

SAVIENT PHARMACEUTICALS INC

FORM 10-Q (Quarterly Report)

Filed 11/9/2006 For Period Ending 9/30/2006

Address	ONE TOWER CENTER EAST BRUNSWICK, New Jersey 08816
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Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

**For the quarterly period ended September 30, 2006
OR**

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-15313

SAVIENT PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

13-3033811
(I.R.S. Employer
Identification No.)

One Tower Center, East Brunswick, New Jersey 08816
(Address of Principal Executive Offices)

(732) 418-9300
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year,
if Changed Since Last Report)

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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

(Check one): Large Accelerated filer Accelerated filer Non-accelerated filer

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

The number of shares outstanding of the registrant's Common Stock, par value \$.01 per share, as of November 5, 2006 was 52,096,177.

SAVIENT PHARMACEUTICALS, INC.

FORM 10-Q
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2006

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PART I — FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS****SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**
(In thousands, except share data)

	September 30, 2006	December 31, 2005
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 197,803	\$ 75,181
Short-term investments	1,138	191
Accounts receivable, net	5,265	11,716
Notes receivable	637	6,635
Inventories, net	6,337	9,419
Prepaid expenses and other current assets	6,054	2,721
	<u>217,234</u>	<u>105,863</u>
Property and equipment, net	1,216	6,144
Goodwill	—	40,121
Other intangibles, net	—	67,638
Other assets (including restricted cash of \$1,280)	3,529	2,925
	<u>\$ 221,979</u>	<u>\$ 222,691</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,984	\$ 5,745
Income taxes payable	22,352	—
Other current liabilities	14,822	15,121
	<u>39,158</u>	<u>20,866</u>
Deferred income taxes	—	20,431
Commitments and contingencies (Note 7)		
Stockholders' Equity:		
Preferred stock—\$.01 par value, 4,000,000 shares authorized no shares issued	—	—
Common stock—\$.01 par value, 150,000,000 shares authorized; 51,997,000 shares issued and outstanding at September 30, 2006 and 61,523,000 shares issued and outstanding at December 31, 2005	519	615
Additional paid in capital	187,945	221,622
Deferred compensation	—	(686)
Accumulated deficit	(5,552)	(41,519)
Accumulated other comprehensive income (loss)	(91)	1,362
	<u>182,821</u>	<u>181,394</u>
Total liabilities and stockholders' equity	<u>\$ 221,979</u>	<u>\$ 222,691</u>

The accompanying notes are an integral part of these consolidated financial statements.

SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2006	2005	2006	2005
Revenues:				
Product sales, net	\$ 39,152	\$ 35,370	\$ 15,889	\$ 11,082
Other revenues	132	941	32	102
	<u>39,284</u>	<u>36,311</u>	<u>15,921</u>	<u>11,184</u>
Cost and expenses:				
Cost of goods sold	3,569	4,145	1,351	1,222
Research and development	12,933	13,208	5,519	4,029
Selling and marketing	7,483	10,836	2,514	3,020
General and administrative	19,260	14,957	4,950	5,611
Commissions and royalties	5	3,782	—	1,316
	<u>43,250</u>	<u>46,928</u>	<u>14,334</u>	<u>15,198</u>
Operating income (loss)	(3,966)	(10,617)	1,587	(4,014)
Investment income	6,794	3,093	3,172	1,198
Other income (expense), net	8,267	1,916	(28)	53
	<u>11,095</u>	<u>(5,608)</u>	<u>4,731</u>	<u>(2,763)</u>
Income (loss) from continuing operations before income taxes	11,095	(5,608)	4,731	(2,763)
Income tax expense (benefit)	891	3	773	(104)
	<u>10,204</u>	<u>(5,611)</u>	<u>3,958</u>	<u>(2,659)</u>
Income (loss) from continuing operations	10,204	(5,611)	3,958	(2,659)
Income from discontinued operations, net of income taxes (includes gain (loss) on sale of discontinued operations) (Note 8)	58,885	2,737	57,911	701
	<u>\$ 69,089</u>	<u>\$ (2,874)</u>	<u>\$ 61,869</u>	<u>\$ (1,958)</u>
Net income (loss)				
Earnings (loss) per common share, from continuing operations:				
Basic	\$ 0.17	\$ (0.09)	\$ 0.06	\$ (0.04)
Diluted	\$ 0.17	\$ (0.09)	\$ 0.06	\$ (0.04)
Earnings per common share, from discontinued operations:				
Basic	\$ 0.96	\$ 0.04	\$ 0.96	\$ 0.01
Diluted	\$ 0.95	\$ 0.04	\$ 0.95	\$ 0.01
Earnings (loss) per common share:				
Basic	\$ 1.13	\$ (0.05)	\$ 1.02	\$ (0.03)
Diluted	\$ 1.12	\$ (0.05)	\$ 1.01	\$ (0.03)
Weighted average number of common and common equivalent shares:				
Basic	61,000	60,736	60,433	60,934
Diluted	61,675	60,736	61,174	60,934

The accompanying notes are an integral part of these consolidated financial statements.

SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock		Additional		Accumulated Deficit	Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Par Value	Paid In Capital	Deferred Compensation			
Balance December 31, 2005	61,523	\$ 615	\$ 221,622	\$ (686)	\$ (41,519)	\$ 1,362	\$ 181,394
Comprehensive income:							
Net income	—	—	—	—	69,089	—	69,089
Unrealized gain on marketable securities, net	—	—	—	—	—	49	49
Currency translation adjustment	—	—	—	—	—	(1,502)	(1,502)
Total comprehensive income							67,636
Transition effect of adoption of SFAS No. 123(R)	—	—	(686)	686	—	—	—
Restricted stock grants	131	1	(1)	—	—	—	—
Amortization of deferred compensation	—	—	547	—	—	—	547
Forfeiture of restricted stock grants	(83)	(1)	1	—	—	—	—
Issuance of common stock	134	1	406	—	—	—	407
Repurchase and retirement of common stock	(10,000)	(100)	(36,069)	—	(33,122)	—	(69,291)
ESPP compensation expense	—	—	377	—	—	—	377
Stock option compensation expense	—	—	780	—	—	—	780
Exercise of stock options	292	3	968	—	—	—	971
Balance, September 30, 2006 (Unaudited)	51,997	\$ 519	\$ 187,945	\$ —	\$ (5,552)	\$ (91)	\$ 182,821

The accompanying notes are an integral part of these consolidated financial statements.

SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2006	2005
Cash flows from operating activities:		
Net income (loss)	\$ 69,089	\$ (2,874)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,269	1,708
Amortization of intangible assets	2,417	3,037
Deferred income taxes	(755)	(928)
Gain related to receipt of Omrix shares	(575)	—
Gain on sale of oral liquid pharmaceuticals business	(77,174)	—
Loss on sale of global biologics manufacturing business	—	4
Gain on sale of Delatestryl	(5,884)	—
Unrealized loss (gain) on trading securities	(418)	62
Loss on sales of trading securities	—	226
Proceeds from sales of trading securities	—	2,375
Common stock issued as payment for services	101	109
Amortization of deferred compensation	547	229
Stock based compensation	1,157	—
Changes in:		
Accounts receivable, net	595	5,632
Inventories, net	(1,130)	474
Prepaid expenses and other current assets	(6,533)	(1,409)
Assets held for sale	—	(1,502)
Accounts payable	(2,161)	(2,068)
Income taxes payable	22,353	—
Liabilities held for sale	—	(2,044)
Other current liabilities	(628)	(8,389)
Deferred revenues	1,957	(616)
Net cash provided by (used in) operating activities	4,227	(5,974)
Cash flows from investing activities:		
Proceeds from the sale of oral liquid pharmaceuticals business	176,000	—
Proceeds from sale of investment in Omrix	—	1,624
Proceeds from sale of global biologics manufacturing business	—	55,000
Proceeds from the collection of note receivable issued in connection with the sale of global biologics manufacturing business	6,700	—
Proceeds from sale of Delatestryl	5,531	—
Capital expenditures	(2,592)	(1,230)
Changes in other long-term assets	5	—
Net cash provided by investing activities	185,644	55,394
Cash flows from financing activities:		
Repurchase and retirement of common stock	(69,291)	—
Repayment of long-term debt	—	(5,838)
Proceeds from issuance of common stock	1,277	1,377
Net cash used in financing activities	(68,014)	(4,461)
Effect of exchange rate changes	765	(1,120)
Net increase in cash and cash equivalents	122,622	43,839
Cash and cash equivalents at beginning of period	75,181	22,447
Cash and cash equivalents at end of period	\$ 197,803	\$ 66,286

Supplementary information:

Interest paid	\$	—	\$	91
Income taxes paid	\$	3,337	\$	735

The accompanying notes are an integral part of these consolidated financial statements.

SAVIENT PHARMACEUTICALS, INC.**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)****1 — Basis of Presentation**

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and notes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the unaudited interim financial statements furnished herein include all adjustments necessary for a fair presentation of the Company's financial position at September 30, 2006 and the results of its operations and cash flows for the nine month periods ended September 30, 2006 and 2005. Interim financial statements are prepared on a basis consistent with the Company's annual financial statements. Results of operations for the nine-month period ended September 30, 2006 are not necessarily indicative of the operating results that may be expected for the year ending December 31, 2006.

The consolidated balance sheet as of December 31, 2005 was derived from the audited financial statements at that date but does not include all of the information and notes required by accounting principles generally accepted in the United States of America for complete financial statements. For further information, refer to the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2005. Certain prior period amounts have been reclassified to conform to current period presentations.

2 — Inventories

Inventories are stated at the lower of cost or market. If inventory costs exceed expected market value due to obsolescence or quantities in excess of expected demand, reserves are recorded for the difference between the cost and the market value. These reserves are determined based on estimates. The inventory obsolescence reserve is approximately \$5.6 million as of September 30, 2006.

The Company's inventories include Oxandrin® inventories that the Company believes would potentially be in excess of the expected product demand if the U.S. Food and Drug Administration, or FDA, approves a generic form of the product in the near term. The amount of such potential excess will vary depending upon the timing of the approval of a generic product, the number of generic products that are approved and the rate by which generic sales reduce demand for branded Oxandrin.

Inventories at September 30, 2006 and December 31, 2005 are summarized below:

	<u>September 30, 2006</u>	<u>December 31, 2005</u>
	<u>(Unaudited)</u>	
	<u>(In thousands)</u>	
Raw material	\$ 4,095	\$ 3,960
Work in process	795	141
Finished goods	7,094	13,058
Inventory reserves	(5,647)	(7,740)
	<u>6,337</u>	<u>9,419</u>
Total	<u>\$ 6,337</u>	<u>\$ 9,419</u>

3 — Revenue Recognition*Revenue recognition — Product sales*

Product sales are recognized when title to the product has transferred to the Company's customers in accordance with the terms of the sale. The Company recognizes revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" as amended by Staff Accounting Bulletin No. 104 (together, "SAB 104"), and Statement of Financial Accounting Standards No. 48 "Revenue Recognition When Right of Return Exists" ("SFAS No. 48"). SAB 104 states that revenue should not be recognized until it is realized or realizable and earned. Revenue is

SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

3 — Revenue Recognition — (Continued)

realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the seller's price to the buyer is fixed and determinable, and (4) collectibility is reasonably assured. SFAS No. 48 states that revenue from sales transactions where the buyer has the right to return the product shall be recognized at the time of sale only if (1) the seller's price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (3) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (5) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated.

The Company's net product revenues represent total product revenues less allowances for returns, Medicaid rebates, other government rebates, other rebates, discounts, and distribution fees.

Allowance for returns — In general, the Company provides credit for product returns that are returned six months prior to and up to twelve months after the product expiration date. The Company's product sales in the United States primarily relate to Oxandrin. Upon shipment, we estimate an allowance for future returns. The Company will provide additional return reserves for contemporaneous events that were not known and knowable at the time of shipment. In order to reasonably estimate future returns, the Company analyzes both quantitative and qualitative information including, but not limited to, actual return rates by lot productions, the level of product manufactured by the Company, the level of product in the distribution channel, expected shelf life of the product, current and projected product demand, the introduction of competitors' new or generic products that may erode current demand, and general economic and industry wide indicators. The Company also utilizes the guidance provided in SFAS No. 48 and SAB 104 in establishing its return estimates. SFAS No. 48 discusses potential factors that may impair the ability to make a reasonable estimate including: (1) the susceptibility of the product to significant external factors, such as technological obsolescence or changes in demand, (2) relatively long periods in which a particular product may be returned, (3) absence of historical experience with similar types of sales of similar products, or inability to apply such experience because of changing circumstances, for example, changes in the selling enterprise's marketing policies or relationships with its customers, and (4) absence of a large volume of relatively homogeneous transactions. SAB 104 provides additional factors that may impair the ability to make a reasonable estimate including: (1) significant increases in or excess levels of inventory in a distribution channel, (2) lack of "visibility" into or the inability to determine or observe the levels of inventory in a distribution channel and the current level of sales to end users, (3) expected introductions of new products that may result in the technological obsolescence of and larger than expected returns of current products, (4) the significance of a particular distributor to the registrant's (or a reporting segment's) business, sales and marketing, (5) the newness of a product, (6) the introduction of competitors' products with superior technology or greater expected market acceptance, and (7) other factors that affect market demand and changing trends in that demand for the registrant's products. The allowance for product returns as of September 30, 2006 and December 31, 2005 was \$2.3 million and \$2.9 million, respectively. This allowance is included in other current liabilities on the Company's balance sheet.

Allowances for Medicaid, other government rebates and other rebates — The Company's contracts with Medicaid, other government agencies such as the Federal Supply System and other non-governmental entities commit us to providing those entities with our most favorable pricing. This ensures that the Company's products remain eligible for purchase or reimbursement under these programs. Based upon our contracts and the most recent experience with respect to sales through each of these channels, the Company provides an allowance for rebates. The Company monitors the sales trends and adjusts the rebate percentages on a regular basis to reflect the most recent rebate experience. The allowance for rebates as of September 30, 2006 and

SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

3 — Revenue Recognition — (Continued)

December 31, 2005 was \$1.7 million and \$2.5 million, respectively. This allowance is included in other current liabilities on the Company's balance sheet.

Commercial discounts — The Company sells directly to drug wholesalers. Terms of these sales vary, but generally provide for invoice discounts for prompt payment. These discounts are recorded by the Company at the time of sale. Gross product revenue is also reduced for promotions and pricing incentives.

Distribution fees — The Company has a distribution arrangement with a third party which includes payment terms equal to a flat monthly fee plus a per transaction fee for specified services. The Company also records distribution fees associated with wholesaler distribution services from one of its largest customers.

Revenue recognition — Other

Other revenues primarily represent royalty income which is recognized as earned upon receipt of confirmation of payment from contracting third parties. In 2005, other revenues also represented funds received by the Company for research and development projects. The Company recognized revenues upon performance of such funded research. The Company did not have revenue related to research and development projects in 2006.

Discontinued operations for the three and nine months ended September 30, 2005 included contract fee revenue which consisted of a license for marketing and distribution rights and research and development projects. In accordance with SAB 104 contract fee revenues were recognized over the estimated term of the related agreements which ranged from 5 to 16 years. Discontinued operations for the nine months ended September 30, 2005 also included royalties from third parties that were recognized as earned upon receipt of confirmation of payment from contracting parties.

4 — Earnings Per Share of Common Stock

The Company has applied Statement of Financial Accounting Standards No. 128, *Earnings Per Share*, in its calculation and presentation of earnings per share — “basic” and “diluted”. Basic earnings per share are computed by dividing income available to common stockholders (the numerator) by the weighted average number of common shares (the denominator) for the period. The computation of diluted earnings per share is similar to basic earnings per share, except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potentially dilutive common shares had been issued as calculated using the treasury stock method.

The numerator in calculating both basic and diluted earnings (loss) per common share for each period presented is the reported net income (loss). The denominator is based on the following weighted average number of common shares:

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2006	2005	2006	2005
	(Unaudited) (In thousands)			
Basic	61,000	60,736	60,433	60,934
Incremental common stock equivalents	675	—	741	—
Diluted	61,675	60,736	61,174	60,934

The difference between basic and diluted weighted average common shares resulted from the assumption that dilutive stock options outstanding were exercised and dilutive restricted stock had vested. For the three and nine months ended September 30, 2006, options to purchase 598,100 and 621,793 shares, respectively, of our common stock were not included in the diluted earnings per share calculation since the exercise price of these options exceeded the average value of the Company's stock for the period. For the three and nine months ended September 30, 2005, all



SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

4 — Earnings Per Share of Common Stock — (Continued)

outstanding options as of such date were excluded from the computation of diluted earnings per share as their effect would have been anti-dilutive since the Company reported a net loss for that period.

