UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

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

For the Quarterly Period Ended September 30, 2001

Commission file number 000-28637

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

For The Transition Period From _____ To _____.

BIOSANTE PHARMACEUTICALS, INC.

(Exact name of small business issuer as specified in its charter)

Delaware	**58-2301143**
(State of Incorporation)	(IRS Employer Identification No.)

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

(847) 478-0500
(Issuer's telephone number, including area code)

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of the latest practicable date.

Class	Outstanding as of November 13, 2001
Common stock, no par value	63,208,798

Transitional Small Business Disclosure Format (check one): Yeso No ☒

BIOSANTE PHARMACEUTICALS, INC.

FORM 10-QSB
SEPTEMBER 30, 2001

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Balance Sheets
September 30, 2001 and December 31, 2000 (Unaudited)

	September 30, 2001	December 31, 2000
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 5,978,971	$ 2,611,755
Prepaid expenses and other sundry assets	114,700	64,341
	6,093,671	2,676,096
PROPERTY AND EQUIPMENT, NET	397,151	390,821
	$ 6,490,822	$ 3,066,917
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 100,026	$ 44,746
Accrued compensation	250,293	258,598
Other accrued expenses	27,401	137,919
Due to Antares	651,049	-
Convertible debenture	-	500,000
	1,028,769	941,263
COMMITMENTS		
STOCKHOLDERS' EQUITY		
Capital stock		
Issued and Outstanding		
4,676,024 (2000 - 4,687,684) Class C special stock	468	469
63,208,798 (2000 - 52,952,943) Common stock	22,300,906	17,782,857
	22,301,374	17,783,326
Deferred unearned compensation	-	(18,000)
Deficit accumulated during the development stage	(16,839,321)	(15,639,672)
	5,462,053	2,125,654
	$ 6,490,822	$ 3,066,917

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Operations
Three and nine months ended September 30, 2001 and 2000 and the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2001
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative period from August 29, 1996 (date of incorporation) to Sept. 30, 2001
	2001	2000	2001	2000	

REVENUE					
Licensing income	$ 1,747,386	$ -	$ 1,747,386	$ -	$ 1,747,386
Interest income	62,829	60,184	145,781	182,070	892,317
	1,810,215	60,184	1,893,167	182,070	2,639,703
EXPENSES					
Research and development	719,132	239,548	1,339,357	1,594,762	5,623,729
General and administration	720,461	416,219	1,683,491	1,024,674	7,493,729
Depreciation and amortization	21,458	25,156	69,968	73,367	451,802
Loss on disposal of capital assets	-	-	-	-	157,545
Costs of acquisition of Structured Biologicals Inc.	-	-	-	-	375,219
Purchased in-process research and development	-	-	-	-	5,377,000
	1,461,051	680,923	3,092,816	2,692,803	19,479,024
NET INCOME (LOSS)	$ 349,164	$ (620,739)	$ (1,199,649)	$ (2,510,733)	$ (16,839,321)
BASIC AND DILUTED NET INCOME (LOSS) PER SHARE	$ -	$ (0.01)	$ (0.02)	$ (0.04)	$ (0.37)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	67,265,408	57,603,438	63,831,945	57,501,885	45,984,423

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Cash Flows
Nine months ended September 30, 2001 and 2000 and the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2001
(Unaudited)

	Nine Months Ended Sept. 30,		Cumulative period from August 29, 1996 (date of incorporation) to September 30,
	2001	2000	2001
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$ (1,199,649)	$ (2,510,733)	$ (16,839,321)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	69,968	73,367	451,802
Amortization of deferred unearned compensation	18,000	-	42,290
Repurchase of licensing rights (Note 4)	125,000	-	125,000
Purchased in-process research and development	-	-	5,377,000
Loss on disposal of equipment	-	-	157,545
Changes in other assets and liabilities affecting cash flows from operations			
Prepaid expenses and other sundry assets	(50,359)	(26,889)	(111,732)
Accounts payable and accrued expenses	(63,543)	(131,792)	(362,467)
Due to Antares	651,049	-	651,049
Due from SBI	-	-	(128,328)
Net cash used in operating activities	(449,534)	(2,596,047)	(10,637,162)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchase of capital assets	(76,298)	(31,567)	(972,388)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Issuance of convertible debenture	-	500,000	500,000
Proceeds from sale or conversion of shares	3,893,048	88,045	17,088,521
Net cash provided by financing activities	3,893,048	588,045	17,588,521
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,367,216	(2,039,569)	5,978,971
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	2,611,755	5,274,552	-
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 5,978,971	$ 3,234,983	$ 5,978,971
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION			
Acquisition of SBI			
Purchased in-process research and development	$ -	$ -	$ 5,377,000

Other net liabilities assumed	-	-	**(831,437)**
	-	-	**4,545,563**
Less: common stock issued therefore	-	-	**4,545,563**
	$ -	**$** -	**$** -
Income tax paid	**$** -	**$** -	**$** -
Interest paid	**$** -	**$** -	**$** -

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
FORM 10-QSB
SEPTEMBER 30, 2001

Notes to Financial Statements (Unaudited)

1. INTERIM FINANCIAL INFORMATION

In the opinion of management, the accompanying unaudited financial statements contain all necessary adjustments, which are of a normal recurring nature, to present fairly the financial position of BioSante Pharmaceuticals, Inc. as of September 30, 2001 and December 31, 2000, the results of operations for the three and nine months ended September 30, 2001 and 2000 and for the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2001, and the cash flows for the nine months ended September 30, 2001 and 2000 and for the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2001, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three and nine month periods ended September 30, 2001 are not necessarily indicative of the results that may be expected for the year ended December 31, 2001.

These unaudited interim financial statements should be read in conjunction with the financial statements and related notes contained in BioSante's Annual Report on Form 10-KSB for the year ended December 31, 2000.

