateriality.

(I)

Represents the tax effect of the above pro forma adjustments as calculated at the statutory rate. The tax effect of the adjustments is determined to be zero because it relates to a non-deductible expense for tax purposes. In addition, the combined company will have available net operating loss (NOL) carryforwards and research and development carryforwards that may be utilized to offset any current income and related taxes. Utilization of the NOL and research and development carryforwards may be subject to substantial annual limitation due to ownership change limitations provided by Section 382 of the Code, as well as similar state provisions. It is expected that the combined company will continue to provide a full valuation allowance on its deferred tax assets.

Table of Contents

**NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION (Continued)**

**3. Pro Forma Adjustments (Continued)**

(J)

Represents the elimination of ANI preferred stock dividends as there will be no preferred stock outstanding after the merger.

(K)

Represents transaction bonuses due to certain members of ANI management upon the closing of the merger transaction which will be paid in shares of BioSante common stock as described in the section entitled "Management of the Combined Company Following the Merger  Executive Compensation  Transaction Bonus Agreements and Related Arrangements" beginning on page 268.

Table of Contents

## MANAGEMENT OF THE COMBINED COMPANY FOLLOWING THE MERGER

### Directors and Executive Officers of the Combined Company Following the Merger

Pursuant to the terms of the merger agreement, the board of directors of the combined company will consist of five directors of ANI and two directors of BioSante, ANI's chairman of the board will serve as chairman of the board of the combined company and ANI's current executive officers will serve as executive officers of the combined company. Accordingly, the following five of BioSante's current seven directors will resign effective upon completion of the merger: Louis W. Sullivan, M.D., Edward C. Rosenow, III, M.D., John T. Potts, Jr., M.D., Stephen M. Simes and Stephen A. Sherwin, M.D. In addition, all of BioSante's current executive officers will resign from their respective positions at BioSante effective upon completion of the merger.

The following table lists the names and ages as of December 31, 2012 and positions of the individuals who are expected to serve as directors and executive officers of the combined company upon completion of the merger:

| Name | Age | Title |
|---|---|---|
| Robert E. Brown, Jr. | 62 | Chairman of the Board |
| Arthur S. Przybyl | 55 | President, Chief Executive Officer and Director |
| Tracy L. Marshbanks, Ph.D. | 49 | Director |
| Thomas T. Penn | 66 | Director |
| Robert Schrepfer | 41 | Director |
| Fred Holubow | 73 | Director |
| Ross Mangano | 67 | Director |
| Charlotte C. Arnold | 47 | Vice President and Chief Financial Officer |
| James G. Marken | 50 | Vice President, Operations |
| Robert J. Jamnick | 55 | Vice President, Quality and Product Development |

***Robert E. Brown, Jr.*** has been a director of ANI since July 2010. Mr. Brown has been active in the venture capital and private equity business for over 30 years and has been the sole stockholder, director and President of MVP Management Company (MVP Management) since 2000. MVP Management conducts business as MVP Capital Partners (MVP Capital), and is the investment management company for Meridian Venture Partners II, L.P. (MVP II), a mid-sized venture capital and private equity firm focused on expansion capital and microcap buyout investments, and the owner of 12,477 shares of ANI common stock, 67,599 shares of ANI series A preferred stock, 13,638 shares of ANI series B preferred stock, 11,364 shares of ANI series C preferred stock and 1,376,596 shares of ANI series D preferred stock, representing approximately 57 percent of ANI capital stock. Mr. Brown is the Managing Partner of MVP II and the President and sole stockholder and sole director of Meridian Venture Partners II Co., the corporate general partner of the general partner of MVP II. Mr. Brown serves on the ANI board of directors as MVP II's designee. Mr. Brown co-founded MVP II in 2000 and its predecessor fund, Meridian Venture Partners, in 1987. Prior to 1987, Mr. Brown was a principal in a merchant banking firm active in both private equity and investment banking. Mr. Brown began his professional career as a certified public accountant with Arthur Andersen & Co. Subsequently, he worked for a subsidiary of The Penn Central Corporation as a financial analyst, and after graduation from law school, practiced corporate tax law at the firm of Morgan, Lewis & Bockius in Philadelphia. In his role at MVP Capital, Mr. Brown has served on the board of directors of numerous privately-held portfolio companies, including several healthcare related companies such as Implex Corporation, Dorland Data Networks, Omega Health Systems, Air Medical Group Holdings, and MCMC LLC. Mr. Brown holds an A.B. degree from Princeton University, an M.B.A. from the Wharton School of the University of Pennsylvania, and a J.D. from the Law School of the University of Pennsylvania.