5 — Stockholders' Equity

Stock-Based Compensation

Stock Options

Prior to January 1, 2006, the Company accounted for stock-based compensation under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations, as permitted by Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*. No stock-based employee compensation cost was recognized in the Statement of Operations for any periods ending prior to January 1, 2006 as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant. Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, ("SFAS No. 123(R)") using the modified- prospective-transition method. Under this transition method, compensation cost in 2006 includes costs for options granted prior to, but not amortized as of, December 31, 2005. The modified-prospective-transition method does not result in the restatement of prior periods.

The adoption of SFAS No. 123(R) resulted in a decrease in income from continuing operations and net income of approximately \$251,000 and \$780,000 for the three and nine months ended September 30, 2006, respectively. Prior to the adoption of SFAS No. 123(R), the Company disclosed the stock-based compensation pro forma expense effect on net loss and earnings per share which for the three and nine months ended September 30, 2005 is illustrated below (for the purposes of this pro forma disclosure, the value of the options is estimated using a Black-Scholes option-pricing model and amortized to expense over the options vesting periods):

	Nine Months Ended September 30, 2005	Three Months Ended September 30, 2005
	(Unaudited) (In thousands)	
Net loss as reported	\$ (2,874)	\$ (1,958)
Deduct:		
Total stock-based compensation expense determined under fair value based method for all awards, net of related tax effects	1,074	316
Pro forma net loss	\$ (3,948)	\$ (2,274)
Loss per share:		
Basic – as reported	\$ (0.05)	\$ (0.03)
Basic – pro forma	\$ (0.07)	\$ (0.04)
Diluted – as reported	\$ (0.05)	\$ (0.03)
Diluted – pro forma	\$ (0.07)	\$ (0.04)

As of September 30, 2006, there was \$1.5 million of unrecognized compensation cost, adjusted for estimated forfeitures, related to unamortized stock option compensation which is expected to be recognized over a weighted average period of approximately 1.6 years. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. In addition, as future grants are made, additional compensation costs will be incurred.

SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

5 — Stockholders' Equity — (Continued)

In November 2005, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position No. 123(R)-3 ("FSP No. 123(R)-3"), *Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards*. FSP No. 123(R)-3 provides an elective alternative transition method for calculating the pool of excess tax benefits available to absorb tax deficiencies recognized subsequent to the adoption of SFAS No. 123(R). Companies may take up to one year from the effective date of FSP No. 123(R)-3 to evaluate the available transition alternatives and make a one-time election as to which method to adopt. The Company is currently in the process of evaluating these alternative methods.

Options are granted to certain employees and directors at prices equal to the closing market value of the stock on the dates the options are granted. The options granted have a term of 10 years from the grant date. Options granted to employees generally vest ratably over a four year period and options granted to board members have a one year vesting period. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date for the option and each vesting date. The Company has estimated the fair value of all stock option awards as of the date of the grant by applying the Black-Scholes pricing valuation model. The application of this valuation model involves assumptions that are highly subjective, judgmental and sensitive in the determination of compensation expense. The weighted average key assumptions used in determining the fair value of options granted during the three and nine months ended September 30, 2006 and 2005 and the weighted average fair market value of options granted during the three and nine months ended September 30, 2006 and 2005 are as follows:

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2006	2005	2006	2005
Weighted-average volatility	65%	64%	64%	61%
Weighted-average risk-free interest rate	4.9%	4.1%	4.9%	4.2%
Weighted average expected life in years	6.1	7.0	6.1	7.0
Dividend yield	0.0%	0.0%	0.0%	0.0%
Weighted average fair market value	\$ 3.28	\$ 2.12	\$ 3.49	\$ 2.57

Historical information was the primary basis for the selection of the expected volatility and expected dividend yield. The expected lives of the options are based upon the simplified method as set forth by Staff Accounting Bulletin No. 107 issued by the Securities and Exchange Commission which estimates expected life as the midpoint between vesting and the grant contractual life. The risk-free interest rate was selected based upon yields of U.S. Treasury issues with a term equal to the expected life of the option being valued.

Stock option activity during the nine months ended September 30, 2006 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in yrs)	Aggregate Intrinsic Value of In-the-Money Options
(Unaudited)				
(In thousands, except weighted average data)				
Outstanding at December 31, 2005	3,030	\$ 4.97	6.95	
Granted	712	5.16		
Exercised	(293)	3.32		
Cancelled	(558)	5.49		
Outstanding at September 30, 2006	2,891	\$ 5.08	6.94	\$ 5,874
Exercisable at September 30, 2006	1,802	\$ 5.46	5.74	\$ 3,623

SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

5 — Stockholders' Equity — (Continued)

The aggregate intrinsic value in the previous table reflects the total pretax intrinsic value (the difference between the Company's closing stock price on the last trading day of the period and the exercise price of the options, multiplied by the number of in-the-money stock options) that would have been received by the option holders had all option holders exercised their options on September 30, 2006. The intrinsic value of the Company's stock options changes based on the closing price of the Company's stock. The total intrinsic value of options exercised during the period was approximately \$933,000. The intrinsic value is calculated as the difference between the market value as of September 30, 2006 and the exercise price of the shares. The closing price per share of the Company's common stock on September 30, 2006 was \$6.51.

Restricted Stock

Starting in 2005, the Company issued restricted stock awards to certain of its employees. Restricted stock awards are recorded as deferred compensation and amortized to compensation expense over the life of the vesting period which have ranged from one to four years in duration. For the nine months ended September 30, 2006, the Company issued 131,000 shares of restricted stock to its employees at a weighted average grant date fair value of \$4.62 amounting to approximately \$605,000. These shares vest over either a three or four year period and are expensed, based on the closing market price of the Company's stock on the date of issuance, on a straight-line basis over the vesting period. During the three and nine months ended September 30, 2006 approximately \$108,000 and \$275,000, respectively, of deferred restricted stock compensation cost has been amortized to expense. Daily pro rata vesting is calculated for employees terminated involuntarily without cause. During the nine months ended September 30, 2006, approximately 84,000 shares valued at approximately \$246,000 have been forfeited. At September 30, 2006, approximately 307,000 shares remained unvested and there was approximately \$771,000 of unrecognized compensation cost related to restricted stock.

During 2006, the Company issued performance share awards to certain employees which could result in the issuance of up to 249,500 shares of restricted stock if identified performance objectives are achieved at designated target levels. Compensation cost related to performance shares is based upon the grant date fair value of the shares and management's best estimate as to whether or not the performance criteria will be satisfied. This amount is recognized ratably over the performance period. During the three and nine months ended September 30, 2006, approximately \$272,000 of deferred performance share compensation cost has been amortized to expense. Compensation cost adjustments will be made based upon changes in estimates of whether the performance criteria will be satisfied. During the three and nine months ended September 30, 2006, no restricted stock shares have been vested related to the performance shares award program.

Employee Stock Purchase Plan

In April 1998, the Company adopted its 1998 Employee Stock Purchase Plan (the "1998 ESPP"). The 1998 ESPP is qualified as an employee stock purchase plan under Section 423 of the Internal Revenue Code of 1986, as amended. Prior to the adoption of SFAS No. 123 (R), and under the accounting guidance that preceded SFAS No. 123(R), the 1998 ESPP was considered to be non-compensatory. Under the 1998 ESPP, the Company will grant rights to purchase shares of common stock under the 1998 ESPP ("Rights") at prices not less than 85% of the lesser of (i) the fair market value of the shares on the date of grant of such Rights or (ii) the fair market value of the shares on the date such Rights are exercised. Therefore, the 1998 ESPP is considered compensatory under SFAS No. 123(R) since, along with other factors, it includes a purchase discount of greater than 5%. During the nine months ended September 30, 2006, the Company recorded approximately \$377,000 of compensation expense related to participation in the 1998 ESPP which resulted in a decrease in income from continuing operations and net income.

SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

5 — Stockholders' Equity — (Continued)

Repurchase of Common Stock

During September, 2006, the Company used a portion of the proceeds received in the disposition of the Company's U.K. subsidiary, Rosemont Pharmaceuticals, Ltd (see Note 8) to repurchase and retire 10 million shares of its common stock in order to reduce the dilution of its common stock and increase shareholder value at a price of \$6.80 per share through a modified "Dutch auction" tender offer. This resulted in a cash outlay of approximately \$69.3 million, including professional fees of approximately \$1.3 million associated with conducting the tender offer. The Company allocated the excess of the purchase price over par value between additional paid in capital and accumulated deficit. The portion of the excess allocated to additional paid in capital was based upon the pro rata portion of the additional paid in capital of the shares repurchased.

6 — Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and their basis for income tax purposes and the tax effects of capital loss, net operating loss and tax credit carryforwards. Valuation allowances reduce deferred tax assets to the amounts that are more likely than not to be realized.

Based upon the uncertainty of the Company's business, the likelihood of the Company being able to fully realize its deferred income tax benefits against future income is uncertain. Accordingly, at September 30, 2006, the Company had a \$10.0 million valuation allowance against its deferred income tax assets. However, in the third quarter of 2006 the Company reduced its deferred tax asset and corresponding valuation allowance by approximately \$12.4 million as a result of the gain on sale of Rosemont which we anticipate will permit us to use a significant portion of the net operating loss carryforward and a portion of general business credits.

The Company's provision for income taxes from continuing operations for the three and nine months ended September 30, 2006 is below the statutory rate primarily due to the utilization of a significant portion of a net operating loss carryforward and a portion of general business credits.

7 — Commitments and Contingencies

Litigation

On December 20, 2002, a purported shareholder class action was filed against the Company and three of its former officers. The action was pending under the caption *In re Bio-Technology General Corp. Securities Litigation*, in the U.S. District Court for the District of New Jersey. Plaintiff alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and sought unspecified compensatory damages. The plaintiff purported to represent a class of shareholders who purchased shares of the Company between April 19, 1999 and August 2, 2002. The complaint asserted that certain of the Company's financial statements were materially false and misleading because the Company restated its earnings and financial statements for the years ended 1999, 2000 and 2001, as described in the Company's Current Report on Form 8-K dated, and its press release issued, on August 2, 2002. Five nearly identical actions were filed in January and February 2003, in each instance claiming unspecified compensatory damages. In September 2003, the actions were consolidated and co-lead plaintiffs and co-lead counsel were appointed in accordance with the Private Securities Litigation Reform Act. The parties subsequently entered into a stipulation which provided for the lead plaintiff to file an amended consolidated complaint. Plaintiffs filed such amended complaint and the Company filed a motion to dismiss the action. On August 10, 2005, citing the failure of the amended complaint to set forth particularized facts that give rise to a strong inference that the defendants acted with the required state of mind, the Court granted the Company's motion to dismiss the action without prejudice and granted plaintiffs leave to file an amended complaint. On October 11, 2005, the plaintiffs filed a second

SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

7 — Commitments and Contingencies — (Continued)

amended complaint, again seeking unspecified compensatory damages, purporting to set forth particularized facts to support their allegations of violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by the Company and its former officers. On December 13, 2005, the Company filed a motion to dismiss the second amended complaint. On October 26, 2006, the United States District Court for the District of New Jersey dismissed, with prejudice, the second amended complaint. The district court declined to allow plaintiffs to file another amended complaint, however, plaintiffs have 30 days from the date of the dismissal to appeal the district court's decision.

On September 26, 2006, the Company filed a lawsuit against Barr Laboratories, Inc. ("Barr"), a wholly-owned subsidiary of Barr Pharmaceuticals, Inc., for infringement of certain of the Company's patents related to various methods of using Oxandrin (oxandrolone). The action is pending under the caption *Savient Pharmaceuticals, Inc. v. Barr Laboratories, Inc.* in the U.S. District Court for the District of New Jersey. The suit was brought in response to Barr's filing of an Abbreviated New Drug Application, or ANDA, with the FDA seeking approval to engage in the commercial manufacture, use and sale of specified dosages of oxandrolone tablets prior to expiration of the Company's patents, all of which are listed in Approved Drug Products with Therapeutic Equivalence Evaluations for Oxandrin. The Company intends to take the actions necessary to defend its patent rights relating to the use of Oxandrin and anticipates a favorable outcome.

Sale of Delatestryl

On January 9, 2006, the Company completed its sale to Indevus Pharmaceuticals Inc. of Delatestryl, its injectable testosterone product for male hypogonadism. Under the terms of the sale, Indevus paid to the Company an initial payment of \$5 million, subject to adjustment based on outstanding trade inventory, and Indevus agreed to pay a portion of the net sales of the product for the first three years following closing of the transaction based on an escalating scale. Additionally, Indevus purchased the entire inventory of finished product from the Company in three installments totaling approximately \$1.9 million. The Company recorded a gain on sale of Delatestryl in the first quarter of 2006. The gain on the sale of Delatestryl of approximately \$5.9 million is included in other income for the nine months ended September 30, 2006.

License for Soltamox

On April 24, 2006, the Company entered into a distribution agreement with Cytogen Corporation granting Cytogen exclusive marketing rights for Soltamox in the United States. Cytogen paid the Company an upfront licensing fee of \$2 million. The Company recorded this upfront licensing fee as a deferred revenue liability and initially amortized the fee as other revenue over the term of the license. On August 4, 2006, the Company divested its interest in its oral liquid pharmaceuticals business, Rosemont Pharmaceuticals, Ltd, including certain intellectual property related to Soltamox. As a result, the Company recognized the remaining deferred revenue related to the upfront fee as part of the gain on sale of Rosemont (see Note 8).

Additional Settlement Proceeds

In February 2006, the Company received an additional payment of \$500,000 under the human growth hormone intellectual property dispute settlement with Novo Nordisk which was previously announced in February 2005. The proceeds were recorded in the first quarter of 2006 and are included in other income for the nine months ended September 30, 2006.

Settlement with Ross Pharmaceuticals Limited (Ross)

The Oxandrin co-promotion agreement with Ross terminated in December 2005. Final reconciliation of the agreement determined that Ross had overcharged Savient in error by approximately \$1.3 million. Ross agreed to compensate the Company for this error and as such, the Company recognized the \$1.3 million in the first quarter of 2006 which is included in other income for the nine months ended September 30, 2006.

SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

7 — Commitments and Contingencies — (Continued)

Ross satisfied its obligation to the Company in October 2006 via a combination of a cash payment and an accounts receivable credit.

Sublease of a Portion of the Corporate Offices

In March 2006, the Company subleased to a third party approximately 12,400 square feet of its administrative headquarters offices in East Brunswick, New Jersey at an average annual base rental of \$340,000 for an initial term of 5 years, terminable after 3 years.

Receipt of Omrix Biopharmaceuticals, Inc. (“Omrix”) Stock

In February 2005, the Company sold to Catalyst Investments, L.P. (“Catalyst”) all of its holdings of Omrix common stock for \$1,625,000, plus the right to receive additional consideration or shares of Omrix common stock in the event that Catalyst was able to realize a gain on its Omrix investment on specified terms. On April 21, 2006, Omrix completed its initial public offering. Pursuant to the terms of the Company’s agreement with Catalyst, Catalyst satisfied its obligations in full by transferring to the Company 52,725 shares of Omrix common stock. The Company recorded the value of the Omrix stock based upon a basis value of \$10.90 per share. The shares were subject to a lock-up period that expired in October 2006.

The closing market price per share of Omrix common stock on September 30, 2006 was \$18.83. As of September 30, 2006, the Company recorded the Omrix shares within short-term investments at a value of approximately \$993,000 and classified the shares as trading securities. For the three and nine months ended September 30, 2006, the Company included approximately \$575,000 in other income related to the Company’s basis in the Omrix shares. The Company adjusted the value of the Omrix shares to reflect the market price as of September 30, 2006 which resulted in investment income of approximately \$418,000 for the three and nine months ended September 30, 2006.

8 — Discontinued Operations

On August 4, 2006, the Company entered into a Purchase and Sale Agreement (the “Agreement”) with Ingleby (1705) Limited (Close Brothers Private Equity) (“Close Brothers”) for the sale of Rosemont Pharmaceuticals Ltd, the Company’s oral liquid pharmaceuticals business in the United Kingdom. Under the terms of the sale, Close Brothers paid to the Company an aggregate purchase price of \$176 million for the issued share capital of Rosemont’s parent company and certain other related assets. Net proceeds from the transaction after selling costs and taxes are estimated to be approximately \$151 million. Additionally, Close Brothers purchased certain intellectual property and other assets and rights from the Company which relate to the business of Rosemont, including certain intellectual property related to the Soltamox product. The pre-tax gain on disposition of Rosemont was approximately \$77.2 million.

