

BIOSANTE PHARMACEUTICALS INC

Form 10-Q

May 10, 2013

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

(Mark one)

**QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2013

**TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number 001-31812

**BIOSANTE PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**58-2301143**  
(IRS Employer Identification Number)

**111 Barclay Boulevard**  
**Lincolnshire, Illinois 60069**  
(Address of principal executive offices)

**(847) 478-0500**  
(Registrant's telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES  NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES  NO

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if smaller reporting company)	Smaller reporting company <input type="checkbox"/>

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

As of May 10, 2013, 24,422,240 shares of common stock and 65,211 shares of class C special stock of the registrant were outstanding.



Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**FORM 10-Q**

**MARCH 31, 2013**

**TABLE OF CONTENTS**

<b>Description</b>		<b>Page</b>
<b>PART I.</b>	<b>FINANCIAL INFORMATION</b>	
<b>ITEM 1.</b>	<b>Financial Statements</b>	
	<u>Condensed Balance Sheets as of March 31, 2013 and December 31, 2012 (unaudited)</u>	1
	<u>Condensed Statements of Operations for the three months ended March 31, 2013 and 2012 (unaudited)</u>	2
	<u>Condensed Statements of Cash Flows for the three months ended March 31, 2013 and 2012 (unaudited)</u>	3
	<u>Notes to the Condensed Financial Statements (unaudited)</u>	4-14
<u>ITEM 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>ITEM 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	29
<u>ITEM 4.</u>	<u>Controls and Procedures</u>	30
<b>PART II.</b>	<b>OTHER INFORMATION</b>	31
<u>ITEM 1.</u>	<u>Legal Proceedings</u>	31
<u>ITEM 1A.</u>	<u>Risk Factors</u>	31
<u>ITEM 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	39
<u>ITEM 3.</u>	<u>Defaults Upon Senior Securities</u>	39
<u>ITEM 4.</u>	<u>Mine Safety Disclosures</u>	39
<u>ITEM 5.</u>	<u>Other Information</u>	40
<u>ITEM 6.</u>	<u>Exhibits</u>	40
<u>SIGNATURE PAGE</u>		42



Table of Contents

---

*This quarterly report on Form 10-Q contains forward-looking statements. For this purpose, any statements contained in this report that are not statements of historical fact may be deemed to be forward-looking statements. You can identify forward-looking statements by those that are not historical in nature, particularly those that use terminology such as believe, may, could, would, might, possible, potential, project, will, should, expect, intend, plan, predict, anticipate, estimate, approximate, contemplate and continue, the negative of these words, other words and terms of similar meaning and the use of future dates. In evaluating these forward-looking statements, you should consider various factors, including those listed in this report under the headings Part I. Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Forward-Looking Statements and Part II. Item 1A. Risk Factors. These factors may cause BioSante's actual results to differ materially from any forward-looking statement. BioSante assumes no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements.*

*As used in this report, references to BioSante, the company, we, BioSante's or us, unless the context otherwise requires, refer to BioSante Pharmaceuticals, Inc. References to ANI in this report refer to ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. References to the combined company refer to BioSante and its wholly owned subsidiary, ANI, as the surviving entity after the merger and incorporating the merged business of ANI, and, when used in the context of board and management composition and share ownership after the merger, refer to BioSante as the parent company. References to Merger Sub refer to ANI Merger Sub, Inc., a newly formed, wholly owned subsidiary of BioSante.*

*References to the merger agreement refer to that certain amended and restated agreement and plan of merger dated as of April 12, 2013 among BioSante, Merger Sub and ANI, as amended from time to time. References to the prior merger agreement refer to that certain agreement and plan of merger dated as of October 3, 2012 between BioSante and ANI, which prior merger agreement was superseded and replaced by the merger agreement. References to the merger refer to the merger of Merger Sub with and into ANI, with ANI surviving as the surviving entity and as a wholly owned subsidiary of BioSante as contemplated under the merger agreement.*

*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 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 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 ANI stockholders refer to holders of shares of ANI capital stock.*

*BioSante owns or has rights to various trademarks, trade names or service marks, including BioSante®, LibiGel®, The Pill-Plus and Elestrin. This report also contains trademarks, trade names and service marks that are owned by other persons or entities.*



Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Condensed Balance Sheets**

March 31, 2013 and December 31, 2012 (Unaudited)

	March 31, 2013	December 31, 2012
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 29,388,772	\$ 34,794,341
Restricted cash	2,260,100	
Prepaid expenses and other assets	277,874	378,803
	<b>31,926,746</b>	<b>35,173,144</b>
<b>PROPERTY AND EQUIPMENT, NET</b>		<b>166,386</b>
<b>OTHER ASSETS</b>		
Investments	3,413,762	3,413,762
Deposits	15,878	15,878
	<b>\$ 35,356,386</b>	<b>\$ 38,769,170</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 164,352	\$ 1,128,644
Accrued compensation	879,385	1,078,683
Other accrued expenses	112,784	502,452
Current portion of convertible senior notes	8,169,215	7,883,886
<b>TOTAL LIABILITIES</b>	<b>9,325,736</b>	<b>10,593,665</b>
<b>STOCKHOLDERS EQUITY</b>		
<b>Capital stock</b>		
<b>Issued and outstanding</b>		
2013 - 65,211; 2012 - 65,211 Class C special stock	391	391
2013 - 24,422,240; 2012 - 24,422,240 Common stock	273,277,795	273,132,001
	<b>273,278,186</b>	<b>273,132,392</b>
Accumulated deficit	(247,247,536)	(244,956,887)
	<b>26,030,650</b>	<b>28,175,505</b>
	<b>\$ 35,356,386</b>	<b>\$ 38,769,170</b>

See accompanying notes to the condensed financial statements.



Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Condensed Statements of Operations****Three months ended March 31, 2013 and 2012 (Unaudited)**

	Three Months Ended March 31,	
	2013	2012
<b>REVENUE</b>		
Royalty revenue	\$ 145,040	\$ 114,000
	<b>145,040</b>	<b>114,000</b>
<b>EXPENSES</b>		
Research and development	972,049	5,183,217
General and administration	1,949,114	1,831,852
Depreciation and amortization	166,386	30,866
	<b>3,087,549</b>	<b>7,045,935</b>
<b>OTHER</b>		
Convertible note fair value adjustment	(285,329)	(3,210,338)
Gain on sale of intellectual property	1,000,000	
Interest expense	(64,671)	(124,196)
Interest income	1,860	1,992
<b>NET LOSS</b>	<b>\$ (2,290,649)</b>	<b>\$ (10,264,477)</b>
<b>BASIC AND DILUTED NET LOSS PER SHARE</b>	<b>\$ (0.09)</b>	<b>\$ (0.53)</b>
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING</b>	<b>24,487,451</b>	<b>19,377,768</b>

See accompanying notes to the condensed financial statements.

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Condensed Statements of Cash Flows****Three months ended March 31, 2013 and 2012 (Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>CASH FLOWS (USED IN) OPERATING ACTIVITIES</b>		
Net loss	\$ (2,290,649)	\$ (10,264,477)
Adjustments to reconcile net loss to net cash (used in) operating activities		
Depreciation and amortization	166,386	30,866
Loss on disposal of fixed assets		432
Gain on sale of intellectual property	(1,000,000)	
Employee and director stock-based compensation	145,794	313,027
Convertible note fair value adjustment	285,329	3,210,338
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses and other assets	100,928	84,227
Accounts payable and accrued liabilities	(1,553,257)	(1,063,726)
<b>Net cash (used in) operating activities</b>	<b>(4,145,469)</b>	<b>(7,689,313)</b>
<b>CASH FLOWS (USED IN) INVESTING ACTIVITIES</b>		
Funding of restricted cash	(2,260,100)	
Proceeds from sale of intellectual property	1,000,000	
Purchase of fixed assets		(54,234)
Purchase of investment		(7,955)
<b>Net cash (used in) investing activities</b>	<b>(1,260,100)</b>	<b>(62,189)</b>
<b>NET (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>(5,405,569)</b>	<b>(7,751,502)</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>34,794,341</b>	<b>57,225,234</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 29,388,772</b>	<b>\$ 49,473,732</b>
<b>SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION</b>		
<b>Noncash financing activities</b>		
Shares issued for convertible senior notes and accrued interest	\$	\$ 10,132,534

See accompanying notes to the condensed financial statements.

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.  
FORM 10-Q  
MARCH 31, 2013**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED)**

**1. DESCRIPTION OF BUSINESS**

BioSante Pharmaceuticals, Inc. (the Company) is a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. The Company's products, either approved or in human clinical development, include: (1) LibiGel, once daily transdermal testosterone gel in Phase III development for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD); (2) a 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); (3) The Pill-Plus (triple component contraceptive), once daily use of various combinations of estrogens, progestogens and androgens in Phase II development; and (4) Elestrin, once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S. by Meda Pharmaceuticals, Inc. (Meda), the Company's licensee.

On October 3, 2012, the Company entered into an agreement and plan of merger (the Prior Merger Agreement) with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (ANI). The Prior Merger Agreement provided that, subject to the terms and conditions set forth in the Prior Merger Agreement, ANI would merge with and into the Company, with the Company continuing as the surviving company (the Prior Merger). Following completion of the Prior Merger, stockholders of ANI immediately prior to the effective time of the Prior Merger were expected to own approximately 53% of the outstanding shares of common stock of the combined company, and stockholders of the Company immediately prior to the effective time of the Prior Merger were expected to own approximately 47% of the outstanding shares of common stock of the combined company, assuming the Company's net cash as defined in the Prior Merger Agreement and generally consisting of the Company's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the Prior Merger, was \$18.0 million. The exchange ratios in the Prior Merger were subject to potential adjustment as described in the Prior Merger Agreement depending upon the amount of the Company's net cash as of a determination date prior to the closing date of the Prior Merger, but in no event were ANI stockholders immediately prior to the effective time of the Prior Merger to own less than 50.1% (or Company stockholders immediately prior to the effective time of the Prior Merger to own more than 49.9%) of the outstanding shares of common stock of the combined company.

