SAVIENT PHARMACEUTICALS INC
Form 10-Q
August 09, 2004

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

FORM 10-Q

Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended June 30, 2004

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	**13-3033811**
(State or other jurisdiction of incorporation or organization)	(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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

Indicate the number of shares outstanding of each of the issuer s classes of Common Stock, as of the latest practicable date.

The number of shares outstanding of the registrant s Common Stock, par value $.01 per share, as of August 5, 2004 was **60,251,265**.

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SAVIENT PHARMACEUTICALS, INC.

FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2004

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	June 30, 2004	December 31, 2003
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 21,021	$ 17,219
Short-term investments	5,370	5,582
Accounts receivable, net	14,009	33,375
Inventories	19,912	20,216
Deferred income taxes	252	2,888
Prepaid expenses and other current assets	3,815	4,163
Total current assets	64,379	83,443
Property and equipment, net	68,912	70,426
Intangible assets, net	73,713	75,743
Goodwill	40,121	40,121
Deferred income taxes		13,767
Severance pay funded	2,815	2,660
Other assets (including restricted cash of $1,280)	3,778	4,380
Total assets	$ 253,718	$ 290,540
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable (including income tax payable of $1,546 at June 30, 2004 and $4,774 at December 31, 2003)	$ 14,492	$ 16,816
Current portion of long-term debt	7,034	7,020
Deferred revenues	880	848
Other current liabilities	18,867	19,846
Total current liabilities	41,273	44,530
Long-term debt	2,383	5,903
Deferred revenues	7,869	7,836
Severance pay	6,353	5,851
Negative goodwill	16,028	16,028
Deferred income taxes	22,138	22,962
Commitments and contingent liabilities (note 7)		
Stockholders equity:		

Preferred stock - $.01 par value; 4,000 shares authorized; no shares issued		
Common stock - $.01 par value; 150,000 shares authorized; issued: 60,053 at June 30, 2004 and 59,618 at December 31, 2003	601	595
Additional paid-in capital	217,707	216,706
Accumulated deficit	(62,557)	(31,931)
Accumulated other comprehensive income	1,923	2,060
Total stockholders equity	157,674	187,430
Total liabilities and stockholders equity	$ 253,718	$ 290,540

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

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SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES

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

	Six Months Ended June 30,		Three Months Ended June 30,	
	2004	**2003**	**2004**	**2003**
Revenues:				
Product sales, net	$ 46,633	$ 54,998	$ 14,262	$ 28,048
Contract fees	450	743	220	377
Royalties	3,804	1,570	2,872	1,047
Other revenues	294	1,601	254	1,464
	51,181	58,912	17,608	30,936
Expenses:				
Research and development	15,546	13,856	6,882	7,408
Marketing and sales	12,534	11,978	5,868	5,407
General and administrative	12,767	11,496	7,395	6,445
Retirement	2,110		2,110	
Cost of product sales	16,233	9,680	7,570	5,194
Amortization of intangibles associated with acquisition	2,025	2,025	1,012	1,012
Commissions and royalties	2,910	2,231	1,507	1,821
	64,125	51,266	32,344	27,287
Operating (loss) income	(12,944)	7,646	(14,736)	3,649
Other (expense) income, net	(696)	421	(769)	39
(Loss) income before income taxes	(13,640)	8,067	(15,505)	3,688
Income taxes	16,986	2,572	16,409	1,176
Net (loss) income	(30,626)	5,495	(31,914)	2,512
(Loss) earnings per common share:				
Basic	(0.51)	$ 0.09	(0.53)	$ 0.04
Diluted	(0.51)	$ 0.09	(0.53)	$ 0.04
Weighted average number of common and common equivalent shares:				
Basic	59,849	58,942	59,962	59,044
Diluted	59,849	59,182	59,962	59,485

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

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SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES

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

	Common Stock		Additional		Accumulated Other	Total
	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Comprehensive (Loss) Income	Stockholders Equity
Balance, December 31, 2003	59,618	$ 595	$ 216,706	$ (31,931)	$ 2,060	$ 187,430
Comprehensive income:						
Net loss for six months ended June 30, 2004				(30,626)		(30,626)
Unrealized loss on marketable securities, net					(353)	(353)
Currency translation adjustment					216	216
Total comprehensive income						(30,763)
Issuance of common stock	435	6	1,001			1,007
Balance, June 30, 2004	60,053	$ 601	$ 217,707	$ (62,557)	$ 1,923	$ 157,674

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

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SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES

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

	Six Months Ended June 30,	
	2004	**2003**
Cash flows from operating activities:		
Net (loss) income	$ (30,626)	$ 5,495
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	3,297	1,978
Amortization of intangible assets associated with acquisition	2,025	2,025
Deferred revenues	65	(530)
Deferred income taxes	15,611	(704)
Provision for severance pay	502	502
Unrealized loss on investments		(286)
Gain on sales of short-term investments	(7)	(265)
Gain on sales of fixed assets		(36)
Common stock issued as payment for services	40	143
Write down of investment	1,000	
Changes in: Accounts receivables, net	19,366	16,097
Inventories	304	(566)
Prepaid expenses and other current assets	348	(3,944)
Accounts payable	(2,295)	(9,363)
Other current liabilities	(979)	1,023
Net cash provided by operating activities	8,651	11,569
Cash flows from investing activities:		
Short-term investments	(960)	(21)
Capital expenditures	(1,779)	(4,104)
Changes in other long-term assets	70	(21)
Other investments	(500)	
Severance pay funded	(155)	(308)
Cash paid in acquisition		(41)
Proceeds from sales of fixed assets		38
Proceeds from sales of short-term investments	826	1,204
Net cash used in investing activities	(2,498)	(3,253)
Cash flows from financing activities:		
Repayment of long-term debt	(3,534)	(2,470)
Proceeds from issuance of common stock	967	759
Net cash used in financing activities	(2,567)	(1,711)
Effect of exchange rate changes	216	247

Net increase in cash and cash equivalents	3,802	6,852
Cash and cash equivalents at beginning of period	17,219	12,211
Cash and cash equivalents at end of period	$ 21,021	$ 19,063
Supplementary Information		
Other information:		
Income tax paid	$ 2,536	$ 3,039
Interest paid	$ 162	$ 261

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

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SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 June 30, 2004 and the results of its operations and cash flows for the three and six months ended June 30, 2004 and 2003. Except for the valuation allowance recorded in connection with the Company s deferred tax assets described in note 6 below, all such adjustments are of a normal and recurring nature. Interim financial statements are prepared on a basis consistent with the Company's annual financial statements. Results of operations for the three- and six-month periods ended June 30, 2004 are not necessarily indicative of the operating results that may be expected for the year ending December 31, 2004.

The consolidated balance sheet as of December 31, 2003 has been 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, 2003.

2. Inventories

Inventories are stated at the lower of cost or market. Cost is determined using the weighted-average method. If inventory costs exceed expected market value due to obsolescence or unmarketability, reserves are recorded for the difference between the cost and the market value. These reserves are determined based on estimates. The reserves at June 30, 2004 were $94,000.

Inventories at June 30, 2004 and December 31, 2003 are summarized below:

	June 30, 2004	December 31, 2003
	(Unaudited)	
	(In thousands)	
Raw material	$ 3,880	$ 6,635
Work in process	3,471	1,720
Finished goods	12,561	11,861
Total	$ 19,912	$ 20,216

3. Allowances for Returns

Product sales are recognized when product is shipped and collectability is probable, net of discounts, sales incentives, sales allowances and sales returns.

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SAVIENT PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Through December 31, 2003, sales returns had been minimal and insignificant to the Company s results of operations. However, in the first quarter of 2004, the Company recorded a sales return allowance of $1,085,000 to cover anticipated returns from wholesaler customers of expiring 10-mg Oxandrin tablets. In addition, in the second quarter of 2004, the Company received notification from its wholesaler customers that they would be returning $2,021,000 of expiring 10-mg Oxandrin product, primarily as a result of returns from their retail customers. Accordingly, the Company recorded a corresponding provision for these additional returns in the second quarter of 2004. Furthermore, during the second quarter of 2004, the Company received and recorded a $555,000 return of expiring 2.5-mg Oxandrin product. Historically, the Company had experienced virtually no returns of the 2.5-mg Oxandrin tablet because of the product s five-year shelf life. The 10-mg Oxandrin tablet, which was introduced in the second half of 2002, currently has a two-year shelf life.

As a result of the Company s recent returns experience, the Company changed its estimates regarding future returns and recorded an additional provision for future returns of $1,030,000 in the second quarter of 2004, resulting in an aggregate provision for returns in the first six months of 2004 of $4,691,000. The Company will continue to monitor its products to assure that future reserves for returns are provided as appropriate. The Company bases its estimates of the allowance for returns on a variety of factors, including actual return experience of its products, estimated inventory levels of its wholesaler customers and other relevant factors. Changes in facts and circumstances and the demand for the Company s products could result in material changes in the amount of returned product, and actual results may differ materially from the Company s estimates. The Company will regularly review the factors that influence its estimates and, if necessary, make adjustments when the Company believes that actual product returns may differ from established reserves. As of June 30, 2004, the Company s provision for future returns, which is reflected as a contra account to accounts receivable, was $2,959,000.

4. Earnings Per Share of Common Stock

The Company has applied Statement of Financial Accounting Standards (SFAS) 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.