During July 2005, the Company sold its former global biologics manufacturing business which primarily operated in Israel through its former Bio-Technology General (Israel) Ltd. subsidiary, which was referred to as BTG-Israel. Financial results related to BTG-Israel are included in discontinued operations for the three and nine months ended September 30, 2005. The loss on disposition of the BTG-Israel business was \$4,000.

A summary statement of discontinued operations of the former BTG-Israel and the former Rosemont businesses for the three and nine months ended September 30, 2006 and September 30, 2005, as it was included in the consolidated financial statements of the Company, is shown below. As BTG-Israel was sold in July 2005, its operations are only included in the three and nine months ended September 30, 2005.

SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

8 — Discontinued Operations — (Continued)

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2006	2005	2006	2005
	(Unaudited) (In thousands)			
Revenues:				
Product sales, net	\$ 24,181	\$ 37,882	\$ 4,637	\$ 9,727
Contract fees	43	635	43	51
Royalties	—	2,386	—	—
	24,224	40,903	4,680	9,778
Cost and expenses:				
Cost of goods sold	8,403	16,031	1,751	2,643
Research and development	1,736	3,738	345	716
Selling and marketing	4,092	5,569	653	1,696
General and administrative	2,232	4,181	358	919
Amortization of intangibles	2,417	3,038	392	1,013
Commissions and royalties	—	58	—	(17)
	18,880	32,615	3,499	6,970
Operating income from discontinued operations	5,344	8,288	1,181	2,808
Other expense, net	(1,696)	(3,002)	(138)	(896)
Gain on disposition of oral liquid pharmaceuticals business	77,174	—	77,174	—
Loss on disposition of global biologics manufacturing business	—	(4)	—	(4)
	80,822	5,282	78,217	1,908
Income tax expense	21,937	2,545	20,306	1,207
	\$ 58,885	\$ 2,737	\$ 57,911	\$ 701

All revenues included in discontinued operations primarily relate to non-U.S. customers.

SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

9 — Segment Information

The Company has identified one reportable segment: Specialty Pharmaceuticals. Prior to 2005, the Company's operations were not managed along segment lines. The Specialty Pharmaceuticals segment includes products which are branded prescription pharmaceuticals including Oxandrin and our former product Delatestryl. Certain research and development expenses related to Puricase[®] (PEG-uricase) are also included with the Specialty Pharmaceuticals segment. The Company's former global biologics manufacturing business and its former oral liquid pharmaceuticals business are included as discontinued operations.

Historically, the Company allocated management fees between its Specialty Pharmaceuticals segment and its former oral liquid pharmaceuticals business based on various factors, including management time. These fees were eliminated in consolidation. With the disposition of the former oral liquid pharmaceuticals business, the Company has reclassified certain corporate allocations from discontinued operations into continuing operations.

The Company's Specialty Pharmaceuticals segment is operated primarily in the United States. All Specialty Pharmaceuticals product revenue was generated in the United States.

Information about the Company's segment, as reconciled to enterprise totals, is presented below:

	Nine Months Ended September 30, 2006		
	Specialty Pharmaceuticals	Discontinued Operations	Total
	(Unaudited, in thousands)		
Revenues	\$ 39,284		\$ 39,284
Operating income (loss) before depreciation and amortization	(3,395)		(3,395)
Less:			
Depreciation and amortization	571		571
Operating loss as reported	(3,966)		(3,966)
Other income, net	15,061		15,061
Income tax expense	(891)		(891)
Income from continuing operations	10,204		10,204
Income from discontinued operations	—	58,885	58,885
Net income	\$ 10,204	\$ 58,885	\$ 69,089
Segment assets	\$ 221,979	\$ —	\$ 221,979
Expenditures for segment assets	\$ 371	\$ 2,221	\$ 2,592

SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

9 — Segment Information — (Continued)

	Nine Months Ended September 30, 2005		
	Specialty	Discontinued	Total
	Pharmaceuticals	Operations	
	(Unaudited, in thousands)		
Revenues	\$ 36,311		\$ 36,311
Operating loss before depreciation and amortization	(9,772)		(9,772)
Less:			
Depreciation and amortization	845		845
Operating loss as reported	(10,617)		(10,617)
Other income, net	5,009		5,009
Income tax expense	(3)		(3)
Loss from continuing operations	(5,611)		(5,611)
Income from discontinued operations	—	2,737	2,737
Net income (loss)	\$ (5,611)	\$ 2,737	\$ (2,874)
Segment assets	\$ 101,858	\$ 128,631	\$ 230,489
Expenditures for segment assets	\$ 101	\$ 1,129	\$ 1,230
	Three Months Ended September 30, 2006		
	Specialty	Discontinued	Total
	Pharmaceuticals	Operations	
	(Unaudited, in thousands)		
Revenues	\$ 15,921		\$ 15,921
Operating income (loss) before depreciation and amortization	1,768		1,768
Less:			
Depreciation and amortization	181		181
Operating income as reported	1,587		1,587
Other income, net	3,144		3,144
Income tax expense	(773)		(773)
Income from continuing operations	3,958		3,958
Income from discontinued operations	—	57,911	57,911
Net income	\$ 3,958	\$ 57,911	\$ 61,869
Segment assets	\$ 221,979	\$ —	\$ 221,979
Expenditures for segment assets	\$ 46	\$ 873	\$ 919

SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

9 — Segment Information — (Continued)

	Three Months Ended September 30, 2005		
	Specialty Pharmaceuticals	Discontinued Operations	Total
	(Unaudited, in thousands)		
Revenues	\$ 11,184		\$ 11,184
Operating loss before depreciation and amortization	(3,749)		(3,749)
Less:			
Depreciation and amortization	265		265
Operating loss as reported	(4,014)		(4,014)
Other income, net	1,251		1,251
Income tax benefit	104		104
Loss from continuing operations	(2,659)		(2,659)
Income from discontinued operations	—	701	701
Net income (loss)	\$ (2,659)	\$ 701	\$ (1,958)
Segment assets	\$ 101,858	\$ 128,631	\$ 230,489
Expenditures for segment assets	\$ —	\$ 145	\$ 145

10 — Subsequent Events

Litigation

On October 26, 2006, the United States District Court for the District of New Jersey dismissed with prejudice the class action originally filed on December 20, 2002, against the Company and three of its former officers in connection with the restatement of the Company's earnings and financial statements for the years ended 1999, 2000 and 2001.

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

Our management's discussion and analysis of financial condition and results of operations contains statements which constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements that set forth anticipated results based on management's plans and assumptions. From time to time, we also provide forward-looking statements in other materials we release to the public as well as oral forward-looking statements. Such statements discuss our strategy, expected future financial position, results of operations, cash flows, financing plans, development of products, strategic alliances, intellectual property, competitive position, plans and objectives of management. We often use words such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "will" and similar expressions to identify forward-looking statements. In particular, the statements regarding our new strategic direction and its potential effects on our business, the development of our lead drug candidate Puricase® (PEG-uricase) are forward-looking statements. Additionally, forward-looking statements include those relating to future actions, prospective products or product approvals, future performance, financing needs, liquidity or results of current and anticipated products, sales efforts, expenses, interest rates, foreign exchange rates and the outcome of contingencies, such as legal proceedings and financial results.

We cannot guarantee that any forward-looking statement will be realized. Achievement of future results is subject to risks, uncertainties and potentially inaccurate assumptions. Should known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected.

We undertake no obligation to publicly update forward-looking statements. You are advised, however, to consult any further disclosures we make on related subjects in our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.

Overview

We are a biopharmaceutical company engaged in developing and marketing pharmaceutical products that target unmet medical needs in both niche and broader markets. Our lead product development candidate, Puricase® (PEG-uricase) for treatment failure gout, has reported positive Phase 1 and 2 clinical data; patient dosing in Phase 3 clinical studies began in June 2006. Savient's experienced management team is committed to advancing its pipeline and expanding its product portfolio by in-licensing late-stage compounds and exploring co-promotion and co-development opportunities that fit the Company's expertise in specialty pharmaceuticals and biopharmaceuticals with an initial focus in rheumatology. We were founded in 1980 as Bio-Technology General Corp. and changed our name to Savient Pharmaceuticals, Inc. in June 2003. Our primary mission is to develop and commercialize novel therapeutic products. We coordinate our administration, finance, business development, clinical development, sales, marketing, quality assurance and regulatory affairs activities primarily from our headquarters in East Brunswick, New Jersey.

We currently market one product in the United States, Oxandrin®, used to promote weight gain following involuntary weight loss. We also have one product in Phase 3 clinical development, Puricase (PEG-uricase), intended for treatment-failure gout, which has received "orphan drug" designation by the FDA. We have repositioned Savient to be a specialty focused company concentrating on the development of Puricase (PEG-uricase), our product candidate for the control of hyperuricemia in patients with treatment-failure gout in whom conventional treatment is contraindicated or shown to be ineffective. Puricase (PEG-uricase) commenced Phase 3 trials in the United States in May 2006 and began Phase 3 patient dosing in June 2006; subsequent to this we commenced patient dosing in Canada and Mexico.

Prior to August 2006, we also marketed more than 100 pharmaceutical products in oral liquid form in the United Kingdom and some E.U. countries through our former U.K. subsidiary, Rosemont Pharmaceuticals, Ltd ("Rosemont"). We sold Rosemont in August 2006. Following the sale of Rosemont, we are concentrating our business development efforts principally on completing a transaction with a partner for the clinical development and commercialization of Puricase (PEG-uricase) outside of the United States. We continue to identify and evaluate late stage compounds and technologies for possible in-licensing/partnering activities in certain therapeutic areas.

We currently operate within one “Specialty Pharmaceuticals” segment which includes the selling and marketing of Oxandrin and the research and development activities of Puricase (PEG-uricase).

Specialty Pharmaceuticals

Our financial results have been heavily dependent on Oxandrin since its product launch in December 1995. Sales of Oxandrin accounted for 100% and 92% of our continuing net product sales for the nine months ended September 30, 2006 and 2005, respectively. One company has, and we believe several companies may have, filed Abbreviated New Drug Applications, or ANDAs, with the FDA relating to a generic drug with the same active pharmaceutical ingredient as Oxandrin. Given the pendency of our two Citizens Petitions before the FDA, our patent infringement lawsuit against Barr, and the stay of FDA action regarding Barr’s ANDA, we cannot predict when generic competition for Oxandrin may begin. If approved by the FDA, introduction of these generic products would cause a significant decrease in our Oxandrin revenues, which would adversely affect us financially and could require us to scale back some of our business activities. As a result, we anticipate that Oxandrin will be a less significant product for our future operating results.

In May 2006, we received written notification of approval from the FDA of a Special Protocol Assessment (SPA) for Puricase (PEG-uricase). We have implemented the protocols in support of a marketing application for the orphan drug indication of the control of hyperuricemia in patients with treatment-failure gout in whom conventional therapy is contraindicated or has been ineffective. In June 2006, we began patient dosing in our Phase 3 clinical studies of Puricase (PEG-uricase). Patient recruitment for the clinical trials is expected to be completed by early 2007. We are targeting to file a Biologics License Agreement (BLA) for Puricase (PEG-uricase) with the FDA in early 2008 and expect an FDA action date by early 2009.

On January 9, 2006, we completed the sale of our Delatestryl product to Indevus Pharmaceuticals Inc. Under the terms of the sale, Indevus paid us an initial payment of \$5 million, subject to adjustment based on outstanding trade inventory, and agreed to pay us a portion of the net sales of the product for the first three years following closing of the transaction based on an escalating scale. Additionally, Indevus purchased our finished product inventory from us in three installments totaling approximately \$1.9 million. Prior to the sale, product sales of Delatestryl had decreased significantly as a result of the FDA’s allowance of the reintroduction of a generic version of Delatestryl into the market in March 2004.

Discontinued Operations

During August 2006, we sold our oral liquid pharmaceuticals business in the United Kingdom to Ingleby (1705) Limited (Close Brothers Private Equity) (“Close Brothers”). Under the terms of the sale, Close Brothers paid to us an aggregate purchase price of \$176 million for the issued share capital of Rosemont’s parent company and certain other related assets. Net proceeds from the transaction after selling costs and taxes are estimated to be approximately \$151 million. Additionally, Close Brothers purchased certain intellectual property and other assets and rights from us which relate to the business of Rosemont, including certain intellectual property related to the Soltamox product. The pre-tax gain on disposition of the oral liquid pharmaceuticals business was approximately \$77.2 million.

During July 2005, we sold our former global biologics manufacturing business which primarily operated in Israel through our former Bio-Technology General (Israel) Ltd. subsidiary, which was referred to as BTG-Israel. Financial results related to BTG-Israel are included in discontinued operations for the three and nine months ended September 30, 2005. The loss on disposition of the BTG-Israel business was \$4,000.

Revenue from discontinued operations, operating income from discontinued operations, and income from discontinued operations for the three and nine months ended September 30, 2006 and 2005 are as follows:

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2006	2005	2006	2005
	(Unaudited) (In thousands)			
Revenues from discontinued operations	\$ 24,224	\$ 40,903	\$ 4,680	\$ 9,778
Operating income from discontinued operations	\$ 5,344	\$ 8,288	\$ 1,181	\$ 2,808
Income from discontinued operations	\$ 58,885	\$ 2,737	\$ 57,911	\$ 701

Revenues from discontinued operations decreased by \$16.7 million, or 41%, for the nine months ended September 30, 2006, as compared to the nine months ended September 30, 2005. Our discontinued operations during 2005 included revenues from our former global biologics manufacturing business and our former oral liquid pharmaceuticals business, whereas our revenues during 2006 only included revenues from our former oral liquid pharmaceuticals business. Discontinued operations revenues decreased by \$5.1 million, or 52%, for the three months ended September 30, 2006, as compared to the three months ended September 30, 2005. This decrease is primarily attributable to a full period of revenues related to our former oral liquid pharmaceuticals business for the three months ended September 30, 2005, as compared to a partial period of revenue during the three months ended September 30, 2006, as we sold this business on August 4, 2006.

Operating income from discontinued operations decreased by \$1.6 million, or 58%, and \$2.9 million, or 36%, for the three and nine months ended September 30, 2006, as compared to the three and nine months ended September 30, 2005, respectively. These decreases were primarily attributable to a full period of operations related to our former oral liquid pharmaceuticals business for the three months ended September 30, 2005 as compared to a partial period of operations during the three months ended September 30, 2006, as the former business was sold on August 4, 2006.

Income from discontinued operations increased by \$57.2 million and \$56.1 million, for the three and nine months ended September 30, 2006, as compared to the three and nine months ended September 30, 2005, respectively. This increase was primarily attributable to the gain on the sale of our former oral liquid pharmaceuticals business, net of income taxes which are estimated to be approximately \$21.1 million.

The results of discontinued operations are not included in the discussion below entitled “Results of Operations.”

Results of Operations

The results of operations discussion relates to continuing operations. The results of our discontinued operations were discussed above in the section entitled “Discontinued Operations.” We have historically derived our revenues from product sales as well as from collaborative arrangements with third parties. Our revenues and expenses have in the past displayed, and may in the future continue to display, significant variations. These variations may result from a variety of factors, including:

- the timing and amount of product sales;
- changing demand for our products including seasonal buying and usage patterns;
- our inability to provide adequate supply for our products;
- changes in wholesaler buying patterns;
- returns of expired product;
- changes in government or private payor reimbursement policies for our products;
- increased competition from new or existing products, including generic products;
- the timing of the introduction of new products;

- the timing and realization of milestone and other payments relating to license agreements;
- the timing and amount of expenses relating to our operations;
- the extent and timing of costs of obtaining, enforcing and defending intellectual property rights; and
- any charges related to acquisitions or divestitures.

The following table summarizes net sales of our commercialized products and their percent of net product sales for the periods indicated:

	Nine Months Ended September 30,				Three Months Ended September 30,			
	2006		2005		2006		2005	
	(Unaudited) (Dollars in thousands)							
Oxandrin	\$ 39,127	100%	\$ 32,408	92%	\$ 15,995	101%	\$ 10,194	92%
Delatestryl	25	—	2,962	8%	(106)	(1)%	888	8%
	\$ 39,152	100%	\$ 35,370	100%	\$ 15,889	100%	\$ 11,082	100%

We believe that sales of our products will vary from period to period based on the purchasing patterns of our customers, particularly related to wholesaler inventory management trends, and our focus on:

- maintaining or increasing business with our existing products;
- expanding into new markets; and
- commercializing additional products.

Results of Operations for the Nine Months Ended September 30, 2006 and September 30, 2005.

Revenues

Total revenues were \$39.3 million and \$36.3 million for the nine months ended September 30, 2006 and 2005, respectively, an increase of \$3.0 million, or 8%. This increase resulted primarily from higher product sales of \$3.8 million, partially offset by a decrease in other revenue of \$0.8 million.