The Prior Merger Agreement was approved by ANI's stockholders on March 15, 2013. The Company adjourned its special meeting of stockholders called to approve the Prior Merger until April 12, 2013 to give the Company's stockholders additional time to vote. As of April 12, 2013, voting instructions to vote shares in favor of the Prior Merger had been received from holders of approximately 36% of the outstanding shares of the Company's capital stock, which was short of the required majority needed to approve the Prior Merger. Of those shares as to which voting instructions had been given, approximately 84% were to be voted in favor of the Prior Merger. However, no voting instructions on the Prior Merger had been received from holders of a total of approximately 13.8 million shares, or approximately 57% of the outstanding shares of the Company's capital stock. Two other proposals submitted to the Company's stockholders in connection with the Prior Merger, a reverse stock split and a name change, also received affirmative voting instructions from holders of a majority of the shares as to which voting instructions were received, but neither received affirmative voting instructions with respect to the required majority of the outstanding shares of the Company's capital stock. Subsequent to March 15, 2013, the Company determined that it likely would not receive sufficient additional voting instructions prior to April 12, 2013 (or on any later date) to either approve the Prior Merger and the two other related proposals or to indicate that the Company's



Table of Contents

stockholders had rejected the Prior Merger or these other proposals. Accordingly, the Board of Directors of the Company decided to begin discussions with ANI about a possible restructured merger.

On April 12, 2013, the Company, ANI Merger Sub, Inc., a newly created, wholly owned subsidiary of the Company formed solely for purposes of effecting the merger (Merger Sub), and ANI entered into an amended and restated agreement and plan of merger (the New Merger Agreement), pursuant to which, upon the terms and subject to the conditions set forth in such agreement, Merger Sub will be merged with and into ANI, and after which ANI will be a wholly owned subsidiary of the Company (the New Merger). The New Merger Agreement supersedes and replaces in its entirety the Prior Merger Agreement. Following consummation of the transactions contemplated by the New Merger Agreement, the stockholders of ANI immediately prior to the effective time of the New Merger will own 57% of the outstanding shares of common stock of the Company and the stockholders of the Company immediately prior to the effective time of the New Merger will own 43% of the outstanding shares of common stock of the Company. The required Company stockholder vote for the New Merger will be a majority of the shares of the Company's common stock and class C special stock present and entitled to vote at the stockholders meeting at which the issuance of shares of the Company's common stock in connection with the New Merger will be considered. The proposed New Merger with ANI is more fully described in Note 3, Proposed New Merger with ANI.

On January 31, 2013, the Company entered into an asset purchase agreement with Aduro BioTech, Inc., a clinical-stage immunotherapy company (Aduro), pursuant to which the Company sold all of its assets related to its GVAX cancer vaccine portfolio in exchange for a \$1.0 million cash payment plus the potential for future royalty, milestone and sublicense payments. The agreement with Aduro is more fully described in Note 9, Sale of GVAX Cancer Vaccine Assets.

**2. BASIS OF PRESENTATION**

In the opinion of management, the accompanying unaudited condensed financial statements contain all necessary adjustments, which are of a normal recurring nature, to present fairly the financial position of the Company as of March 31, 2013 and December 31, 2012, the results of operations for the three months ended March 31, 2013 and 2012, and the cash flows for the three months ended March 31, 2013 and 2012, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three month period ended March 31, 2013 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2013. The Company does not have items of other comprehensive income for either of the three month periods ended March 31, 2013 or 2012; and therefore, has not presented comprehensive income.

These unaudited interim condensed financial statements should be read in conjunction with the financial statements and related notes contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2012.

On June 1, 2012, the Company effected a one-for-six reverse split of its outstanding common stock and class C special stock. These unaudited interim condensed financial statements give retroactive effect to the reverse stock split.

**3. PROPOSED NEW MERGER WITH ANI**

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

### *Amended and Restated Agreement and Plan of Merger*

On April 12, 2013, the Company, Merger Sub and ANI entered into the New Merger Agreement, pursuant to which, upon the terms and subject to the conditions set forth in the New Merger Agreement, Merger Sub will merge with and into ANI, and after which ANI will be a wholly owned subsidiary of the Company. The New Merger Agreement amends and restates in its entirety the Prior Merger Agreement. Pursuant to the terms of the New Merger Agreement, at the effective time of the New Merger, each

Table of Contents

outstanding share of capital stock of ANI will be converted into the right to receive a number of shares of common stock of the Company, if any, as determined pursuant to the exchange ratios described in the New 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 Company or ANI after the New Merger. No fractional shares of common stock of the Company will be issued in connection with the New Merger, and holders of ANI capital stock will be entitled to receive cash in lieu thereof. Following the consummation of the transactions contemplated by the New Merger Agreement, the stockholders of ANI immediately prior to the effective time of the New Merger will own 57% of the outstanding shares of the Company's common stock and the stockholders of the Company immediately prior to the effective time of the New Merger will own 43% of the outstanding shares of common stock of the Company. Unlike the exchange ratio provision in the Prior Merger Agreement, the respective percentage ownerships of the stockholders of ANI and the Company after the New Merger are fixed at 57% and 43%, respectively, and are not subject to adjustment based on the Company's net cash. The New Merger is intended to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (Code).

The New Merger Agreement provides that, immediately following the effective time of the New Merger, the Board of Directors of the Company will consist of five current directors of ANI and two current directors of the Company, and ANI's current executive officers are expected to serve as executive officers of the Company.

Consummation of the New Merger is subject to a number of conditions, including, but not limited to (i) approval of the issuance of shares of common stock of the Company in the New Merger by the Company's stockholders and the adoption and approval of the New Merger Agreement and the transactions contemplated thereby by the ANI stockholders; (ii) written opinions of counsel that the New Merger will qualify as a reorganization within the meaning of Section 368(a) of the Code; and (iii) other customary closing conditions.

Each of the Company and ANI have made customary representations, warranties and covenants in the New 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 execution of the New Merger Agreement and consummation of the New Merger (and the Company will not incur compensation expenses for employees and consultants in excess of specified monthly amounts); (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 New Merger Agreement and the transactions contemplated thereby and ANI's Board of Directors will recommend that ANI's stockholders adopt and approve the New Merger Agreement, subject to certain exceptions; and (iv) the Company will convene and hold a meeting of its stockholders for the purpose of considering the approval of the issuance of shares of the Company's common stock in the New Merger and the Company's Board of Directors will recommend that the Company's stockholders adopt and approve such proposal, subject to certain exceptions. Each of the Company 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 the Company in the event of its receipt of a superior proposal.

The New Merger Agreement contains certain termination rights in favor of each of ANI and the Company in certain circumstances. If the New Merger Agreement is terminated due to certain triggering events specified in the New Merger Agreement, the Company will be required to pay ANI a termination fee of up to \$1.0 million or ANI will be required to pay the Company a termination fee of up to \$750,000. The New Merger Agreement also provides that under specified circumstances, the Company may be required to reimburse ANI up to \$500,000 for ANI's expenses in connection with the transaction. Any expenses paid by the Company will be credited against the \$1.0 million termination fee if the termination fee subsequently becomes payable by the Company.

Table of Contents

*Amended and Restated Voting Agreements*

Concurrently and in connection with the execution of the New Merger Agreement, certain of ANI's stockholders, who collectively held approximately 90% of the outstanding shares of ANI capital stock as of April 12, 2013, entered into amended and restated voting agreements with the Company, pursuant to which each such ANI stockholder agreed to vote its shares of ANI capital stock in favor of the New Merger, the New Merger Agreement and the transactions contemplated by the New Merger Agreement and against certain transactions or certain actions that would delay, prevent or nullify the New Merger or the transaction contemplated by the New Merger Agreement. In addition, one of ANI's stockholders, who held approximately 57% of the outstanding shares of ANI capital stock as of April 12, 2013, entered into an amended and restated voting agreement, pursuant to which such ANI stockholder agreed to vote in favor of the election of the two directors designated by the Company at the first annual meeting of stockholders following completion of the New Merger.

In addition, certain of the Company's stockholders, directors and officers, who collectively held approximately two percent of the outstanding shares of the Company's capital stock as of April 12, 2013, entered into amended and restated voting agreements with ANI, pursuant to which each such stockholder of the Company agreed to vote its shares of the Company's capital stock in favor of the issuance of shares of the Company's common stock in the New Merger and against certain transactions or certain actions that would delay, prevent or nullify the New Merger or the transaction contemplated by the New Merger Agreement.

These voting agreements will terminate upon the earlier of the effective time of the New Merger or termination of the New Merger Agreement; provided, however, that the voting agreement pursuant to which ANI's stockholder agreed to vote in favor of the election of the two directors designated by the Company at the first annual meeting of stockholders following completion of the New Merger will terminate upon the earlier of completion of the first annual meeting of stockholders following completion of the New Merger or the termination of the New Merger Agreement.

*Amended and Restated Lock-Up Agreements*

Concurrently and in connection with the execution of the New Merger Agreement, ANI's chief executive officer and chief financial officer and certain of ANI's stockholders, who collectively held approximately 85% of the outstanding shares of ANI capital stock as of April 12, 2013, entered into amended and restated lock-up agreements with the Company, pursuant to which each such ANI stockholder will be subject to a six-month lock-up on the sale of shares of the Company's common stock received in the New Merger. The amended and restated lock-up agreements for ANI's chief executive officer and chief financial officer, however, will permit these individuals to begin immediately after the effectiveness of the New Merger to sell up to one-half of their shares in market transactions pursuant to a trading plan adopted pursuant to Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the Exchange Act).