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

	Six Months Ended June 30,		Three Months Ended June 30,	
	(Unaudited)		(Unaudited)	
(In thousands)	2004	2003	2004	2003
Basic	59,849	58,942	59,962	59,044
Incremental shares for assumed conversion of options		240		441
Diluted	59,849	59,182	59,962	59,485

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The difference between basic and diluted weighted average common shares resulted from the assumption that the dilutive stock options outstanding were exercised. For the six months ended June 30, 2004 and 2003, options to purchase 8,285,000 shares and 7,490,500 shares, respectively, were not included in the diluted earnings per share calculation as their effect would have been anti-dilutive.

5. Stock-based compensation

As permitted by SFAS No. 123, *Accounting for Stock Based Compensation*, the Company accounts for stock-based compensation arrangements with employees in accordance with the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*. Compensation expense for stock options issued to employees is based on the difference on the date of grant between the fair value of the Company s stock and the exercise price of the option. No stock-based employee compensation cost is reflected in net income, as all granted options had an exercise price equal to the market value of the underlying common stock at the date of grant. The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force (EITF) Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction With Selling, Goods or Services.* All transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based compensation:

	Six months ended June 30,		Three months ended June 30,	
	(Unaudited)		(Unaudited)	
	2004	2003	2004	2003
	(in thousands except per share data)		(in thousands except per share data)	
Net (loss) income				
As reported	$ (30,626)	$ 5,495	$ (31,914)	$ 2,512
Deduct:				
Total stock based employee compensation expense determined under fair value based method for all awards, net of related tax effects	2,573	6,594	773	2,928
Pro forma net loss	$ (33,199)	$ (1,099)	$ 32,687	$ (416)
Basic (loss) earnings per common share:				
As reported	$ (0.51)	$ 0.09	$ (0.53)	$ 0.04
Pro forma	$ (0.55)	$ (0.02)	$ (0.55)	$ (0.01)
Diluted (loss) earnings per common share:				
As reported	$ (0.51)	$ 0.09	$ (0.53)	$ 0.04
Pro forma	$ (0.55)	$ (0.02)	$ (0.55)	$ (0.01)

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

6. Income Taxes

Deferred income taxes are recognized for the tax consequences of temporary differences by applying the enacted statutory tax rates to differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for capital and net operating losses and tax credits carry forward. A valuation allowance against deferred income tax assets is required if the Company determines that it is more likely than not that a part of or the entire amount of deferred income tax assets will not be realized.

Based upon the Company s current business outlook and the change in its strategic direction, the likelihood of the Company being able to fully realize its deferred income tax benefits against future income is uncertain. Accordingly, in the second quarter of 2004, the Company recorded a $16,272,000 valuation allowance against its deferred income tax assets and a corresponding provision for income taxes. The remaining deferred income tax asset and deferred income tax liability relate primarily to foreign operations. The balance of the current period income tax provision is comprised of the income taxes payable on income earned in a foreign jurisdiction offset by limited recoveries of income taxes in jurisdictions where losses have been incurred.

7. Commitments and Contingencies

The Company has received notification of claims filed that certain of its products may infringe certain third-party patents in the normal course of operations. Management believes that these claims have no merit, and the Company intends to defend them vigorously. The Company does not expect the outcome of these claims to have a significant adverse effect on its financial position, results of operations or cash flows. However, were an unfavorable ruling to occur in any subsequent period, there exists the possibility of a material adverse effect on the Company s operating results. No accrual can be determined at this time.

On December 20, 2002, a purported stockholder class action was filed against the Company and three of its officers. The action is pending under the caption A.F.I.K. Holding SPRL v. Fass, No. 02-6048 (HAA) in the U.S. District Court for the District of New Jersey and alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. Plaintiff purports to represent a class of stockholders who purchased shares of the Company between April 19, 1999 and August 2, 2002. The complaint asserts that 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 reflected in the Company s Form 8-K and accompanying press release issued August 2, 2002. Five virtually identical actions were filed in January and February 2003. 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 lead plaintiffs filed an amended consolidated complaint in March 2004. In July 2004, the Company filed a brief in support of a motion to dismiss this case. The Company cannot predict when the court will make a decision on this motion.

On October 27, 2003, the Company received a letter addressed to the Board of Directors from attorneys for a purported stockholder of the Company demanding that the Company commence legal proceedings to recover its damages against directors who served on the Company s board immediately prior to the June 2003 Annual Meeting of Stockholders, Fulbright & Jaworski L.L.P., Arthur Andersen LLP, the partners of Arthur Andersen responsible for the audit of Savient s financial statements for 1999, 2000 and 2001, as well as all other officers and directors responsible for the alleged wrongdoing. The letter claims that some or all of these persons were responsible for the material overstatement of Savient s assets, earnings and net worth, and that these persons caused Savient to disseminate false and misleading press releases and filings with the SEC. A special committee to the Board, consisting of directors who were not directors prior to the June 2003 Annual Meeting of Stockholders, has investigated this demand and has determined that litigation relating to this matter should not proceed.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company intends to vigorously defend against all allegations of wrongdoing. The Company has referred these claims to its directors and officers insurance carrier, which has reserved its rights as to coverage with respect to these actions.

In the second quarter of 2004, the Company recorded retirement expense of $2,110,000, reflecting a provision for a retirement payment and other related benefits in connection with the Company s previously disclosed retirement agreement with its former Chief Executive Officer. In June 2004, this former executive elected to receive his retirement payment in one lump sum. The Company made the payment on July 15, 2004.

The Company is obligated under certain circumstances to indemnify certain customers for certain or all expenses incurred and damages suffered by them as a result of any infringement of third-party patents. In addition, the Company is obligated to indemnify its officers and directors against all reasonable costs and expenses related to stockholder and other claims pertaining to actions taken in their capacity as officers and directors which are not covered by the Company's directors and officers insurance policy. These indemnification obligations are in the regular course of business and in most cases do not include a limit on maximum potential future payments, nor are there any recourse provisions or collateral that may offset the cost. As of June 30, 2004, the Company has not recorded a liability for any obligations arising as a result of these indemnification obligations.

The United States Internal Revenue Service is conducting an audit of the Company s federal income tax return for the year ended December 31, 2002. The Company is also subject to ongoing tax audits by the City of New York and State of New Jersey. In addition, the State of Israel, Ministry of Finance, Income Tax Authority, is conducting a tax audit of the Company s wholly owned subsidiary, Bio-Technology General (Israel) Ltd., for the years ended December 31, 2000, 2001, and 2002. Although there can be no assurances, the Company believes that any adjustments that may arise as a result of these audits will not have a material adverse effect on the Company s financial position or results of operations.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing in Item 1 of this Quarterly Report on Form 10-Q. The following discussion and analysis and other portions of this Quarterly Report on Form 10-Q contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. All statements, other than statements of historical facts, included in this report regarding our strategy, expected future financial position, results of operations, cash flows, financing plans, discovery and development of products, potential acquisitions, strategic alliances, intellectual property, competitive position, plans and objectives of management are forward-looking statements. Words such as anticipate, believe, estimate, expect, intend, plan, will and other similar expressions help identify forward-looking statements, although not all forward-looking statements contain these identifying words. In particular, the statements regarding our new strategic direction and its potential effects on our business are forward-looking statements. These forward-looking statements involve substantial risks and uncertainties and are based on our current expectations, assumptions, estimates and projections about our business and the biopharmaceutical and specialty pharmaceutical industries in which we operate. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. We have included important factors in the cautionary statements included in this report, particularly in the section entitled Risk Factors That May Affect Results, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements.

Overview

We are engaged in the research, development, manufacture and marketing of pharmaceutical products that address unmet medical needs in both niche and larger market segments. We distribute our products on a worldwide basis. In the United States we distribute our products primarily through a direct sales force that includes both our own employees and representatives of a contract sales organization. In the United Kingdom we distribute our oral liquid pharmaceutical products and in Israel we distribute our products primarily through direct sales forces. We distribute our products primarily through third-party license and distribution relationships elsewhere in the world. Through a combination of internal research and development, acquisitions, collaborative relationships and licensing arrangements, we have assembled a diverse portfolio of therapeutic products, many of which are currently being marketed, several of which are in registration or clinical trials and one of which is in pre-clinical development.

We were founded in 1980 as Bio-Technology General Corp. to develop, manufacture and market novel therapeutic products. In September 2002, we acquired Rosemont Pharmaceuticals Limited, a specialty pharmaceutical company located in the United Kingdom. Rosemont develops, manufactures and markets pharmaceutical products in oral liquid form. We coordinate our overall administration, finance, business development, human clinical studies, U.S. sales and marketing activities, quality assurance and regulatory affairs primarily at our corporate headquarters in East Brunswick, New Jersey. We carry out the development, manufacture, distribution and sale of our oral liquid pharmaceutical products through Rosemont in the United Kingdom. We currently carry out our pre-clinical studies, research and development activities and manufacturing of our biotechnology-derived products primarily through Bio-Technology General (Israel) Ltd., our wholly owned subsidiary in Israel, which we refer to as BTG-Israel. As described below under the caption New Strategic Direction, we are exploring our strategic options for the divestiture of our operations in Israel, including BTG-Israel.

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Our financial results have been heavily dependent on Oxandrin sales since we introduced the product in December 1995. Sales of Oxandrin accounted for 40% of our total product sales in the first half of 2004 and 47% of our total product sales in the first half of 2003. Sales of Oxandrin accounted for 46% of our total product sales in 2003, 48% in 2002 and 54% in 2001. Oxandrin sales in the first six months of 2004 were adversely affected by returns during the period and a provision for future returns. Oxandrin sales in 2002 were adversely affected by our change to selling directly to wholesalers rather than through a third-party distributor. Several companies have filed drug master files with the FDA relating to a generic drug with oxandrolone, the same active pharmaceutical ingredient in Oxandrin. Although we cannot predict when generic competition for Oxandrin will begin, it is possible that the FDA may approve one or more generic versions of Oxandrin as early as the third quarter of 2004. The introduction of generic oxandrolone products would likely cause a significant decrease in our revenues from sales of Oxandrin, which would adversely affect us financially and could require us to scale back some of our business activities.