2. REVENUE RECOGNITION

The Company recognizes revenue from licensing arrangements in the form of upfront license fees, milestone payments, royalties and other fees. Revenue is recognized when cash is received and the Company has completed all of its obligations under the licensing arrangement which are required for the payment to be non-refundable. Any ancillary payments related to the products being licensed, such as royalties to the head licensor, are netted against revenues at the time of revenue recognition. To date, there has been no royalty revenue recognized. Interest income on invested cash balances is recognized on the accrual basis as earned.

3. BASIC AND DILUTED NET INCOME (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 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 reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Because BioSante has incurred net losses from operations in each of the periods presented, except for the quarter period ended September 30, 2001, there is generally no difference between basic and diluted net loss per share amounts. The computation of diluted net loss per share does not include options and warrants with dilutive potential that would have an antidilutive effect on net loss per share. For the quarter ended September 30, 2001, the Company recognized net income, and accordingly, there is a dilutive effect on net income per share due to the inclusion of 11,762,801 dilutive options and warrants in the denominator in computing net income per share, which makes the total diluted weighted average number of shares for the three month period ended September 30, 2001 equal to 79,028,209. However, due to rounding, basic net income per share is zero, and therefore, dilutive net income per share is also zero.

4. LICENSE AND SUPPLY AGREEMENTS

On June 13, 2000, BioSante entered into a licensing agreement and a supply agreement with Antares Pharma Inc. (the entity that resulted from the merger of Permatec Technologie, AG with Medi-Ject Corporation), covering four hormone products for the treatment of hormone deficiencies in men and women. The agreement requires BioSante to pay Antares a percentage of future net sales, if any, as a royalty. Under the terms of the license agreement, BioSante is also obligated to make milestone payments upon the occurrence of certain future events. Under terms of the supply agreement, Antares has agreed to manufacture or have manufactured and sell exclusively to BioSante, and BioSante has agreed to purchase exclusively from Antares, BioSante's total requirements for the products covered under the license agreement between the two parties.

As allowed by the licensing agreement with Antares, on September 1, 2000, BioSante entered into a sub-license agreement with Paladin Labs Inc. ("Paladin") to market the female hormone replacement products in Canada. In exchange for the sub-license, Paladin agreed to make an initial investment in BioSante, make future milestone payments and pay royalties on sales of the products in Canada. The milestone payments will be in the form of a series of equity investments by Paladin in BioSante's common stock at a 10% premium to the market price of BioSante's common stock at the date of the equity investment.

During the third quarter 2001, Paladin made a series of equity investments in BioSante as a result of certain sub-licensing transactions and BioSante reaching certain milestones. These equity investments resulted in BioSante issuing an additional 189,394 shares of its common stock to Paladin at a 10 percent premium to BioSante's market price. The dollar value of the premium is recorded as licensing income in the statements of operations.

In a series of amendments executed during 2001 between BioSante and Antares, BioSante returned to Antares the license rights to one of the four previously licensed hormone products, namely the estradiol patch, in all countries of the licensed territory. Additionally, BioSante returned to Antares the license rights to the single entity estrogen and testosterone gel products in Malaysia and Australia. In exchange for the return to Antares of the estradiol patch in all the countries and the estradiol and testosterone gel products in Malaysia and Australia, Antares granted BioSante a credit for approximately $600,000 of manufacturing and formulation services and a license for an undisclosed transdermal hormone replacement gel product. During the third quarter of 2001,

Antares informed the Company that the total costs for manufacturing and formulation services had exceeded the $600,000 credit. Accordingly, beginning in third quarter of 2001 and going forward, the Company will be required to reimburse Antares for such services.

On August 7, 2001, BioSante entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. (Solvay) covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone replacement gel product licensed from Antares in June 2000. Under the terms of the agreement, Solvay has sub-licensed BioSante's estrogen/progestogen combination transdermal hormone replacement gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin), future milestone payments and escalating sales-based royalties. Solvay will be responsible for all costs of development and marketing of the product. BioSante has retained co-promotion rights to the product and will be compensated for sales generated by BioSante over and above those attributable to Solvay's marketing efforts. The Canadian rights to this product had previously been sub-licensed to Paladin as part of that sub-license arrangement and were repurchased by the Company prior to the Solvay transaction in exchange for $125,000, paid by the issuance of 173,611 shares of BioSante common stock with a market value of $125,000 at the date of the transaction.

5. CONVERTIBLE DEBENTURE

In connection with entering into the sub-license agreement with Paladin as described in Note 4, BioSante issued a convertible debenture to Paladin in the principal amount of $500,000. On August 13, 2001, BioSante exercised its right and declared the debenture converted in full at a price of $1.05 per share. Accordingly, 476,190 shares of BioSante common stock were issued to Paladin. This was a non-cash financing transaction.

6. PRIVATE PLACEMENT FINANCING

On April 4, 2001, BioSante closed a private placement raising $3.7 million upon the issuance of units, which consisted of an aggregate of 9,250,000 shares of common stock and five-year warrants to purchase an aggregate of 4,625,000 shares of common stock. The price of each unit, which consisted of one share of common stock plus a warrant to purchase one half-share of common stock was $0.40, the approximate market price of BioSante's common stock at closing. The exercise price of the warrant is $0.50 per full share. Transaction costs related to the private placement have been netted against the proceeds.