Table of Contents

***Arthur S. Przybyl*** joined ANI in March 2009 as President and Chief Executive Officer. Mr. Przybyl is an experienced healthcare executive in a career that spans over 25 years and includes the management of both specialty pharmaceutical and medical device companies. Prior to joining ANI, Mr. Przybyl served as President and Chief Executive Officer of Akorn, Inc., a NASDAQ-listed specialty pharmaceutical company that manufactures and markets ophthalmic, liquid and lyophilized injectable, and vaccine drug products from August 2002 through January 2009. Prior to Akorn, Mr. Przybyl was President of privately-held Hearing Innovations, Inc. and President and Chief Operating Officer of NASDAQ-listed company Bioject, Inc., both medical device companies. During his career, Mr. Przybyl has held several sales and marketing management positions, including Senior Vice President, Sales and Marketing for International Medication Systems, Inc. and Director Corporate Marketing and National Accounts for LyphoMed, Inc., both specialty pharmaceutical companies. Mr. Przybyl was chosen to serve on the board of directors of the combined company because of his extensive experience as an executive in the healthcare industry, including as President and Chief Executive Officer of ANI. As a member of the executive team of the combined company, Mr. Przybyl will serve a vital function in the link between management and the board of directors of the combined company, enabling the board of directors to perform its oversight function with the benefits of management's perspective on the business.

***Tracy L. Marshbank, Ph.D.*** has been a director of ANI since 2006, serving on both the Audit and Compensation Committees of the ANI board of directors during that period. Dr. Marshbanks is a Managing Director of First Analysis Corp. (First Analysis), a financial services firm, where he has been employed since 1999. First Analysis manages First Analysis Venture Operations and Research, L.L.C. (FAVOR), the indirect owner of 3,810 shares of ANI common stock, 30,762 shares of ANI series B preferred stock, 8,237 shares of ANI series C preferred stock and 394,680 shares of ANI series D preferred stock, representing an aggregate of approximately 17 percent of ANI capital stock. In his role at First Analysis, Dr. Marshbanks focuses on growth equity investments in private companies in the healthcare and the cleantech/environmental sectors and serves as an analyst having followed public companies within the chemical, life science tools, and medical technology industries. Prior to First Analysis, he was employed by Amoco Corp. in a number of positions ranging from Research and Development to Marketing. He has served on the boards of directors of other privately-held companies within healthcare, including manufacturers of medical devices and diagnostic tests. Dr. Marshbanks earned a B.S. and Ph.D. in Chemical Engineering from Colorado State University and Purdue University, respectively, in addition to an M.B.A., with a finance concentration, from the University of Chicago. Dr. Marshbanks holds Series 7 and 63 Securities Licenses as well as a Research Analyst Qualification (Series 86 & 87). Dr. Marshbanks was chosen to serve on the board of directors of the combined company because he brings investor and financial analyst experience and perspective to the board. In addition, he has exposure to the broader healthcare market and technical expertise related to manufacturing and process industries.