Product sales were \$39.2 million and \$35.4 million for the nine months ended September 30, 2006 and 2005, respectively, an increase of \$3.8 million, or 11%. This increase is primarily attributable to higher sales of Oxandrin, partially offset by lower sales of our former Delatestryl product.

- Sales of Oxandrin were \$39.1 million and \$32.4 million for the nine months ended September 30, 2006 and 2005, respectively, an increase of \$6.7 million, or 21%. This increase is primarily attributable to a price increase instituted in January 2006, higher stocking levels by our wholesalers, and a reduction in the level of Medicaid rebates as Oxandrin was one of numerous products placed upon greater restriction for reimbursement in Florida.
- Sales of Delatestryl decreased \$2.9 million for the nine months ended September 30, 2006 compared with the same period in 2005. On January 9, 2006, we completed the sale of Delatestryl to Indevus Pharmaceuticals, Inc. which terminated our sales of this product.

Other revenues were \$0.1 million and \$1.0 million for the nine months ended September 30, 2006 and 2005 respectively, a decrease of \$0.9 million, or 86%. The decrease was attributable to lower royalties which resulted from the sale of the exclusive rights to certain intellectual property in December 2005 as part of a litigation settlement.

Cost of goods sold

Cost of goods sold was \$3.6 million and \$4.1 million for the nine months ended September 30, 2006 and 2005, respectively, a decrease of \$0.5 million, or 14%. Cost of goods sold as a percentage of product sales decreased from 12% for the nine months ended September 30, 2005 to 9% for the nine months ended September 30, 2006 due in part to higher product mix of Oxandrin and a reduction in inventory reserves.



Research and development expenses

Research and development expenses were \$13.0 million and \$13.2 million for the nine months ended September 30, 2006 and 2005, respectively, a decrease of \$0.2 million, or 2%. This decrease was primarily attributable to a reduction in toxicology studies for Prosaptide, for which development efforts were terminated in December 2005 and a reduction in Puricase (PEG-uricase) patent and trademark expenses, offset partially by Puricase (PEG-uricase) clinical development expenses due to the initiation of the Phase 3 clinical study in May 2006 and an increase related to Puricase (PEG-uricase) manufacturing process development costs.

Selling and marketing expenses

Selling and marketing expenses were \$7.5 million and \$10.8 million for the nine months ended September 30, 2006 and 2005, respectively, a decrease of \$3.3 million, or 31%. This decrease was primarily attributable to a planned reduction in the sales force and corresponding marketing expenses as a result of a strategic change to target only high volume prescribers of Oxandrin.

General and administrative expenses

General and administrative expenses were \$19.3 million and \$15.0 million for the nine months ended September 30, 2006 and 2005, respectively, an increase of \$4.3 million, or 29%. This increase was primarily due to outsourced accounting and finance service fees of \$1.4 million, consulting fees related to complying with Sarbanes-Oxley initiatives of \$0.6 million, \$0.5 million related to compensation expense for stock options and higher legal expenses related to third-party litigation settlements.

Commissions and royalties expenses

Commissions and royalties expenses were \$5,000 and \$3.8 million for nine months ended September 30, 2006 and 2005, respectively, a decrease of \$3.8 million. This decrease was primarily attributable to the termination of our agreement with Ross Pharmaceuticals Limited on sales of Oxandrin for the long-term care market and an elimination of the royalties that we previously paid related to arrangements involving our former Delatestryl and Mircette products.

Investment income

Investment income was \$6.8 million and \$3.1 million for the nine months ended September 30, 2006 and September 30, 2005, respectively, an increase of \$3.7 million, or 120%. This increase primarily resulted from significantly higher cash balances on hand in 2006 and higher effective interest rates. Additionally, \$0.4 million was recorded for an unrealized appreciation gain related to the investment in Omrix to reflect the market price as of September 30, 2006.

Other income (expense), net

Other income (expense) represented income of \$8.3 million and \$1.9 million for the nine months ended September 30, 2006 and 2005, respectively, an increase of \$6.4 million. This increase is primarily attributable to the gain on the sale of Delatestryl of approximately \$5.9 million, a \$1.3 million settlement due from Ross Pharmaceutical Limited related to commission payment overcharges in 2006, and \$0.6 million of income from the receipt of Omrix stock from Catalyst Investments, L.P. as part of the February 2005 agreement between Catalyst and us, partially offset by patent litigation settlements that occurred in 2005.

Income tax expense

Income tax expense was \$0.9 million and \$3,000 for the nine months ended September 30, 2006 and 2005, respectively, an increase of \$0.9 million. This increase was primarily attributable to income from continuing operations for the nine months ended September 30, 2006 as compared to a loss from continuing operations for the nine months ended September 30, 2005. The Company's tax provision from continuing operations for the nine months ended September 30, 2006 is below the statutory rate due to the utilization of a significant portion of a net operating loss carryforward and a portion of general business credits.

Results of Operations for the Three Months Ended September 30, 2006 and September 30, 2005

Revenues

Total revenues were \$15.9 million and \$11.2 million for the three months ended September 30, 2006 and 2005 respectively, an increase of \$4.7 million, or 42%. This increase resulted primarily from higher product sales of \$4.8 million, partially offset by a decrease in other revenues of \$0.1 million.

Product sales were \$15.9 million and \$11.1 million for the three months ended September 30, 2006 and 2005, respectively, an increase of \$4.8 million, or 43%. This increase is primarily attributable to higher sales of Oxandrin, partially offset by lower sales of our former Delatestryl product.

- Sales of Oxandrin were \$16.0 million and \$10.2 million for the three months ended September 30, 2006 and 2005 respectively, an increase of \$5.8 million, or 57%. This increase is primarily attributable to a price increase instituted in January 2006, higher stocking levels by our wholesalers and a reduction in the level of Medicaid rebates.
- Sales of Delatestryl decreased \$1.0 million for the three months ended September 30, 2006 compared with the same period in 2005. On January 9, 2006 we completed the sale of Delatestryl to Indevus Pharmaceuticals, Inc. which terminated our sales of this product. During the three months ended September 30, 2006, we adjusted Delatestryl product return reserves related to product sales that occurred prior to selling Delatestryl to Indevus.

Other revenues were \$32,000 and \$0.1 million for the three months ended September 30, 2006 and 2005, respectively, a decrease of \$0.1 million. The decrease was attributable to lower royalties which resulted from the sale of the exclusive rights to certain intellectual property in December 2005 as part of a litigation settlement.

Cost of goods sold

Cost of goods sold was \$1.4 million and \$1.2 million for the three months ended September 30, 2006 and 2005, respectively, an increase of \$0.2 million, or 11%. Cost of goods sold as a percentage of product sales decreased from 11% for the three months ended September 30, 2005, to 9% for the three months ended September 30, 2006, due in part to higher product mix of Oxandrin and a reduction in inventory reserves.

Research and development expenses

Research and development expenses were \$5.5 million and \$4.0 million for the three months ended September 30, 2006 and 2005, respectively, an increase of \$1.5 million, or 37%. This increase was primarily attributable to Puricase (PEG-uricase) clinical development expenses due to the initiation of the Phase 3 clinical study in May 2006 and an increase in manufacturing process development costs related to Puricase (PEG-uricase).

Selling and marketing expenses

Selling and marketing expenses were \$2.5 million and \$3.0 million for the three months ended September 30, 2006 and 2005, respectively, a decrease of \$0.5 million, or 17%. This decrease was primarily attributable to a planned reduction in the sales force and corresponding marketing expenses as a result of a strategic change to target only high volume prescribers of Oxandrin.

General and administrative expenses

General and administrative expenses were \$5.0 million and \$5.6 million for the three months ended September 30, 2006 and 2005, respectively, a decrease of \$0.6 million, or 12%. This decrease was primarily due to the \$0.8 million reclassification of professional fees to discontinued operations offsetting our gain on the sale of our oral liquid pharmaceuticals business and lower audit fees of \$0.2 million due to restatement activities in 2005. Partially offsetting these lower costs was an increase of \$0.3 million related to consulting expenses.

Commissions and royalties expenses

Commissions and royalties expenses were \$1.3 million for the three months ended September 30, 2005. We did not incur any commissions and royalties expenses during the three months ended September 30, 2006. This decrease was primarily attributable to the termination of our agreement with Ross Pharmaceuticals Limited on sales of Oxandrin for the long-term care market and an elimination of the royalties that we previously paid related to arrangements involving our former Delatestryl and Mircette products.

Investment income

Investment income was \$3.2 million and \$1.2 million for the three months ended September 30, 2006 and September 30, 2005, respectively, an increase of \$2.0 million, or 165%. This increase primarily resulted from significantly higher cash balances on hand in 2006 and higher effective interest rates. Additionally, \$0.4 million was recorded for an unrealized appreciation gain related to the investment in Omrix to reflect the market price as of September 30, 2006.

Other income (expense), net

Other income (expense) represented an expense of \$28,000 for the three months ended September 30, 2006 and income of \$53,000 for the three months ended September 30, 2005. The net decrease of \$81,000 in other income is primarily attributable to lower note receivable interest income as a result of lower note receivables outstanding for the three months ended September 30, 2006 as compared to the three months ended September 30, 2005.

Income tax expense (benefit)

Income tax expense was \$0.8 million for the three months ended September 30, 2006, compared to an income tax benefit of \$0.1 million for the three months ended September 30, 2005, an increase of \$0.9 million in expense. This increase was primarily attributable to income from continuing operations for the three months ended September 30, 2006 as compared to a loss from continuing operations for the three months ended September 30, 2005. The Company's tax provision from continuing operations for the three months ended September 30, 2006 is below the statutory rate due to the utilization of a significant portion of a net operating loss carryforward and a portion of general business credits.

Liquidity and Capital Resources

Our historic cash flows have fluctuated significantly as a result of changes in our revenues, operating expenses, capital spending, working capital requirements, the issuance of common stock, the divestiture of subsidiaries, the repurchase of our common stock, and other financing activities. We expect that cash flows in the near future will be primarily determined by the levels of our net income, working capital requirements, asset purchases and/or divestitures and milestone payment obligations and financings, if any.

As previously discussed, during August 2006, we sold our U.K. subsidiary, Rosemont Pharmaceuticals, Ltd to Ingleby (1705) Limited (Close Brothers Private Equity) ("Close Brothers"). Under the terms of the sale, Close Brothers paid to us an aggregate purchase price of \$176 million for the issued share capital of Rosemont's parent company and certain other related assets. Net proceeds from the transaction after selling costs and taxes are estimated to be approximately \$151 million.

We used a portion of the proceeds received in the Rosemont disposition to repurchase and retire 10 million shares of our common stock in order to reduce the dilution of our common stock and increase shareholder value at a price of \$6.80 per share through a modified "Dutch auction" tender offer. This resulted in a cash outlay of approximately \$69.3 million, including professional fees of approximately \$1.3 million associated with conducting the tender offer.

At September 30, 2006, we had \$198.9 million in cash, cash equivalents and short-term investments. We primarily invest our cash equivalents and short-term investments in highly liquid, interest-bearing, investment grade and government securities in order to preserve principal. As a result of our sale of Rosemont, we have an approximate \$21.1 million tax payment due in December 2006. This payment reflects the expected utilization of net operating loss carryforwards and general business credits.

Cash Provided by (Used in) Operating Activities

Cash provided by operating activities was \$4.2 million for the nine months ended September 30, 2006, compared to cash used in operating activities of \$6.0 million for the nine months ended September 30, 2005. The increase in the cash provided by operating activities for the nine months ended September 30, 2006 was primarily due to net income of \$69.1 million, adjustments to net income including depreciation and amortization and non-cash compensation, and an increase in income taxes payable primarily due to the accrual of income taxes related to the disposition of our oral liquid pharmaceuticals business, partially offset by the pre-tax gain on sale of our oral liquid pharmaceuticals business of \$77.2 million, the gain on sale of Delatestryl of \$5.9 million, gain on receipt of Omrix stock and unrealized gain on the appreciation of Omrix stock, and working capital uses primarily related to inventories, prepaid and other current assets, and other current liabilities. Cash used in operating activities for the nine months ended September 30, 2005 was primarily due to a net loss of \$2.9 million and working capital uses primarily related to prepaid and other current assets, accounts payable, other current liabilities, and net assets held for sale, partially offset by adjustments to net income including depreciation and amortization, non-cash compensation, and proceeds from trading securities.

Cash Provided by Investing Activities

Net cash provided by investing activities was \$185.6 million and \$55.4 million for the nine months ended September 30, 2006 and 2005, respectively. Net cash provided by investing activities for the nine months ended September 30, 2006 was primarily attributable to the proceeds of \$176.0 million from the sale of our oral liquid pharmaceuticals business, the proceeds of \$5.5 million from the sale of Delatestryl and the proceeds of \$6.7 million from the collection of a note receivable issued in connection with the sale of our global biologics manufacturing business, partially offset by \$2.6 million of capital expenditures. Net cash provided by investing activities for the nine months ended September 30, 2005 was attributable to proceeds from the sale of our former global biologics manufacturing business of \$55.0 million and proceeds related to the sale of an investment in Omrix of \$1.6 million, partially offset by capital expenditures of \$1.2 million.

Cash Provided by (Used in) Financing Activities

Net cash used in financing activities was \$68.0 million and \$4.5 million for the nine months ended September 30, 2006 and 2005, respectively. The net cash used in financing activities for the nine months ended September 30, 2006 was primarily attributable to the repurchase and retirement of 10 million shares of our common stock through a modified “Dutch auction” tender offer which resulted in a cash outlay of approximately \$69.3 million, which included professional fees of approximately \$1.3 million associated with conducting the tender offer, partially offset by \$1.3 million of proceeds received from issuance of common stock pursuant to our employee stock purchase plan and the exercise of employee stock options. The net cash used in financing activities for the nine months ended September 30, 2005 was primarily attributable to debt repayments of \$5.8 million, partially offset by \$1.4 million of proceeds received from issuance of common stock pursuant to our employee stock purchase plan and the exercise of employee stock options.

Future Liquidity Resources

We believe that our cash resources as of September 30, 2006, together with anticipated product sales, will be sufficient to fund our ongoing operations for at least the next two years. However, we may fail to achieve our anticipated liquidity levels as a result of unexpected events or failure to achieve our goals. Our future capital requirements will depend on many factors, including the following:

- the timing and amount of product sales, particularly our continued ability to sell Oxandrin prior to the introduction of generic versions of the product;
- continued progress in our research and development programs, particularly with respect to Puricase (PEG-uricase);
- the timing of, and the costs involved in, manufacturing and obtaining regulatory approvals, including regulatory approvals for Puricase (PEG-uricase), and any other product candidates that we may seek to develop in the future;

- the timing and magnitude of any future milestone payment obligations;
- fluctuations in foreign exchange rates for sales denominated in currencies other than the U.S. dollar;
- the quality and timeliness of the performance of our third party suppliers and distributors;
- the cost of commercialization activities, including product marketing, sales and distribution;
- the costs involved in preparing, filing, prosecuting, maintaining, and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation;
- the outcome of pending purported class action and other related, or potentially related, actions and the litigation costs with respect to such actions; and
- our ability to establish and maintain collaborative arrangements.

If we are required to seek additional funding for our operations, we might not be able to obtain such additional funds or, if such funds are available, such funding might be on unacceptable terms. We continue to seek additional collaborative research and development and licensing arrangements in order to provide additional cash flow from operations. However, we may not be able to enter into any such agreements.

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. Applying these principles requires our judgment in determining the appropriateness of acceptable accounting principles and methods of application in diverse and complex economic activities. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of revenues, expenses, assets and liabilities, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and other assumptions that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our 2005 Annual Report on Form 10-K, we believe the following accounting policies include management estimates that are most critical to our reported financial results:

Product revenue recognition. Product sales are recognized when title to the product has transferred to our customers in accordance with the terms of the sale. We recognize revenue in accordance with the SEC's Staff Accounting Bulletin No. 101, "*Revenue Recognition in Financial Statements*," as amended by Staff Accounting Bulletin No. 104 (together, "SAB 104"), and SFAS No. 48 "*Revenue Recognition When Right of Return Exists*" ("SFAS No. 48"). SAB 104 states that revenue should not be recognized until it is realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured. SFAS No. 48 states that revenue from sales transactions where the buyer has the right to return the product shall be recognized at the time of sale only if (1) the seller's price to the buyer is substantially fixed or determinable at the date of sale; (2) the buyer has paid and the obligation is not contingent on resale of the product; (3) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product; (4) the buyer acquiring the product for resale has economic substance apart from that provided by the seller; (5) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer; and (6) the amount of future returns can be reasonably estimated.