7. COMMITMENTS

University of California License

BioSante's license agreement with the University of California requires BioSante to undertake various obligations, including:

- Payment of royalties to the University based on a percentage of the net sales of any products incorporating the licensed technology;
- Payment of minimum annual royalties on February 28 of each year beginning in the year 2004 in the amounts set forth below, to be credited against earned royalties, for the life of the agreement;

Year	Minimum Annual Royalty Due
2004	$ 50,000
2005	100,000
2006	150,000
2007	200,000
2008	400,000
2009	600,000
2010	800,000
2011	1,500,000
2012	1,500,000
2013	1,500,000

- Development of products incorporating the licensed technology until a product is introduced to the market;
- Payment of the costs of patent prosecution and maintenance of the patents included in the agreement, which for the year ended December 31, 2000 amounted to $11,722;
- Meeting performance milestones relating to:
    - Hiring or contracting with personnel to perform research and development, regulatory and other activities relating to the commercial launch of a proposed product;
    - Testing proposed products and obtaining government approvals;
    - Conducting clinical trials; and
    - Introducing products incorporating the licensed technology into the market.
- Entering into partnership or alliance arrangements or agreements with other entities regarding commercialization of the technology covered by the license.
- BioSante has agreed to indemnify, hold harmless and defend the University of California and its affiliates, as designated in the license agreement, against any and all claims, suits, losses, damage, costs, fees and expenses resulting from or arising out of exercise of the license agreement, including but not limited to, any product liability claims.

Antares Pharma, Inc. License

BioSante's license agreement with Antares required BioSante to make a $1.0 million upfront payment to Antares. $250,000 of this upfront payment was creditable against future milestone or other payments and was utilized in the third quarter of 2001. The result was a $250,000 reduction in research and development expense in the statement of operations during the quarter ended September 30, 2001 as the initial $1.0 million payment had been expensed in its entirety in 2000. BioSante expects to fund the development of the products, make milestone payments and once regulatory approval to market is received and sales of the products commence, pay royalties on the sales of products. BioSante must also make cash payments to Antares for manufacturing and formulation services incurred by Antares related to the products.

BioSante's sub-license agreement (of the Antares license) with Paladin Labs Inc. required Paladin to make an initial investment in BioSante of $500,000 in the form of a convertible debenture, which was converted in full on August 13, 2001 resulting in the issuance of 476,190 shares of BioSante common stock to Paladin. Paladin will also make milestone payments to BioSante in the form of a series of equity investments at a 10 percent premium to BioSante's market price at the time the equity investment is made. In addition, Paladin will pay BioSante a royalty on sales of the sub-licensed products.

BioSante's sub-license agreement (of the Antares license) with Solvay Pharmaceuticals requires Solvay to make future milestone payments to BioSante and escalating sales-based royalties, portions of which BioSante will also pay to Antares. Solvay will be responsible for all costs of development and marketing of the product. BioSante has retained co-promotion rights to the product and will be compensated for sales generated by BioSante over and above those attributable to Solvay's marketing efforts.

8. NEW ACCOUNTING PRONOUNCEMENTS

On July 20, 2001, the Financial Accounting Standards Board issued SFAS No. 141, "Business Combinations" (SFAS 141) and SFAS No. 142, "Goodwill and Other Intangible Assets" (SFAS 142). These statements establish new accounting and reporting standards for business combinations and associated goodwill and intangible assets. They require, among other things, elimination of the pooling of interests method of accounting, no amortization of acquired goodwill, and a periodic assessment for impairment of all goodwill and intangible assets acquired in a business combination. SFAS 141 is effective for all business combinations accounted for by the purchase method that are completed after June 30, 2001. SFAS 142 will be effective for the Company's fiscal year beginning January 1, 2002.

On August 16, 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations". The pronouncement addresses the recognition and remeasurement of obligations associated with the retirement of tangible long-lived assets. On October 3, 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets". SFAS 144, which supercedes SFAS No. 121 "Accounting for Long-lived Assets and for Long-Lived Assets to be Disposed Of" and the accounting and reporting provisions of Accounting Principles Board Opinion No. 30, "Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual, and Infrequently Occurring Events and Transactions", applies to long-lived assets (including discontinued operations) and it develops one accounting model for long-lived assets that are to be disposed of by sale. SFAS 143 will be effective for the Company's fiscal year beginning January 1, 2003. SFAS 144 will be effective for the Company's fiscal year beginning January 1, 2002.

The Company does not believe that the issuance of these pronouncements will have an impact on its financial statements.

9. SUBSEQUENT EVENT

On October 1, 2001, BioSante licensed its Bio-VantÔ calcium phosphate based vaccine adjuvant on a non-exclusive basis to Corixa Corporation for use in several potential vaccines to be developed by Corixa. Under the agreement, Corixa has agreed to pay BioSante milestone payments upon the achievement by Corixa of certain milestones plus royalty payments on sales by Corixa if and when vaccines are approved using Bio-VantÔ and sold on a commercial basis. If Corixa sub-licenses vaccines that include Bio-VantÔ, BioSante will share in milestone payments and royalties received by Corixa. The license agreement covers access to Bio-VantÔ for a variety of cancer, infectious and autoimmune disease vaccines.

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

This Form 10-QSB contains forward-looking statements. For this purpose, any statements contained in this Form 10-QSB that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, words such as "may," "will," "expect," believe," "anticipate," "estimate" or "continue" or the negative or other variations thereof or comparable terminology are intended to identify forward-looking statements. These statements by their nature involve substantial risks and uncertainties, and actual results may differ materially depending on a variety of factors, including those described under this section and the section entitled "Risk Factors" below and those contained under the caption "Risk Factors" contained in BioSante's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2000.

The following discussion of the results of the operations and financial condition of BioSante should be read in conjunction with BioSante's financial statements and the related notes thereto.

Overview

We are a development stage biopharmaceutical company engaged in the development and commercialization of hormone replacement products to treat hormone deficiencies in men and in women. We also are engaged in the development and commercialization of vaccine adjuvants or immune system boosters, proprietary novel vaccines, drug delivery systems and the purification of the milk of transgenic animals, all applications using calcium phosphate nanoparticles, or CAP.