***Thomas T. Penn*** has been a director of ANI since 2009. Mr. Penn is employed by MVP Management, of which he serves as Vice President. MVP Management conducts business as MVP Capital Partners. MVP Management is the investment management company for MVP II, of which Mr. Penn is a Partner and which is the owner of 12,477 shares of ANI common stock, 67,599 shares of ANI series A preferred stock, 13,638 shares of ANI series B preferred stock, 11,364 shares of ANI series C preferred stock and 1,376,596 shares of ANI series D preferred stock, representing approximately 57 percent of ANI capital stock. Mr. Penn serves on the ANI's board as MVP II's designee. Mr. Penn is also managing director at and 50 percent owner of Penn Venture I LLC, the general partner for Penn Venture Partners, L.P., an investment fund focused on investments in Central Pennsylvania, holding the managing director position since 2007. Previously, Mr. Penn served as chief executive officer of Tektagen, Inc. and as director of several privately held life sciences and healthcare companies. Mr. Penn was chosen to serve on the board of directors of the combined company primarily because of his significant experience as a director and executive officer in the life sciences industry.

Table of Contents

***Robert Schrepfer*** has been a director of ANI since July 2010. Since 2005, Mr. Schrepfer has served as Assistant Portfolio Manager at Healthcare Value Capital, LLC, an SEC-registered healthcare investment firm. Mr. Schrepfer co-manages the firm's private equity portfolio and oversees investments in healthcare services, devices and specialty pharmaceuticals. In addition, he is principal and founder of National Healthcare Analysis Group, LLC and serves as Chief Financial Officer of National Healthcare Analysis Partners 1, LP, a partnership that seeks to identify and pursue healthcare fraud. Between 2003 and 2005, Mr. Schrepfer was Managing Director at Bear Stearns & Co. Inc., providing sell side research coverage of the pharmaceuticals industry. Mr. Schrepfer served as Clinical Director and Director of Outcomes and Research at the Centers for Aquatic Rehabilitation from 1997 to 2001. Mr. Schrepfer received an M.B.A. in Finance and Health Sector Management from Duke University and an M.S. in Physical Therapy from the University of Indianapolis. He is currently a member of the Health Sector Advisory Council at Duke University. Mr. Schrepfer is a previous holder of Series 7 and 63 Securities Licenses as well as a Research Analyst Qualification (Series 86 & 87). Mr. Schrepfer was chosen to serve on the board of directors of the combined company because of his experience managing investments in specialty pharmaceuticals and other healthcare services companies and providing research coverage of the pharmaceuticals industry.

***Fred Holubow*** has been a director of BioSante since 1999. Mr. Holubow is the Principal of Petard Risk Analysis and a General Partner of Starbow Partners, an investor in early stage healthcare ventures, a position he has held since January 2012. From 2001 to December 2011, Mr. Holubow served as a Managing Director of William Harris Investors, Inc., a registered investment advisory firm. From 1982 to 2001, Mr. Holubow served as Vice President of Pegasus Associates, a registered investment advisory firm he co-founded. He specializes in analyzing and investing in pharmaceutical and biotechnology companies. Mr. Holubow previously served on the boards of directors of the following public companies: Micrus Endovascular Corporation, ThermoRetec Corporation, Savient Pharmaceuticals, Inc. (formerly Bio-Technology General Corp.), Gynex Pharmaceuticals, Inc. and Unimed Pharmaceuticals, Inc.

BioSante believes Mr. Holubow's qualifications to serve as a member of the board of directors of the combined company include his significant experience of analyzing and investing in pharmaceutical and biotechnology companies both in his current position as a Principal of Petard Risk Analysis and a General Partner of Starbow Partners and in his prior positions as a Managing Director of William Harris Investors and Vice President of Pegasus Associates. In addition, through his experience of serving on the boards of directors and more specifically the audit committees of several other public companies, Mr. Holubow has developed a substantial financial and accounting expertise with pharmaceutical and biotechnology companies, which he contributes to the BioSante board of directors, and more specifically, to the Audit and Finance Committee in his role as Chair of the Audit and Finance Committee.

***Ross Mangano*** has been a director of BioSante since 1999. Mr. Mangano has been the President and a director of Oliver Estate, Inc., a management company specializing in investments in public and private companies, since 1971. Mr. Mangano in the past has served on the boards of directors of Cerprobe Corporation, Tower Federal Savings & Loan, Cypress Communications, Inc. and Mego Financial Corp.