Our net product revenues represent total product revenues less allowances for returns, Medicaid rebates, other government rebates, discounts, and distribution fees.

Allowances for returns. In general, we provide credit for product returns that are returned six months prior to or up to twelve months after the product expiration date. Our product sales in the United States primarily relate to the following three products:

<u>Product</u>	<u>Expiration (in years)</u>
Oxandrin 2.5 mg	5
Oxandrin 10 mg (1)	3
Delatestryl (2)	5

- (1) In 2006, the Company determined, based on its review of stability data, that the Oxandrin 10mg dosage form demonstrated stability over a three-year shelf life and thus the Company modified the product's label to indicate a 3 year expiration date. Product with three-year expiration dating was first sold to our customers in May 2006.
- (2) On January 9, 2006, the Company completed its sale of Delatestryl to Indevus Pharmaceuticals, Inc. The Company continues to evaluate product returns on sales of Delatestryl that occurred prior to the sale date to Indevus.

Upon sale, we estimate an allowance for future returns. We provide additional reserves for contemporaneous events that were not known and knowable at the time of shipment. In order to reasonably estimate future returns, we analyze both quantitative and qualitative information including, but not limited to, actual return rates by lot productions, the level of product manufactured by us, the level of product in the distribution channel, expected shelf life of the product, current and projected product demand, the introduction of new or generic products that may erode current demand, and general economic and industry wide indicators. Certain specifics regarding these analyses are as follows:

- Actual return rates — We track actual returns by product and analyze historical return trends. We use these historical trends as part of our overall process of estimating future returns.
- The level of product manufactured — The level of product produced has an impact on the valuation of that product. For productions that exceed anticipated future demand, a valuation adjustment will be required. Generally, this valuation adjustment occurs as an offset to gross inventory. Currently, we have mandated that product with less than twelve months of expiry dating will not be sold into the channel.
- Level of product in the distribution channel — We review wholesaler inventory and third-party prescription data to ensure that the level of product in the channel is at a reasonable level. Currently, the level of product in the distribution channel appears reasonable for five-year, three-year and two-year expiration product.
- Estimated shelf life — Product returns generally occur due to product expiration. Therefore, it is important for us to ensure that product sold into the channel has excess dating that will allow the product to be sold through the channel without nearing its expiration date. Currently we have mandated that product with less than twelve months of expiry dating will not be sold into the channel. We have taken the appropriate measures to enforce this policy, including setting up certain controls with our third party distributor. In addition, we entered into a distributor service agreement with one of our large wholesalers which limits the level of product at the wholesaler. The terms of this agreement are consistent with the industry's movement toward a fee-for-service approach which we believe has resulted in better channel inventory management, higher levels of channel transparency, and more consistent buying and selling patterns. Since a majority of our sales flow through three large wholesalers, we expect that these industry changes will have a direct impact on our future sales to wholesalers, inventory management, product returns and estimation capabilities.
- Current and projected demand — We analyze prescription demand data provided by industry standard third-party sources. This data is used to estimate the level of product in the channel and to determine future sales trends.
- Product launches and new product introductions — For future product launches, we will analyze projected product demand and production levels in order to estimate return and inventory reserve allowances. New product introductions, including generics, will be monitored for market erosion and adjustments to return estimates will be made accordingly.

We also utilize the guidance provided in SFAS No. 48 and SAB 104 in establishing our return estimates. SFAS No. 48 discusses potential factors that may impair the ability to make a reasonable estimate including: (1) the susceptibility of the product to significant external factors, such as technological obsolescence or changes in demand, (2) relatively long periods in which a particular product may be returned, (3) absence of historical experience with similar types of sales of similar products, or inability to apply such experience because of changing circumstances, for example, changes in the selling enterprise's marketing policies or relationships with its customers, and (4) absence of a large volume of relatively homogeneous transactions. SAB 104 provides additional factors that may impair the ability to make a reasonable estimate including: (1) significant increases in or excess levels of inventory in a distribution channel (sometimes referred to as "channel stuffing"), (2) lack of "visibility" into or the inability to determine or observe the levels of inventory in a distribution channel and the current level of sales to end users, (3) expected introductions of new products that may result in the technological obsolescence of and larger than expected returns of current products, (4) the significance of a particular distributor to the registrant's (or a reporting segment's) business, sales and marketing, (5) the newness of a product, (6) the introduction of competitors' products with superior technology or greater expected market acceptance, and (7) other factors that affect market demand and changing trends in that demand for the registrant's products.

The aggregate net return allowance reserves as of September 30, 2006 and December 31, 2005 was \$2.3 million and \$2.9 million, respectively.

Allowances for Medicaid and other government rebates. Our contracts with Medicaid and other government agencies such as the Federal Supply System commit us to providing those agencies with our most favorable pricing. This ensures that our products remain eligible for purchase or reimbursement under these government-funded programs. Based upon our contracts and the most recent experience with respect to sales through each of these channels, we provide an allowance for rebates. We monitor the sales trends and adjust the rebate percentages on a regular basis to reflect the most recent rebate experience. The aggregate net rebate accrual balances as of September 30, 2006 and December 31, 2005 was \$1.7 million and \$2.5 million, respectively.

Inventory valuation. We state inventories at the lower of cost or market. If inventory costs exceed expected market value due to obsolescence or quantities in excess of expected demand, we record reserves for the difference between the cost and the market value. We determine these reserves based on estimates.

The aggregate net inventory valuation reserves as of September 30, 2006 and December 31, 2005 were \$5.6 million and \$7.7 million, respectively.

Our inventories include Oxandrin inventories that we believe would potentially be in excess of expected product demand if the FDA approves a generic form of the product in the near term. The amount of such potential excess will vary depending upon the timing of the approval of a generic product, the number of generic products that are approved and the rate by which generic sales reduce demand for branded Oxandrin.

Stock Based Compensation. Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, ("SFAS No. 123(R)") using the modified-prospective-transition method. Under this transition method, compensation cost in 2006 includes cost for options granted prior to, but not amortized, as of December 31, 2005. The modified-prospective-transition method does not result in the restatement of prior periods which were accounted for under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations, as permitted by Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*. Options are granted to certain employees and directors at prices equal to the market value of the stock on the dates the options are granted. The options granted have a term of 10 years from the grant date and granted options for employees generally vest ratably over a four year period. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date for the option and each vesting date. We have estimated the fair value of all stock option awards as of the date of the grant by applying the Black-Scholes pricing valuation model. The application of this valuation model involves assumptions that are highly subjective, judgmental and sensitive in the determination of compensation expense, including the option's expected term and the price volatility of the underlying stock.

The cumulative effect on income from continuing operations and net income for the nine months ended September 30, 2006 related to the adoption of SFAS No. 123(R) is approximately \$1.2 million which includes both stock option and employee stock purchase plan expenses. As of September 30, 2006, there was \$1.5 million of unrecognized compensation cost, adjusted for estimated forfeitures, related to unamortized stock option compensation which is expected to be recognized over a weighted average period of approximately 1.6 years. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures.

During 2006, we issued performance share awards to certain employees which could result in the issuance of up to 249,500 shares of restricted stock if identified performance objectives are achieved at designated target levels. Compensation cost related to performance shares is based upon the grant date fair value of the shares and management's best estimate as to whether or not the performance criteria will be satisfied. This amount is recognized ratably over the performance period. During the three and nine months ended September 30, 2006 approximately \$272,000 of deferred performance share compensation cost has been amortized to expense. Compensation cost adjustments will be made based upon changes in estimates of whether the performance criteria will be satisfied. During the three and nine months ended September 30, 2006 no restricted stock shares have been vested related to the performance shares award program.

Recently Issued Accounting Standards

In June 2006, the FASB issued FASB Interpretation No. 48 (FIN 48), "Accounting for Uncertainty in Income Taxes." FIN 48 prescribes detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes." Tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon the adoption of FIN 48 and in subsequent periods. FIN 48 will be effective for fiscal years beginning after December 15, 2006 and the provisions of FIN 48 will be applied to all tax positions upon initial adoption of the Interpretation. The cumulative effect of applying the provisions of this Interpretation will be reported as an adjustment to the opening balance of retained earnings upon adoption. The Company is currently evaluating the potential impacts of FIN 48 on its financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk is the exposure to loss resulting from changes in interest rates, foreign currency exchange rates, commodity prices and equity prices. To date our exposure to market risk has been limited. We do not currently hedge any market risk, although we may do so in the future. We do not hold or issue any derivative financial instruments for trading or other speculative purposes.

Our material interest-bearing assets consist of cash and cash equivalents and short-term investments, including investments in commercial paper, time deposits and other debt instruments. Our investment income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates, and other market conditions.

ITEM 4. CONTROLS AND PROCEDURES

We are required to maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act are 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 management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO) as appropriate, to allow timely decisions regarding required disclosure.

As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2005, management identified five material weaknesses in connection with its assessment of the effectiveness of our internal control over financial reporting. In June 2006, based on the recommendation of management, our Audit Committee approved a Sarbanes Oxley Remediation Plan which provided a strategy and timeline for correcting the five material weaknesses. Significant progress has been made in correcting these deficiencies.

In connection with the preparation of the Form 10-Q for the nine-months ended September 30, 2006, management, under the supervision of the CEO and CFO, conducted an evaluation of disclosure controls and procedures. Based on that evaluation, the CEO and CFO concluded that our disclosure controls and procedures were not effective as of September 30, 2006. Management believes that three of the material weaknesses identified in the Company's Annual Report on Form 10-K for the year ended December 31, 2005 have been corrected. The two remaining material weaknesses which management believes are in the process of being corrected, are planned to be completed by December 31, 2006.

The following is a description of the material weaknesses described in our Annual Report on Form 10-K for the year ended December 31, 2005, and the corrective action that has been taken:

- Insufficient personnel resources that are in dedicated permanent positions within the finance function with sufficient skills and industry knowledge of Generally Accepted Accounting Principles and tax, which resulted in insufficient documentation and monitoring over the financial statement close and restatement of quarterly financial reporting attributed to (a) deficiencies in the analysis of estimates relating to product returns, inventory obsolescence and rebates and (b) errors in the income tax provision.

We have strengthened our financial staff with the hiring of an Interim Chief Financial Officer in October 2005, to coordinate the financial restatement effort (completed January 2006) and to strengthen financial controls and procedures. In July 2006 we hired a permanent Senior Vice President and Chief Financial Officer with significant pharmaceutical industry and SEC experience. We further strengthened our financial staff with the hiring of a Vice President of Finance and Controller in February 2006. The accounting staff has been strengthened with the addition of individuals responsible for financial reporting, budgeting and financial analysis. The finance organization is also supported by financial consultants on an as needed basis.

The finance organization is comprised of a self sufficient tax department which coordinates all tax financial reporting matters and tax compliance processes.

With the additions made to the financial staff, we have enhanced our segregation of duties within the Company.

Management believes that changes necessary to fully remediate this weakness were in place by September 30, 2006 but testing of these controls has not been completed within this time frame. Testing to confirm operating effectiveness is planned to be completed in the fourth quarter of 2006.

- There were deficiencies in the income tax analysis consisting of (a) insufficient review of the U.K. tax provision by Rosemont management in the United Kingdom and by the corporate tax function, (b) insufficient monitoring of U.K. tax regulation changes and (c) inaccurate calculation of quarterly tax provision.

We retained a U.K. tax specialist during the first quarter of 2006 to review our U.K. subsidiary's tax provision and to provide technical tax expertise as needed. We engaged external tax consultants in the U.S. in the first quarter of 2006 to provide additional tax expertise related to the 2005 year end closing process and to provide on going tax support. We acquired research tools and tax provision and preparation software and enhanced our review procedures related to both domestic and foreign tax calculations. We established periodic meetings to discuss tax issues and tax implications of business activities.

Management believes that changes necessary to correct this weakness have been implemented, and testing to confirm operating effectiveness was successfully performed during the second quarter of 2006. Management believes that the changes in internal controls implemented to remediate this weakness continue to operate effectively as of September 30, 2006. We note, however, that the report of our independent registered public accounting firm is not due until our Annual Report on Form 10-K for the year ended December 31, 2006.

- There was insufficient communication at the intercompany and intradepartmental level and between us and our third-party service and data providers. At the intradepartmental level, inconsistent exchange of important financial information between our finance and operating functions led to errors in reporting.

We have instituted communication protocols that will foster improved shared intelligence between the finance function and other departments including, but not limited to, legal, commercial operations, research and development and executive management. We have conducted reviews of significant contracts by the accounting department for completeness, accuracy and proper accounting treatment, including accounting input into the contract terms prior to the execution of contracts. Prior to the sale of our U.K. subsidiary on August 4, 2006, we had commenced an increase in the communication level between parent and subsidiary personnel, including the establishment of standardized periodic meetings to discuss business results and objectives.

With regard to improving communications with third parties, we established periodic meetings with third party process providers in order to educate these parties regarding our enhanced policies and procedures. We have had third party process providers educate us on the level of data that they provide, the controls over their processes, and how we can better utilize the information that is currently available. Included within this education process were visits by Company personnel to the third party process providers servicing locations. We instituted monthly reporting standards from third party process providers and third party vendors/ customers that will enhance our estimation capabilities. We have historically received many of these reports; however, standards related to these reports will assist us with financial reporting timing and accuracy.

Management believes that the changes necessary to correct this weakness were in place and operating effectively as of September 30, 2006 and considers this issue to be fully resolved as of September 30, 2006. We note, however, that the report of our independent registered public accounting firm is not due until our Annual Report on Form 10-K for the year ended December 31, 2006.

- There were insufficient controls over the Cash and Treasury process including (a) authorization, monitoring and segregation of duties over wire transfers, (b) non-timely revision of signature authority over our bank accounts and (c) monitoring and segregation of duties with respect to access to check stock at our U.K. subsidiary.

We have evaluated the segregation of duties and have implemented changes that personnel generating wire transfers are independent from the authorization and reconciliation processes. We have implemented additional procedures to provide timely updating of bank signature cards, and updated applicable bank signature cards. Prior to the sale of our U.K. subsidiary on August 4, 2006, we implemented improved check stock access control and monitoring at Rosemont during the second quarter of 2006.

Management believes that changes in internal control necessary to correct this weakness have been implemented, and testing to confirm operating effectiveness was successfully performed as of September 30, 2006. Management considers this issue to be fully resolved as of September 30, 2006. We note, however, that the report of our independent registered public accounting firm is not due until our Annual Report on Form 10-K for the year ended December 31, 2006.

- There was insufficient control over the authorization of the Employee Stock Purchase Plan purchases and accounting for pro forma stock based compensation expense in accordance with SFAS No. 123, *Accounting for Stock Based Compensation*, the latter of which resulted in errors to and restatement of the historically reported pro forma stock based compensation expense disclosures. The insufficient coordination of data exchanged between us and certain third party service providers resulted in certain errors in the administration of the stock incentive award programs.

We implemented controls so that quarterly Employee Stock Purchase Plan purchases are reviewed and approved by senior management. We have hired consultants to provide guidance regarding SFAS No. 123(R) implementation as well as improving the level of expertise in the accounting department with the hiring of senior accounting personnel. We have increased communication frequency and manage the relationship more effectively with the Company's third party stock award administrator to coordinate all stock award activity and to assist with software applications related to stock based expense calculations and related stock based accounting requirements.

Management believes that changes necessary to fully remediate this weakness were in place by September 30, 2006 but testing of these controls has not been completed within this time frame. Testing to confirm operating effectiveness is planned to be completed in the fourth quarter of 2006.

Although the Sarbanes-Oxley Remediation Plan was approved by our Audit Committee, and corrective actions have been implemented, management will not determine that its internal control weaknesses have been corrected until:

- new internal controls over financial reporting are implemented and operational for a period of time;
- testing is performed and satisfactory results are obtained to confirm that the new controls are operating effectively; and
- management and its independent registered public accounting firm conclude that these controls are operating effectively.