Our hormone replacement products, which we license on an exclusive basis from Antares Pharma, Inc., address a variety of hormone deficiencies that affect both men and women. Symptoms of these hormone deficiencies include impotence, lack of sex drive, muscle weakness and osteoporosis in men and menopausal symptoms in women including hot flashes, vaginal atrophy, decreased libido and osteoporosis.

The products we in-licensed from Antares are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), and a combination of estradiol and a progestogen (another female hormone). The gels are designed to be quickly absorbed through the skin after application on the arms, abdomen or thighs, delivering the required hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue.

Under the terms of our license agreement with Antares, we acquired exclusive marketing rights, with the right to grant sub-licenses, to the single active ingredient testosterone and estradiol products for all therapeutic indications in the U.S., Canada, Mexico, Israel, Indonesia, New Zealand, China and South Africa. We acquired exclusive marketing rights, with the right to grant sub-licenses, for the combination estradiol and progestogen product in the U.S. and Canada. In partial consideration for the license of the hormone replacement products, we paid Antares an upfront license fee of $1.0 million. In addition, under the terms of the license agreement, we agreed to fund the development of the proposed products, make milestone payments and, after all necessary regulatory approvals are received, pay royalties to Antares on sales of the products.

In a series of amendments executed during 2001 between BioSante and Antares, BioSante returned to Antares the license rights to one of the four previously licensed hormone products, namely the estradiol patch, in all countries of the licensed territory. Additionally, BioSante returned to Antares the license rights to the single entity estrogen and testosterone gel products in Malaysia and Australia. In exchange for the return to Antares of the estradiol patch in all the countries and the estradiol and testosterone gel products in Malaysia and Australia, Antares granted BioSante a credit for approximately $600,000 of manufacturing and formulation services and a license for another undisclosed additional transdermal hormone replacement gel product.

On August 7, 2001, BioSante entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. (Solvay) covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone replacement gel product licensed from Antares in June 2000. Under the terms of the agreement, Solvay sub-licensed BioSante's estrogen/progestogen combination transdermal hormone replacement gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin), future milestone payments and escalating sales-based royalties. Solvay will be responsible for all costs of development and marketing of the product. BioSante has retained co-promotion rights to the product and will be compensated for sales generated by BioSante over and above those attributable to Solvay's marketing efforts. The Canadian rights to this product had previously been sub-licensed to Paladin as part of that sub-license arrangement and were repurchased by the Company prior to the Solvay transaction in exchange for $125,000, paid by the issuance of 173,611 shares of BioSante common stock with a market value of $125,000 at the date of the transaction.

In September 2000, we sub-licensed the marketing rights to our portfolio of female hormone replacement products in Canada to Paladin Labs Inc. In exchange for the sub-license, Paladin agreed to make an initial investment in our company, make future milestone payments and pay royalties on sales of the products in Canada. The milestone payments will be in the form of a series of equity investments by Paladin in BioSante common stock at a 10 percent premium to the market price of our stock at the time the equity investment is made. Upon execution of the sub-license agreement, Paladin made an initial investment of $500,000 in our company in the form of a convertible debenture, convertible into our common stock at $1.05 per share. On August 13, 2001, BioSante exercised its right and declared the debenture converted in full. Accordingly, 476,190 shares of BioSante common stock were issued to Paladin on August 23, 2001. During the third quarter 2001, Paladin made a series of equity investments in BioSante as a result of certain sub-licensing transactions and BioSante reaching certain milestones. These equity investments resulted in BioSante issuing an additional 189,394 shares of its common stock to Paladin.

Our strategy with respect to our hormone replacement product portfolio is to conduct human clinical trials of our proposed hormone replacement products, which are required to obtain approval from the U.S. Food and Drug Administration, or FDA, to market the products in the United States.

Our CAP technology, which we license on an exclusive basis from the University of California, is based on the use of extremely small, solid, uniform particles, which we call "nanoparticles," as immune system boosters and for drug delivery. We have identified four potential applications for our CAP technology:

- the creation of improved versions of current vaccines by the "adjuvant" activity of our proprietary nanoparticles that enhance the ability of a vaccine to stimulate an immune response;
- the development of new, unique vaccines against diseases for which there currently are few or no effective methods of prevention (*e.g.*, genital herpes);
- the creation of inhaled forms of drugs that currently must be given by injection (*e.g.*, insulin); and
- the purification of the milk of transgenic animals, in which protein pharmaceuticals are grown.

Our strategy with respect to CAP over the next 12 months, is to continue development of our nanoparticle technology and actively to seek collaborators and licensees to accelerate the development and commercialization of products incorporating this technology. We received clearance in August 2000 from the FDA to initiate a Phase I clinical trial of our CAP as a vaccine adjuvant and delivery system based on an Investigational New Drug Application that we filed in July 2000. The Phase I trial was a double-blind, placebo-controlled trial in 18 subjects to determine the safety of CAP as a vaccine adjuvant. The trial was completed in October 2000. The results showed that there was no apparent difference in side effect profile between CAP and placebo.

On October 1, 2001, BioSante licensed its Bio-VantÔ calcium phosphate based vaccine adjuvant on a non-exclusive basis to Corixa Corporation for use in several potential vaccines to be developed by Corixa. Under the agreement, Corixa has agreed to pay BioSante milestone payments upon the achievement by Corixa of certain milestones plus royalty payments on sales by Corixa if and when vaccines are approved using Bio-VantÔ and sold on a commercial basis. If Corixa sub-licenses vaccines that include Bio-VantÔ, BioSante will share in milestone payments and royalties received by Corixa. The license agreement covers access to Bio-VantÔ for a variety of cancer, infectious and autoimmune disease vaccines.