BioSante believes Mr. Mangano's qualifications to serve as a member of the board of directors of the combined company include his significant general business experience as President of Oliver Estate, Inc. and his significant experience analyzing and investing in public and private companies. In addition, BioSante believes Mr. Mangano provides the board of directors of the combined company valuable business, leadership and management experience and insights into many aspects of the combined company's business.

Table of Contents

***Charlotte C. Arnold*** has served as ANI's Vice President and Chief Financial Officer since May 2009. In that role, Ms. Arnold leads ANI's finance and accounting department as well as information technology. Between March 2004 and May 2009, Ms. Arnold served as director of ANI. Ms. Arnold has more than 20 years of experience in finance, corporate development and operations. Before becoming ANI's Chief Financial Officer, Ms. Arnold was a Founding Partner at Laurel Capital, a growth equity and microcap buyout private equity firm, from October 2007 to March 2009. Prior to Laurel, Ms. Arnold was an employee and Vice President of MVP Management, where she was responsible for four platform investments, including the initial acquisition of ANI. Previously, Ms. Arnold was a Director with Ben Franklin Technology Partners, a nationally-known economic development organization and worked in the Entrepreneurial Services assurance practice of PricewaterhouseCoopers in Philadelphia. Ms. Arnold holds a B.A. degree from UCLA, an MBA from the Wharton School of Business, and is a certified public accountant.

***James G. Marken*** serves as Vice President, Operations, a position he has held since March 2009. Mr. Marken joined ANI in March 2007 as General Manager of the Minnesota facilities. As Vice President, Operations, Mr. Marken has been principally responsible for the following areas: warehousing, pharmaceutical manufacturing, packaging, engineering/maintenance, calibrations and purchasing. Mr. Marken brings over 20 years of pharmaceutical industry experience to the combined company. Prior to joining ANI in March 2007, he worked for Solvay Pharmaceuticals as plant manager and in various departments including quality control, validation and manufacturing. Mr. Marken holds a B.S. degree in Chemistry from Bemidji State University.

***Robert J. Jamnick*** serves as Vice President, Quality and Product Development, a position he has held since July 2010. Mr. Jamnick joined ANI in May 2007 as Director Quality Assurance/Quality Control for the Baudette facilities. Mr. Jamnick came to ANI after a career spanning over 25 years at Solvay Pharmaceuticals, where he held various technical and managerial positions in quality assurance, quality control, technical services and research and development. Form March 2009 to July 2010, Mr. Jamnick served as Executive Director Global Quality of ANI. In his current position, Mr. Jamnick is responsible for quality control, quality assurance, product development, regulatory affairs and technical services. Mr. Jamnick holds a Bachelor's degree in Chemistry and Biology from Bemidji State University.

**Director Independence**

Prior to completion of the merger, the BioSante board of directors will affirmatively determine which of the seven individuals that will serve as directors of the combined company is an "independent director" as defined under the Listing Rules of The NASDAQ Stock Market. The Listing Rules of The NASDAQ Stock Market provide a list of disqualifying criteria for the independence determination. For example, under these rules, a director who is, or during the past three years was, employed by the company or by any parent or subsidiary of the company, other than prior employment as an interim chairman or interim chief executive officer, would not be considered independent. No director qualifies as independent unless the board of directors affirmatively determines that the director does not have a material relationship with the listed company that would interfere with the exercise of independent judgment. Based on information provided by the directors and by BioSante and ANI with regard to each of the seven individuals expected to serve as a member of the board of directors of the combined company and such individual's business and personal activities as they may relate to BioSante, ANI, the combined company and their respective management, it is anticipated that all of the seven individuals that will serve as directors of the combined company will be "independent" other than Mr. Przybyl, Mr. Brown and Mr. Penn.