*Contingent Value Rights Agreement*

Pursuant to the terms of the New Merger Agreement, the Company has the right to issue contingent value rights (CVRs) to holders of the Company's common stock immediately prior to completion of the New Merger. It is anticipated that the CVRs will be issued upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between the Company, ANI and Computershare, as rights agent. Pursuant to the terms of the contingent value rights agreement, one CVR will be issued for each share of the Company's common



## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

stock outstanding as of the record date, which has been set by the Company's Board of Directors for June 19, 2013. The CVRs will not be certificated and will not be attached to the shares of the Company's common stock. Each CVR will be a non-transferable (subject to certain limited exceptions) right potentially to receive certain cash payments, during the ten-year period after the distribution of the rights, resulting from the LibiGel program, including (i) 66% of any net cash payments received by the Company as a result of a sale, transfer, license or similar transaction relating to the Company's

Table of Contents

LibiGel program, as determined pursuant to the agreement, and (ii) 5% of net revenues from direct sales of LibiGel products after the New Merger, assuming that the Company incurs less than \$2.5 million of additional development expenses. The amount potentially payable under the contingent value rights agreement will not exceed \$50 million in the aggregate.

*Rescission of Prior CVR Distribution*

On March 15, 2013, the Company's Board of Directors had declared a distribution of CVRs to be effective as of April 12, 2013, the date of the adjourned stockholders meeting for the Prior Merger, but conditioned upon completion of the Prior Merger. As a result of the New Merger Agreement, the Company's Board of Directors rescinded this prior distribution of CVRs and intends to take action to issue the CVRs under the contingent value rights agreement at an appropriate time prior to completion of the New Merger.

**4. LIQUIDITY AND CAPITAL RESOURCES**

Substantially all of the Company revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. The Company's business operations to date have consisted primarily of licensing and research and development activities, and if the Company does not complete its proposed New Merger with ANI, the Company would expect this to continue for the immediate future. To date, the Company 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. (Cell Genesys) to fund its ongoing business operations and short-term liquidity needs.

As of March 31, 2013, the Company had \$29.4 million of cash and cash equivalents. As of March 31, 2013, the Company had outstanding \$8,277,850 in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013 (the 2013 Notes). Subsequent to the end of the first quarter of 2013, on April 30, 2013 immediately prior to the May 1, 2013 maturity date of the 2013 Notes, the Company repaid in its entirety the outstanding principal amount of the 2013 Notes, plus all accrued and unpaid interest thereon through such date. Absent the receipt of any additional licensing income or financing, the Company expects its cash and cash equivalents balance to decrease as it continues to use cash to fund its operations. Assuming the proposed New Merger between the Company and ANI is completed, the Company expects its cash and cash equivalents as of March 31, 2013 to meet its liquidity requirements through at least the anticipated closing of the New Merger at the end of the second quarter of 2013. If the proposed New Merger between the Company and ANI is not completed, the Company will need to reevaluate its strategic alternatives, which may include continuing as an independent, stand-alone business, a sale of the Company, or other strategic transaction. The Company's liquidity position will be dependent upon the strategic alternative selected; however, assuming the Company does not enter into another strategic transaction, and assuming the Company decides not to commence new efficacy trials for LibiGel, the Company expects its cash and cash equivalents as of March 31, 2013 will be sufficient to meet its liquidity requirements for at least the next three to five years. Additional financing would be required should the Company decide to commence new efficacy trials for LibiGel. These estimates may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier.

The Company does not have any existing credit facilities under which the Company could borrow funds. In the event that the Company would require additional working capital to fund future operations, the Company could seek to acquire such funds through additional equity or debt financing arrangements. If the Company raises additional funds by issuing equity securities, the Company's stockholders may experience dilution. Debt financing, if available, may involve covenants restricting the Company's operations or its ability to incur debt. There is no assurance that any financing transaction will be available on terms acceptable to the Company, or at all. As an alternative to raising additional financing, the Company may choose to license one or more of the Company's 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, or sell certain assets or rights under the

Company's existing license agreements.

Table of Contents

The Company is subject to pending purported class action and shareholder derivative litigation, which litigation is described in more detail in Note 10, Commitments and Contingencies. Such litigation could divert management's attention, harm the Company's business and/or reputation and result in significant liabilities, as well as harm the Company's ability to raise additional financing and execute certain strategic alternatives.

The Company can provide no assurance that additional financing, if needed, will be available on terms favorable to the Company, or at all. This is particularly true if investors are not confident in the success of the Company's proposed New Merger with ANI, the Company's LibiGel clinical development program, the future value of the Company and/or economic and market conditions deteriorate. If the Company does not complete its proposed New Merger with ANI and if adequate funds are not available or are not available on acceptable terms when the Company needs them, the Company may need to reduce its operating costs or the Company may be forced to explore other strategic alternatives, such as other business combination transactions or winding down the Company's operations and liquidating the Company. In such case, the Company's stockholders could lose some or all of their investment.

**5. BASIC AND DILUTED NET LOSS PER SHARE**

The basic and diluted net loss per share is computed based on the weighted average number of shares of common stock and class C special stock outstanding, all being considered as equivalent of one another. Basic net loss per share is computed by dividing the net loss by the weighted average number of shares outstanding for the reporting period. Diluted net loss per share is intended to reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Because the Company has incurred net losses from operations in each of the periods presented, the Company's outstanding options, warrants and convertible debt are antidilutive; accordingly, such securities are excluded from the computation of diluted net loss per share and there is no difference between basic and diluted net loss per share amounts.

**6. CONVERTIBLE SENIOR NOTES**

At March 31, 2013 and December 31, 2012, the Company had \$8,277,850 in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 outstanding. On April 30, 2013, immediately prior to the May 1, 2013 maturity date of the 2013 Notes, the Company repaid in its entirety the outstanding principal amount of the 2013 Notes, plus all accrued and unpaid interest thereon of \$129,341 through such date.

The 2013 Notes were general, unsecured obligations of the Company and are described in Note 7 to the Company's financial statements for the year ended December 31, 2012. As of March 31, 2013, the 2013 Notes were not eligible for redemption. The indenture governing the 2013 Notes, as supplemented by the supplemental indenture, did not contain any financial covenants and did not restrict the Company from paying dividends, incurring additional debt or issuing or repurchasing the Company's other securities. In addition, the indenture, as supplemented by the supplemental indenture, did not protect the holders of the 2013 Notes in the event of a highly leveraged transaction or a fundamental change of the Company except in certain circumstances specified in the indenture.

In February 2012, the Company issued an aggregate of 1.9 million shares of its common stock to one of the holders of the 2013 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. A non-cash fair value adjustment of \$(2,545,530) was recorded during the three months ended March 31, 2012 as a result of the cancellation of such notes. The fair value adjustment recorded upon cancellation of these 2013 Notes was primarily attributable to the time value effect of

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

settling these obligations at a date prior to the stated maturity of the 2013 Notes. No 2013 Notes were cancelled during the three months ended March 31, 2013.

The Company elected to record the 2013 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

Table of Contents

would require specialized valuation, bifurcation and recognition. Accordingly, the Company has adjusted the carrying value of the 2013 Notes to their fair value as of March 31, 2013, with changes in the fair value of the Notes occurring since December 31, 2012, reflected in fair value adjustment in the statements of operations. The fair value of the 2013 Notes is based on Level 2 inputs. The recorded fair value of the 2013 Notes of an aggregate of \$8,169,215 as of March 31, 2013 differs from their total stated aggregate principal amount of \$8,277,850 as of such date by \$108,635. The recorded fair value of the 2013 Notes of an aggregate of \$7,883,886 as of December 31, 2012 differed from their total stated aggregate principal amount of \$8,277,850 as of such date by \$393,964. During the three months ended March 31, 2013, the Company recorded a fair value adjustment of \$(285,329) related to the 2013 Notes that remained outstanding as of March 31, 2013, that increased the recorded liability and corresponding expense. For the three months ended March 31, 2012, the Company recorded a fair value adjustment of \$(664,808).

There was an immaterial change in the aggregate fair value of the 2013 Notes due to instrument specific credit risk for the three months ended March 31, 2013 and 2012.

The Company established the value the 2013 Notes based upon contractual terms of the 2013 Notes, as well as certain key assumptions.

The assumptions as of March 31, 2013 were:

	<b>2013 Notes</b>
Average risk-free rate	0.04%
Volatility of BioSante common stock	35.6%
Discount rate for principal payments in cash	20.0%

The assumptions as of December 31, 2012 were:

	<b>2013 Notes</b>
Average risk-free rate	0.08%
Volatility of BioSante common stock	79.9%
Discount rate for principal payments in cash	19.4%

The discount rate was based on observed yields as of the measurement date for debt securities of entities having a Ca and Caa3 rating for long-term corporate obligations as assigned by Moody's Investors Service. Volatility was based on the historical fluctuations in the Company's stock price for a period of time equal to the remaining time until the debt maturity. The risk-free rate was based on observed yields as of the measurement date of one-year, two-year and three-year U.S. Treasury Bonds.

## 7. STOCK-BASED COMPENSATION

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

All options are granted under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the 2008 Plan). As of March 31, 2013, 1,116,555 shares of the Company's common stock remained available for issuance under the 2008 Plan.

During the three months ended March 31, 2013, the Company did not grant any options under the 2008 Plan. Options to purchase an aggregate 75,672 shares of the Company's common stock expired and were cancelled during the three months ended March 31, 2013. No options were exercised during the three months ended March 31, 2013.

No warrants were granted or exercised during the three months ended March 31, 2013.

Table of Contents

**8. STOCKHOLDERS EQUITY**

During the three months ended March 31, 2013, the Company did not issue any shares of capital stock. Employee and director stock-based compensation expense of \$145,794 was recorded for the three months ended March 31, 2013.