In February 2004, we filed a Citizens Petition with the FDA requesting that, in the interest of public health, the FDA establish specific bio-equivalence requirements for oral products containing oxandrolone. This petition cited, among other things, serious safety issues regarding interactions between oxandrolone and anti-coagulant drugs containing the active pharmaceutical ingredient warfarin. We requested in our petition that any company wishing to introduce an oxandrolone product into the U.S. market should, prior to the issuance of marketing approval, be required to also conduct a clinical study to investigate the interaction between their product and warfarin and demonstrate that it is identical to the interaction between Oxandrin and warfarin. As of the date of this report, we have not received any indication that the FDA has taken any action on the petition.

We expect that sales of our human growth hormone product to our Japanese distributor will be relatively stable in the coming years, as moderate increases in sales volume will be partially offset by price decreases resulting from continuing pricing pressure from the Japanese Ministry of Health. Sales of Delatestryl have 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, and could decrease further in the future. We began to depreciate our new manufacturing facility in Be er Tuvia, Israel and certain equipment in January 2004. We estimate that depreciation expense will aggregate approximately $3,500,000 to $4,000,000 annually once all equipment at the Be er Tuvia facility is placed in service. As a result, cost of product sales as a percentage of product sales will increase in 2004 as compared to 2003.

New Strategic Direction

In July 2004, we announced a change in our strategic business plan to reposition our company to focus on the full development of our pipeline products. This will include an enhanced focus on the clinical development of our two product candidates currently in Phase 2 clinical trials Prosaptide for peripheral neuropathic pain, and Puricase for severe, refractory gout. We also intend to concentrate on an active in-licensing program to access and develop novel compounds in clinical stage development.

As part of this new plan, we intend to divest assets that are not consistent with our refined business objectives and are exploring our strategic options for the divestiture of our operations in Israel, including BTG-Israel. We believe that a sale of our Israeli operations on favorable terms should provide the incremental resources that we will require to fund the advancement of our drug development programs. However, we cannot assure you that we will be successful in completing such a divestiture or that any such divesture will generate sufficient proceeds to adequately fund our future operations.

Based upon our current business outlook and the change in our strategic direction, the likelihood of our being able to fully realize our deferred income tax benefits against future income is uncertain. Accordingly, in the second quarter of 2004 we recorded a $16,272,000 valuation allowance against our deferred income tax assets and a corresponding provision for income taxes.

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Critical Accounting Policies

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.

We discuss our critical accounting policies in our Annual Report on Form 10-K for the year ended December 31, 2003 in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and the Use of Estimates. In addition to the critical accounting policies discussed in our Annual Report on Form 10-K, we have identified the following additional critical accounting policy:

Allowances for returns. We recognize product sales when product is shipped and collectability is probable, net of discounts, sales incentives, sales allowances and sales returns.

Through December 31, 2003, sales returns had been minimal and insignificant to our results of operations. However, in the first quarter of 2004, we recorded a sales return allowance of $1,085,000 to cover anticipated returns from our wholesaler customers of expiring 10-mg Oxandrin tablets. In addition, in the second quarter of 2004, we received notification from our wholesaler customers that they would be returning $2,021,000 of expiring 10-mg Oxandrin product, primarily as a result of returns from their retail customers. Accordingly, we recorded a corresponding provision for these additional returns in the second quarter of 2004. Furthermore, during the second quarter of 2004, we received and recorded a $555,000 return of expiring 2.5-mg Oxandrin product. Historically, we had experienced virtually no returns of the 2.5-mg Oxandrin tablet because of the product s five-year shelf life. The 10-mg Oxandrin tablet, which was introduced in the second half of 2002, currently has a two-year shelf life.

As a result of our recent returns experience, we changed our estimates regarding future returns and recorded an additional provision for future returns of $1,030,000 in the second quarter of 2004, resulting in an aggregate provision for returns in the first six months of 2004 of $4,691,000. We will continue to monitor our products to assure that future reserves for returns are provided as appropriate. We base our estimates of the allowance for returns on a variety of factors, including actual return experience of our products, estimated inventory levels of our wholesaler customers and other relevant factors. Changes in facts and circumstances and the demand for our products could result in material changes in the amount of returned product, and actual results may differ materially from our estimates. We will regularly review the factors that influence our estimates and, if necessary, make adjustments when we believe that actual product returns may differ from established reserves. As of June 30, 2004, our provision for future returns, which is reflected as a contra account to accounts receivable, was $2,959,000.

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Results of Operations

The following table sets forth for the periods indicated the percentage of revenues represented by certain items reflected on our statements of operations.

	Six Months Ended June 30,		Three Months Ended June 30,	
	2004	2003	2004	2003
Revenues:				
Products sales, net	91.1%	93.3%	81.0%	90.7%
Contract fees	0.9	1.3	1.3	1.2
Royalties	7.4	2.7	16.3	3.4
Other revenues	0.6	2.7	1.4	4.7
Total	100.0	100.0	100.0	100.0
Expenses:				
Research and development	30.4	23.5	39.1	23.9
Marketing and sales	24.5	20.3	33.3	17.5
General and administrative	24.9	19.5	42.0	20.8
Retirement	4.1		12.0	
Cost of product sales	31.7	16.4	43.0	16.8
Amortization of intangibles associated with acquisition	4.0	3.5	5.7	3.3
Commissions and royalties	5.7	3.8	8.6	5.9
Total	125.3	87.0	183.7	88.2
Operating (loss) income	(25.3)	13.0	(83.7)	11.8
Other (expense) income, net	(1.3)	0.7	(4.4)	0.1
(Loss) income before income taxes	(26.6)	13.7	(88.1)	11.9
Income taxes	33.2	4.4	93.2	3.8
Net (loss) income	(59.8)%	9.3%	(181.3)%	8.1%

We have historically derived our revenues from product sales as well as from collaborative arrangements with third parties. The sources of revenue under our third-party arrangements include up front contract fees, funding for additional research, reimbursement for producing certain experimental materials, milestone payments and royalties on sales of product. Our funding for additional research includes funding that we receive from the Office of the Chief Scientist of the State of Israel. If we are successful in divesting our operations in Israel, future funding from the Office of the Chief Scientist would not be available to us. We anticipate that product sales will constitute the majority of our revenues for the foreseeable future.

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 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;

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- 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 extent and timing of costs of obtaining, enforcing and defending intellectual property rights; and
- any charges related to acquisitions.

The decrease in the value of the U.S. dollar against the British pound sterling had a positive effect on Rosemont s revenues measured in U.S. dollars and had a negative effect on Rosemont s expenses measured in U.S. dollars. This decrease also had a positive effect on our overall net (loss) income.

The following table summarizes sales of our commercialized products as a percentage of total product sales for the periods indicated:

	Six Months Ended June 30,				Three Months Ended June 30,			
	2004		2003		2004		2003	
	(dollars in thousands)				(dollars in thousands)			
Oxandrin	$ 18,606	39.9%	$ 25,984	47.2%	$ 24	0.2%	$ 14,121	50.4%
Oral liquid pharmaceutical products	15,852	34.0	12,044	21.9	8,648	60.6	6,422	22.9
Human growth hormone	4,497	9.6	8,162	14.8	2,568	18.0	3,732	13.3
Delatestryl	3,735	8.0	4,592	8.4	1,020	7.2	1,442	5.1
BioLon	3,082	6.6	3,456	6.3	1,579	11.0	1,823	6.5
Other	861	1.9	760	1.4	423	3.0	508	1.8
Total	$ 46,633	100.0%	$ 54,998	100.0%	$ 14,262	100.0%	$ 28,048	100.0%

We believe that our product mix will vary from period to period based on the purchasing patterns of our customers and our focus on:

- increasing market penetration of our existing products;
- expanding into new markets; and
- commercializing additional products.

In particular, quarterly fluctuations in sales of Oxandrin have had a significant impact on our quarterly results of operations, and we expect this to continue in future periods.

The following table summarizes our U.S., United Kingdom and other international product sales as a percentage of total product sales for the periods indicated:

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	Six Months Ended June 30, (dollars in thousands) 2004		2003		Three Months Ended June 30, (dollars in thousands) 2004		2003	
United States	$ 22,242	47.7%	$ 30,522	55.5%	$ 1,044	7.3%	$ 15,572	55.5%
United Kingdom	15,117	32.4	11,389	20.7	8,016	56.2	5,984	21.3
Other International	9,274	19.9	13,087	23.8	5,202	36.5	6,492	23.2
Total	$ 46,633	100.0%	$ 54,998	100.0%	$ 14,262	100.0%	$ 28,048	100.0%

Comparison of Six Months Ended June 30, 2004 and June 30, 2003.

Revenues. Total revenues decreased by $7,731,000, or 13.1%, in the six months ended June 30, 2004 to $51,181,000 from $58,912,000 in the six months ended June 30, 2003. The decrease in total revenues resulted primarily from the decrease in product sales, net, and other revenues, partially offset by an increase in royalties.

Product sales, net decreased by $8,365,000, or 15.2%, in the six months ended June 30, 2004 to $46,633,000 from $54,998,000 in the six months ended June 30, 2003. The decrease resulted primarily from decreases in net sales of Oxandrin, human growth hormone, Delatestryl, and BioLon, partially offset by an increase in sales of Rosemont s oral liquid pharmaceutical products.