Our goal is to develop and commercialize our portfolio of hormone replacement products and CAP technology into a wide range of pharmaceutical products and to expand this product portfolio as appropriate. Our strategy to obtain this goal is to:

- Accelerate the development of our hormone replacement products.
- Continue to develop our nanoparticle-based CAP platform technology and seek assistance in the development through corporate partner sub-licenses.
- License or otherwise acquire other drugs that will add value to our current product portfolio.
- Implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies.

We currently expect to add employees as we continue to develop and commercialize our hormone replacement products and products incorporating our CAP technology or in-license or otherwise acquire products in late-stage human clinical development.

All of our revenue to date has been derived from interest earned on invested funds and upfront payments earned on sub-licensing transactions. We have not commercially introduced any products. Since our inception, we have experienced significant operating losses. We incurred a net loss of $3,437,195 for the year ended December 31, 2000, resulting in an accumulated deficit of $15,639,672. We incurred a net loss of $1,199,649 for the nine months ended September 30, 2001, and as of September 30, 2001, our accumulated deficit was $16,839,321. We expect to incur substantial and continuing losses for the foreseeable future as our product development programs expand and various preclinical and clinical trials commence. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend upon, among other factors:

- the timing and cost of product development;
- the progress and cost of preclinical and clinical development programs;
- the costs of licensure or acquisition of new products,
- the timing and cost of obtaining necessary regulatory approvals; and
- the timing and cost of obtaining third party reimbursement.

In order to generate revenues, we must successfully develop and commercialize our proposed products in pre-clinical development, in late-stage human clinical development, or already on the market that we may in-license or otherwise acquire or enter into collaborative agreements with others who can successfully develop and commercialize them. Even if our proposed products and the products we may license or otherwise acquire are commercially introduced, they may never achieve market acceptance and we may never generate revenues or achieve profitability.

Results of Operations

Three Months Ended September 30, 2001 Compared to Three Months Ended September 30, 2000

General and administrative expenses increased from $416,219 during the three month period ended September 30, 2000 to $720,461 during the three month period ended September 30, 2001. This increase of approximately 73% is due primarily to expenses related to personnel-related issues and the higher legal expenses related to the increase in our patent, collaboration and licensing activities.

Research and development expenses increased from $239,548 during the three month period ended September 30, 2000 to $719,132during the three month period ended September 30, 2001. This increase is the result of certain manufacturing and formulation services provided by and paid to Antares (offset slightly by a credit from Antares of $250,000) and increased expenses during the three month period ended September 30, 2001 associated with the clinical development of our hormone replacement product portfolio. As a result of our hormone replacement product in-license agreement entered into in June 2000, we expect that our research and development expenses will increase significantly. We also are required under the terms of our license agreement with the University of California to have available certain amounts of funds dedicated to research and development activities. The amount of our research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending on: (1) the resources available; (2) our development schedule; (3) results of studies, clinical trials and regulatory decisions; and (4) competitive developments.

We earned licensing income of $1,747,386 for the three month period ended September 30, 2001 as a result of a sub-license agreement signed with Solvay Pharmaceuticals, B.V. Licensing income consists of up-front, milestone and similar payments under license agreements and is recognized when earned under the terms of the applicable agreements, net of any related license payments due to other parties.

Interest income increased slightly from $60,184 during the three month period ended September 30, 2000 to $62,829 during the three month period ended September 30, 2001 as a result of higher average cash balances, offset by lower interest rates.

Net income for the three month period ended September 30, 2001 was $349,164, compared to a net loss of $620,739 for the three month period ended September 30, 2000. The overall decrease in the net loss is the result of sub-licensing income of $1,747,386 ($2.5 million upfront sub-license fee received from Solvay less license related payments due others, principally Antares) during the three month period ended September 30, 2001, offset by increased expenses during the three month period ended September 30, 2001 associated with (1) personnel-related expenses, (2) legal expenses related to increased patent, collaboration and licensing activities, and (3) increased expenses associated with the clinical development of our hormone replacement product portfolio. We anticipate that we will incur operating losses for the foreseeable future.

Nine Months Ended September 30, 2001 Compared to Nine Months Ended September 30, 2000

General and administrative expenses increased from $1,024,674 during the nine month period ended September 30, 2000 to $1,683,491 during the nine month period ended September 30, 2001. This increase of approximately 64% is due primarily to expenses related to personnel-related expenses and the higher legal expenses related to the increase in our patent, collaboration and licensing activities.

Research and development expenses decreased from $1,594,762 during the nine month period ended September 30, 2000 to $1,339,357 during the nine month period ended September 30, 2001. This overall decrease is the result of a $1.0 million upfront license fee paid to Antares during the nine month period ended September 30, 2000, offset by increased expenses during the nine month period ended September 30, 2001 associated with the clinical development of our hormone replacement product portfolio and payment to Antares for certain manufacturing and formulation services. 2001 also included recognition of a $250,000 credit from Antares, which represented the portion of the initial $1.0 million upfront license fee paid in 2000 which was creditable against future payments. As a result of our hormone replacement product in-license agreement entered into in June 2000, we expect that our research and development expenses will increase significantly. We are required under the terms of our license agreement with the University of California to make available certain amounts of funds dedicated to research and development activities. The amount of BioSante's research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending on: (1) the resources available; (2) its development schedule; (3) results of studies, clinical trials and regulatory decisions; and (4) competitive developments.

Interest income decreased from $182,070 during the nine month period ended September 30, 2000 to $145,781 during the nine month period ended September 30, 2001 as a result of lower average cash balances and as a result of lower interest rates on invested cash balances. We expect interest income to decline in future periods as we use our cash balances for operations.