**9. SALE OF GVAX CANCER VACCINE ASSETS**

On January 31, 2013, the Company entered into an asset purchase agreement with Aduro pursuant to which the Company sold all of its assets related to its GVAX cancer vaccine portfolio in exchange for a \$1.0 million cash payment plus the potential for future royalty, milestone and sublicense payments. The royalty rate payable by Aduro to the Company on net sales of GVAX products is 2% of net sales for the longer of: (1) the remaining life on any applicable GVAX patent; or (2) the seventh anniversary of the first commercial sale of each GVAX product. A \$2.0 million milestone payment will be payable by Aduro to the Company upon the achievement of \$10.0 million in net sales of GVAX-pancreas products and a \$2.0 million milestone payment will be payable by Aduro to the Company upon the achievement of \$10.0 million in net sales of GVAX-prostate products, with a maximum amount payable of \$50.0 million for each category of products. Additional launch and sales-based milestone payments will be payable by Aduro to the Company upon the achievement of certain specified net sales of other GVAX containing products, other than products to treat pancreas or prostate cancer. The maximum amount payable by Aduro to the Company under the agreement for royalties and milestone payments is \$162.0 million. The Company also is entitled to receive 50 percent of all amounts received by Aduro from milestone and royalty payments from The John P. Hussman Foundation related to melanoma, net of related costs borne by Aduro.

**10. COMMITMENTS AND CONTINGENCIES**

*Antares Pharma, Inc. License*

The Company's license agreement with Antares Pharma, Inc. (Antares) requires the Company to fund the development of the licensed products, make milestone payments and pay royalties on the sales of products related to this license. As of March 31, 2013 and 2012, the Company paid or accrued \$145,040 and \$114,000, respectively, to Antares as a result of royalties generated by Elestrin revenues.

*Wake Forest License*

In April 2002, the Company exclusively in-licensed from Wake Forest University Health Sciences and Cedars-Sinai Medical Center three issued U.S. patents claiming triple component therapy (the combination use of estrogen plus progestogen plus androgen, e.g. testosterone) and obtained an option to license the patents for triple component contraception. The financial terms of the license included an upfront payment by the Company in exchange for exclusive rights to the license and regulatory milestone payments, maintenance payments and royalty payments by the Company if a product incorporating the licensed technology gets approved and subsequently marketed. In July 2005, the Company exercised the option for an exclusive license for the three U.S. patents for triple component contraception. The financial terms of this license included an



## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

upfront payment, regulatory milestone payments, maintenance payments and royalty payments by the Company if a product incorporating the licensed technology gets approved and subsequently marketed. In December 2012, the Company and Wake Forest University Health Sciences and Cedars-Sinai Medical Center entered into an amendment to the license agreement pursuant to which the Company received a fully paid-up right and exclusive license to the licensed technology in exchange for a \$300,000 payment.

The Company has agreed to indemnify, hold harmless and defend Wake Forest University Health Sciences and Cedars-Sinai Medical Center against any and all claims, suits, losses, damages, costs, fees and expenses resulting from or arising out of exercise of the license agreement, including but not limited to, any

Table of Contents

product liability claims. The Company has not recorded any liability in connection with this obligation as no events occurred that would require indemnification.

*Unpaid Annual Bonuses for 2012*

On February 25, 2013, the Company's Board of Directors, upon recommendation of the Compensation Committee, and after reviewing recent accomplishments of the Company's management team not relating to the Company's Prior Merger with ANI, including in particular the sale of the GVAX cancer vaccine assets to Aduro, the amendment to the license and development agreement with Teva and other developments with respect to LibiGel, awarded annual cash bonuses to the Company's executive and other officers. The amount of the individual bonuses ranged from \$25,000 to \$200,000 and, in the case of each executive, amounted to less than, and in some cases, substantially less than, target bonuses under the Company's performance incentive plan. The payment of these bonuses will have no effect on the severance payments anticipated to be paid to these individuals upon termination of their employment in connection with the proposed New Merger with ANI. These bonuses will not be paid until immediately prior to the effective time of the proposed New Merger with ANI. Until payment of these bonuses, the Compensation Committee has the power and authority to revoke, reduce or delay their payment. As of March 31, 2013, the Company had accrued \$350,000 related to these bonuses. Pursuant to the terms of the New Merger Agreement, these bonuses will be paid only if the New Merger occurs and the Company has net cash that equals or exceeds a specified minimum amount.

*Employee Reduction Implications*

As a result of the conclusion of the Company's LibiGel Phase III cardiovascular events and breast cancer safety study, as announced by the Company in September 2012, and in light of the Company's proposed New Merger with ANI, the Company plans to reduce its workforce further during 2013 effective upon completion of the New Merger. In connection with the announced reduction, the Company will pay \$1,127,719 to non-executive officers in aggregate severance costs during 2013. If the proposed New Merger with ANI is completed, the employment of the Company's two executive officers will terminate immediately following completion of the New Merger and such officers will be entitled to receive severance cash payments ranging from \$770,000 to \$1,490,100 and other severance benefits, such as continuing health insurance, in connection with such termination. In January 2013, the Company funded a rabbi trust with approximately \$2.3 million of cash for the purpose of providing a funding mechanism to make severance payments to these two executive officers who will become entitled to such payments six months after the closing of the proposed New Merger with ANI. Cash held in the rabbi trust is considered restricted cash based on the terms of the rabbi trust and included as a separate line item under current assets in the Company's balance sheet.

*Pending Litigation*

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 the Company and its President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of the Company'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 the Company's securities resulting in violations of Section 10(b) of the Exchange Act, 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 the Company'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. The Company believes the action is without merit and intends to defend the action vigorously. On November 6, 2012, the plaintiff filed a consolidated amended

complaint. On December 28, 2012, the Company and Mr. Simes filed motions to

Table of Contents

dismiss the consolidated amended complaint. Briefing on the motion to dismiss is complete and the parties await the Court's ruling.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of the Company 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 the Company's directors as defendants and the Company 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 the Company'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, the plaintiffs filed their consolidated amended 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 the amended complaint in the action pending in District Court, and on January 18, 2013, the defendants filed a motion to dismiss the amended complaint in the action pending in Illinois state court. Briefing on these motions is complete and the parties await the Courts' rulings.

The lawsuits are in their early stages; and, therefore, the Company 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 the Company's operations. Depending on the outcome or resolution of these lawsuits, they could have a material effect on the Company's operations, including its financial condition, results of operations, or cash flows. No amounts have been accrued related to these lawsuits as of March 31, 2013.

**11. FAIR VALUE MEASUREMENTS**

The Company accounts for its convertible debt and U.S. Treasury money market fund at fair value. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, a fair value hierarchy has been established that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk.



Table of Contents

Financial assets and liabilities recorded at fair value on a recurring basis as of March 31, 2013 and December 31, 2012 are classified in the tables below in one of the three categories described above:

Description	March 31, 2013 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market fund	\$ 28,452,314		\$ 28,452,314	
Restricted cash	2,260,100		2,260,100	
Total assets	\$ 30,712,414		\$ 30,712,414	
<b>Liabilities:</b>				
2013 Notes	\$ 8,169,215		\$ 8,169,215	
Total liabilities	\$ 8,169,215		\$ 8,169,215	

Description	December 31, 2012 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market fund	\$ 34,210,555		\$ 34,210,555	
Total assets	\$ 34,210,555		\$ 34,210,555	
<b>Liabilities:</b>				
2013 Notes	7,883,886		7,883,886	
Total liabilities	\$ 7,883,886		\$ 7,883,886	

The Company made an election to record the values of the 2013 Notes at fair value with gains and losses related to fluctuations in the value of these financial liabilities recorded in earnings immediately. The fair values of the 2013 Notes are estimated based on the risk-free borrowing rate, the volatility of the Company's stock, and the current borrowing rates for similar companies. See Note 6, "Convertible Senior Notes" for more information and disclosures regarding key assumptions used in this fair value determination.

## 12. SUBSEQUENT EVENTS

On April 19, 2013, Ceregene, Inc., an early stage pharmaceutical development company in which the Company is an investor, announced that data from one of Ceregene's Phase 2 clinical studies did not demonstrate statistically significant efficacy on the primary endpoint. As a result, the Company believes that the fair value of this investment may be impaired when compared to its \$3.2 million historical book value. An updated analysis of fair value to determine impairment, if any, has not yet been performed, but will be performed during the second quarter of 2013.

Table of Contents

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

This Management's Discussion and Analysis provides material historical and prospective disclosures intended to enable investors and other users to assess BioSante's financial condition and results of operations. Statements that are not historical are forward-looking and involve risks and uncertainties discussed under the heading "Forward-Looking Statements" below. The following discussion of BioSante's results of operations and financial condition should be read in conjunction with BioSante's financial statements and the related notes thereto included elsewhere in this report.

**Overview**

BioSante is a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. 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 BioSante, with the goal of maximizing stockholder value.

**Recent Development and Proposed New Merger with ANI**

***Background***

On October 3, 2012, BioSante entered into an agreement and plan of merger (referred to as the prior merger agreement) with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (ANI). The prior merger agreement provided that, upon the terms and subject to the conditions set forth in the agreement, ANI would merge with and into BioSante, with BioSante continuing as the surviving company (referred to as the prior merger). The prior merger agreement was approved by ANI stockholders on March 15, 2013. BioSante adjourned its special meeting of stockholders called to approve the prior merger until April 12, 2013 to give BioSante stockholders additional time to vote. As of April 12, 2013, voting instructions to vote shares in favor of the prior merger had been received from holders of approximately 36 percent of the outstanding shares of BioSante capital stock, which was short of the required majority needed to approve the prior merger. Of those shares as to which voting instructions had been given, approximately 84 percent were to be voted in favor of the prior merger. However, no voting instructions on the prior merger had been received from holders of a total of approximately 13.8 million shares, or approximately 57 percent of the outstanding shares of BioSante capital stock. Two other proposals submitted to BioSante stockholders in connection with the prior merger, a reverse stock split and a name change, also received affirmative voting instructions from holders of a majority of the shares of BioSante capital stock as to which voting instructions were received, but neither received affirmative voting instructions with respect to the required majority of the outstanding shares of BioSante capital stock.