Table of Contents

**Board Committees of the Combined Company**

The board of directors of the combined company will have the same committee structure as BioSante prior to the merger and therefore will have an Audit and Finance Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each of these committees will operate under a charter that has been previously approved by the board of directors of BioSante and will have the composition and responsibilities described below. The board of directors of the combined company from time to time may establish other committees to facilitate the management of the company and may change the composition and the responsibilities of the existing committees.

The table below summarizes the anticipated membership of each of the three standing board committees of the combined company after the merger.

| Director | Audit and Finance | Compensation | Nominating and Corporate Governance |
|---|---|---|---|
| Tracy L. Marshbanks, Ph.D. | Chair | Chair | Member |
| Robert Schrepfer | Member | Member | Chair |
| Fred Holubow | Member | | |
| Ross Mangano | | Member | Member |

***Audit and Finance Committee***

The primary responsibilities of the Audit and Finance Committee of the combined company will include:

- overseeing the combined company's accounting and financial reporting processes, systems of internal control over financial reporting and disclosure controls and procedures on behalf of the board of directors and reporting the results or findings of its oversight activities to the board;
- having sole authority to appoint, retain and oversee the work of the combined company's independent registered public accounting firm and establishing the compensation to be paid to the independent registered public accounting firm;
- establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls and/or or auditing matters and for the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters;
- reviewing and pre-approving all audit services and permissible non-audit services to be performed for the combined company by its independent registered public accounting firm as provided under the federal securities laws and rules and regulations of the SEC; and
- overseeing the combined company's system to monitor and manage risk, and legal and ethical compliance programs, including the establishment and administration (including the grant of any waiver from) a written code of ethics applicable to each of the combined company's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions.

The Audit and Finance Committee will have the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

It is anticipated that the Audit and Finance Committee of the combined company will consist of Mr. Holubow, Dr. Marshbanks and Mr. Schrepfer. It is expected that the board of directors of the combined company will determine that each anticipated member of the Audit and Finance Committee will qualify as "independent" for purposes of membership on audit committees pursuant to the Listing Rules of The NASDAQ Stock Market and the rules and regulations of the SEC and is "financially

Table of Contents

literate" as required by the Listing Rules of The NASDAQ Stock Market. In addition, it is expected that the board of directors of the combined company will determine that Mr. Holubow qualifies as an "audit committee financial expert" as defined by the rules and regulations of the SEC and meets the qualifications of "financial sophistication" under the Listing Rules of The NASDAQ Stock Market as a result of his Masters in Business Administration in Finance, and his previous experience as an investment analyst and portfolio manager for over 40 years and as a former member of an audit committee of another public company.

***Compensation Committee***

The primary responsibilities of the Compensation Committee of the combined company will include:

- recommending to the board of directors for its determination the annual salaries, incentive compensation, long-term incentive compensation, special or supplemental benefits or perquisites and any and all other compensation applicable to the combined company's chief executive officer and other executive officers;

- reviewing and making recommendations to the board of directors regarding any revisions to corporate goals and objectives with respect to compensation for the combined company's chief executive officer and other executive officers and establishing and leading a process for the full board of directors to evaluate the performance of the combined company's chief executive officer and other executive officers in light of those goals and objectives;

- administering the combined company's equity-based compensation plans applicable to any employee of the combined company and recommending to the board of directors specific grants of options and other awards for all executive officers and determining specific grants of options and other awards for all other employees, under the combined company's equity-based compensation plans;

- reviewing and discussing with the President and Chief Executive Officer and reporting periodically to the board of directors plans for executive officer development and corporate succession plans for the President and Chief Executive Officer and other key executive officers and employees; and

- annually reviewing and discussing with management the "Compensation Discussion and Analysis" section of the combined company's proxy statement in connection with the combined company's annual meeting of stockholders and based on such review and discussions make a recommendation to the board of directors as to whether the "Compensation Discussion and Analysis" section should be included in the combined company's proxy statement in accordance with applicable rules and regulations of the SEC and any other applicable regulatory bodies.