BioSante incurred a net loss of $1,199,649 for the nine month period ended September 30, 2001, compared to a net loss of $2,510,733 for the nine month period ended September 30, 2000. The overall decrease in the net loss is the result of a $1.0 million upfront license fee paid to Antares during the nine month period ended September 30, 2000, offset by the combination of $1.7 million, net, in revenue from a sub-license upfront payment received by BioSante and increased expenses during the nine month period ended September 30, 2001 associated with (1) personnel-related expenses, (2) legal expenses related to increased patent, collaboration and licensing activities, and (3) increased expenses associated with the clinical development of our hormone replacement product portfolio and payment to Antares for certain manufacturing and formulation services. We anticipate that our operating losses will continue for the foreseeable future.

Liquidity and Capital Resources

To date, we have raised equity financing and received licensing income to fund our operations, and we expect to continue this practice to fund our ongoing operations. Since inception, we have raised net proceeds of approximately $12.9 million from private equity financings, class A and class C stock conversions, warrant exercises and in the third quarter 2000, the issuance of a $500,000 convertible debenture, which was converted into 173,611 shares of common stock in the third quarter of 2001. In addition, as a result of licensing upfront payments and milestones, we have received an additional $2.1 million. In April 2001, we closed on a $3.7 million private placement of units. The units consisted of an aggregate of 9,250,000 shares of common stock and five-year warrants to purchase an aggregate of 4,625,000 shares of common stock. The price of each unit, which consisted of one share of common stock plus a warrant to purchase one half-share of common stock, was $0.40, the approximate market price of our common stock at closing. The exercise price of the warrant is $0.50 per full share.

Our cash and cash equivalents were $5,978,971 and $2,611,755 at September 30, 2001 and December 31, 2000, respectively. The increase in our cash balances is due to our $3.7 million private placement which closed in April 2001 and the $2.5 million upfront payment received from Solvay from the sub-license of one of our hormone replacement transdermal gel products. We used cash in operating activities of $449,534 for the nine month period ended September 30, 2001 versus cash used in operating activities of $2,596,047 for the nine month period ended September 30, 2000. This change reflects the combination of the upfront payment received from Solvay, offset by cash expenditures associated with: (1) increased general and administrative and research and development personnel-related expenses, (2) legal fees associated with the increase in patent, licensing and collaboration activities; and (3) increased expenses related to the clinical development of our hormone replacement product portfolio and expenses related to manufacturing and formulation services provided by Antares. Offsetting these increased expenses for the nine month period ended September 30, 2001 versus the nine month period ended September 30, 2000 is the $1.0 million upfront license fee payment to Antares paid in June 2000. Net cash used in investing activities was $76,298 for the nine month period ended September 30, 2001 versus $31,567 used in investing activities for the nine month period ended September 30, 2000. The uses of cash in investing activities during both nine month periods ended September 30, 2001 and 2000 were capital expenditures for the purchases of computer equipment. Additionally, during the nine month period ended September 30, 2001, we relocated our business office thus incurring the capital expenditures of used office equipment and furniture. Net cash provided by financing activities was $3,893,048 for the nine months ended September 30, 2001 compared to $588,045 for the nine months ended September 30, 2000. Net cash provided during the nine months ended September 30, 2001 was the result of the receipt of cash proceeds (net of transaction costs) as described above pursuant to our private placement of units which closed in April 2001 and licensing milestone payments received while net cash provided during the nine months ended September 30, 2000 was the result of the conversion of shares of class C stock into shares of common stock and the issuance of the Paladin convertible debenture.

We did not have any material commitments for capital expenditures as of September 30, 2001. We have, however several financial commitments, including product development milestone payments to the licensor of our hormone products, payments under the license agreement with the University of California, as well as minimum annual lease payments.

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Therefore, we will likely need to raise substantial additional capital to fund our operations. We cannot be certain that any financing will be available when needed. If we fail to raise additional financing as we need it, we may have to delay or terminate our own product development programs or pass on opportunities to in-license or otherwise acquire new products that we believe may be beneficial to our business. We expect to continue to spend capital on:

- research and development programs;
- pre-clinical studies and clinical trials;
- regulatory processes;
- establishment of our own marketing capabilities or a search for third party manufacturers and marketing partners to manufacture and market our products for us; and
- the licensure or acquisition of new products.

The amount of capital we may need will depend on many factors, including the:

- progress, timing and scope of our research and development programs;
- progress, timing and scope of our pre-clinical studies and clinical trials;
- time and cost necessary to obtain regulatory approvals;
- time and cost necessary to seek third party manufacturers to manufacture our products for us;
- time and cost necessary to establish our own sales and marketing capabilities or to seek marketing partners to market our products for us;
- time and cost necessary to respond to technological and market developments;
- changes made or new developments in our existing collaborative, licensing and other commercial relationships; and
- new collaborative, licensing and other commercial relationships that we may establish.

In addition, our license agreement with the licensor of our hormone products requires us to make certain payments as development milestones are achieved and our license agreement with the University of California, requires us to have available minimum amounts of funds each year for research and development activities relating to our licensed technology and to achieve research and development milestones. Moreover, our fixed expenses, such as rent, license payments and other contractual commitments, may increase in the future, as we may:

- enter into additional leases for new facilities and capital equipment;
- enter into additional licenses and collaborative agreements; and
- incur additional expenses associated with being a public company.

Our cash on hand as of September 30, 2001 was $5,978,971. We believe this cash will be sufficient to fund our operations through March 2003. We have based this estimate, however, on assumptions that may prove to be wrong. As a result, we may need to obtain additional financing prior to that time. In addition, we may need to raise additional capital at an earlier time to fund our ongoing research and development activities, acquire new products or take

advantage of other unanticipated opportunities. Any additional equity financings may be dilutive to our existing shareholders, and debt financing, if available, may involve restrictive covenants on our business. In addition, insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to facilitate the commercial introduction of our proposed products, prevent commercial introduction of our products altogether or restrict us from acquiring new products that we believe may be beneficial to our business.