Subsequent to March 15, 2013, BioSante determined that it was not likely to receive sufficient additional voting instructions prior to April 12, 2013 (or on any later date) to either approve the prior merger and the two other related proposals or to indicate that BioSante stockholders had rejected the prior merger or these other proposals. Accordingly, the BioSante board of directors decided to begin discussions with ANI about a

possible restructured merger.



Table of Contents

*Amended and Restated Agreement and Plan of Merger*

On April 12, 2013, BioSante and ANI entered into an amended and restated agreement and plan of merger, pursuant to which, upon the terms and subject to the conditions contained therein, a newly formed wholly owned subsidiary of BioSante (Merger Sub) will be merged with and into ANI, after which ANI will be a wholly owned subsidiary of BioSante. The merger agreement amends and restates in its entirety the prior merger agreement. The required BioSante stockholder vote for the merger will be a majority of the shares of BioSante common stock and class C special stock present and entitled to vote at the stockholders meeting at which the issuance of shares of BioSante common stock in the merger will be considered.

Pursuant to the terms of the merger agreement, at the effective time of the merger, each outstanding share of capital stock of ANI will be converted into the right to receive a 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 BioSante or ANI 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 the consummation of the transactions contemplated by the merger agreement, the stockholders of ANI immediately prior to the effective time of the merger will own 57 percent of the outstanding shares of BioSante common stock and the stockholders of BioSante immediately prior to the effective time of the merger will own 43 percent of the outstanding shares of BioSante common stock. Unlike the exchange ratio provision in the prior merger agreement, the respective percentage ownerships of the ANI and BioSante stockholders in BioSante after the merger are fixed at 57 percent and 43 percent, respectively, and are not subject to adjustment based on BioSante's net cash. 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 Code).

The merger agreement provides that, immediately following the effective time of the merger, the BioSante board of directors will consist of five current directors of ANI and two current directors of BioSante, and ANI's current executive officers are expected to serve as executive officers of BioSante.

Consummation of the merger is subject to a number of conditions, including, but not limited to (i) approval of the issuance of shares of BioSante common stock in the merger by BioSante stockholders and the adoption and approval of the merger agreement and the transactions contemplated thereby by ANI stockholders; (ii) written opinions of counsel that the merger will qualify as a reorganization within the meaning of Section 368(a) of the Code; and (iii) other customary closing conditions.

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 execution of the merger agreement and consummation of the merger (and BioSante will not incur compensation expenses for employees and consultants in excess of specified monthly amounts); (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 ANI board of directors will recommend that ANI stockholders adopt and approve the merger agreement, subject to certain exceptions; and (iv) BioSante will convene and hold a meeting of its stockholders for the purpose of considering the approval of the issuance of shares of BioSante common stock in the merger and the BioSante board of directors will recommend that BioSante stockholders adopt and approve such proposal, 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.



Table of Contents

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.

***Amended and Restated Voting Agreements***

Concurrently and in connection with the execution of the merger agreement, certain of ANI stockholders, who collectively held approximately 90 percent of the outstanding shares of ANI capital stock as of April 12, 2013, entered into amended and restated voting agreements with BioSante, pursuant to which each such 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 April 12, 2013, entered into an amended and restated voting agreement, pursuant to which such ANI stockholder agreed to vote in favor of the election of the two directors designated by BioSante at the first annual meeting of stockholders following completion of the merger.

In addition, certain of BioSante stockholders, directors and officers, who collectively held approximately two percent of the outstanding shares of BioSante capital stock as of April 12, 2013, entered into amended and restated voting agreements with ANI, pursuant to which each such BioSante stockholder agreed to vote its shares of BioSante capital stock in favor of the issuance of shares of BioSante common stock in the merger and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transactions contemplated by the merger agreement.

These voting agreements will terminate upon the earlier of the effective time of the merger or termination of the merger agreement; provided, however, that the voting agreement pursuant to which the ANI stockholder agreed to vote in favor of the election of the two directors designated by BioSante at the first annual meeting of stockholders following completion of the merger will terminate upon the earlier of completion of the first annual meeting of stockholders following completion of the merger or the termination of the merger agreement.

***Amended and Restated 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 capital stock as of April 12, 2013, entered into amended and restated lock-up agreements with BioSante, pursuant to which each such ANI stockholder will be subject to a six-month lock-up on the sale of shares of BioSante common stock received in the merger. The amended and restated lock-up agreements for ANI's chief executive officer and chief financial officer, however, will permit these individuals to begin immediately after the effectiveness of the merger to sell up to one-half of their shares in market transactions pursuant to a trading plan adopted pursuant to Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the Exchange Act).

*Contingent Value Rights Agreement*

On March 15, 2013, the BioSante board of directors had declared a distribution of contingent value rights (CVRs) to be effective as of April 12, 2013, the date of the adjourned BioSante stockholders meeting for the prior merger, but conditioned upon completion of the prior merger. As a result of the merger

Table of Contents

agreement, the BioSante board of directors rescinded this prior distribution of CVRs and intends to take action to issue the CVRs under the contingent value rights agreement at an appropriate time prior to the merger.

Pursuant to the terms of the merger agreement, BioSante has the right to issue CVRs to existing BioSante stockholders immediately prior to completion of the merger. The CVRs will be issued upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between BioSante, ANI and Computershare, as rights agent. Pursuant to the terms of the contingent value rights agreement, one CVR will be issued for each share of BioSante common stock outstanding as of the record date, which was set by BioSante's Board of Directors for June 19, 2013. The 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 potentially to receive certain cash payments, during the ten-year period after the distribution of the rights, resulting from the LibiGel program, including (i) 66 percent of any net cash payments received by BioSante as a result of a sale, transfer, license or similar transaction relating to BioSante's LibiGel program, as determined pursuant to the agreement, and (ii) five percent of net revenues from direct sales of LibiGel products after the merger, assuming that BioSante incurs less than \$2.5 million of additional development expenses. The amount potentially payable under the contingent value rights agreement will not exceed \$50 million in the aggregate.

**Business Overview**

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).
- 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), BioSante's licensee.

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,

Table of Contents

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 has developed a protocol for new LibiGel efficacy trials. If BioSante decides to commence new LibiGel efficacy trials, BioSante plans to seek an FDA SPA agreement covering aspects of new efficacy trials prior to commencing such trials. If the proposed merger with ANI is completed, it is unlikely that BioSante or the combined company will commence new efficacy trials.

Elestrin was BioSante's first FDA approved product and now is one of BioSante's two FDA approved products. Meda (which acquired Jazz Pharmaceuticals, Inc.'s women's health business and which in turn had 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 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 was developed initially 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, AbbVie Inc., 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. 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.

Table of Contents

In October 2012, BioSante entered into an amendment to its agreement with Teva pursuant to which Teva made a non-refundable \$1.0 million payment to BioSante upon the signing of the amendment and a non-refundable \$750,000 payment in December 2012. Teva also 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®; and (2) \$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.

BioSante licenses the technology underlying certain of its gel products, including LibiGel and Elestrin, but not the male testosterone gel, from Antares Pharma, Inc. (Antares). 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 March 31, 2013, 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 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.

On January 31, 2013, BioSante entered into an asset purchase agreement with Aduro BioTech, Inc. (Aduro) pursuant to which BioSante sold all of its assets related to its GVAX cancer vaccine portfolio in exchange for a \$1.0 million cash payment plus the potential for future royalty, milestone and sublicense payments. The royalty rate payable by Aduro to BioSante on net sales of GVAX products is two percent of net sales for the longer of: (1) the remaining life on any applicable GVAX patent; or (2) the seventh anniversary of the first commercial sale of each GVAX product. A \$2.0 million milestone payment will be payable by Aduro to BioSante upon the achievement of \$10.0 million in net sales of GVAX-pancreas products and a \$2.0 million milestone payment will be payable by Aduro to BioSante upon the achievement of \$10.0 million in net sales of GVAX-prostate products, with a maximum amount payable of \$50.0 million for each



Table of Contents

category of products. Additional launch and sales-based milestone payments will be payable by Aduro to BioSante upon the achievement of certain specified net sales of other GVAX containing products, other than products to treat pancreas or prostate cancer. The maximum amount payable by Aduro to BioSante under the agreement for royalties and milestone payments is \$162.0 million. BioSante also is entitled to receive 50 percent of all amounts received by Aduro from milestone and royalty payments from The John P. Hussman Foundation related to melanoma, net of related costs borne by Aduro.

**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 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. (Cell Genesys) to fund its ongoing business operations and short-term liquidity needs.

As of March 31, 2013, BioSante had \$29.4 million of cash and cash equivalents and had outstanding \$8,277,850 in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013. Subsequent to the end of the first quarter of 2013, on April 30, 2013 immediately prior to the May 1, 2013 maturity date of the convertible senior notes, BioSante repaid in its entirety the outstanding principal amount of the notes, plus all accrued and unpaid interest thereon through such date. 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 with ANI is completed, BioSante expects its cash and cash equivalents as of March 31, 2013 to meet its liquidity requirements through at least the anticipated closing of the merger at the end of the second quarter of 2013. If the proposed merger with 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, 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 new efficacy trials for LibiGel, BioSante expects its cash and cash equivalents as of March 31, 2013 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 new efficacy trials for LibiGel. These estimates may prove incorrect or BioSante, nonetheless, may choose to raise additional financing earlier.

BioSante incurred expenses of \$972,049 on research and development activities during the three months ended March 31, 2013, which is a 86 percent decrease compared to the same period in 2012, primarily as a result of the conclusion of the LibiGel safety study in September 2012. BioSante anticipates that its research and development expenses for the remainder of 2013 will be approximately \$0.6 million, including \$0.2 million of severance costs, and will consist primarily of expenses associated with the conclusion of the safety study. This estimate assumes no further development of LibiGel and completion of the proposed merger with ANI, but does not include research and development expenses to be incurred by the combined company after completion of the merger.

General and administrative expenses for the three months ended March 31, 2013 increased 6 percent compared to the same period in 2013 primarily as a result of an increase in professional fees and other administrative expenses primarily in connection with the proposed merger with ANI.