Sales of Oxandrin in the six months ended June 30, 2004 were $18,606,000, a decrease of $7,378,000, or 28.4%, from $25,984,000 in the first six months of 2003. This decrease resulted principally from the negative impact of returns of expiring product, from a provision for future returns and from lower purchases by wholesalers as they reduced their inventory levels, even though Oxandrin prescriptions remained steady in the first six months of 2004. These decreases were partially offset by interim price increases since the first quarter of 2003. Through December 31, 2003, sales returns had been minimal and insignificant to our results of operations. However, in the first quarter of 2004, we recorded a sales return allowance of $1,085,000 to cover anticipated returns from wholesaler customers of expiring 10-mg Oxandrin tablets. In addition, in the second quarter of 2004, we received notification from our wholesaler customers that they would be returning $2,021,000 of expiring 10-mg Oxandrin product, primarily as a result of returns from their retail customers. Accordingly, we recorded a corresponding provision for these additional returns in the second quarter of 2004. Furthermore, during the second quarter of 2004, we received and recorded a $555,000 return of expiring 2.5-mg Oxandrin product. Historically, we had experienced virtually no returns of the 2.5-mg Oxandrin tablet because of the product s five-year shelf life. The 10-mg Oxandrin tablet, which was introduced in the second half of 2002, currently has a two-year shelf life. As a result of our recent returns experience, we changed our estimates regarding future returns and recorded an additional provision for returns of $1,030,000 in the second quarter of 2004. The aggregate provision for returns in the first six months of 2004 was $4,691,000. We will continue to monitor our products to assure that future reserves for returns are recorded as appropriate. Changes in facts and circumstances and the demand for our products could result in material changes in the amount of returned product, and actual results may differ materially from our estimates.

Sales of oral liquid pharmaceutical products in the six months ended June 30, 2004 were $15,852,000, an increase of $3,808,000, or 31.6%, from $12,044,000 in the first six months of 2003. A portion of the increase was attributable to the decrease in the value of the U.S. dollar relative to the British pound sterling. Measured in pounds sterling, Rosemont s sales in the six months ended June 30, 2004 increased by 16.3% over sales in the first six months of 2003.

Sales of human growth hormone in the six months ended June 30, 2004 were $4,497,000, a decrease of $3,665,000, or 44.9%, from $8,162,000 in the first six months of 2003. Sales to our European distributor decreased to $3,082,000 in the first half of 2004 from $4,270,000 in the first half of 2003. Sales to our Japanese distributor were $3,300,000 the first half of 2003. We had no sales to this distributor in the same period in 2004.

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Sales of Delatestryl in the six months ended June 30, 2004 were $3,735,000, a decrease of $857,000, or 18.7%, from $4,592,000 in the first six months of 2003. The decrease in sales was attributable to the reintroduction of a competing generic product into the market in March 2004. We expect our Delatestryl sales for the remainder of 2004 to be significantly lower than our 2003 sales of $12,343,000 as a result of the reintroduction of this competing generic product. Changing wholesaler expectations of market demand for Delatestryl and the availability of supply of Delatestryl and competing products have caused significant volatility in Delatestryl sales in recent years and quarters.

Sales of BioLon in the six months ended June 30, 2004 were $3,082,000, a decrease of $374,000 or 10.8%, from $3,456,000 in the first six months of 2003. In March 2004 we terminated our exclusive distribution agreement with Akorn, Inc. relating to the distribution of BioLon in the United States. We are currently seeking a new partner to market BioLon in the United States.

Contract fees were $450,000 in the six months ended June 30, 2004 and $743,000 in the six months ended June 30, 2003. These amounts represent mainly contract fees received in prior periods but recognized in the six months ended June 30, 2004 and 2003 in accordance with SAB 101.

Royalties in the six months ended June 30, 2004 were $3,804,000, an increase of $2,234,000, or 142.3%, from $1,570,000 in the first six months of 2003. These revenues consist principally of royalties that we receive from third-party sales of our Mircette, Silkis and insulin products. The increase in royalties in the first half of 2004 was primarily attributable to fees of $2,250,000 that we earned in the second quarter of 2004 as a result of the achievement of sales milestones under our license agreement with Diosynth b.v. relating to our insulin product.

Other revenues decreased by $1,307,000, or 81.6%, in the six months ended June 30, 2004 as compared to the same period in 2003, primarily attributable to a decrease in partial research and development funding from the Office of the Chief Scientist of the State of Israel.

Research and development expense increased by $1,690,000, or 12.2%, in the six months ended June 30, 2004 to $15,546,000 from $13,856,000 in the six months ended June 30, 2003. The increase resulted principally from increases in clinical trial and product development expenses related to our development of Prosaptide, Puricase, Soltamox, our oral liquid formulation of tamoxifen, an off-patent drug for the treatment of both advanced and early stage breast cancers, other oral liquid pharmaceutical products and Oxandrin. The increase was partially offset by a reduction in our discovery research and pre-clinical activities and associated compensation costs.

Marketing and sales expense increased by $556,000, or 4.6%, in the six months ended June 30, 2004 to $12,534,000 from $11,978,000 in the six months ended June 30, 2004. The increase is primarily attributable to the cost of sales force automation systems, establishment of a contract sales organization in 2004, and increased compensation expense, partially offset by decreases in sales meeting and sale data expenses. These expenses primarily related to the sales and marketing force in the United States that we established to promote distribution of Oxandrin in the United States and oral liquid pharmaceutical products in the United Kingdom. As a percentage of product sales, marketing and sales expense increased to 26.9% in the six months ended June 30, 2004 from 21.8% in the first six months of 2003, primarily as a result of the decrease in net product sales.

General and administrative expense increased by $1,271,000, or 11.1%, in the six months ended June 30, 2004 to $12,767,000 from $11,496,000 in the six months ended June 30, 2003. The increase was principally attributable to increases in consulting expenses related to our implementation of provisions of the Sarbanes-Oxley Act and to the development of our new strategic plan, as well as to increases in legal and insurance expenses.

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Retirement expense of $2,110,000 in the six months ended June 30, 2004 includes a provision for a retirement payment and other related benefits in connection with our previously disclosed retirement agreement with our former Chief Executive Officer. In June 2004, this former executive elected to receive his retirement payment in one lump sum. We made the payment on July 15, 2004.

Cost of product sales increased by $6,553,000, or 67.7%, in the six months ended June 30, 2004 to $16,233,000 from $9,680,000 in the six months ended June 30, 2003. Cost of product sales as a percentage of product sales increased from 17.6% in the six months ended June 30, 2003 to 34.8% in the six months ended June 30, 2004. The major portion of the increase is attributable to expenses of $4,819,000 in the six months ended June 30, 2004 relating to the operation of our manufacturing facility in Be er Tuvia. During the six months ended June 30, 2003, we capitalized the costs of operating the facility because the facility was not yet ready for its intended use. Much of the operating costs of the Be er Tuvia facility relate to process validation and similar qualification activities, as opposed to costs related to the manufacture of products for commercial sale. In addition, depreciation of the Be er Tuvia facility, including depreciation of certain equipment placed in service, commenced during the first quarter of 2004. This resulted in an additional charge to cost of product sales of $1,516,000 during the six months ended June 30, 2004. Although the expenses relating to the Be er Tuvia facility were partially offset by a decrease in the cost of product sales attributable to the reduction in sales in the first half of 2004 compared to 2003, there was no reduction in cost of product sales in the first half of 2004 corresponding to product returns recorded and reserved for in that period. Cost of product sales as a percentage of product sales also varies from year to year and quarter to quarter depending on the quantity and mix of products sold. Oxandrin and human growth hormone have relatively low manufacturing costs relative to their sales prices; whereas BioLon, Delatestryl and Rosemont s products have higher manufacturing costs relative to their sales prices. We expect cost of product sales to continue to increase in 2004 as we begin to depreciate more of the equipment in our Be er Tuvia facility as it comes into service. We currently anticipate that depreciation on the entire facility, including all equipment, will aggregate approximately $3,500,000 to $4,000,000 annually.

Amortization of intangibles associated with acquisition. In connection with our acquisition of Rosemont, we recorded intangibles of $80,800,000, consisting of developed products, trademarks and patents. We are amortizing these intangibles using the straight-line method over the estimated useful life of approximately 20 years. We recorded $2,025,000 of amortization of these intangibles in the first six months of 2004 and 2003.

Commissions and royalties expense was $2,910,000 in the six months ended June 30, 2004, compared to $2,231,000 in the six months ended June 30, 2003. The increase of $679,000, or 30.4%, is primarily attributable to increased commissions paid to the Ross Products Division of Abbott Laboratories, or Ross, on their purchases of Oxandrin for the long-term market, partially offset by a decrease in royalties that we were required to pay for our Delatestryl and Mircette products due to a decrease in the sales of those products. Ross co-promotes Oxandrin with us in the United States to residents of long-term care facilities, who are particularly at risk for losing lean body mass. Prior to March 31, 2003, Ross had instead been able, under its agreement with Savient, to purchase Oxandrin from us at a discount which was classified as a sales allowance.

Other expense, net was $696,000 for the six months ended June 30, 2004, compared to other income, net, of $421,000 for the three months ended June 30, 2003. The increase in expenses is primarily attributable to the write down in the value of our investment in Marco Hi-Tech JV, Ltd. In 2003, we agreed to invest an aggregate of $1,500,000 in Marco preferred stock and acquired an option to market Marco s Huperzine-A product candidate which is in clinical trials for the treatment of Alzheimer s disease. As of March 31, 2004, we had invested $1,000,000 in Marco. In the second quarter of 2004, we elected not to make our final $500,000 investment in Marco. As a result, our preferred stock has converted into Marco common stock and our option to market Huperzine-A has terminated. Although we will continue to hold the Marco common stock, based on our assessment of the status of the development of Marco's product candidate, we have written down the entire amount of our $1,000,000 investment in Marco.