Risk Factors

There are several important factors that could cause our actual results to differ materially from those anticipated by us or which are reflected in any of our forward-looking statements. These factors, and their impact on the success of our operations and our ability to achieve our goals, include the following and those listed under the caption "Risk Factors" in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2000:

We have a history of operating losses, expect continuing losses and may never achieve profitability.

We have incurred losses in each year since our amalgamation in 1996 and expect to incur substantial and continuing losses for the foreseeable future. We incurred a net loss of $1,199,649 for the nine month period ended September 30, 2001, and as of September 30, 2001, our accumulated deficit was $16,839,321.

All of our revenue to date has been derived from interest earned on invested fundsand upfront payments earned on sub-licensing transactions. We have not commercially introduced any products. We expect to incur substantial and continuing losses for the foreseeable future as our own product development programs expand and various preclinical and clinical trials commence. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the timing and cost of product development;
- the progress and cost of preclinical and clinical development programs;
- the costs of licensure or acquisition of new products;
- the timing and cost of obtaining necessary regulatory approvals; and
- the timing and cost of obtaining third party reimbursement.

In order to generate revenues, we must successfully develop and commercialize our own proposed products or products in the late-stage human clinical development phase or already on the market that we may in-license or otherwise acquire, or enter into collaborative agreements with others who can successfully develop and commercialize them. Even if our proposed products and the products we may license or otherwise acquire are commercially introduced, they may never achieve market acceptance and we may never generate revenues or achieve profitability.

We are a development stage company with a short operating history, making it difficult for you to evaluate our business and your investment.

We are in the development stage and our operations and the development of our proposed products are subject to all of the risks inherent in the establishment of a new business enterprise, including:

- the absence of an operating history;
- the lack of commercialized products;
- insufficient capital;
- expected substantial and continual losses for the foreseeable future;
- limited experience in dealing with regulatory issues;
- the lack of manufacturing experience and limited marketing experience;
- an expected reliance on third parties for the development and commercialization of our proposed products;
- a competitive environment characterized by numerous, well-established and well-capitalized competitors; and
- reliance on key personnel.

Because we are subject to these risks, you may have a difficult time evaluating our business and your investment in our company.

Our proposed products are in the product development stages and will likely not be commercially introduced for several years, if at all.

Our proposed products are in the product development stages and will require further development, pre-clinical and clinical testing and investment prior to commercialization in the United States and abroad. We cannot assure you that any of our proposed products will:

- be successfully developed;
- prove to be safe and efficacious in clinical trials;
- meet applicable regulatory standards;
- demonstrate substantial protective or therapeutic benefits in the prevention or treatment of any disease;
- be capable of being produced in commercial quantities at reasonable costs; or
- be successfully marketed.

We do not anticipate that any of our proposed products will receive the requisite regulatory approvals for commercialization in the United States or abroad for a number of years, if at all, and we cannot assure you that any of our proposed products, if approved and marketed, will generate significant product revenue and provide an acceptable return on our investment.

If we fail to obtain regulatory approval to commercially manufacture or sell any of our future products, or if approval is delayed, we will be unable to generate revenue from the sale of our products.

We must obtain regulatory approval to sell any of our products in the United States and abroad. In the United States, we must obtain the approval of the FDA for each vaccine or drug that we intend to commercialize. The FDA approval process is typically lengthy and expensive, and approval is never certain. Products distributed abroad are subject to similar foreign government regulation.

Generally, only a very small percentage of newly discovered pharmaceutical products that enter pre-clinical development are approved for sale. Because of the risks and uncertainties in biopharmaceutical development, our proposed products could take a significantly longer time to gain regulatory

approval than we expect or may never gain approval. If regulatory approval is delayed or never obtained, our management's credibility, the value of our company and our operating results could be adversely affected.

Moreover, even if the FDA approves a product, such approval may be conditioned upon commercially unacceptable limitations on the indications for which a product may be marketed, and further studies may be required to provide additional data on safety or effectiveness. The FDA may also require post-marketing surveillance programs to monitor the product's side effects. The later discovery of previously unknown problems with a product or manufacturer may result in restrictions or sanctions on the product or manufacturer, including the withdrawal of the product from the market.

To obtain regulatory approval to market our products, costly and lengthy pre-clinical studies and human clinical trials are required, and the results of the studies and trials are highly uncertain.

As part of the FDA approval process, we must conduct, at our own expense, pre-clinical studies on animals and clinical trials on humans on each of our proposed products. We expect the number of pre-clinical studies and human clinical trials that the FDA will require will vary depending on the product, the disease or condition the product is being developed to address and regulations applicable to the particular product. We may need to perform multiple pre-clinical studies using various doses and formulations before we can begin human clinical trials, which could result in delays in our ability to market any of our products. Furthermore, even if we obtain favorable results in pre-clinical studies on animals, the results in humans may be different.

After we have conducted pre-clinical studies in animals, we must demonstrate that our products are safe and effective for use on the target human patients in order to receive regulatory approval for commercial sale. The data obtained from pre-clinical and human clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. Adverse or inconclusive human clinical results would prevent us from filing for regulatory approval of our products. Additional factors that can cause delay or termination of our human clinical trials include:

- slow patient enrollment;
- longer treatment time required to demonstrate efficacy;
- adverse medical events or side effects in treated patients; and
- lack of effectiveness of the product being tested.

Because our industry is very competitive and our competitors have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us, we may not succeed in developing our proposed products and bringing them to market.

Competition in the pharmaceutical industry is intense. Potential competitors in the United States and abroad are numerous and include pharmaceutical, chemical and biotechnology companies, most of which have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us. Academic institutions, hospitals, governmental agencies and other public and private research organizations are also conducting research and seeking patent protection and may develop and commercially introduce competing products or technologies on their own or through joint ventures. We cannot assure you that our competitors will not succeed in developing similar technologies and products more rapidly than we do or that these competing technologies and products will not be more effective than any of those that we are currently developing or will develop.