The Compensation Committee will have the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

It is anticipated that the Compensation Committee of the combined company will consist of Dr. Marshbanks, Mr. Mangano and Mr. Schrepfer.

***Nominating and Corporate Governance Committee***

The primary responsibilities of the Nominating and Corporate Governance Committee of the combined company will include:

- identifying individuals qualified to become board members;

Table of Contents

recommending director nominees for each annual meeting of the combined company's stockholders and director nominees to fill any vacancies that may occur between meetings of stockholders;

being aware of the best practices in corporate governance and developing and recommending to the board of directors a set of corporate governance standards to govern the board of directors, its committees, the company and its employees in the conduct of the business and affairs of the combined company;

developing and overseeing the annual board and board committee evaluation process; and

establishing and leading a process for determination of the compensation applicable to the non-employee directors on the board.

The Nominating and Corporate Governance Committee will have the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

It is anticipated that the Nominating and Corporate Governance Committee of the combined company will consist of Mr. Schrepfer, Mr. Mangano and Dr. Marshbanks.

**Certain Relationships and Related Transactions**

It is anticipated that the policies and procedures of the combined company with respect to the review, approval or ratification of related-person transactions will be substantially similar to BioSante's current policies and procedures on such matters.

***BioSante Related Transactions***

The BioSante board of directors has delegated to the Audit and Finance Committee, pursuant to the terms of a written policy, the authority to review, approve and ratify related party transactions. If it is not feasible for the Audit and Finance Committee to take an action with respect to a proposed related party transaction, the BioSante board of directors or another committee of the BioSante board of directors, may approve or ratify it. No member of the BioSante board of directors or any committee may participate in any review, consideration or approval of any related party transaction with respect to which such member or any of his or her immediate family members is the related party.

BioSante's policy defines a "related party transaction" as a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which BioSante (including any of its subsidiaries) were, are or will be a participant and in which any related party had, has or will have a direct or indirect interest.

Prior to entering into or amending any related party transaction, the party involved must provide notice to BioSante's finance department of the facts and circumstances of the proposed transaction, including:

the related party's relationship to BioSante and his or her interest in the transaction;

the material facts of the proposed related party transaction, including the proposed aggregate value of such transaction or, in the case of indebtedness, the amount of principal that would be involved;

the purpose and benefits of the proposed related party transaction with respect to BioSante;

if applicable, the availability of other sources of comparable products or services; and

an assessment of whether the proposed related party transaction is on terms that are comparable to the terms available to an unrelated third party or to employees generally.

Table of Contents

If BioSante's finance department determines the proposed transaction is a related party transaction and the amount involved will or may be expected to exceed $10,000 in any calendar year, the proposed transaction is submitted to the Audit and Finance Committee for its prior review and approval or ratification. In determining whether to approve or ratify a proposed related party transaction, the Audit and Finance Committee will consider, among other things, the following:

- the purpose of the transaction;
- the benefits of the transaction to BioSante;
- the impact on a director's independence in the event the related party is a non-employee director, an immediate family member of a non-employee director or an entity in which a non-employee director is a partner, shareholder or executive officer;
- the availability of other sources for comparable products or services;
- the terms of the transaction; and
- the terms available to unrelated third parties or to employees generally.

Related party transactions that involve $10,000 or less must be disclosed to the Audit and Finance Committee but are not required to be approved or ratified by the Audit and Finance Committee.

BioSante also produces quarterly reports to the Audit and Finance Committee of any amounts paid or payable to, or received or receivable from, any related party. These reports allow BioSante to identify any related party transactions that were not previously approved or ratified. In that event, the transaction will be promptly submitted to the Audit and Finance Committee for consideration of all the relevant facts and circumstances, including those considered when a transaction is submitted for pre-approval. Under BioSante's policy, certain related party transactions as defined under the policy, such as certain transactions not requiring disclosure under the rules of the SEC, will be deemed to be pre-approved by the Audit and Finance Committee and will not be subject to these procedures.

There were no related party transactions for BioSante during 2011, and as of the latest practicable date before the printing of this joint proxy statement/prospectus, there were no related party transaction for BioSante during 2012.