BioSante recognized a net loss for the three months ended March 31, 2013 of \$2.3 million compared to a net loss of \$10.3 million for the three months ended March 31, 2012. This decrease 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. BioSante recognized a net loss per share for the three

months ended March 31, 2013 of \$0.09 compared to a net loss per share of \$0.53 for the three months ended

Table of Contents

March 31, 2012. The decrease in net loss per share was primarily the result of the lower net loss described above in the three months ended March 31, 2013 as compared to the same period in 2012. BioSante expects to continue to incur continuing losses for the foreseeable future.

On April 19, 2013, Ceregene, Inc., an early stage pharmaceutical development company in which BioSante is an investor, announced that data from one of Ceregene's Phase 2 clinical studies did not demonstrate statistically significant efficacy on the primary endpoint. As a result, BioSante believes that the fair value of this investment may be impaired when compared to its \$3.2 million historical book value. An updated analysis of fair value to determine impairment, if any, has not yet been performed, but will be performed during the second quarter of 2013. If the fair value of this investment is impaired, BioSante will incur an investment impairment charge.

**Results of Operations***Three Months Ended March 31, 2013 Compared to Three Months Ended March 31, 2012*

The following table sets forth BioSante's results of operations for the three months ended March 31, 2013 and 2012.

	Three Months Ended March 31,		\$ Change	% Change
	2013	2012		
Revenue	\$ 145,040	\$ 114,000	\$ 31,040	27.2%
Expenses				
Research and development	972,049	5,183,217	(4,211,168)	(81.2)%
General and administrative	1,949,114	1,831,852	117,262	6.4%
Other expense - Convertible note fair value adjustment	(285,329)	(3,210,338)	(2,925,009)	(91.1)%
Other expense - Interest expense	(64,671)	(124,196)	(59,525)	(47.9)%
Other income - Interest income	1,860	1,992	(132)	(6.6)%
Other income - Gain on sale of intellectual property	1,000,000	0	1,000,000	100.0%
Net loss	\$ (2,290,649)	\$ (10,264,477)	(7,973,828)	(77.7)%
Net loss per common share (basic and diluted)	\$ (0.09)	\$ (0.53)	\$ (0.44)	(83.0)%
Weighted average number of common shares and common equivalent shares outstanding	24,487,451	19,377,768	5,109,683	26.4%

The only revenue recognized during the three months ended March 31, 2013 and 2012 consisted of royalty revenue from Meda, or, in 2012, Jazz Pharmaceuticals, Inc., for Elestrin sales, which royalty revenue is offset by a corresponding obligation to pay Antares royalties representing the same amount. The corresponding obligation to pay Antares a portion of the royalties received, which equaled \$145,040 during the three months ended March 31, 2013 and \$114,000 during the three months ended March 31, 2012, is recorded within general and administrative expenses in the statements of operations.

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

Research and development expenses for the three months ended March 31, 2013 decreased 81 percent compared to the three months ended March 31, 2012 primarily as a result of the conclusion of the LibiGel safety study in September 2012.

General and administrative expenses for the three months ended March 31, 2013 increased 6 percent compared to the three months ended March 31, 2012 primarily as a result of an increase in professional fees and other administrative expenses primarily in connection with BioSante's prior merger with ANI.

Table of Contents

The convertible note fair value adjustment for the three months ended March 31, 2013 included an adjustment of \$285,329 to increase the recorded liability and corresponding expense of the remaining \$8,277,850 in aggregate principal amount of convertible senior notes primarily due to the notes approaching maturity on May 1, 2013. The convertible fair value adjustment for the three months ended March 31, 2012 included an adjustment of \$664,808 to increase the recorded liability and corresponding expense. Additionally, a non-cash fair value adjustment of \$2,545,530 was recorded during the three months ended March 31, 2012 upon cancellation of \$9.0 million in aggregate principal amount of convertible senior notes in February 2012.

Interest expense was \$64,671 and \$124,196 for the three months ended March 31, 2013 and 2012, respectively, as a result of the convertible senior notes. Interest expense decreased during the current year period as a result of the cancellation of approximately \$12.6 million in aggregate principal amount of convertible senior notes due May 1, 2013, including accrued and unpaid interest, during 2012 in exchange for the issuance of approximately 3.7 million shares of common stock.

Interest income decreased \$132 for the three months ended March 31, 2013 compared to the three months ended March 31, 2012 as a result of lower average cash balances during the current year period.

**Liquidity and Capital Resources**

The following table highlights several items from BioSante's balance sheets:

<b>Balance Sheet Data</b>	<b>March 31, 2013</b>	<b>December 31, 2012</b>
Cash and cash equivalents	\$ 29,388,772	\$ 34,794,341
Total current assets	31,926,746	35,173,144
Investments	3,413,762	3,413,762
Total assets	35,356,386	38,769,170
Total current liabilities	9,325,736	10,593,665
Total liabilities	9,325,736	10,593,665
Total stockholders' equity	26,030,650	28,175,505

**Working Capital**

Since inception, BioSante has incurred significant operating losses resulting in an accumulated deficit of \$247.2 million as of March 31, 2013. 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 March 31, 2013, BioSante had \$29.4 million of cash and cash equivalents and \$8,277,850 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 with ANI is completed, BioSante expects its cash and cash equivalents as of March 31, 2013 to meet its liquidity requirements through at least the

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

anticipated closing of the merger at the end of the second quarter of 2013. If the proposed merger with 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, 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 new efficacy trials for LibiGel, BioSante expects its cash and cash equivalents as of March 31, 2013 will be sufficient to meet its liquidity requirements for at least the next three to five years. Substantial additional financing would be required should BioSante decide to commence new efficacy trials

Table of Contents

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 with 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 the proposed merger with ANI is not completed, new LibiGel Phase III efficacy trials if BioSante decides to commence such trials, 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 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;

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

- the perceived, potential and actual commercial success of BioSante's products;
- 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, BioSante's stockholders may experience dilution. Debt financing, if available, may involve covenants restricting BioSante's operations or its ability to incur 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 development and, if approved, commercialization of that licensed product, or sell certain assets or rights under its existing license agreements. A significant decrease in BioSante's cash balance, together with an inability to raise additional financing when needed, may



Table of Contents

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 report. Such litigation could divert management's attention, harm BioSante's 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 can provide no assurance that additional financing, if needed, will be available on terms favorable to it, or at all. This is particularly true if investors are not confident in the success of the proposed merger with ANI, BioSante's LibiGel development program, BioSante's future value, and/or if economic and market conditions deteriorate. If BioSante does not complete the proposed merger with ANI and if adequate funds are not available or are not available on acceptable terms when BioSante needs them, it may need to reduce its operating costs 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's stockholders could lose some or all of their investment.

***Uses of Cash and Cash Flow***

Net cash used in operating activities was \$4.1 million for the three months ended March 31, 2013 compared to net cash used in operating activities of \$7.7 million for the three months ended March 31, 2012. Net cash used in operating activities for the three months ended March 31, 2013 was primarily the result of the net loss for the period, which was lower compared to the prior year period due to the conclusion of the LibiGel safety study in September 2012.

Net cash used in investing activities was \$1.3 million for the three months ended March 31, 2013 compared to net cash used in investing activities of \$62,189 for the three months ended March 31, 2012. Net cash used in investing activities for the three months ended March 31, 2013 was due to funding the rabbi trust. Net cash used in investing activities the three months ended March 31, 2012 was primarily due to the purchase of fixed assets.

Net cash provided by financing activities was \$0 for the three months ended March 31, 2013 and 2012.

***Commitments and Contractual Obligations***

BioSante did not have any material commitments for capital expenditures as of March 31, 2013. Please see the description of BioSante's contractual obligations and commitments as of December 31, 2012 as set forth in BioSante's annual report on Form 10-K for the fiscal year ended December 31, 2012. There were no material changes to such information since that date through March 31, 2013.

***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 its 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.

Table of Contents

**Critical Accounting Policies**

The discussion and analysis of BioSante's condensed financial statements and results of operations are based upon BioSante's condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed 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 Securities and Exchange Commission (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 the company 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 certain of its accounting policies as critical accounting policies. BioSante's critical accounting policies are described in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations section of its annual report on Form 10-K for the fiscal year ended December 31, 2012. There have been no changes to the critical accounting policies described in BioSante's annual report on Form 10-K for the fiscal year ended December 31, 2012.

**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.

**Forward-Looking Statements**

This quarterly report on Form 10-Q contains not only historical information, but also forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act, and are subject to the safe harbor created by those sections. In addition, BioSante or others on its behalf may make forward-looking statements from time to time in oral presentations, including telephone conferences and/or web casts open to the public, in news releases or reports, on its Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that BioSante expects, believes or anticipates will or may occur in the future are forward-looking statements including, in particular, the statements about its plans, objectives, strategies and prospects regarding, among other things, its financial condition, results of operations and business. BioSante has identified some of these forward-looking statements with words like believe, may, could, would, might, possible, potential, project, will, should, plan, predict, anticipate, estimate, hope, approximate, contemplate or continue, the negative of these words, other words and terms of meaning or the use of future dates. These forward-looking statements may be contained in the notes to BioSante's condensed financial statements and elsewhere in this report, including under the heading Part I. Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations. BioSante's forward-looking statements generally relate to:

- the status and timing of its proposed merger with ANI;
- the status and conduct of its LibiGel Phase III clinical development program and the timing of certain events related thereto;

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

- future operating expenses, anticipated burn rate and whether and how long its existing cash and cash equivalents will be sufficient to fund its operations;
  
- efforts to explore and evaluate various strategic alternatives with respect to its products and the possible effect such strategic alternatives may have on its business, including in particular its LibiGel Phase III clinical development program;

Table of Contents

- the market size and market acceptance of its approved products and products in development;
- the effect of new accounting pronouncements and future health care, tax and other legislation;
- its need, ability and expected timing of any actions to raise additional capital through future equity and other financings; and
- its continuing losses.