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Income taxes. Provision for income taxes for the six months ended June 30, 2004 was $16,968,000, compared to $2,572,000 for the three months ended June 30, 2003. The increase in provision for income taxes was primarily attributable to the $16,272,000 valuation allowance that we recorded in the second quarter of 2004 to reflect the uncertainty of our being able to use the benefits of our deferred tax assets in the future based upon our current business outlook and the change in our strategic direction.

Comparison of Three Months Ended June 30, 2004 and June 30, 2003.

Revenues. Total revenues decreased by $13,328,000, or 43.1%, in the three months ended June 30, 2004 to $17,608,000 from $30,936,000 in the three months ended June 30, 2003. The decrease was primarily attributable to the decrease in product sales, net, and other revenues, partially offset by an increase in contract fees.

Product sales, net, decreased by $13,786,000, or 49.2%, in the three months ended June 30, 2004 to $14,262,000 from $28,048,000 in the second quarter of 2003. The decrease was primarily attributable to decreases in the net sales of Oxandrin, Human growth hormone, Delatestryl, and BioLon, partially offset by an increase in the sales of Rosemont s oral liquid pharmaceutical products.

Sales of Oxandrin in the three months ended June 30, 2004, net of product returns and provision for future reserves, were $24,000, representing a significant decrease from $14,121,000 in the second quarter of 2003. In addition to the effects of the returns and the provision for future returns, the decrease in Oxandrin sales in the second quarter of 2004 resulted from lower purchases by wholesalers as they reduced their inventory levels. These decreases were partially offset by interim price increases since the first quarter of 2003.

Sales of oral liquid pharmaceutical products in the three months ended June 30, 2004 were $8,648,000, an increase of $2,226,000, or 34.7%, from $6,422,000 in the second quarter of 2003. A portion of the increase was attributable to the decrease in the value of the U.S. dollar relative to the British pound sterling. Measured in pounds sterling, Rosemont s sales in the three months ended June 30, 2004 increased by 20.2% over the sales in the second quarter of 2003.

Sales of human growth hormone were $2,568,000 in the three months ended June 30, 2004, a decrease of $1,164,000, or 31.2%, from $3,732,000 in the second quarter of 2003. Sales to our Japanese distributor were $1,926,000 in the second quarter of 2003. We had no sales to this distributor in the same period in 2004.

Sales of Delatestryl in the three months ended June 30, 2004 were $1,020,000, a decrease of $422,000, or 29.3%, from $1,442,000 in the second quarter of 2003. The decrease in sales was attributable to the reintroduction of a competing generic product into the market in March 2004. We expect our Delatestryl sales for the remainder of 2004 to be significantly lower than our 2003 sales of $12,343,000 as a result of the reintroduction of this competing generic product. Changing wholesaler expectations of market demand for Delatestryl and the availability of supply of Delatestryl and competing products have caused significant volatility in Delatestryl sales in recent years and quarters.

Contract fees were $220,000 in the three months ended June 30, 2004 and $377,000 in the three months ended June 30, 2003. These amounts represent mainly contract fees received in prior periods but recognized in the three-month periods ended June 30, 2004 and 2003 in accordance with SAB 101.

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Royalties in the three months ended June 30, 2004 were $2,872,000, an increase of $1,825,000, or 174.3%, from $1,047,000 in the second quarter of 2003. The increase was primarily attributable to the fees of $2,250,000 that we earned in the second quarter of 2004 under our Diosynth license agreement, partially offset by decreases in royalties earned on sales of our Mircette and insulin products.

Other revenues decreased by $1,210,000, or 82.7%, in the three months ended June 30, 2004 as compared to the same period in 2003, primarily attributable to a decrease in partial research and development funding from the Office of the Chief Scientist of the State of Israel.

Research and development expense decreased by $526,000, or 7.1%, in the three months ended June 30, 2004 to $6,882,000 from $7,408,000 in the three months ended June 30, 2003. The decrease resulted principally from decreases in clinical trial and product development expenses related to our development of Prosaptide and Puricase, discovery, research and pre-clinical activities and associated compensation costs, partially offset by increases in product development expenses related to Soltamox, our oral liquid formulation of tamoxifen, an off-patent drug for the treatment of both advanced and early stage breast cancers and other oral liquid pharmaceutical products.

Marketing and sales expense increased by $461,000, or 8.5%, in the three months ended June 30, 2004 to $5,868,000 from $5,407,000 in the three months ended June 30, 2003. The increase is primarily attributable to the establishment of a contract sales organization in 2004, partially offset by a reduction in compensation expense. As a percentage of product sales, marketing and sales expense increased to 41.1% in the three months ended June 30, 2004 from 19.3% in the second quarter of 2003, primarily as a result of the decrease in net product sales. These expenses primarily related to the sales and marketing force in the United States that we established to promote distribution of Oxandrin in the United States and oral liquid pharmaceutical products in the United Kingdom.

General and administrative expense increased by $950,000, or 14.7%, in the three months ended June 30, 2004 to $7,395,000 from $6,445,000 in the three months ended June 30, 2003. The increase was primarily attributable to increases in consulting expenses related to our implementation of provisions of the Sarbanes-Oxley Act and to the development of our new strategic plan, as well as to increases in legal expenses.

Retirement expense of $2,110,000 in the quarter ended June 30, 2004 includes a provision for a retirement payment and other related benefits in connection with our previously disclosed retirement agreement with our former Chief Executive Officer. In June 2004 this former executive elected to receive his retirement payment in one lump sum. We made the payment on July 15, 2004.

Cost of product sales increased by $2,376,000, or 45.7%, in the three months ended June 30, 2004 to $7,570,000 from $5,194,000 in the three months ended June 30, 2003. Cost of product sales as a percentage of product sales increased from 18.5% in the three months ended June 30, 2003 to 53.1% in the three months ended June 30, 2004. The major portion of the increase is attributable to expenses of $2,487,000 for the three months ended June 30, 2004 relating to the operation of our Be er Tuvia manufacturing facility. In addition, depreciation of the Be er Tuvia facility was $953,000 in the three months ended June 30, 2004, compared to no depreciation in the second quarter of 2003. Although the expenses relating to the Be er Tuvia facility were partially offset by a decrease in the cost of product sales attributable to the reduction in sales in the second quarter of 2004 compared to 2003, there was no reduction in cost of product sales in the first half of 2004 corresponding to product returns recorded and reserved for in that period.

Amortization of intangibles associated with acquisition. We recorded $1,012,000 of amortization of intangibles related to our acquisition of Rosemont in the three months ended June 30, 2004 and June 30, 2003.

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Commissions and royalties expense decreased by $314,000, or 17.2%, in the three months ended June 30, 2004 to $1,507,000 from $1,821,000 in the three months ended June 30, 2003, primarily as a result of a decrease in the sales of Delatestryl and Mircette.

Other expense, net was $769,000 for the three months ended June 30, 2004, compared to other income, net of $39,000 for the three months ended June 30, 2003. The increase in expenses is primarily attributable to the write down in the value of our investment in Marco Hi-Tech JV, Ltd.

Income taxes. Provision for income taxes for the three months ended June 30, 2004 was $16,409,000, compared to $1,176,000 for the three months ended June 30, 2003. The increase in provision for income taxes was primarily attributable to the $16,272,000 valuation allowance that we recorded against our deferred income tax assets in the second quarter of 2004 to reflect the uncertainty of our being able to fully realize our deferred income tax benefits against future income, based upon our current business outlook and the change in our strategic direction.

Liquidity and Capital Resources

Our working capital at June 30, 2004 was $23,106,000, compared to $38,913,000 at December 31, 2003.

Our 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 and other financing activities. We expect that cash flow in the near future will be primarily determined by the levels of our net income, working capital requirements and financings, if any, that we may undertake. Net cash increased by $3,802,000 in the six months ended June 30, 2004.

Net cash provided by operating activities was $8,651,000 in the six months ended June 30, 2004, compared to $11,569,000 in the six months ended June 30, 2003. Net loss was $30,626,000 in the six months ended June 30, 2004, compared to net income of $5,495,000 in the six months ended June 30, 2003. In the six months ended June 30, 2004, net cash provided by operating activities was greater than our net loss principally as a result of the non-cash effect on net income of the $16,272,000 provision for income tax that we recorded in connection with the corresponding valuation allowance against our U.S. deferred tax assets. Net cash provided by operating activities also differed from our net loss in the first half of 2004 because of a decrease in accounts receivable of $19,366,000, depreciation and amortization of $3,297,000, amortization of intangible assets associated with acquisition of $2,025,000 and the $1,000,000 write down in the value of our investment in Marco Hi-Tech JV, Ltd., partially offset by a decrease in accounts payable of $2,295,000. The decrease in accounts receivable in the six months ended June 30, 2004 is attributable principally to the decrease in product sales in the second quarter of 2004 and to the collection of accounts receivable that were outstanding as of December 31, 2003. The provisions for product returns that we recorded in the first half of 2004 accounted for $4,691,000 of the decrease in accounts receivable since December 31, 2003.