***ANI Related Transactions***

ANI does not have a formal policy on related party transactions, but it conducts a review of all related party transactions for potential conflict of interest situations on an ongoing basis and all such transactions relating to directors and executive officers must be approved by the independent and disinterested members of the ANI board of directors. There were no related party transactions for ANI during 2009, 2010, 2011, and as of the latest practicable date before the printing of this joint proxy statement/prospectus, there were no related party transaction for ANI during 2012, except as described below:

***Director and Executive Officer Compensation***

Please see "Management of the Combined Company Following the Merger  Director Compensation" and "  Executive Compensation" for information regarding the compensation of ANI's directors and those of its executive officers who will continue as executive officers of the combined company and for information regarding employment, bonus and other agreements ANI has in place with such directors and/or executive officers.

Table of Contents

***Investments by Related Parties***

In 2009, ANI issued $2,502,814 of secured subordinated convertible notes (the 2009 convertible notes) and related warrants. The 2009 convertible notes, which bore interest at 10 percent per annum, were due on September 3, 2011. Interest on the 2009 convertible notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The 2009 convertible notes were secured by a second lien on substantially all of ANI's assets and included financial covenants and limitations on ANI's ability to enter into certain transactions while the 2009 convertible notes were outstanding. Among the investors in the 2009 convertible notes were the following:

**2009 Convertible Notes**

| Investor | Affiliations with ANI | Principal Amount(1) | Shares of ANI Series D Preferred Stock Issued upon Conversion of: | | Warrants Issued |
|---|---|---|---|---|---|
| | | | Principal | Interest | |
| MVP II | Owns 56.7 percent of ANI capital stock<br><br>ANI directors Robert E. Brown, Jr. and Thomas T. Penn are affiliated with MVP II(2) | 1,591,100 | 211,941 | 16,085 | Common stock warrants: 12,477<br>Series D preferred stock warrants: 2,235 |
| First Analysis | Owns 16.7 percent of ANI capital stock<br><br>ANI director Tracy L. Marshbanks, Ph.D. is managing director of First Analysis Corporation(3) | 319,443 | 42,522 | 15,315 | Common stock warrants: 3,809 |
| Healthcare Value Master Fund, Ltd. | Owns 1.6 percent of ANI capital stock<br><br>ANI director Robert Schrepfer is employed by the investment advisor to HVMF but is not deemed to be an affiliate of ANI(4) | 152,172 | 20,275 | 7,380 | Common stock warrants: 1,841 |
| Argentum Capital Partners II, L.P. | Owns 11.3 percent of ANI capital stock. | 301,159 | 40,111 | 14,304 | Common stock warrants: 2,693<br>Series D preferred stock warrants: 300 |

(1) Represents the largest aggregate principal amount outstanding since issuance.

(2) The notes were held by Meridian Venture Partners II, L.P. (MVP II). MVP II GP, L.P. (GP) is the general partner of MVP II. Meridian Venture Partners II, Co. (MVP Corp.), is the general partner of GP. MVP Management Company (MVP Management) d/b/a MVP Capital Partners, is the

Table of Contents

management company for MVP II and also renders financial and business advisory services to several of the companies in which MVP II has invested. Robert E. Brown, Jr., a director of ANI, is the President, sole stockholder and sole director of MVP Corp, the sole stockholder, director and President of MVP Management, as well as a limited partner of GP and one of two principals of MVP II that are licensed by the Small Business Administration (SBA). SBA-licensed principals are charged with approving all investment-related decisions on behalf of small business investment companies licensed by the SBA, such as MVP II. Thomas T. Penn, a director of ANI, is a Vice President of MVP Corp, a Vice President and employee of MVP Management, a limited partner of GP and one of the two SBA-licensed principals of MVP II. Charlotte C. Arnold, ANI's Vice President and Chief Financial Officer, is a former employee and Vice President of MVP Management, and has a vested interest in 6 percent of GP's interest in MVP II. MVP Management has been receiving advisory and monitoring fees from ANI and will receive a fee at the closing of the merger, as further described below. Pursuant to the applicable provisions of the MVP II limited partnership agreement and to comply with applicable SBA regulations, 50 percent of all such fees received by MVP Management are paid over or credited to MVP II.