Forward-looking statements are based on current expectations about future events affecting BioSante and are subject to uncertainties and factors that affect all businesses operating in a global market as well as matters specific to BioSante. These uncertainties and factors are difficult to predict and many of them are beyond BioSante's control. The following are some of the uncertainties and factors known to BioSante that could cause its actual results to differ materially from what it has anticipated in its forward-looking statements or otherwise could materially adversely affect its business, financial condition or operating results:

- risk relating to its proposed merger with ANI;
- the future and success of its LibiGel Phase III clinical development program;
- its ability to generate significant revenues and obtain profitability;
- its ability to obtain additional capital when needed or on acceptable terms and the effect of any future equity or debt financings on its stockholders;
- the resolution of its pending purported class action and shareholder derivative litigation and the effect of such resolution on its business, operating results and financial condition;
- its ability to maintain the listing of its common stock on The NASDAQ Global Market;

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

- its ability 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;
- its ability to acquire or invest in new businesses, products and technologies by way of a license, acquisition or merger transaction and the effect of such a transaction on its stockholders, business, operating results and financial condition;
- its success in developing new products and technologies, obtaining any required regulatory approvals for such products and technologies and obtaining market acceptance and commercial success with respect to such new products and technologies;
- results of its clinical studies and the actions of certain regulatory bodies, including the FDA;
- its ability to submit and receive an FDA SPA agreement and other applications for and obtain and maintain required regulatory approvals on a timely basis or at all;
- the timing of when, if ever, its products will be approved and introduced commercially;
- the size of the market and the level of market acceptance of its products if and when they are commercialized;

Table of Contents

- its dependence upon the maintenance of its license with Antares and, to a lesser extent, other licensors;
  
- its dependence upon its licensees for the development, marketing and sale of certain of its products, including in particular Teva with respect to its male testosterone gel and the uncertainty involved in when or if Teva will launch commercially its male testosterone gel and the commercial success of such product and the amount of revenues BioSante may receive, if any, from such product;
  
- its ability to achieve projected goals and objectives within the time periods that it anticipates or announces publicly;
  
- uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy;
  
- its ability to protect its proprietary technology and to operate its business without infringing the proprietary rights of third parties;
  
- its ability to compete in a competitive industry;
  
- its dependence upon key employees;
  
- the risk of product liability lawsuits against BioSante or its licensees;
  
- its ability to maintain effective internal control over financial reporting;
  
- changes in applicable laws or regulations and our failure to comply with applicable laws and regulations;
  
- changes in generally accepted accounting principles and the effect of new accounting pronouncements; or
  
- conditions and changes in the biopharmaceutical industry or in general economic or business conditions.

For more information regarding these and other uncertainties and factors that could cause our actual results to differ materially from what BioSante has anticipated in its forward-looking statements or otherwise could materially adversely affect its business, financial condition or operating results, see BioSante's annual report on Form 10-K for the fiscal year ended December 31, 2012 under the heading "Part I Item 1A. Risk Factors" on pages 19 through 53 of such report and later in this report under the heading "Part II Item 1A. Risk Factors".

All forward-looking statements included in this report are expressly qualified in their entirety by the foregoing cautionary statements. BioSante cautions readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the uncertainties and factors described above and in BioSante's annual report on Form 10-K for the fiscal year ended December 31, 2012 under the heading "Part I Item 1A. Risk Factors" and later in this report under the heading "Part II Item 1A. Risk Factors" as well as others that BioSante may consider immaterial or does not anticipate at this time. Although BioSante believes that the expectations reflected in its forward-looking statements are reasonable, BioSante does not know whether its expectations will prove correct. Expectations reflected in



Table of Contents

forward-looking statements can be affected by inaccurate assumptions BioSante might make or by known or unknown uncertainties and factors, including those described above and in BioSante's annual report on Form 10-K for the fiscal year ended December 31, 2012 under the heading Part I Item 1A. Risk Factors and later in this report under the heading Part II Item 1A. Risk Factors. The risks and uncertainties described above are not exclusive and further information concerning BioSante and its business, including factors that potentially could materially affect its financial results or condition, may emerge from time to time. BioSante assumes no obligation to update, amend or clarify forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. BioSante advises you, however, to consult any further disclosures BioSante makes on related subjects in its annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K BioSante files with or furnishes to the SEC.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

BioSante is exposed to interest rate sensitivity on its cash equivalents and restricted cash in money market funds and its previously 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 report, all of BioSante's cash equivalents and restricted cash are only invested in U.S. Treasury money market funds.

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**

<b>As of March 31, 2013</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>Total</b>	<b>Fair Value March 31, 2013</b>
Cash Equivalents	\$ 28,452,314				\$ 28,452,314
Restricted Cash	2,260,100				2,260,100
<b>Total Cash Equivalents &amp; Restricted Cash</b>	<b>\$ 30,712,414</b>				<b>\$ 30,712,414</b>
Average Interest Rate	0.01%				
<b>Fixed Interest Rate 2013 Convertible</b>					
Senior Notes	\$ 8,277,850			\$ 8,277,850	\$ 8,169,215
Average Interest Rate	3.125%			3.125%	
<b>As of December 31, 2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>Total</b>	<b>Fair Value December 31, 2012</b>
Total Cash Equivalents	\$ 34,210,555				\$ 34,210,555
Average Interest Rate	0.01%				
	\$ 8,277,850			\$ 8,277,850	\$ 7,883,886

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

Fixed Interest Rate 2013 Convertible Senior  
Notes

Average Interest Rate	3.125%	3.125%
-----------------------	--------	--------

Table of Contents

**ITEM 4. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

BioSante maintains disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that the information required to be disclosed by BioSante in the reports it files or submits under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to BioSante's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating its disclosure controls and procedures, BioSante recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and BioSante is required to apply its judgment in evaluating the cost-benefit relationship of possible internal controls. BioSante's management evaluated, with the participation of its Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of its disclosure controls and procedures as of the end of the period covered in this quarterly report on Form 10-Q. Based on that evaluation, BioSante's Chief Executive Officer and Chief Financial Officer concluded that BioSante's disclosure controls and procedures were effective as of the end of such period to provide reasonable assurance that information required to be disclosed in BioSante's Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that material information relating to BioSante is made known to management, including BioSante's Chief Executive Officer and Chief Financial Officer, particularly during the period when BioSante's periodic reports are being prepared.

**Changes in Internal Control Over Financial Reporting**

There was no change in BioSante's internal control over financial reporting that occurred during the three months ended March 31, 2013 that has materially affected, or is reasonably likely to materially affect BioSante's internal control over financial reporting.

Table of Contents

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

A description of BioSante's legal proceedings in Note 10 to its unaudited condensed financial statements included in this report is incorporated herein by reference.

**ITEM 1A. RISK FACTORS**

BioSante is affected by risks specific to it as well as factors that affect all businesses. In addition to the other information set forth in this report, careful consideration should be taken of the factors described in BioSante's most recent annual report on Form 10-K for the fiscal year ended December 31, 2012 under the heading Part I Item 1A. Risk Factors, which could materially adversely affect BioSante's business, financial condition or operating results. Other than as described below, there has been no material change to those risk factors.

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

Pursuant to the terms of the merger agreement, BioSante will issue shares of BioSante common stock to ANI stockholders representing 57 percent of the outstanding shares of BioSante common stock as of immediately following completion of the merger. After such issuance, the shares of BioSante common stock outstanding immediately prior to completion of the merger will represent 43 percent of the outstanding shares of BioSante common stock as of immediately following completion of the merger. Accordingly, the issuance of shares of BioSante common stock to ANI stockholders in the merger will reduce significantly the relative voting power of each share of BioSante common stock held by current BioSante stockholders. Consequently, 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 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 will represent 57 percent of the outstanding shares of BioSante common stock as of immediately following 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 number of shares of outstanding capital stock of either or both of BioSante and ANI as of immediately 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 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 more than the current market value of BioSante common stock.

Table of Contents

***The percentage of outstanding shares of BioSante that ANI stockholders will receive in the merger is 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 BioSante stockholders.***

As of March 31, 2013, BioSante had outstanding options to purchase an aggregate of approximately 1.0 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 were convertible into an aggregate of 370,871 shares of BioSante common stock. The convertible senior notes were due on May 1, 2013 and thus did not convert into 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. It is possible that prior to completion of the merger BioSante may issue additional equity securities. The number of shares of BioSante common stock that will be issued to ANI stockholders pursuant to the merger will represent 57 percent of the outstanding shares of BioSante common stock as of immediately following completion of the merger, and this percentage is 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 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.***

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

- third parties may seek to terminate and/or renegotiate their relationships with BioSante as a result of the merger, whether pursuant to the terms of their existing agreements with BioSante or otherwise; and
- the attention of BioSante management may be directed toward completion of the merger and related matters and may be diverted from the day-to-day business operations of BioSante, including from other opportunities that otherwise might be beneficial to BioSante.

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.

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

Completion of the merger is subject to a number of conditions and there can be no assurance that the conditions to completion of the merger will be satisfied. If the merger is not completed, BioSante 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;

Table of Contents

- the BioSante board of directors will need to reevaluate BioSante's strategic alternatives, which alternatives may include a sale 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;
- BioSante will incur substantial transaction costs in connection with the merger whether or not the merger is completed;
- BioSante may not realize any of the anticipated benefits of having completed the merger; and
- under the merger agreement, BioSante 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 BioSante's business, financial condition, results of operations, or the trading price of BioSante common stock.

***BioSante has 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 has incurred and will continue to incur significant transaction costs in connection with the merger. These costs primarily are associated with the fees of BioSante's financial advisor, attorneys and accountants. Most of these costs will be paid by BioSante 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. 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.