Net cash used in investing activities was $2,498,000 in the six months ended June 30, 2004, compared to $3,253,000 in the six months ended June 30, 2003. Net cash used in investing activities included capital expenditures of $1,779,000 in the first half of 2004 and $4,104,000 in the first half of 2003. We incurred these capital expenditures in the first half of 2004 primarily for the upgrade of Rosemont s manufacturing facility and in the first half of 2003 primarily for the construction of the Be er Tuvia facility.

Net cash used in financing activities was $2,567,000 in the six months ended June 30, 2004, compared to $1,711,000 in the six months ended June 30, 2003. These amounts primarily reflected repayment of $3,534,000 of debt in the first half of 2004 and $2,470,000 in the first half of 2003, in each case partially offset by net proceeds from our issuance of common stock primarily pursuant to our employee stock purchase plan.

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In June 2000 BTG-Israel entered into a $20,000,000 credit facility with Bank Hapoalim B.M. to finance a portion of the costs of completing the construction of our Be er Tuvia manufacturing facility. Loans under the credit facility bear interest at the rate of LIBOR plus 1%. The credit facility is secured by the assets of BTG-Israel and is guaranteed by us. At June 30, 2004, we had outstanding borrowings of $8,889,000 under the credit facility, of which $3,333,000 is due during the remainder of 2004 and the remaining $5,556,000 is due in 2005. Borrowings are repaid monthly in equal installments.

In June 2003, Rosemont commenced an upgrade of its manufacturing facility in order to obtain FDA approval to enable Rosemont to manufacture oral liquid pharmaceutical products for supply into the U.S. market. We estimated the total capital cost for this project to be approximately $2,000,000. We expended approximately $1,900,000 of this amount through June 30, 2004, including approximately $300,000 in the three months ended June 30, 2004. At June 30, 2004, we had committed approximately $100,000 in additional expenditures that we expect to make during the remainder of 2004.

We believe that our cash resources as of June 30, 2004, together with anticipated product sales and anticipated proceeds from the divestiture of our operations in Israel, will be sufficient to fund our ongoing operations and debt service obligations for the foreseeable future. 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:

- our ability to divest our operations in Israel on attractive terms or at all;
- 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 Prosaptide and Puricase;
- the timing of, and the costs involved in, obtaining regulatory approvals, including regulatory approvals for Prosaptide, Puricase and any other product candidates that we may seek to develop in the future and regulatory approval to enable Rosemont to manufacture oral liquid pharmaceutical products for supply into the U.S. market;
- 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.

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If we are required to seek additional funding for our operations, we cannot assure you that we will be able to obtain additional funds or, if such funds are available, that such funding will be on favorable terms. We continue to seek additional collaborative research and development and licensing arrangements in order to provide revenue from sales of certain products and funding for a portion of the research and development expenses relating to the products covered. However, we cannot assure you that we will be able to enter into any such agreements.

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RISK FACTORS THAT MAY AFFECT RESULTS

You should carefully consider the risks and uncertainties described below. If any of the following risks or uncertainties actually occurs, our business, prospects, financial condition and operating results would likely suffer, possibly materially.

Risks Relating to our New Strategic Direction

We are repositioning our company to focus on product development, including an enhanced focus on the clinical development of Prosaptide and Puricase, our two product candidates currently in Phase 2 clinical trials. If we are unable to commercialize either or both of these product candidates, or 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.

In July 2004, we announced a change in our strategic business plan to reposition our company to focus on the full development of our pipeline products. This will include an enhanced focus on the clinical development of Prosaptide and Puricase, our two product candidates currently in Phase 2 clinical trials, and an active in-licensing program to access and develop novel compounds in clinical stage development.

Our ability to commercialize Prosaptide, Puricase and any other product candidate that we may develop in the future will depend on several factors, including:

- successfully completing pre-clinical studies and clinical trials;
- receiving marking 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.

In July 2003 we commenced a Phase 2(b) clinical trial of Prosaptide in patients with HIV-associated peripheral neuropathy to supplement the findings of a previous Phase 2 clinical trial. We currently expect to complete this Phase 2(b) clinical trial in early-2005. In February 2004 we initiated a Phase 2 clinical trial of Puricase, which we anticipate will be completed in late 2004. We cannot assure you that either of these clinical trails will be successful. Even if these trials are successful, we will be required to conduct additional clinical trials before a New Drug Application, or NDA, can be filed with the FDA for marketing approval of these product candidates. Clinical testing is expensive, 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 Prosaptide or Puricase, 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;

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- 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 or post-approval commitments that render the product not commercially viable; 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 planned clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant delays in clinical trial delays 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 new strategic focus includes an in-licensing program to access and develop novel compounds in clinical stage development. We may not be successful in our efforts to expand our portfolio of products in this manner.

As part of the change in our strategic business plan, we announced that we intend to concentrate on an active in-licensing program to access and develop novel compounds in clinical stage development. To date, we have had limited success in in-licensing compounds, and we may continue to have difficulty in this area for a number of reasons. In particular, the licensing and acquisition of pharmaceutical products is a competitive area. Numerous companies are also pursuing strategies to license 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 licensing or otherwise acquiring suitable product candidates include the following:

- we may be unable to identify suitable products or product candidates within our areas of expertise;

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- 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 will suffer.

The divestiture of our operations in Israel will be complex, time-consuming and expensive, and may disrupt or distract our management and other employees. If we are unable to divest these operations on favorable terms, we may not achieve the expected benefits of our new strategic direction.

Also as part of the change in our strategic business plan, we announced that we are exploring strategic options for the divestiture of our operations in Israel, including our Bio-Technology General (Israel) Ltd. subsidiary. We believe that this divestiture would provide the incremental resources required to fund the advancement of our drug development programs. However, divestiture of our operations in Israel will be complex, time-consuming and expensive, and may disrupt or distract our management and other employees. We may not be able to sell our Israeli operations for an attractive price or at all. This divestiture could involve substantial transaction costs and we may not ultimately achieve expected benefits and cost reductions.

Risks Related to Our Business

A significant portion of our revenues is represented by sales of Oxandrin. Sales of Oxandrin have declined substantially during the first six months of 2004 as compared to 2003. Oxandrin may begin facing generic competition as early as the third quarter of 2004, which would likely cause a significant further decrease in Oxandrin sales.

Sales of Oxandrin for the first six months of 2004 amounted to $18.6 million, representing approximately 40% of our total product sales for that period. Sales of Oxandrin amounted to $57.6 million in 2003, representing 46% of total product sales, $45.9 million in 2002 representing 48% of total product sales, and $47.2 million in 2001 representing 54% of total product sales. Several companies have filed drug master files with the FDA relating to a generic drug with the same active pharmaceutical ingredient as Oxandrin. While we cannot predict when generic competition for Oxandrin will begin, it is possible that the FDA may approve one or more generic versions of Oxandrin as early as the third quarter of 2004. The introduction of these generic products would likely 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.

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

We make a significant portion of our sales of Oxandrin in the United States to 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. We believe that Oxandrin sales in the second quarter of 2004 were negatively affected by reduced purchases by wholesalers as they reduced their inventory levels. 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.

Our results of operations have been adversely affected by recent returns of Oxandrin. Future returns of Oxandrin or other products could also affect our results of operations.

In the first half of 2004, we experienced returns of expiring Oxandrin for the first time. Accordingly, our revenues from Oxandrin sales were reduced by approximately $3.7 million as a result of sales return allowances that we recorded in the first six months of 2004. In addition, as a result of our recent returns experience, we recorded an additional provision for future returns of approximately $1.0 million in the second quarter of 2004. We will continue to monitor our products to assure that future reserves for returns are provided as appropriate. Future product returns in excess of our reserves would reduce our revenues and adversely affect our results of operations.

We will need substantial capital to develop and commercialize products, and we may be unable to obtain additional 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 products requires substantial funds. In addition, we may require cash to acquire new product candidates. In recent periods, we have satisfied our cash requirements primarily through product sales. Historically, we have also obtained capital through:

- funding of projects through collaborative research and development arrangements;
- contract fees;
- government of Israel funding of a portion of research and development projects, mainly through the office of the Chief Scientist of the Ministry of Industry and Trade; and
- equity and debt financings.

We cannot assure you that these financing alternatives will be available in the future to satisfy our cash requirements. We have applied to the Office of the Chief Scientist for funding of a portion of our research and development activities, but we cannot assure you that the Chief Scientist will continue to provide funding to us. If we are successful in divesting our operations in Israel, future funding from the Office of the Chief Scientist would not be available to us.

We expect that the repositioning of our company will require significant additional capital resources. Although we believe that a divestiture of our Israeli operations on favorable terms would provide the incremental resources required to fund the advancement of our drug development programs, these goals may not be achieved due to unexpected events or our failure to achieve our goals, including as a result of:

- our ability to divest our operations in Israel on attractive terms or at all;

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- 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 Prosaptide and Puricase;
- the timing of, and the costs involved in, obtaining regulatory approvals, including regulatory approvals for Prosaptide, Puricase and any other product candidates that we may seek to develop in the future and regulatory approval to enable Rosemont to manufacture oral liquid pharmaceutical products for supply into the U.S. market;
- 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.

We cannot assure you that we will be able to obtain additional funds or, if such funds are available, that such funding will be on favorable 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 arrangements with collaborative partners or others on less favorable terms than might otherwise be available.

We operate in a highly competitive market. Our competitors may develop alternative technologies 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 products in development becoming obsolete before we can begin marketing these products 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 in December 1995 through December 2000, a significant portion of Oxandrin sales has been for treatment of patients suffering from AIDS-related weight loss. These patients need for Oxandrin may decrease as a result of the development of more effective treatments, such as protease inhibitors. In fact, since January 2001, growth in the AIDS-related weight loss market has slowed substantially. As a result, we are working to expand the use of Oxandrin to treat involuntary weight loss associated with other conditions, such as cancer, burns, non-healing wounds and chronic obstructive pulmonary disease. However, we may not be successful in our efforts.