(3)

The notes were held by FA Private Equity Fund IV, L.P. (FAPEF IV), FA Private Equity Fund IV GmbH & Co. Beteiligungs KG (GmbH), The Productivity Fund IV, L.P. (Productivity Fund) and The Productivity Fund IV Advisors Fund, L.P. (Advisors Fund).

FA Private Equity Management IV, L.L.C. (FAPEM IV) is the sole general partner of FAPEF IV. FAVOR is the ultimate managing member of FAPEM IV and, in that capacity, exercises voting and dispositive control over the shares held by FAPEF IV. Tracy L. Marshbanks, Ph.D., a director of ANI, is a managing director of First Analysis Corporation, which manages FAVOR.

FAPEM IV is the managing limited partner of GmbH. FAVOR is the ultimate managing member of FAPEM IV and, in that capacity, exercises voting and dispositive control over the shares held by GmbH. Dr. Marshbanks is a managing director of First Analysis Corporation, which manages FAVOR.

First Analysis Management Company IV, L.L.C. (FAMC IV) is the sole general partner of Productivity Fund. FAVOR is the managing member of FAMC IV and, in that capacity, exercises voting and dispositive control over the shares held by Productivity Fund. Dr. Marshbanks is a managing director of First Analysis Corporation, which manages FAVOR.

FAMC IV is the sole general partner of Advisors Fund. FAVOR is the managing member of FAMC IV and, in that capacity, exercises voting and dispositive control over the shares held by Advisors Fund. Dr. Marshbanks is a managing director of First Analysis Corporation, which manages FAVOR.

(4)

The notes were held by Healthcare Value Master Fund, Ltd. (HVMF). Mr. Schrepfer is an employee of Healthcare Value Capital, LLC (HVC), the investment adviser to HVMF, but has no ownership interest in and does not serve as general partner or managing member of HVC or its affiliates. Therefore, Mr. Schrepfer is not deemed beneficially to own the securities of ANI held by HVMF. HVC has been receiving advisory fees from ANI and will receive a fee at the closing of the merger, as further described below.

Table of Contents

In 2010, ANI issued $8,474,952 of secured subordinated convertible notes (the 2010 convertible notes) and related warrants. The 2010 convertible notes, which bore interest at 14 percent per annum, were due on September 3, 2011. Interest on the 2010 convertible notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The 2010 convertible notes were secured by a second lien on substantially all of ANI's assets and included financial covenants and limitations on ANI's ability to enter into certain transactions while the 2010 convertible notes were outstanding. Among the investors in the 2010 convertible notes were the following:

**2010 Convertible Notes**

| Investor | Affiliations with ANI | Principal Amount(1) | Shares of ANI Series D Preferred Stock Issued upon Conversion of: | | Warrants Issued |
|---|---|---|---|---|---|
| | | | Principal | Interest | |
| MVP II | Owns 56.7 percent of ANI capital stock<br>ANI directors Robert E. Brown, Jr. and Thomas T. Penn are affiliated with MVP II(2) | 4,774,832 | 535,944 | 295,278 | 11,603 |
| First Analysis | Owns 16.7 percent of ANI capital stock<br>ANI director Tracy L. Marshbanks, Ph.D. is managing director of First Analysis Corporation(3) | 1,453,599 | 193,813 | 61,906 | 5,280 |
| Healthcare Value Master Fund, Ltd. | Owns 1.6 percent of ANI capital stock<br>ANI director Robert Schrepfer is employed by the investment advisor to HVMF but is not deemed to be an affiliate of ANI(4) | 673,223 | 89,763 | 28,268 | 1,475 |
| Argentum Capital Partners II, L.P. | | | | | |