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

BioSante stockholders should be aware that certain of the directors and executive officers of BioSante have arrangements that provide them with interests in the merger that are different from, or in addition to, those of other BioSante stockholders. For instance, in connection with the



## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

merger, Fred Holubow and Ross Mangano, each a current member of the BioSante board of directors, will continue to serve as a director of BioSante following completion of the merger and will receive cash and equity compensation in consideration for such service. The employment of each of BioSante's two current executive officers, Stephen M. Simes and Phillip B. Donenberg, will terminate immediately following completion of the merger and they will be entitled to receive severance benefits in the amount of \$1,578,000 in the case of Mr. Simes and \$844,156 in the case of Mr. Donenberg in connection with such termination. In addition, Mr. Simes and Mr. Donenberg will receive bonuses relating to BioSante's 2012 fiscal year in the amounts of \$200,000 and \$100,000, respectively, which have not been paid and pursuant to the terms of the merger agreement will be paid only if the merger occurs and if BioSante has net cash that equals or exceeds a specified minimum amount. The directors and executive officers of BioSante also have certain rights to indemnification and to directors' and officers' liability insurance that will be provided by BioSante following completion of the merger.

Table of Contents

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

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

- the general prohibition on BioSante'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; and
- the requirement that BioSante submit the proposals required to be submitted to its stockholders in connection with the merger with ANI even if BioSante's board of directors changes its recommendation with respect to such proposals, as applicable.

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 April 12, 2013, 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 April 12, 2013 are subject to a voting agreement, pursuant to which the holders of such shares have agreed to vote in favor of the approval of the issuance of the shares of BioSante common stock and BioSante is required under the terms of the merger agreement to convene and hold the BioSante special meeting regardless of any change in the recommendation of the BioSante board of directors.

These provisions might discourage an otherwise interested third party from considering or proposing an acquisition of BioSante, even one that may be deemed of greater value than the merger to BioSante stockholders. 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 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 the fair value of the shares of capital stock of ANI.***

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

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 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 the merger will be greater than the fair value of ANI.

Table of Contents

***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. Although BioSante has set a record date of June 19, 2013 for the distribution of the CVRs, 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 an amendment to the Form S-4 registration statement or a supplement to the 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.

**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 entitled Risks Related to BioSante, Risks Related to ANI and Risks Related to the Combined Company contained in the registration statement on Form S-4 as filed by BioSante with the SEC in connection with the merger. 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

Table of Contents

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 is 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, BioSante'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 BioSante will 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 BioSante 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 BioSante'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 48 percent of BioSante. 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 BioSante requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of BioSante's assets or any other significant corporate transaction. These stockholders also may exert influence in delaying or preventing a change in control of BioSante, even if such change in control would benefit the other BioSante stockholders. In addition, the significant concentration of stock ownership may affect adversely the market value of BioSante common stock due to investors' perception that conflicts of interest may exist or arise.

Table of Contents

***Future results of the combined company may differ materially from the unaudited pro forma financial statements presented in the joint proxy statement/prospectus filed by BioSante in connection with the merger 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 the Form S-4 registration statement filed by BioSante in connection with the merger, 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 \$3.2 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 or ANI 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 of BioSante or ANI (as the case may be) may become reduced substantially or unavailable for use by the combined company 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. The merger also may result in an ownership change of ANI. Accordingly, the combined company's ability to utilize BioSante's and ANI's net operating losses and tax credit carryforwards may be limited substantially. These limitations, in turn, could result in increased 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 of the Code although they may be subject to other limitations under Section 382 of the Code 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.





Table of Contents

*The NASDAQ Global Market considers the proposed 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. Approval by NASDAQ of the initial listing application requires the BioSante common stock to have a minimum bid price of \$4.00 per share, which likely will not happen. If the initial listing application is denied and if BioSante's common stock is delisted from NASDAQ, it could be more difficult for holders of shares of BioSante to sell their shares.*

NASDAQ considers the merger with ANI 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. Because it is likely that the minimum bid price of BioSante common stock will not be at least \$4.00 upon completion of the merger, it is likely that the new initial listing application will be denied by NASDAQ and NASDAQ will issue BioSante a delisting letter immediately after completion of the merger. If this occurs, BioSante intends to take all reasonable action in order to maintain the listing of BioSante common stock on NASDAQ. There can be no assurance, however, that BioSante will be successful and if BioSante common stock is delisted from NASDAQ, you may have difficulty converting your investments into cash effectively. As a result, the relative price of BioSante common 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.

*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 NASDAQ, 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 may 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 BioSante common stock could decline and the combined company could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities.

Table of Contents

***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 BioSante common stock for that purpose.

***Anti-takeover provisions in BioSante'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.***

BioSante's certificate of incorporation and bylaws, as amended, contains 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 BioSante common stock.

***The sale or availability for sale of a substantial number of shares of BioSante common stock 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 BioSante common stock in the public market after the merger or after expiration of the lock-up period that will apply to two of ANI's executive officers (for a portion of their shares) and certain of its stockholders, 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 BioSante common stock after the merger.

**ITEM 2.**

**UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

Not applicable.

**ITEM 3.        DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4.        MINE SAFETY DISCLOSURES**

Not applicable.

Table of Contents

**ITEM 5. OTHER INFORMATION**

Not applicable.

**ITEM 6. EXHIBITS**

The following exhibits are being filed or furnished with this quarterly report on Form 10-Q:

<b>Exhibit No.</b>	<b>Description</b>
2.1	Amended and Restated Agreement and Plan of Merger dated as of April 12, 2013 by and among BioSante Pharmaceuticals, Inc., ANI Merger Sub, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013) (File No. 001-31812))*
10.1	Form of Amended and Restated Voting Agreement dated as of April 12, 2013 by and between certain stockholders of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and BioSante Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013) (File No. 001-31812))
10.2	Form of Amended and Restated Voting Agreement dated as of April 12, 2013 by and between Meridian Venture Partners II, L.P. and BioSante Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013) (File No. 001-31812))
10.3	Form of Amended and Restated Voting Agreement dated as of April 12, 2013 by and between certain directors and officers of BioSante Pharmaceuticals, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.3 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013) (File No. 001-31812))
10.4	Form of Amended and Restated Lock-Up Agreement dated as of April 12, 2013 by and between the chief executive officer and chief financial officer and certain stockholders of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and BioSante Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.4 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013) (File No. 001-31812))
10.5	Separation Agreement and Release dated as of March 15, 2013 between BioSante Pharmaceuticals, Inc. and Michael C. Snabes, M.D., Ph.D. (incorporated by reference to Exhibit 10.1 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on March 15, 2013) (File No. 001-31812))
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a) (filed herewith)
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a) (filed herewith)
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

32.2 Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)

Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
101	The following materials from BioSante's quarterly report on Form 10-Q for the quarter ended March 31, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Condensed Balance Sheets, (ii) the unaudited Condensed Statements of Operations, (iii) the unaudited Condensed Statements of Cash Flows, and (iv) Notes to Condensed Financial Statements.**

---

\* All exhibits and schedules to the Amended and Restated Agreement and Plan of Merger have been omitted pursuant to Item 601(b)(2) of Regulation S-K. BioSante will furnish the omitted exhibits and schedules to the SEC upon request by the SEC.

\*\* Pursuant to Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this quarterly report on Form 10-Q shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, and shall not be deemed part of a registration statement, prospectus or other document filed under Section 11 or 12 of the Securities Act of 1933, as amended, or otherwise subject to the liability of those sections, except as shall be expressly set forth by specific reference in such filings.

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

May 10, 2013

**BIOSANTE PHARMACEUTICALS, INC.**

By: */s/ Stephen M. Simes*  
Stephen M. Simes  
Vice Chairman, President and Chief  
Executive Officer  
(principal executive officer)

By: */s/ Phillip B. Donenberg*  
Phillip B. Donenberg  
Senior Vice President of Finance, Chief  
Financial Officer and Secretary  
(principal financial and accounting officer)



Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**QUARTERLY REPORT ON FORM 10-Q**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>	<b>Method of Filing</b>
2.1	Amended and Restated Agreement and Plan of Merger dated as of April 12, 2013 by and among BioSante Pharmaceuticals, Inc., ANI Merger Sub, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.*	Incorporated by reference to Exhibit 2.1 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013 (File No. 001-31812))
10.1	Form of Amended and Restated Voting Agreement dated as of April 12, 2013 by and between certain stockholders of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.1 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013 (File No. 001-31812))
10.2	Form of Amended and Restated Voting Agreement dated as of April 12, 2013 by and between Meridian Venture Partners II, L.P. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.2 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013 (File No. 001-31812))
10.3	Form of Amended and Restated Voting Agreement dated as of April 12, 2013 by and between certain directors and officers of BioSante Pharmaceuticals, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.3 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013 (File No. 001-31812))
10.4	Form of Amended and Restated Lock-Up Agreement dated as of April 12, 2013 by and between the chief executive officer and chief financial officer and certain stockholders of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.4 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013 (File No. 001-31812))
10.5	Separation Agreement and Release dated as of March 15, 2013 between BioSante Pharmaceuticals, Inc. and Michael C. Snabes, M.D., Ph.D.	Incorporated by reference to Exhibit 10.1 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on March 15, 2013 (File No. 001-31812))
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith

Table of Contents

<b>Exhibit No.</b>	<b>Description</b>	<b>Method of Filing</b>
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
101	The following materials from BioSante's quarterly report on Form 10-Q for the quarter ended March 31, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Condensed Balance Sheets, (ii) the unaudited Condensed Statements of Operations, (iii) the unaudited Condensed Statements of Cash Flows, and (iv) Notes to Condensed Financial Statements.**	Furnished herewith

---

\* All exhibits and schedules to the Amended and Restated Agreement and Plan of Merger have been omitted pursuant to Item 601(b)(2) of Regulation S-K. BioSante will furnish the omitted exhibits and schedules to the SEC upon request by the SEC.

\*\* Pursuant to Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this quarterly report on Form 10-Q shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, and shall not be deemed part of a registration statement, prospectus or other document filed under Section 11 or 12 of the Securities Act of 1933, as amended, or otherwise subject to the liability of those sections, except as shall be expressly set forth by specific reference in such filings.