No other change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On December 20, 2002, a purported shareholder class action was filed against the Company and three of its former officers. The action was pending under the caption *In re Bio-Technology General Corp. Securities Litigation*, in the U.S. District Court for the District of New Jersey. Plaintiff alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and sought unspecified compensatory damages. The plaintiff purported to represent a class of shareholders who purchased shares of the Company between April 19, 1999 and August 2, 2002. The complaint asserted that certain of the Company's financial statements were materially false and misleading because the Company restated its earnings and financial statements for the years ended 1999, 2000 and 2001, as described in the Company's Current Report on Form 8-K dated, and its press release issued, on August 2, 2002. Five nearly identical actions were filed in January and February 2003, in each instance claiming unspecified compensatory damages. In September 2003, the actions were consolidated and co-lead plaintiffs and co-lead counsel were appointed in accordance with the Private Securities Litigation Reform Act. The parties subsequently entered into a stipulation which provided for the lead plaintiff to file an amended consolidated complaint. Plaintiffs filed such amended complaint and the Company filed a motion to dismiss the action. On August 10, 2005, citing the failure of the amended complaint to set forth particularized facts that give rise to a strong inference that the defendants acted with the required state of mind, the Court granted the Company's motion to dismiss the action without prejudice and granted plaintiffs leave to file an amended complaint. On October 11, 2005, the plaintiffs filed a second amended complaint, again seeking unspecified compensatory damages, purporting to set forth particularized facts to support their allegations of violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by the Company and its former officers. On December 13, 2005, the Company filed a motion to dismiss the second amended complaint. On October 26, 2006, the United States District Court for the District of New Jersey dismissed, with prejudice, the second amended complaint. The district court declined to allow plaintiffs to file another amended complaint, however, plaintiffs have 30 days from the date of the dismissal to appeal the district court's decision.

On September 26, 2006, the Company filed a lawsuit against Barr Laboratories, Inc. ("Barr"), a wholly-owned subsidiary of Barr Pharmaceuticals, Inc., for infringement of certain of the Company's patents related to various methods of using Oxandrin (oxandrolone). The action is pending under the caption *Savient Pharmaceuticals, Inc. v. Barr Laboratories, Inc.* in the U.S. District Court for the District of New Jersey. The suit was brought in response to Barr's filing of an Abbreviated New Drug Application with the FDA seeking approval to engage in the commercial manufacture, use and sale of specified dosages of oxandrolone tablets prior to expiration of the Company's patents, all of which are listed in Approved Drug Products with Therapeutic Equivalence Evaluations for Oxandrin. The Company intends to take the actions necessary to defend its patent rights relating to the use of Oxandrin and anticipates a favorable outcome.

ITEM 1A. RISK FACTORS

Our disclosure and analysis in this Quarterly Report on Form 10-Q contain statements which constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements that set forth anticipated results based on management's plans and assumptions. From time to time, we also provide forward-looking statements in other materials we release to the public as well as oral forward-looking statements. Such statements discuss our strategy, expected future financial position, results of operations, cash flows, financing plans, development of products, strategic alliances, intellectual property, competitive position, plans and objectives of management. We often use words such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "will" and similar expressions to identify forward-looking statements. In particular, the statements regarding our new strategic direction and its potential effects on our business and the development of our lead drug candidate Puricase 1 (PEG-uricase) are forward-looking statements. Additionally, forward-looking statements include those relating to future actions, prospective products or product approvals, future performance, financing needs, liquidity or results of current and anticipated products, sales efforts, expenses, interest rates, foreign exchange rates and the outcome of contingencies, such as legal proceedings, and financial results.

We cannot guarantee that any forward-looking statement will be realized. Achievement of future results is subject to risks, uncertainties and potentially inaccurate assumptions. Should known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected. You should bear this in mind as you consider forward-looking statements.

We undertake no obligation to publicly update forward-looking statements. You are advised, however, to consult any further disclosures we make on related subjects in our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Also note that we provide the following cautionary discussion of risks, uncertainties and possibly inaccurate assumptions relevant to our businesses. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.

Risks Relating to Our Strategic Direction

We have repositioned our company to focus on product development, including Puricase (PEG-uricase), our lead product candidate currently in Phase 3 clinical trials. If we are unable to commercialize this product candidate or any other product candidate that we may pursue in the future, or if we experience significant delays or unanticipated costs in doing so, our business will be materially harmed.

Savient is a specialty focused biopharmaceutical company concentrating on the development of Puricase (PEG-uricase), our product candidate for the control of hyperuricemia in patients with treatment-failure gout in whom conventional treatment is contraindicated or shown to be ineffective. Puricase (PEG-uricase) commenced Phase 3 trials in the United States in May 2006 and began Phase 3 patient dosing in June 2006; subsequent to this we commenced patient dosing in Canada and Mexico. We expect to concentrate our business development efforts principally on completing a transaction with a partner for the clinical development and commercialization of Puricase (PEG-uricase) outside of the United States. We continue to identify and evaluate late stage compounds and technologies for possible in- licensing/partnering activities in certain specialty areas.

Our ability to commercialize Puricase (PEG-uricase) or any other product candidate that we may develop in the future will depend on several factors, including:

- successfully completing clinical trials;
- successfully manufacturing fully comparable clinical and commercial drug supplies;
- receiving marketing approvals from the FDA and similar foreign regulatory authorities;
- establishing commercial manufacturing arrangements with third party manufacturers, to the extent we do not manufacture the product candidates ourselves;
- launching commercial sales of the product, whether alone or in collaboration with others; and
- acceptance of the product in the medical community and with third party payors.

If we are unable to successfully commercialize Puricase (PEG-uricase), or if we experience significant delays or unanticipated costs in doing so, our business will be materially harmed. We will face similar drug development risks for any other product candidates that we may develop in the future.

Puricase (PEG-uricase), and any other product candidate that we may develop in the future, must satisfy rigorous standards of safety and efficacy before they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy clinical trials and extensive manufacturing quality assessments to obtain regulatory approval.

We must successfully complete clinical trials for Puricase (PEG-uricase) before we can apply for its marketing approval.

In December 2004, we administered the last patient dose in a Phase 2 clinical trial of Puricase (PEG-uricase) and we completed the full analysis of the results of this study in April 2005. In May 2005, we reported positive top-line Phase 2 clinical trial results for Puricase (PEG-uricase). The results from the Phase 2 clinical trial showed that Puricase (PEG-uricase) showed effectiveness in reducing uric acid levels. Based on the results of our end of Phase 2 meeting with the FDA and post-meeting interactions, in December 2005, we submitted a Special Protocol Assessment, or SPA, of the Company's Phase 3 protocols. In March 2006 the Company received a written response from the FDA reflecting the agency's agreement with the Phase 3 protocols. On May 3, 2006, the Company announced that it had received written notification from the FDA that the SPA was approved. The Company has implemented the protocols in support of a marketing application for the orphan drug indication of the control of hyperuricemia in patients with treatment-failure gout in whom conventional therapy is contraindicated or has been ineffective. We began Phase 3 patient dosing in June 2006. We have commenced Phase 3 clinical trials in the United States, Canada and Mexico and are actively seeking additional patients for the trials. Our Phase 3 trials may be unsuccessful which would materially harm our business. Even if these trials are successful, we may be required to conduct additional clinical trials or additional manufacturing quality assessments before a Biologics License Agreement, or BLA, can be filed with the FDA for marketing approval or as a condition of approval.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of clinical trials does not ensure that later clinical trials will be successful and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize Puricase (PEG-uricase), including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we expect to be promising;
- enrollment in our clinical trials may be slower than we currently anticipate, or participants may drop out of our clinical trials;
- we might have to suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we currently anticipate;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing or if the results of these trials or tests are not positive or are only modestly positive, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not be able to obtain marketing approval;
- obtain approval for indications that are not as broad as intended; or
- not obtain marketing approval before other companies are able to bring competitive products to market.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether our ongoing clinical trials will be completed on schedule. Similarly, we do not know whether our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant delays in clinical trials could also allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

Our strategic focus includes a licensing initiative to partner our Puricase (PEG-uricase) product outside the United States and to in-license other novel compounds to build our development portfolio. We may not be successful in our licensing efforts and in expanding our portfolio of products in this manner.

As part of our strategic business plan, we intend to seek a development and commercialization partner for Puricase (PEG-uricase) outside the United States and to also concentrate on an active in-licensing program to access and develop novel compounds in later clinical development. To date, we have had limited success in identifying a suitable partner outside the United States and in identifying and in-licensing the appropriate compounds, and we may continue to have difficulty in this area for a number of reasons. In particular, the licensing, partnering and acquisition of pharmaceutical products is a competitive area. Numerous companies are also pursuing strategies to license, partner or acquire products similar to those that we may pursue. These companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Other factors that may prevent us from partnering, licensing or otherwise acquiring suitable product candidates include the following:

- we may be unable to identify a partner outside the United States that possesses the expertise or size necessary to successfully complete the development and commercialization of Puricase (PEG-uricase);
- we may be unable to identify suitable products or product candidates within our areas of expertise;
- we may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return on our investment in the product; or
- companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us.

If we are unable to develop suitable potential product candidates by obtaining rights to novel compounds from third parties, our business could suffer.

Risks Related to Our Business

We incurred an operating loss in the first nine months of 2006 and anticipate that we may incur operating losses for the foreseeable future. If we are unable to commercialize Puricase (PEG-uricase) or any other product candidates, we may never achieve operating profitability.

We incurred an operating loss of \$4.0 million in the first nine months of 2006 which was attributable to lower revenue growth that did not outpace our operating expenses. Our financial results have been substantially dependent on Oxandrin® sales. Sales of Oxandrin accounted for 100% of our continuing net product sales in the nine months ended September 30, 2006 and 92% in the nine months ended September 30, 2005. However, although we cannot predict when generic competition for Oxandrin will begin, the FDA may approve one or more generic versions of Oxandrin at any time. If the FDA approves a generic version of Oxandrin, our revenues will decline significantly, and our results of operations will be materially adversely affected.

Our ability to generate operating profits is dependent on the successful commercialization of Puricase (PEG-uricase) and any other product candidates that we may develop, license or acquire. If we are unable to successfully commercialize Puricase (PEG-uricase) or any other product candidates, or if we experience significant delays or unanticipated costs in doing so, or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never achieve operating profitability. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Generic competition for Oxandrin will have a negative impact on our operating profits if we are unsuccessful in our patent infringement suit.

In September 2006 we filed a lawsuit against Barr Laboratories, Inc. (“Barr”) for infringement of certain of our patents related to various methods of using Oxandrin (oxandrolone). The suit was brought in response to Barr’s filing of an Abbreviated New Drug Application (ANDA) with the FDA seeking approval to engage in the commercial manufacture, use or sale of specified dosages of oxandrolone tablets prior to expiration of the our patents. While we intend to take the actions necessary to defend our patent rights relating to the use of Oxandrin, there is no guarantee that we will be successful, and the introduction of a generic form of Oxandrin on the market will negatively impact our operating profits and may render our existing Oxandrin inventory obsolete.

The full development and commercialization of our development drug product and execution of our strategic business plan will require substantial capital, and we may be unable to obtain such capital. If we are unable to obtain additional financing, our business, results of operations and financial condition may be adversely affected.

The development and commercialization of pharmaceutical products requires substantial funds. In addition, we may require cash to acquire new product candidates and to fully execute on our strategic business plan. In recent periods, we have satisfied our cash requirements primarily through product sales, the divestiture of assets that are not core to our strategic business plan and the monetization of underperforming investments. Historically, we have also obtained capital through collaborations with third parties, contract fees, government funding and equity and debt financings. These financing alternatives might not be available in the future to satisfy our cash requirements.

We might not be able to obtain additional funds or, if such funds are available, such funding might be on unacceptable terms. If we raise additional funds by issuing equity securities, dilution to our then existing stockholders will result. If we raise additional funds through the issuance of debt securities or borrowings, we may incur substantial interest expense and could become subject to financial and other covenants that could restrict our ability to take specified actions, such as incurring additional debt or making capital expenditures. If adequate funds are not available, we may be required to significantly curtail one or more of our commercialization efforts or development programs or obtain funds through sales of assets or arrangements with collaborative partners or others on less favorable terms than might otherwise be available.

A significant portion of our revenues is attributable to sales of Oxandrin. Oxandrin may begin facing generic competition at any time, which would likely cause a significant decrease in Oxandrin sales and render our existing Oxandrin inventory obsolete.

Net sales of Oxandrin were \$39.1 million for the first nine months of 2006 and \$32.4 million for the first nine months of 2005, representing approximately 100% and 92% of our continuing net product sales, respectively.

Oxandrin was deleted from the Florida Medicaid formulary effective January 1, 2006. This may result in lost sales which could be significant to the Company on a going forward basis. There can be no assurances that this may not happen with other state formularies. In addition, the implementation of the Medicare Part D program has created disruption in the market as patients switch to a variety of new prescription coverage programs in all states across the United States.

One company has, and we believe several companies may have, filed Abbreviated New Drug Applications, or ANDAs, with the FDA relating to a generic drug with the same active pharmaceutical ingredient as Oxandrin. Although we cannot predict when generic competition for Oxandrin will begin, and have filed suit against a company we believe is infringing our patent rights, the FDA may approve one or more generic versions of Oxandrin at any time. The introduction of these generic products would likely cause a significant decrease in our Oxandrin revenues, which would adversely affect our results of operations. As a result, we anticipate that Oxandrin will be a less significant product for our future operating results.

Our inventories include Oxandrin inventories that we believe would potentially be in excess of expected product demand if the FDA approves a generic form of the product in the near term. The amount of such

potential excess will vary depending upon the timing of the approval of a generic product, the number of generic products that are approved and the rate by which generic sales reduce demand for branded Oxandrin.

Our efforts to ensure that any generic product containing oxandrolone undergo stringent safety testing before approval by the FDA may not prevail.

In February 2004 we filed a Citizens Petition with the FDA requesting that, in the interest of public health and safety, the Commissioner of Food and Drugs not approve any ANDAs for generic oral products containing oxandrolone prior to their adopting standard bioequivalence standards as well as the requirement for any generic product to have completed a warfarin interaction trial. Our request is based on evidence of significant interaction between Oxandrin and warfarin which requires a warfarin dose reduction of up to 90% in patients when initiating therapy of Oxandrin. This petition cited a serious safety concern in patients using Oxandrin together with anticoagulant drugs containing warfarin if the warfarin dose adjustment was not made appropriately. In addition, our petition cited concerns related to the physical-chemical properties of the oxandrolone drug substance which are important for manufacturing quality assurance. The petition argues that, as a result of these physical-chemical properties, oxandrolone is categorized by the FDA as a “problem drug” in terms of manufacturing.

We have since filed with the FDA affidavits supporting our February 2004 petition. In August and September 2004, two opposition comment letters to our petition were filed with the FDA. In August 2004 the FDA issued a letter to us stating that extensive review of the questions raised in our petition will be required before the FDA can respond. In February 2005 we submitted another supplemental position paper to the FDA in support of our Citizens Petition advocating the adoption of rigorous impurity standards for oxandrolone consistent with those recently published by the United States Pharmacopeia, which will become the standard in 2006. Since the August 2004 letter from the FDA, we have received no further communication from the FDA regarding our first petition.

In September 2005 we filed a second Citizens’ Petition with the FDA requesting that the Commissioner of Food and Drugs not approve any ANDAs for generic oral products containing oxandrolone prior to the expiration of the Company’s exclusive labeling for geriatric dosing on June 20, 2008. We were granted the three years of market exclusivity on June 20, 2005 under section 505(j) of the Federal Food, Drug and Cosmetic Act for changes to the labeling of Oxandrin for its use in geriatric patients based on clinical data which was derived from a clinical study on elderly patients examining the safety and pharmacokinetics of a range of Oxandrin doses and was submitted to the FDA. On the basis of this data, the labeling of Oxandrin was changed to include the specification of a lower starting dose in patients older than 65 years of age. The FDA’s guidance on geriatric labeling also requires that ANDA’s contain the same geriatric labeling as the Reference Listed Drug.

A significant number of patients who are treated with Oxandrin are geriatric patients. Savient’s clinical data confirmed that geriatric patients have different pharmacological reactions to Oxandrin; therefore, geriatric labeling for Oxandrin is necessary for its safe use. In this second Citizens’ Petition we set forth our position that, if fully substitutable generic versions of oxandrolone were to be approved without Oxandrin’s protected geriatric labeling, such drugs would have labeling that is less restrictive and potentially less safe than that of Oxandrin for use by the elderly. In October 2005 and February 2006, three opposition comment letters to our September 2005 petition were filed with the FDA. In March 2006 the FDA issued a letter to us stating that our September 2005 petition raises complex issues which requires extensive review and analysis by FDA officials before they can respond.

There has been no indication from the FDA as to when we might expect a decision on either of our Citizens’ Petitions. However, if we are unsuccessful on our Citizens’ Petition efforts, our sales of Oxandrin would be negatively affected.

Oxandrin sales in particular reporting periods may be affected by wholesalers’ buying patterns and product returns.

Our sales of Oxandrin in the United States are principally to three major drug wholesalers. These sales are affected by fluctuations in the buying patterns of these wholesalers and the corresponding changes in inventory levels that they maintain. These changes may not reflect underlying prescriber demand and can be

influenced by price concessions or announcements of price increases in future periods. Our Oxandrin sales in future periods may be further reduced if wholesalers continue to reduce inventories. This may be more likely if and when a generic version of Oxandrin is introduced.