We license our hormone replacement products and our CAP technology from third parties and may lose the rights to license them.

We license our hormone replacement products from Antares Pharma Inc. and our CAP technology from the University of California. We may lose the right to these technologies if we breach our obligations under the license agreements. Although we intend to use our reasonable best efforts to meet these obligations, if we violate or fail to perform any term or covenant of the license agreements or with respect to the University of California's license agreement within 60 days after written notice from the University of California, Antares and the University of California may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve us of our obligation to pay any royalty or license fees owing at the time of termination. Our failure to retain the right to license our hormone replacement products or CAP technology could harm our business and future operating results. For example, if we were to enter into an outlicense agreement with a third party under which we agree to outlicense our hormone replacement products or CAP technology for a license fee, the termination of the license agreement could either, depending on the terms of the outlicense agreement, cause us to breach our obligations under the outlicense agreement or give the other party a right to terminate that agreement, thereby causing us to lose future revenue generated by the outlicense fees.

If we are unable to protect our proprietary technology, we may not be able to compete as effectively.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, upon our ability to obtain, enjoy and enforce protection for any products we develop or acquire under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties.

Where appropriate, we seek patent protection for certain aspects of our technology. In February 2000, we filed a patent application relating to our technology. However, our owned and licensed patents and patent applications will not ensure the protection of our intellectual property for a number of other reasons:

- We do not know whether our patent applications will result in actual patents. For example, we may not have developed a method for treating a disease before others developed similar methods.

- Competitors may interfere with our patent process in a variety of ways. Competitors may claim that they invented the claimed invention before us or may claim that we are infringing on their patents and therefore cannot use our technology as claimed under our patent. Competitors may also contest our patents by showing the patent examiner that the invention was not original or novel or was obvious.

- We are in the research and development stage and are in the process of developing proposed products. Even if we receive a patent, it may not provide much practical protection. If we receive a patent with a narrow scope, then it will be easier for competitors to design products that do not infringe on our patent. Even if the development of our proposed products is successful and approval for sale is obtained, there can be no assurance that applicable patent coverage, if any, will not have expired or will not expire shortly after this approval. Any expiration of the applicable patent could have a material adverse effect on the sales and profitability of our proposed product.

- Enforcing patents is expensive and may require significant time by our management. In litigation, a competitor could claim that our issued patents are not valid for a number of reasons. If the court agrees, we would lose that patent.

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

It is also unclear whether our trade secrets will provide useful protection. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors. Enforcing a claim that someone else illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Our competitors may independently develop equivalent knowledge, methods and know-how.

Claims by others that our products infringe their patents or other intellectual property rights could adversely affect our financial condition.

The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Patent applications are maintained in secrecy in the United States until the patents are issued and are also maintained in secrecy for a period of time outside the United States. Accordingly, we can conduct only limited searches to determine whether our technology infringes any patents or patent applications of others. Any claims of patent infringement would be time-consuming and could likely:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause product development delays;
- require us to develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although patent and intellectual property disputes in the pharmaceutical industry have often been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt our gross margins. In addition, we cannot be sure that the necessary licenses would be available to us on satisfactory terms, or that we could redesign our products or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing, manufacturing and selling some of our products, which could harm our business, financial condition and operating results.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are exposed to interest rate risk on the investments of our excess cash. The primary objective of our investment activities is to preserve principal while at the same time maximize yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality debt securities. To minimize the exposure due to adverse shifts in interest rates, we invest in short-term securities with maturities of less than one year. Due to the nature of our short-term investments, we have concluded that we do not have a material market risk of exposure.

PART II - OTHER INFORMATION

ITEM 2 - CHANGES IN SECURITIES AND USE OF PROCEEDS

During the three months ended September 30, 2001, we issued an aggregate of 839,195 shares of BioSante common stock to Paladin Labs Inc. as a result of the conversion of a $500,000 convertible debenture at a conversion price of $1.05 per share and certain sub-license milestone payments.

In August 2001, we issued a stock bonus of 125,000 shares of common stock to Stephen Simes at a price of $0.60 per share, a stock bonus of 20,000 shares of our common stock to Phillip Donenberg at a price of $0.60 per share, and a stock bonus of 10,000 shares of common stock to Steve Bell at a price of $0.60 per share.

In September 2001, 11,660 shares of BioSante common stock were issued pursuant to a conversion of Class C stock to common stock at a conversion price of $0.25 per share.

No underwriting commissions or discounts were paid with respect to the sales of the unregistered securities described above. In addition, all of the above sales were made in reliance on either Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering or Regulation D of the Securities Act. In all such transactions, certain inquiries were made by BioSante to establish that such sales qualified for such exemption from the registration requirements. In particular, BioSante confirmed that with respect to the exemption claimed under Section 4(2) of the Securities Act (i) all offers of sales and sales were made by personal contact from officers and directors of BioSante or other persons closely associated with BioSante, (ii) each investor made representations that he or she was sophisticated in relation to this investment (and BioSante has no reason to believe that such representations were incorrect), (iii) each purchaser gave assurance of investment intent and the certificates for the shares bear a legend accordingly, and (iv) offers and sales within any offering were made to a limited number of persons.

ITEM 6 - EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits.

None.

(b) Reports on Form 8-K

No reports on Form 8-K were filed during the quarter ended September 30, 2001.

SIGNATURES

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

November 13, 2001

BIOSANTE PHARMACEUTICALS, INC.

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

By: /s/ Phillip B. Donenberg
Phillip B. Donenberg
Chief Financial Officer, Secretary and Treasurer
(principal financial and accounting officer)