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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. 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. Significant competitive factors include:

- capabilities of our collaborators;
- product safety and efficacy;
- timing and scope of regulatory approval;
- product availability;
- marketing and sales capabilities;
- reimbursement coverage from insurance companies and others;
- the amount of clinical benefit of our product candidates relative to their cost;
- the method of administering a product;
- price; and
- patent protection.

Our competitors may develop 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 many of 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 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 may be unable to manufacture our products in a manner necessary to fulfill demand. Our inability to fulfill demand may permit our licensees and distributors to terminate their agreements, seek alternate suppliers or manufacture the products themselves.

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Further, we depend on third parties for the supply of many of our products. The divestiture of our operations in Israel will likely increase our reliance on third parties for the supply of our products. Failure of any third party to meet applicable regulatory requirement may adversely affect our profit margins or result in unforeseen delays or other problems beyond our control. For example, in July 2001, Bristol-Myers Squibb Company ceased manufacturing Delatestryl for us when it closed the manufacturing facility at which it produced Delatestryl. 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 nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Additional delays or difficulties with our third-party suppliers could significantly delay the manufacture of one or more of our products. If that occurs, we may have to seek alternative sources of supply, which we may not be able to obtain at commercially acceptable rates, if at all. If we cannot enter into alternative supply arrangements, we may have to abandon or sell product lines on unsatisfactory terms. Any of the foregoing 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, or cGMP, and comparable requirements of foreign regulatory bodies. For example, Rosemont is currently upgrading its manufacturing facility to obtain FDA approval, so that it can sell oral liquid formulations in the United States. Similarly, the FDA must approve our Be er Tuvia manufacturing facility before we can sell products manufactured in that facility in the United States. 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 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 were 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.

In October 2003 the FDA issued an approvable letter with respect to Savient HA for the treatment of pain associated with osteoarthritis of the knee. The FDA stated in the letter that final FDA approval was subject to satisfactory inspection of our new manufacturing facility in Israel and finalization of product labeling. In December 2003 we filed with the FDA an amendment to our pre-market approval application, detailing Savient HA manufacture in our new facility. The FDA inspection, which is a prerequisite to obtaining final FDA approval to market Savient HA in the United States, has recently taken place. We expect a final determination from the FDA within the next few months. If we do not receive regulatory approval for the Be er Tuvia facility, we would likely be unable to meet the anticipated increased demand for our products.

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During 2003 we transferred BioLon and Savient HA manufacturing to the Be er Tuvia facility. We expect to transfer human growth hormone manufacturing operations to the Be er Tuvia facility in 2004 or 2005 and file for regulatory approval for the transfer during 2005. The manufacture of each product at the Be er Tuvia facility must be approved by applicable regulatory authorities, including the FDA for products shipped to the U.S., prior to the resumption of manufacturing of that product at the Be er Tuvia facility. Prior to transferring the manufacturing for each product to the Be er Tuvia facility, we plan to build inventory of such product that we believe will be adequate to meet demand over the period required to transfer the manufacturing operations and have them inspected and approved. If it takes longer than expected to complete the transfer or obtain regulatory approval or demand for our product exceeds our expectations, our ability to meet our customers requirements for their products will be adversely affected.

We have limited marketing capability and experience and rely on third parties to market many of our products. If these third parties do not meet our performance expectations, our sales may be adversely affected.

We depend on third-party licensees to distribute and market many of our products, including Bio-Tropin, Biolon, Mircette, Silkis, Bio-Hep-B, and our sodium hyaluronate osteoarthritis and insulin products. The success of these arrangements depends on each licensee s own financial, competitive, marketing and strategic considerations, which include the relative advantages, including patent and proprietary positions, of alternate products being marketed or developed by others. Furthermore, the amounts of any payments to be received by us under our license agreements from sales of product by licensees will depend on the extent to which our licensees devote resources to the development and commercialization of the products. Although we believe that our licensees have an economic motivation to commercialize their products, we have no effective control over the licensees commercialization efforts.

We established a sales and marketing force in the United States during the second half of 1995 to promote distribution of Oxandrin and our other products in the United States. Our Rosemont subsidiary has a sales force that markets Rosemont s products in the United Kingdom. In Israel, we maintain a small sales force to market our products in the Israeli market. In all other territories, we do not yet have an established sales force and rely on third parties to market our products.

Turnover in our sales and marketing employees adversely affects our product sales, as it can take several months to find and train new sales and marketing employees. Competition for experienced sales and marketing employees is intense, and we compete with companies with greater resources and larger product lines. During 2003 we experienced significant difficulty in maintaining our sales and marketing force in the United States as a result of a number of factors, including the limited number of products we market in the United States, the expected introduction of generic versions of Oxandrin, our inability to in-license additional products for our sales and marketing team to sell and the uncertainty created by the proposed acquisition of us by Teva Pharmaceutical Industries Ltd. As a result, in November 2003, we engaged a contract sales organization to fill territories for which we had lost and could not replace sales and marketing employees. The successful marketing of our products will be dependent on the efforts of this contract sales organization, over which we will have little or no control.

The Ross Products Division of Abbott Laboratories, or Ross, markets Oxandrin under a co-promotion agreement with us for the treatment of weight loss by residents of long-term care facilities. According to IMS Health data, the long-term care market represented approximately 16% of Oxandrin wholesaler to end-user sales in 2003, and 14% in each of 2001 and 2002. Prescriptions in the long-term care market decreased by 16.4% in 2003 compared to 2002. Since January 1, 2004, prescriptions in the long-term care market have not further decreased. To date, the average prescription written for the long-term care market involves a lower dose of Oxandrin than the average prescription written for the AIDS market. As a result, the rate of growth in Oxandrin sales may be less than the rate of growth in prescriptions. Ross has the right to terminate our Oxandrin co-promotion agreement at any time upon six months notice. If Ross elects to do so, our Oxandrin sales could be adversely affected until we are able to replace the Ross sales force. However, we may not be able to do so successfully.

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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 new 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, if the results of our ongoing Phase 2 clinical trial for Prosaptide are favorable, we may seek a collaborator in the commercialization of the product candidate, rather than continue to develop it on our own. We may also seek a collaborator for Puricase.

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. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of our products to reach their potential could be limited if our collaborators decrease or fail to increase marketing or spending efforts related to the products that are the subject of the collaborations.

- We may rely on our collaborators to manufacture the products covered by our alliances.

- In a strategic alliance agreement, we may be required to agree not to conduct specified types of research and development in the field that is the subject of the alliance. As a result, our agreements may have the effect of limiting the areas of research, development and commercialization that we may pursue, either alone or in collaboration with third parties.

- 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.

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 will 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 recently enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug and Modernization Act of 2003. While the program established by this statute may increase demand for our products, if we participate in this program our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain. 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.

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A primary trend in the United States 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 12 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.

Beginning in the second quarter of 2003, three states with budget crises 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, which has adversely affected and is expected to continue to adversely affect sales of Oxandrin in those states. Efforts and discussions are ongoing with these state agencies to reverse these recent 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.

We have recently made significant changes in our senior management team. 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.

We have recently made significant changes in our senior management team. On July 13, 2004, Christopher Clement, who had been our president and chief operating officer, became our president and chief executive officer. On May 28, 2004, Philip K. Yachmetz joined us as senior vice president and general counsel. Since January 5, 2004, Alan Rubinfeld has served as acting chief financial officer. We expect to announce our hiring of a permanent chief financial officer soon. Our success will depend in part on our ability to attract, retain and motivate highly qualified personnel and to 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 scientists with expertise in the areas of our activities. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations execute on our business plan. We generally do not enter into employment agreements with any of our scientific personnel. In addition, we do not maintain, and have no current intention of obtaining, key man life insurance on any of our employees.

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

We significantly expanded our international operations with the acquisition of Rosemont on September 30, 2002. Our product sales outside the United States accounted for approximately 52% of our total product sales for the first six months of 2004 and 44% of our total product sales in 2003. Because we sell our products worldwide, our businesses are subject to risks associated with doing business internationally, including:

- difficulties in staffing and managing foreign operations;
- changes in a country s or region s political or economic conditions;
- 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.

Our business may be adversely affected by developments in Israel.

We currently conduct significant research, development and biologics production activities in Israel. These activities are 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 its Arab neighbors. These hostilities have caused security and economic problems in Israel. In addition, since October 2000, there has been a significant increase in violence, primarily in the West Bank and Gaza Strip. During the course of military operations, Israel s military reserves, which include a number of our employees and executives, may be called up, which could adversely affect our ability to conduct our business.

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Any major hostilities involving Israel could adversely affect our research, development and production operations. Ongoing or revived hostilities related to Israel could adversely affect us. For example, from the fourth quarter of 2001 until September 2002, we were required to stop U.S. shipments of BioLon sterilized by our Israeli contractor because the FDA was unable to inspect the new manufacturing facility of this contractor as a result of the violence in Israel at the time. Additionally, in recent years the FDA has from time to time suspended inspections of manufacturing facilities in Israel as a result of violence in Israel. For example, the FDA cancelled its scheduled April 2003 visit to Israel in light of the then existing situation with Iraq. Any such action could delay FDA inspection of the Be er Tuvia facility and, therefore, use of such facility to manufacture products for the U.S. market.