Ross Pharmaceuticals Limited, or Ross, marketed Oxandrin under a co-promotion agreement with us for the treatment of weight loss by residents of long-term care facilities. We terminated the co-promotion agreement effective as of December 31, 2005. To date, the average prescription written for the elderly in the long-term care market involves a lower dose of Oxandrin than the average prescription written for the HIV market. As a result, the rate of growth in Oxandrin sales may be less than the rate of growth in prescriptions. With our termination of the Ross co-promotion agreement we plan to direct a portion of our sales and marketing efforts to increase sales of Oxandrin. However, if we are unsuccessful in these efforts, our sales of Oxandrin would be negatively affected.

Future returns of Oxandrin or other products could also affect our results of operations.

As of September 30, 2006 and December 31, 2005, our allowance for product returns was \$2.3 million and \$2.9 million, respectively. Future product returns in excess of our reserves would reduce our revenues and adversely affect our results of operations.

We operate in a highly competitive market. Our competitors may develop alternative technologies or safer or more effective products before we are able to do so.

The pharmaceutical and biotechnology industries are intensely competitive. The technological areas in which we work continue to evolve at a rapid pace. Our future success will depend upon our ability to compete in the research, development and commercialization of products and technologies in our areas of focus. Competition from pharmaceutical, chemical and biotechnology companies, universities and research institutions is intense and we expect it to increase. Many of these competitors are substantially larger than we are and have substantially greater capital resources, research and development capabilities and experience and manufacturing, marketing, financial and managerial resources than we do. Acquisitions of competing companies by large pharmaceutical companies or other companies could enhance the financial, marketing and other resources available to these competitors.

Rapid technological development may result in our product candidates in development becoming obsolete before we can begin marketing these product candidates or before we are able to recover a significant portion of the research, development and commercialization expenses incurred in the development of those products. For example, since our launch of Oxandrin, a significant portion of Oxandrin sales has been for treatment of patients suffering from HIV-related weight loss. These patients' needs for Oxandrin may decrease as a result of the development of safer or more effective treatments, such as protease inhibitors. In fact, since January 2001, growth in the AIDS-related weight loss market has slowed substantially and actually began to decline as a result of improved therapies to treat HIV-related weight loss.

Our products must compete with others to gain market acceptance and market share. An important factor will be the timing of market introduction of competitive products. For example, the most recent competitor to enter this market was Par Pharmaceutical Companies, Inc. ("Par") with the introduction of megace ES in June 2005. Par is primarily displacing generic megace which represents 75% of our market, but also has an impact on Oxandrin. Accordingly, the relative speed with which we and competing companies can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market will be an important element of market success.

Our competitors may develop safer, more effective or more affordable products or achieve earlier product development completion, patent protection, regulatory approval or product commercialization than we do. Our competitors' achievement of any of these goals could have a material adverse effect on our business. These companies also compete with us to attract qualified personnel and to attract third parties for acquisitions, joint ventures or other collaborations.

Manufacturing our products requires us to meet stringent quality control standards. In addition, we depend on third parties to manufacture our products and plan to rely on third parties to manufacture any future products. If we or these third parties fail to meet applicable quality requirements, our revenues and product development efforts may be materially adversely affected.

The manufacture of our products involves a number of technical steps and requires us, or our third party suppliers and manufacturers to meet stringent quality control specifications imposed by us or by governmental regulatory bodies. In the event of a natural disaster, equipment failure, strike, war or other difficulty, we or our suppliers may be unable to manufacture our products in a manner necessary to fulfill demand. Our inability to fulfill market demand, or the inability of our third party manufacturers to meet our demands will have a direct and adverse impact on our sales and may also permit our licensees and distributors to terminate their agreements.

Further, we depend on third parties for the supply of our products. Failure of any third party to meet applicable regulatory requirements may adversely affect our profit margins or result in unforeseen delays or other problems beyond our control.

Risks involved with engaging third party suppliers include:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party or the inability of the third party to meet our production schedules because of factors beyond our control, such as shortages in qualified personnel; and
- the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Additionally, we rely on a single source supplier for the manufacture of our product candidate Puricase (PEG-uricase) and have a single source supplier of an active ingredient contained in such product with which we currently have no long term supply agreement. We have entered into an arrangement with our former global biologics manufacturing business, BTG-Israel, to serve as the initial primary manufacturer of our product candidate, Puricase (PEG-uricase). To date, BTG-Israel has manufactured all of our requirements of clinical supplies of Puricase (PEG-uricase) and the total Phase 3 clinical supply has been successfully manufactured and shipped to the United States. However, the continued ability of BTG-Israel to consistently perform these activities may be affected by economic, military and political conditions in Israel and in the Middle East in general. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and neighboring countries. These hostilities have, at times, caused security and economic problems in Israel.

Recent hostilities in Israel, Lebanon and other parts of the Middle East have highlighted our need for Puricase (PEG-uricase) supply alternatives. Given the nature and scope of the technology transfer required to manufacture the product outside of BTG-Israel, we are not likely to have alternate sources of supply prior to 2010.

Escalating hostilities involving Israel could adversely affect BTG-Israel's ability to supply adequate quantities of the product under our agreement and in turn affect our ability to complete the clinical development of Puricase (PEG-uricase). While we are in the process of identifying additional alternate sources of supply of Puricase (PEG-uricase) and concluding a long term supply agreement with the supplier of the key active ingredients for the product, the completion of the process to successfully identify and reach agreement with such additional alternate source and the time to conduct a technology transfer to enable the alternate source to scale up and validate its manufacturing processes for Puricase (PEG-uricase) will be lengthy. While this is one of the high priority matters for us, if we experience an interruption in the supply of Puricase (PEG-uricase) from BTG-Israel or the active ingredients from other third party suppliers before we have succeeded in concluding long term supply arrangements and entering into and validating an alternate supply arrangement for Puricase (PEG-uricase) it may adversely affect our financial results, possibly materially.

The manufacture and packaging of pharmaceutical products are subject to the requirements of the FDA and similar foreign regulatory bodies. If we or our third party suppliers fail to satisfy these requirements, our business operations may be materially harmed.

The manufacturing process for pharmaceutical products is highly regulated. Manufacturing activities must be conducted in accordance with the FDA's Current Good Manufacturing Practices, and comparable requirements of foreign regulatory bodies.

Failure by us or our third party suppliers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. Other than by contract, we do not have control over the compliance by our third party suppliers with these regulations and standards.

Changes in manufacturing processes or procedures, including changes in the location where a product is manufactured or changes in a third party supplier may require prior FDA or other governmental review or approval or revalidation of the manufacturing process. This is particularly an issue with biologic products, such as our product candidate Puricase (PEG-uricase). This review or revalidation may be costly and time-consuming.

Because there are a limited number of manufacturers that operate under applicable regulatory requirements, it may be difficult for us to change a third party supplier if we are otherwise required to do so. Similarly, because of the applicable requirements, we may not be able to quickly and efficiently replace our manufacturing capacity if we are unable to manufacture our products at our facilities.

We may not be successful in establishing additional strategic alliances, which could adversely affect our ability to develop and commercialize products and services.

Part of our strategic plan to focus on product development involves entering into new strategic alliances for the development and commercialization of products and services when we believe that doing so will maximize product value. For example, we plan to seek development and commercial partners to commercialize Puricase (PEG-uricase) outside the United States.

If we are unsuccessful in reaching an agreement with a suitable collaborator for our current or future product candidates, we may fail to meet our business objectives for the applicable product or program. We face significant competition in seeking appropriate collaborators. Moreover, these alliance arrangements are complex to negotiate and time-consuming to document. We may not be successful in our efforts to establish additional strategic alliances or other alternative arrangements. The terms of any additional strategic alliances or other arrangements that we establish may not be favorable to us. Moreover, such strategic alliances or other arrangements may not be successful.

The risks that we are likely to face in connection with any future strategic alliances include the following:

- strategic alliance agreements are typically for fixed terms and are subject to termination under various circumstances, including, in many cases without cause;
- our collaborators may change the focus of their development and commercialization efforts;
- we may rely on our collaborators to manufacture the products covered by our alliances;
- the areas of research, development and commercialization that we may pursue, either alone or in collaboration with third parties, may be limited as a result of non-competition provisions of our strategic alliance agreements;
- our collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the products and services that are the subject of the alliance with us; and
- failure to establish steady supply of essential raw materials from vendors.

Our sales depend on payment and reimbursement from third party payors and a reduction in the payment or reimbursement rate could result in decreased use or sales of our products.

Most patients rely on Medicare and Medicaid, private health insurers and other third party payors to pay for their medical needs, including any drugs we or our collaborators may market. If third party payors do not provide adequate coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer. The U.S. Congress enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug and Modernization Act of 2003 which was expanded by the Medicare Part D prescription plan that went into effect January 1, 2006. This is providing a situation where in some cases our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain if we participate in this program. Non-Medicare third party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries.

A primary trend in the U.S. healthcare industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization of our products.

Third party payors are challenging the prices charged for medical products and services, and many third party payors limit reimbursement for newly approved healthcare products. In particular, third party payors may limit the indications for which they will reimburse patients who use any products we may develop. Cost control initiatives could decrease the price we might establish for products that we may develop, which would result in lower product revenues to us.

Some states, including New York, California and Florida, have eliminated or limited reimbursement of prescription drugs for HIV and AIDS, including Oxandrin, under their AIDS Drug Assistance Programs (ADAP) or via their state Medicaid program. For example, the state of Florida removed Oxandrin from its formulary on January 1, 2006. This has affected sales of Oxandrin in those states. Efforts and discussions are ongoing with these state agencies to reverse these changes, but to date we have not been successful and we cannot predict whether we will be successful in the future. If we are not successful, our Oxandrin sales in this HIV/AIDS related involuntary weight loss market will continue to be adversely impacted. States may also shift patient coverage from ADAP and other state prescription programs to the new Medicare Part D prescription programs creating additional market disruption.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

Our ability to successfully develop and commercialize our products will depend on our ability to attract, retain and motivate highly qualified personnel and to establish and maintain continuity and stability within our management team. There is a great deal of competition from other companies and research and academic institutions for the limited number of pharmaceutical development professionals with expertise in the areas of our activities. We generally do not enter into employment agreements with any of our product development personnel. In addition, we do not maintain, and have no current intention of obtaining, “key man” life insurance on any of our employees. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business and products, we may not be able to sustain our operations and execute our business plan.

Economic and political risks and pricing regulation in foreign jurisdictions, and other risks associated with foreign operations, could adversely affect our international sales.

Because we sell our products worldwide, our business is subject to risks associated with doing business internationally, including:

- difficulties in staffing and managing foreign operations;

- mandated price reductions for some or all of the products sold within a foreign jurisdiction;
- changes in a country's or region's political or economic conditions affecting terms of payment;
- longer payment cycles of foreign customers and difficulty of collecting receivables in foreign jurisdictions;
- trade protection measures and import or export licensing requirements;
- less familiarity with business customs and practices;
- the imposition of tariffs and import and export controls;
- the impact of possible recessionary environments in economies outside the United States;
- unexpected changes in regulatory requirements;
- currency exchange rate fluctuations;
- differing labor laws and changes in those laws;
- differing protection of intellectual property and changes in that protection;
- differing tax laws and changes in those laws; and
- differing regulatory requirements and changes in those requirements.

We do not currently engage in currency hedging transactions. However, depending on our sales from international operations and our perception as to currency volatility, we may choose to limit our exposure by the purchase of forward foreign exchange contracts or similar hedging strategies. The currency exchange strategy that we adopt may not be successful in avoiding exchange-related losses. In addition, the above-listed factors may cause a decline in our future international revenue and, consequently, may harm our business. We may not be able to sustain or increase revenue that we derive from international sources.

We may incur substantial costs related to product liability.

The testing and marketing of our products entail an inherent risk of product liability and associated adverse publicity. Pharmaceutical product liability exposure could be extremely large and poses a material risk.

To the extent we elect to test or market products independently, we bear the risk of product liability directly. While we currently have product liability insurance coverage in place, we might not be able to maintain existing insurance or obtain additional insurance on acceptable terms, or at all. It is possible that a single product liability claim could exceed our insurance coverage limits, and multiple claims are possible. Any successful product liability claim made against us could substantially reduce or eliminate any stockholders' equity we may have and could materially harm our financial results. Product liability claims, regardless of their merit, could be costly and divert management's attention, and adversely affect our reputation and the demand for our products.

The ultimate outcome of pending securities litigation is uncertain.

After the restatement of our financial statements for the years ended December 31, 1999, 2000 and 2001 and the first two quarters of 2002, we and some of our former officers were named in a series of similar purported securities class action lawsuits. The complaints in these actions, which have been consolidated into one action, allege violations of U.S. securities law through alleged material misrepresentations and omissions and seek an unspecified award of damages.

In August 2005, citing the failure of the plaintiff's amended complaint to set forth particularized facts that give rise to a strong inference that the defendants acted with the required state of mind, the district court granted our motion to dismiss the action, without prejudice, and granted plaintiffs leave to file an amended complaint. In October 2005 the plaintiffs filed a second amended complaint, again seeking unspecified compensatory damages, purporting to set forth particularized facts to support their allegations of violations of Sections 10(b) and 20(a) of the Exchange Act by us and our former officers. In December 2005 we filed a

motion to dismiss the second amended complaint which has now been fully briefed by both the Company and the Plaintiffs and is pending a decision by the Court. On October 26, 2006, the district court granted our motion to dismiss, with prejudice, plaintiff's second amended complaint. The district court declined to allow plaintiffs to file another amended complaint; however, plaintiffs have 30 days from the date of the dismissal to appeal the district court's decision.

We do not expect that plaintiffs will appeal the district court's decision; however, there can be no guarantee of this. In the event the dismissal is appealed we intend to contest the appeal vigorously. Should the appeal prove successful and an adverse decision in this case is ultimately made, we could be adversely affected financially. We have referred these claims to our directors and officers insurance carrier, which has reserved its rights as to coverage with respect to this action.

Risks Related to our Restatement

The restatement of our consolidated financial statements had, and may continue to have, a material adverse impact on us, including increased costs, and the possibility of legal or administrative proceedings.

In 2005, we determined that our consolidated financial statements for the years ended December 31, 2002, 2003, and 2004 and for the quarter ended March 31, 2005 should be restated. We incurred substantial unanticipated costs for accounting and legal fees in 2005 and 2006 in connection with the restatement, and although the restatement is complete, we may incur additional related costs.

The Division of Corporation Finance of the SEC had provided comments to us relating to certain of our accounting practices. We responded to all of these questions in full and in August 2006 we received a letter from the Division of Corporation Finance stating that its review is complete. Any further comment letters from the Division of Corporation Finance would likely divert more of our management's time and attention and cause us to incur additional costs. Similarly, in the event litigation is pursued or other relief is sought by persons asserting claims for damages allegedly resulting from or based on this restatement, or events related thereto, we may incur additional defense costs beyond our insurance coverage regardless of their outcome. Likewise, such events might cause a diversion of our management's time and attention. If we do not prevail in any such actions, we could be required to pay substantial damages or settlement costs.

We have identified material weaknesses in our internal controls over financial reporting. Certain material weaknesses have not been fully remediated. In addition, we may experience additional material weaknesses in the future. Any material weaknesses in our internal control over financial reporting or our failure to remediate such material weaknesses could result in a material misstatement in our financial statements not being prevented or detected and could adversely affect investor confidence in the accuracy and completeness of our financial statements, as well as our stock price.

We have identified material weaknesses in our internal control over financial reporting relating to insufficient personnel resources, deficiencies in income tax analysis, insufficient communications, insufficient treasury controls, and insufficient controls related to stock based compensation. Certain material weaknesses have not been fully remediated. These material weaknesses and our remediation plans are described further in Item 4 in this Quarterly Report on Form 10-Q. Material weaknesses in our internal control over financial reporting could result in material misstatements in our financial statements not being prevented or detected. While we have implemented a Sarbanes Oxley Remediation Plan, we may experience difficulties or delays in achieving goals under this plan and completing remediation, or may not be able to successfully remediate material weaknesses at all. Any material weakness or unsuccessful remediation could harm investor confidence in the accuracy and completeness of our financial statements, which in turn could harm our business and have an adverse effect on our stock price and our ability to raise additional funds.

Risks Relating to Intellectual Property

If we are unable to obtain and maintain protection for the intellectual property relating to our technology and products, the value of our technology and products will be adversely affected.

