BIOSANTE PHARMACEUTICALS INC
Form 10QSB
November 14, 2003

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

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

For the Quarterly Period Ended September 30, 2003

Commission file number 1-31812

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 x NOo

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 14, 2003
Common stock, $0.0001 par value	13,547,905

Transitional Small Business Disclosure Format (check one): Yes o No x

BIOSANTE PHARMACEUTICALS, INC.

FORM 10-QSB
SEPTEMBER 30, 2003

TABLE OF CONTENTS

In this Form 10-QSB, references to BioSante, the Company, we, our or us, unless the context otherwise requires, refer to BioSante Pharmaceuticals, Inc.

We own or have the rights to use various trademarks, trade names or service marks, including BioSante®, BioVant , NanoVant , CAP-Oral , BioAir , Bio-T-Gel , Bio-E-Gel , Bio-E/P-Gel , LibiGel and LibiGel-E/T .

PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Balance Sheets
September 30, 2003 and December 31, 2002 (Unaudited)

	September 30, 2003	December 31, 2002
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 10,396,015**	**$ 4,883,697**
Due from Teva Pharmaceuticals USA, Inc.		**520,063**
Prepaid expenses and other sundry assets	**235,059**	**144,155**
	10,631,074	**5,547,915**
PROPERTY AND EQUIPMENT, NET	**266,370**	**331,889**
	$ 10,897,444	**$ 5,879,804**
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	**$ 271,694**	**$ 470,871**
Accrued compensation	**168,258**	**313,287**
Other accrued expenses	**236,426**	**236,758**
Due to Antares	**23,750**	**235,303**
	700,128	**1,256,219**
COMMITMENTS		
STOCKHOLDERS EQUITY		
Capital stock		
Issued and Outstanding		
466,602 (2002 - 466,602) Class C special stock	**467**	**467**
13,485,405 (2002 - 8,571,169) Common stock	**36,558,258**	**26,684,841**
	36,558,725	**26,685,308**
Deficit accumulated during the development stage	**(26,361,409)**	**(22,061,723)**
	10,197,316	**4,623,585**
	$ 10,897,444	**$ 5,879,804**

See accompanying notes to the financial statements.

ITEM 1 - FINANCIAL STATEMENTS (CONTINUED)

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Operations
Three and nine months ended September 30, 2003 and 2002 and the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2003
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative period from August 29, 1996 (date of incorporation) to September 30, 2003
	2003	2002	2003	2002	
REVENUE					
Licensing income	$	$ 950,000	$ 65,494	$ 950,000	$ 4,582,943
Interest income	25,399	12,556	55,708	42,527	1,040,448
	25,399	962,556	121,202	992,527	5,623,391
EXPENSES					
Research and development	960,205	1,326,556	2,702,482	2,958,478	13,915,616
General and administration	481,073	413,804	1,648,284	1,364,784	11,522,805
Depreciation and amortization	23,026	23,197	70,122	68,556	636,615
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
	1,464,304	1,763,557	4,420,888	4,391,818	31,984,800
NET LOSS	$ (1,438,905)	$ (801,001)	$ (4,299,686)	$ (3,399,291)	$ (26,361,409)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.12)	$ (0.11)	$ (0.43)	$ (0.49)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	12,022,673	7,375,017	10,056,709	6,986,096	

See accompanying notes to the financial statements.

ITEM 1 - FINANCIAL STATEMENTS (CONTINUED)

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Cash Flows
Nine months ended September 30, 2003 and 2002 and the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2003
(Unaudited)

	Nine Months Ended Sept. 30,		Cumulative period from August 29, 1996 (date of incorporation) to September 30, 2003
	2003	2002	
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	**$ (4,299,686)**	**$ (3,399,291)**	**$ (26,361,409)**
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	**70,122**	**68,556**	**636,615**
Amortization of deferred unearned compensation			**42,290**
Repurchase of licensing rights			**125,000**
Employee compensation paid in shares of common stock			**151,000**
Director compensation paid in shares of common stock	**189,000**		**189,000**
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	**(90,904)**	**(79,992)**	**(232,091)**
Due from licensee (Teva Pharmaceuticals USA, Inc.)	**520,063**		
Accounts payable and accrued expenses	**(316,991)**	**153,478**	**(36,262)**
Due to licensor (Antares/Regents)	**(211,553)**	**(388,425)**	**23,750**
Due from SBI			**(128,328)**
Net cash used in operating activities	**(4,139,949)**	**(3,645,674)**	**(20,055,890)**
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchase of capital assets	**(4,603)**	**(34,841)**	**(1,026,420)**
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Issuance of convertible debenture			**500,000**
Proceeds from sale of capital stock	**9,656,870**	**4,435,844**	**30,978,325**
Net cash provided by financing activities	**9,656,870**	**4,435,844**	**31,478,325**
NET INCREASE IN CASH AND CASH EQUIVALENTS	**5,512,318**	**755,329**	**10,396,015**
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	**4,883,697**	**4,502,387**	

CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 10,396,015**	**$ 5,257,716**	**$ 10,396,015**
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 therefor			**4,545,563**
	$	**$**	**$**
Income tax paid	**$**	**$**	**$**
Interest paid	**$ 1,995**	**$**	**$ 1,995**
SIGNIFICANT NON-CASH TRANSACTIONS			
Fair value of common stock warrants issued in connection with the sale of capital stock	**$ 539,872**	**$**	**$ 539,872**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
FORM 10-QSB
SEPTEMBER 30, 2003

Notes to the 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. (the Company) as of September 30, 2003, the results of operations for the three and nine months ended September 30, 2003 and 2002 and for the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2003, and the cash flows for the nine months ended September 30, 2003 and 2002 and for the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2003, 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, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003.

On May 31, 2002, the Company effected a one-for-ten reverse split of its issued and outstanding shares of common stock and class C stock. All share and per share stock numbers in this Form 10-QSB have been adjusted to reflect the reverse stock split.

These unaudited interim financial statements should be read in conjunction with the financial statements and related notes contained in the Company s Annual Report on Form 10-KSB for the year ended December 31, 2002.

New Financial Accounting Standards Board (FASB) Interpretation

In November 2002, the FASB Emerging Issues Task Force (EITF) issued FASB Interpretation (FIN) 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others (FIN45), which elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The disclosure requirements of FIN 45 became effective for financial statements of interim and annual periods ending after December 15, 2002, while the initial recognition and measurement provisions of FIN 45 became effective for all for guarantees issued or modified after December 31, 2002. The Company does not believe that the adoption of FIN 45 will have a material impact on the Company s financial position, cash flow or results of operations.

2. 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 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 the Company has incurred net losses from operations in each of the periods presented, 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.

3. LICENSE AGREEMENTS

In June 1997, the Company entered into a licensing agreement with the Regents of the University of California, which has subsequently been amended, pursuant to which the University has granted the Company an exclusive license to seven United States patents owned by the University, including rights to sublicense such patents. The license agreement with the University of California requires the Company to undertake various obligations, including but not limited to, the payment of royalties based on net sales, when and if they occur, and the payment of minimum annual royalties.

In June 2000, the Company entered into a license agreement with Antares Pharma Inc. covering four hormone therapy products for the treatment of men and women. The license agreement requires the Company to pay Antares a percentage of future net sales, if any, as a royalty. Under the terms of the license agreement, the Company is also obligated to make milestone payments upon the occurrence of certain events.

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

In August 2001, the Company entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product licensed from Antares. Under the terms of the agreement, Solvay sub-licensed the Company s estrogen/progestogen combination transdermal hormone therapy gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin Labs Inc.), future milestone payments and escalating sales-based royalties. During the third quarter ended September 30, 2002, the Company received a $950,000 milestone payment pursuant to the Solvay sub-license agreement for certain milestones achieved.

In October 2001, the Company sub-licensed its BioVant 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 the Company milestone payments upon the achievement of certain milestones plus royalty payments on sales if and when vaccines are approved using BioVant and sold on a commercial basis. If Corixa sub-licenses vaccines that include BioVant, the Company will share in milestone payments and royalties received by Corixa. The sub-license agreement covers access to BioVant for a variety of cancer, infectious and autoimmune disease vaccines.

In April 2002, the Company exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, *e.g.* testosterone) and an option for triple hormone contraception. The financial terms of the license include an upfront payment by the Company, regulatory milestones, maintenance payments and royalty payments by the Company if a product incorporating the licensed technology is approved and subsequently marketed.

In December 2002, the Company signed a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. under which Teva USA and the Company will collaborate on the development of a hormone therapy product for

the U.S. market. Upon signing the U.S. development and license agreement, the Company received an upfront payment of $1.5 million. In addition, Teva will pay the Company development and sales-related milestone payments plus royalties on sales of the product commercialized in this collaboration. In exchange, the Company granted Teva exclusive rights to develop and market a certain hormone therapy product. Teva also is responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product.

4. COMMITMENTS

University of California License

The Company s license agreement with the University of California requires the Company 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 beginning for the year 2004 to be paid by February 28 of the following year 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
Total	$6,800,000

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, 2002 and the nine months ended September 30, 2003 amounted to $12,240 and $0, respectively;

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;

Indemnifying, holding harmless and defending 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 the license agreement, including but not limited to, any product liability claims. The Company has not recorded any liability related to this obligation as no events occurred that would require indemnification.

Antares Pharma, Inc. License

The Company s license agreement with Antares Pharma, Inc. requi