As discussed elsewhere in these risk factors, we are currently exploring strategic options for the divestiture of our operations in Israel. The risks associated with owning operations in Israel may reduce the number of prospective buyers for our operations in Israel, and could adversely affect the price we would receive in a divestiture.

We may incur substantial 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 pose a material risk. Although we have so far been able to obtain indemnification from pharmaceutical companies commercializing our products, other companies with which we collaborate may not agree to do so. Furthermore, the companies that agree to these indemnification obligations may not have adequate financial resources to satisfy their obligation.

To the extent we elect to test or market products independently, we will bear the risk of product liability directly. We currently have $20 million of product liability insurance coverage in place. We cannot assure you that we will 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 merits, 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 current and former officers were named in a series of similar purported securities class action lawsuits. The complaints in theses actions allege violations of U.S. securities law through alleged material misrepresentations and omissions and seek an unspecified award of damages.

In addition, members of our board of directors prior to June 2003 and Arthur Andersen LLP, our prior auditor, were named in derivative actions that claimed, among other things, that our directors breached their fiduciary duties by failing to implement and maintain an adequate internal accounting control system. While these derivative suits were dismissed by the court, we have received a letter on behalf of a purported shareholder demanding that we commence an action against most of our directors, certain former directors, Arthur Andersen and others who were responsible for the actions that resulted in the restatement of our financial statements. A special committee of our board of directors, consisting of directors who were not directors prior to our June 2003 annual meeting of stockholders, has investigated this demand and has determined that litigation relating to this matter should not proceed.

We intend to contest the pending securities actions against us vigorously. However, an adverse decision in these cases could adversely affect us financially. We have referred these claims to our directors and officers insurance carrier, which has reserved its rights as to coverage with respect to these actions.

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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, it will adversely affect our business.

Our research, 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.

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There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology 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 United States Patent and Trademark Office and opposition proceedings in the European 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.

We currently are, and in the future 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 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 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 are currently a party to several lawsuits and disputes regarding intellectual property, including:

- with Genentech, relating to human growth hormone in Israel;
- with Genentech, relating to human growth hormone in Japan;
- with Biogen, relating to our hepatitis-B vaccine in Singapore; and
- with Barr Laboratories, relating to Mircette in the United States.

These lawsuits, which are described in greater detail in our Annual Report on Form 10-K for the year ended December 31, 2003 in the section titled Item 3. Legal Proceedings , have diverted, and are expected to continue to divert, the efforts and attention of our key management and technical personnel. We have incurred, and expect to continue to incur, substantial legal fees and expenses in connection with these lawsuits. As a result, these lawsuits, regardless of their eventual outcomes, have been, and will continue to be, costly and time-consuming. Furthermore, 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

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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. 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 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.

Failure to obtain 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.

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. To date, the length of time required to obtain regulatory approval of genetically engineered products has been significantly longer than expected, both for us and the biotechnology industry in general. We believe that these delays have in the past negatively impacted our ability to attract funding and that, as a result, the terms of such financings have been less favorable to us than they might otherwise have been had our product revenues provided sufficient funds to finance the large costs of taking a product from discovery through commercialization. As a result, we have had to license the commercialization of many of our products to third parties in exchange for research funding and royalties on product sales, resulting in lower revenues than if we had commercialized the products on our own.

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 cannot assure you that we or our employees have been or will 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.

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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. The market price of our common stock may be influenced 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 would a less volatile stock. 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 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 biopharmaceutical 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.

Future exercises of outstanding stock options or the issuance of shares in acquisitions or other transactions could lead to sales of our common stock and adversely reduce the market price of our common stock.

The market price of our common stock could be adversely affected by future exercises of outstanding stock options and the issuance of common stock in acquisitions of businesses, products or other technologies. At June 30, 2004 options to purchase an aggregate of approximately 8,300,000 shares of common stock were outstanding. A portion of these options have exercise prices below the current market price of the common stock. Shares of common stock issuable upon exercise of these outstanding options will be freely tradable without restriction, unless held by one of our affiliates. The sale of a significant amount of these shares at one time could adversely affect the market price of our common stock.

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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;
- 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 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. For example, in 1999, the first five months of 2000 and the second half of 2001, our revenues and earnings were adversely affected by Accredo s decision to reduce the amount of Oxandrin inventory it carried. We also expect our revenues and earnings to be adversely affected once 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;

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- 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 4,000,000 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 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 obligations under our credit facility bear interest at floating rates. Therefore, changes in prevailing interest rates affect our interest expense. As of June 30, 2004, the outstanding principal amount of our credit facility was $8,889,000. A 100 basis point increase in market interest rates would result in an increase to our annual interest expense of $89,000 before giving effect to required monthly principal payments.

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 interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates, and other market conditions.

As a result of our operations in Israel and the United Kingdom, we are subject to currency exchange rate fluctuations that can affect our results of operations. Our results of operations in the second half of 2003 and the first half of 2004 benefited from the decrease in value of the U.S. dollar relative to the British pound sterling and to the euro. We manage our Israeli operations with the objective of protecting against any material net financial loss from the effects of Israeli inflation and currency devaluations on our non-U.S. dollar assets and liabilities, as measured in U.S. dollars. The cost of our operations in Israel, as expressed in U.S. dollars, is influenced by the extent to which any increase in the rate of inflation in Israel is not offset, or is offset on a lagging basis, by a devaluation of the Israeli Shekel relative to the U.S. dollar. To date, BTG-Israel s revenues, as measured in Shekels, have consisted primarily of research funding from the Office of the Chief Scientist of the State of Israel, as well as product sales in Israel. To the extent that BTG-Israel s expenses as measured in Shekels exceed its revenues in Shekels, devaluations of the Shekel have been and will continue to be a benefit to our financial condition. However, should BTG-Israel s revenues in Shekels exceed its expenses in Shekels in any material respect, the devaluation of the Shekel will adversely affect our financial condition. Furthermore, to the extent the devaluation of the Shekel relative to the U.S. dollar does not substantially offset the increase in the costs of local goods and services in Israel, our financial results will be adversely affected as local expenses measured in U.S. dollars will increase.

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Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2004. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that as of June 30, 2004, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our chief executive officer and chief financial officer by others, particularly during the period in which this report was prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

During the course of their review of the financial information included in this Quarterly Report on Form 10-Q, Grant Thornton LLP, our independent auditors, informed our management and our audit committee that they identified deficiencies in our internal controls relating to our communication with and supervision of our accounting staff at our Israeli subsidiary, Bio-Technology General (Israel) Ltd. These deficiencies were identified in connection with the manner in which the accounting staff at our Israeli subsidiary accounted for inter-company revenues and costs of good sold during the second quarter of 2004. Grant Thornton has informed us that they believe that these deficiencies constitute a material weakness in our internal controls. However, we have no reason to believe that this weakness resulted in any material inaccuracies to our financial statements in that the transaction in question has been properly accounted for in the financial statements included in this report.

In response to this situation, we are implementing the following steps to remediate this weakness in our internal controls:

- prohibiting the accounting staff of our subsidiaries to change accounting policies or methodologies without prior review and approval from our chief financial officer;

- requiring the accounting staff at each of our subsidiaries to prepare a standardized financial reporting package that must be prepared and provided to us as part of the process of closing financial records at the end of each quarter; and

- causing the appropriate members of our financial reporting staff to visit with the accounting staff of each of our subsidiaries to ensure proper education and compliance with these new policies.

We believe that the successful implementation of these steps will adequately address the deficiencies in our controls that were identified by our independent auditors. We expect that these measures will be implemented prior to the commencement of the financial records closing process and preparation of our financial statements for quarter ending September 30, 2004.

No other changes 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 June 30, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For a discussion of legal proceedings to which we are a party or are subject, see our Annual Report on Form 10-K for the year ended December 31, 2003 in the section titled Item 3. Legal Proceedings.

On August 3, 2004, the United States District Court for the District of Delaware found in our favor in our litigations with Novo Nordisk. The court found Novo Nordisk s patent relating to human growth hormone in the United States invalid and unenforceable due to inequitable conduct by Novo Nordisk. As a result of this ruling, we expect Teva Pharmaceutical Industries Ltd. to bring our human growth hormone product to market in the United States later this year. We currently have an agreement with Teva granting Teva exclusive marketing rights for our human growth hormone product in the United States, under the brand name Tev-Tropin.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

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

(b) Reports on Form 8-K

The following Current Reports on Form 8-K were filed or furnished by us during the three months ended June 30, 2004.

1. We furnished a Current Report on Form 8-K with the Securities and Exchange Commission on May 4, 2004, pursuant to Item 12, containing a press release we issued on May 4, 2004 to report our financial results for the three months ended March 31, 2004.

2. We filed a Current Report on Form 8-K with the Securities and Exchange Commission on May 21, 2004, pursuant to Item 5, that on May 21, 2004, we issued a press release.

3. We furnished a Current Report on Form 8-K with the Securities and Exchange Commission on June 17, 2004, pursuant to Item 9, containing information regarding a retirement payment to our former Chairman and Chief Executive Officer.

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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)

/s/ Alan Rubinfeld

Alan Rubinfeld
Acting Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Dated: August 9, 2004

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EXHIBIT INDEX

Exhibit No.	Description
3.1	Certificate of Incorporation, as amended (1)
3.2	By-laws, as amended (2)
10.1	Employment agreement dated May 28, 2004, between Philip K. Yachmetz and the Registrant.
10.2	Amendment dated June 6, 2004 to employment letter dated December 23, 2003, between Alan J. Rubinfeld and the Registrant.
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

(1) Incorporated by reference from the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 1994.

(2) Incorporated by reference from the Registrant s Current Report on Form 8-K, dated October 7, 1998.