Our success will depend in large part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology and

products. The patent situation in the field of biotechnology and pharmaceuticals is highly uncertain and involves complex legal and scientific questions. We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how. We seek to protect this information in part by confidentiality agreements with our employees, consultants and third parties. These agreements may be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. If our confidential information or trade secrets become publicly known, they may lose their value to us.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business may be adversely affected.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or patent applications under which we do not hold licenses or other rights. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biopharmaceutical industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the U.S. Patent and Trademark Office and opposition proceedings in the European Patent Office or in another patent office, regarding intellectual property rights with respect to our products and technology. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

In the future we may be involved in costly legal proceedings to enforce or protect our intellectual property rights or to defend against claims that we infringe the intellectual property rights of others.

Litigation is inherently uncertain and an adverse outcome could subject us to significant liability for damages or invalidate our proprietary rights. Legal proceedings that we initiate to protect our intellectual property rights could also result in counterclaims or countersuits against us. Any litigation, regardless of its outcome, could be time-consuming and expensive to resolve and could divert our management's time and attention. Any intellectual property litigation also could force us to take specific actions, including:

- cease selling products or undertaking processes that are claimed to be infringing a third party's intellectual property;
- obtain licenses to make, use, sell, offer for sale or import the relevant technologies from the intellectual property's owner, which licenses may not be available on reasonable terms, or at all;
- redesign those products or processes that are claimed to be infringing a third party's intellectual property; or
- pursue legal remedies with third parties to enforce our indemnification rights, which may not adequately protect our interests.

We have been involved in several lawsuits and disputes regarding intellectual property in the past. We could be involved in similar disputes or litigation with other third parties in the future. An adverse decision in any intellectual property litigation could have a material adverse effect on our business, results of operations and financial condition.

Regulatory Risks

We are subject to stringent governmental regulation, and our failure to comply with applicable regulations could adversely affect our ability to conduct our business.

Virtually all aspects of our business are subject to extensive regulation by numerous federal and state governmental authorities in the United States, such as the FDA, as well as by foreign countries where we manufacture or distribute our products. Of particular significance are the requirements covering research and development, testing, manufacturing, quality control, labeling and promotion of pharmaceutical products for human use. All of our products, manufacturing processes and facilities require governmental licensing or approval prior to commercial use and maintenance of those approvals during commercialization. A pharmaceutical product cannot be marketed in the United States until it has been approved by the FDA, and then can only be marketed for the indications and claims approved by the FDA. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of an NDA or a BLA are substantial. The approval process applicable to products of the type being developed by us usually takes five to seven years from the commencement of human clinical trials and typically requires substantial expenditures. We and our collaborators may encounter significant delays or excessive costs in our or their respective efforts to secure necessary approvals or licenses. Before obtaining regulatory approval for the commercial sale of our products, we are required to conduct pre-clinical and clinical trials to demonstrate that the product is safe and efficacious for the treatment of the target indication. The timing of completion of clinical trials depends on a number of factors, many of which are outside our control. In addition, we and our collaborators may encounter delays or rejections based upon changes in the policies of regulatory authorities. The FDA and foreign regulatory authorities have substantial discretion to terminate clinical trials, require additional testing, delay or withhold registration and marketing approval, and mandate product withdrawals.

Regulation by governmental authorities in the United States and other countries is a significant factor affecting the timing of the commercialization of our products and our ongoing research and development activities. The timing of regulatory approvals is not within our control. Failure to obtain and maintain requisite governmental approvals, or failure to obtain approvals of the scope requested, could delay or preclude us or our collaborators from marketing our products, could limit the commercial use of the products and could also allow competitors time to introduce competing products ahead of product introductions by us.

Even after regulatory approval is obtained, use of the products could reveal side effects that, if serious, could result in suspension of existing approvals and delays in obtaining approvals in other jurisdictions.

Failure to comply with applicable regulatory requirements can, among other things, result in significant fines or other sanctions, termination of clinical trials, suspension of regulatory approvals, product recalls, seizure of products, imposition of operating restrictions and criminal prosecutions. While we have developed and instituted a corporate compliance program based on current best practices, we or our employees might not be, or might fail to be, in compliance with all potentially applicable federal and state regulations.

Further, FDA policy or similar policies of regulatory agencies in other countries may change and additional governmental requirements may be established that could prevent or delay regulatory approval of our products. We cannot predict what effect changes in regulations, enforcement positions, statutes or legal interpretation, when and if promulgated, adopted or enacted, may have on our business in the future. Changes could, among other things, require changes to manufacturing methods or facilities, expanded or different labeling, new approvals, the recall, replacement or discontinuance of certain products, additional record keeping and expanded scientific substantiation. These changes, or new legislation, could adversely affect our business.

Risks Relating to an Investment in Our Common Stock

Our stock price is volatile, which could adversely affect your investment.

Our stock price is volatile. Since June 1, 2001, our common stock traded as high as \$13.57 per share and as low as \$1.77 per share. The market price of our common stock may be influenced by many factors, including:

- our ability to successfully implement our new strategic direction;
- announcements of technological innovations or new commercial products by us or our competitors;
- announcements by us or our competitors of results in pre-clinical testing and clinical trials;
- regulatory developments;
- patent or proprietary rights developments;
- public concern as to the safety or other implications of biotechnology products;
- changes in our earnings estimates and recommendations by securities analysts;
- period-to-period fluctuations in our financial results; and
- general economic, industry and market conditions.

The volatility of our common stock imposes a greater risk of capital losses on our stockholders than a less volatile stock would. In addition, volatility makes it difficult to ascribe a stable valuation to a stockholder's holdings of our common stock. The stock market in general and the market for pharmaceutical and biotechnology companies in particular have also experienced significant price and volume fluctuations that are often unrelated to the operating performance of particular companies. In the past, following periods of volatility in the market price of the securities of pharmaceutical and biotechnology companies, securities class action litigation has often been instituted against these companies. Such litigation would result in substantial costs and a diversion of management's attention and resources, which could adversely affect our business.

We expect our quarterly results to fluctuate, which may cause volatility in our stock price.

Our revenues and expenses have in the past and may in the future continue to display significant variations. These variations may result from a variety of factors, including:

- the amount and timing of product sales;
- changing demand for our products;

- our inability to provide adequate supply for our products;
- changes in wholesaler buying patterns;
- returns of expired product;
- changes in government or private payor reimbursement policies for our products;
- increased competition from new or existing products, including generic products;
- the timing of the introduction of new products;
- the timing and realization of milestone and other payments from licensees;
- the timing and amount of expenses relating to research and development, product development and manufacturing activities;
- the timing and amount of expenses relating to sales and marketing;
- the timing and amount of expenses relating to general and administrative activities;
- the extent and timing of costs of obtaining, enforcing and defending intellectual property rights; and
- any charges related to acquisitions.

Because many of our expenses are fixed, particularly in the short-term, any decrease in revenues will adversely affect our earnings until revenues can be increased or expenses reduced. We also expect our revenues and earnings to be adversely affected if a generic version of Oxandrin is introduced. Because of fluctuations in revenues and expenses, it is possible that our operating results for a particular quarter or quarters will not meet the expectations of public market analysts and investors, which could cause the market price of our common stock to decline. We believe that period-to-period comparisons of our operating results are not a good indication of our future performance and stockholders should not rely on those comparisons to predict our future operating or share price performance.

Effecting a change of control of our company could be difficult, which may discourage offers for shares of our common stock.

Our certificate of incorporation and the Delaware General Corporation Law contain provisions that may delay or prevent an attempt by a third party to acquire control of us. These provisions include the requirements of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits designated types of business combinations, including mergers, for a period of three years between us and any third party that owns 15% or more of our common stock. This provision does not apply if:

- our board of directors approves of the transaction before the third party acquires 15% of our stock;
- the third party acquires at least 85% of our stock at the time its ownership goes past the 15% level; or
- our board of directors and two-thirds of the shares of our common stock not held by the third party vote in favor of the transaction.

We have also adopted a stockholder rights plan intended to deter hostile or coercive attempts to acquire us. Under the plan, if any person or group acquires more than 20% of our common stock without approval of our board of directors under specified circumstances, our other stockholders have the right to purchase shares of our common stock, or shares of the acquiring company, at a substantial discount to the public market price. As a result, the plan makes an acquisition much more costly to a potential acquirer.

Our certificate of incorporation also authorizes us to issue up to 4 million shares of preferred stock in one or more different series with terms fixed by our board of directors. Stockholder approval is not necessary to issue preferred stock in this manner. Issuance of these shares of preferred stock could have the effect of making it more difficult for a person or group to acquire control of us. No shares of our preferred stock are currently outstanding. While our board of directors has no current intention or plan to issue any preferred stock, issuance of these shares could also be used as an anti-takeover device.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

The following table sets forth information in connection with purchases made by, or on behalf of, the Company or any affiliated purchaser of the Company, of shares of the Company's common stock during the quarterly period ended September 30, 2006.

	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
July 1 – July 31, 2006	—	—	—	—
August 1 – August 31, 2006	—	—	—	—
September 1 – September 30, 2006	10,000,000	\$ 6.80	10,000,000	—
Total	10,000,000	\$ 6.80	10,000,000	—

(1) August 14, 2006, the Company commenced an offer to purchase up to 10 million shares of its common stock in a modified "Dutch auction" tender offer at a price of not greater than \$6.80 nor less than \$5.80 per share. The tender offer closed on September 12, 2006. The Company accepted for purchase 10 million shares of its common stock at a price of \$6.80 per share. This resulted in a cash outlay of approximately \$69.3 million, including professional fees of approximately \$1.3 million associated with conducting the tender offer.

ITEM 6. EXHIBITS

a) Exhibits

The exhibits listed in the Exhibit Index are included in this report.

SIGNATURES

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

SAVIENT PHARMACEUTICALS, INC.
(Registrant)

By: /s/ Christopher Clement

Christopher Clement
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Brian Hayden

Brian Hayden
Chief Financial Officer
(Principal Financial Officer)

Dated: November 9, 2006

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
2.1	Purchase and Sale Agreement dated as of August 4, 2006, among Savient Pharmaceuticals, Inc. and Savient Pharma Holdings, Inc., on the one hand, and INGLEBY (1705) Limited, on the other hand (1)
3.1	Certificate of Incorporation of the Registrant, as amended.*
10.1	Employment Agreement, dated July 5, 2006, between the Company and Brian J. Hayden
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as amended
31.2	Certification of the principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as amended
32.1	Statement pursuant to 18 U.S.C. §1350
32.2	Statement pursuant to 18 U.S.C. §1350

* Originally filed on the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1994.

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated August 10, 2006, as subsequently amended on August 16, 2006.

(2) Incorporated by reference to the Registrant's Current Report on Form 8-K, dated July 11, 2006.

CERTIFICATE OF INCORPORATION
OF
BIO-TECHNOLOGY GENERAL CORP.

The undersigned, for the purposes of organizing a corporation pursuant to the provisions of the General Corporation Law of the State of Delaware, does make and file this Certificate of Incorporation and does hereby certify as follows:

FIRST: The name of the corporation is BIO-TECHNOLOGY GENERAL CORP. (hereinafter referred to as the "Corporation").

SECOND: The address of the Corporation's registered office in Delaware is 100 West Tenth Street, City of Wilmington, County of New Castle. The name of its registered agent at such address is The Corporation Trust Company.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware.

FOURTH: The total number of shares of stock which the Corporation shall have authority to issue is One Thousand (1,000) shares of Common Stock, and the par value of each of such shares shall be One Cent (\$.01) per share.

FIFTH: The name and mailing address of the incorporator is:

Name

Randy F. Rock

Mailing Address

c/o Reavis & McGrath
345 Park Avenue
New York, New York 10154

SIXTH: In furtherance and not in limitation of the powers conferred by statute, the Board of Directors of the Corporation is expressly authorized to make alter or repeal the by-laws of the Corporation.

SEVENTH: Whenever a compromise or arrangement is proposed between this Corporation and its creditors or any class of them and/or between this Corporation and its stockholders or any class of them, any court of equitable jurisdiction within the State of Delaware may, on the application in a summary way of this Corporation or of any creditor or stockholder thereof or on the application of any receiver or receivers appointed for this Corporation under the provisions of Section 291 of Title 8 of the Delaware Code or on the application of trustees in dissolution or of any receiver or receivers appointed for the Corporation under the provisions of Section 279 of Title 8 of the Delaware Code order a meeting of the creditors or class of creditors, and/or of the stockholders or class of stockholders of this Corporation, as the case may be, to be summoned in such manner as the said court directs. If a majority in number representing three-fourths in value of the creditors or class of creditors, and/or of the stockholders or class of stockholders of this Corporation, as the case may be, agree to any compromise or arrangement and to any reorganization of this Corporation as a consequence of such compromise or arrangement, the said compromise or arrangement and the said reorganization shall, if sanctioned by the court to which the said application has been made, be binding on all the creditors or class of creditors, and/or on all the stockholders or class of stockholders, of this Corporation, as the case may be, and also on the Corporation.

IN WITNESS WHEREOF, I, the undersigned, being the incorporator hereinbefore named, hereby declare and certify that the facts herein stated are true, and accordingly have hereunto set my hand this 26th day of June, 1980.

(L.S.)

/s/ Randy F. Rock

Randy F. Rock

CERTIFICATE OF AMENDMENT

TO THE

CERTIFICATE OF INCORPORATION

OF

BIO-TECHNOLOGY GENERAL CORP.

BIO-TECHNOLOGY GENERAL CORP., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "Corporation"), DOES HEREBY CERTIFY:

FIRST: The Board of Directors of the Corporation, by unanimous written consent, has duly adopted the amendment to the Corporation's Certificate of Incorporation set forth below.

SECOND: Said Amendment amends Article Fourth of Corporation's the Corporation's Certificate of Incorporation to read in its entirety as follows:

"FOURTH: (1) The total number of shares of stock which the Corporation is authorized to issue is Nine Million (9,000,000) shares, each with par value of One Cent (\$.01), and Five Million (5,000,000) shares thereof shall be Common Stock and Four Million (4,000,000) shares thereof shall be Preferred Stock.

(2) The shares of Preferred Stock shall have such designations, voting powers, preferences, and relative, participating, optional, or special rights, and the qualifications, limitations, or restrictions thereon as shall be fixed by resolution of the Board of Directors."

THIRD: The Corporation has not received any payment for any of its stock.

FOURTH: The aforesaid amendment was duly adopted in accordance with the applicable provisions of Section 241 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, Bio-Technology General Corp. has caused this certificate to be signed by its President and its corporate seal to be hereunto affixed and attested by its Secretary, this 21st day of November, 1980.

BIO-TECHNOLOGY GENERAL CORP.

[SEAL]

By: s/ Frederick R. Adler
President

ATTEST:

s/ A.C. Paterson
Secretary

**CERTIFICATE OF AMENDMENT
OF
CERTIFICATE OF INCORPORATION
OF
BIO-TECHNOLOGY GENERAL CORP.**

Bio-Technology General Corp. , a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, (the "Corporation"), **DOES HEREBY CERTIFY:**

FIRST: Articles FIRST and SECOND of the Certificate of Incorporation of the Corporation is hereby amended and replaced in its entirety with the following:

"FIRST: The name of the corporation is Savient Pharmaceuticals, Inc. (hereinafter referred to as the "Corporation").

SECOND: The address of the Corporation's registered office in Delaware is Corporation Trust Center, 1209 Orange Street, City of Wilmington, 19801, County of New Castle. The name of its registered agent at such address is The Corporation Trust Company."

SECOND: The Certificate of Amendment of the Certificate of Incorporation herein certified was duly adopted in accordance with the applicable provisions of Section 242 of the General Corporation Law of the State of Delaware.

THIRD: The Certificate of Amendment herein certified was duly adopted at the annual meeting of the stockholders of the Corporation duly called and held, upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware, at which meeting the necessary number of shares as required by statute voted in favor of the amendment to the Corporation's Certificate of Incorporation.

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Amendment of Certificate of Incorporation to be signed, under penalties of perjury, and the facts stated herein are true and correct.

Dated: June 23, 2003

SAVIENT PHARMACEUTICALS, INC.

By: /s/ Robert M. Shaw

Name: Robert M. Shaw

Title: Executive Vice President and
Chief Administrative Officer

Attest:

/s/ Rhonda De Stefano
Rhonda De Stefano, Esq.

CERTIFICATIONS

I, Christopher G. Clement, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Savient Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 9, 2006

By: /s/ Christopher G. Clement

President and Chief Executive Officer

CERTIFICATIONS

I, Brian Hayden, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Savient Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 9, 2006

By: /s/ Brian Hayden

Chief Financial Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Savient Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christopher G. Clement, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 9, 2006

By: /s/ Christopher G. Clement

President and Chief Executive Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Savient Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian Hayden, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 9, 2006

By: /s/ Brian Hayden

Chief Financial Officer
