SAVIENT PHARMACEUTICALS INC
Form 10-Q
August 10, 2009

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

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2009
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, 14th Floor, 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 S NO £

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES £ NO £

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

Large accelerated filer S	Accelerated filer £	Non-accelerated filer £ (Do not check if a smaller reporting company)	Smaller reporting company £

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

The number of shares outstanding of the issuers Common Stock, par value $.01 per share, as of August 10, 2009 was 61,621,985.

SAVIENT PHARMACEUTICALS, INC.

FORM 10-Q
FOR THE THREE MONTHS ENDED JUNE 30, 2009

TABLE OF CONTENTS

		Page
PART I FINANCIAL INFORMATION		
Item 1.	Financial Statements:	3
	Consolidated Balance Sheets	3
	Consolidated Statements of Operations	4
	Consolidated Statement of Changes in Stockholders Equity	5
	Consolidated Statements of Cash Flows	6
	Notes to Consolidated Financial Statements	7
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	29
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	44
Item 4.	Controls and Procedures	44
PART II OTHER INFORMATION		
Item 1.	Legal Proceedings	45
Item 1A.	Risk Factors	46
Item 4.	Submission of Matters to a Vote of Security Holders	66
Item 6.	Exhibits	66
	Signatures	67
	Exhibit Index	68

PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share data)

	June 30, 2009	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 74,749	$ 76,315
Short-term investments (including restricted investments)	1,806	2,282
Accounts receivable, net	798	822
Inventories, net	1,240	1,892
Recoverable income taxes		5,526
Prepaid expenses and other current assets	3,055	2,782
Total current assets	81,648	89,619
Deferred income taxes, net	4,801	4,200
Property and equipment, net	1,163	1,393
Other assets (including restricted cash and investments)	2,100	3,010
Total assets	$ 89,712	$ 98,222
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 3,001	$ 5,888
Deferred revenues	249	451
Warrant liability	48,442	
Other current liabilities	16,406	18,650
Total current liabilities	68,098	24,989
Other liabilities	10,712	9,809
Commitments and contingencies		
Stockholders Equity:		
Preferred stock $.01 par value 4,000,000 shares authorized; no shares issued		
Common stock $.01 par value 150,000,000 shares authorized; 61,376,000 issued and outstanding at June 30, 2009 and 54,654,000 shares issued and outstanding at December 31, 2008	613	547
Additional paid-in-capital	238,201	214,467
Accumulated deficit	(228,372)	(151,614)

Accumulated other comprehensive income		460		24
Total stockholders equity		10,902		63,424
Total liabilities and stockholders equity	$	89,712	$	98,222

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

SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenues:				
Product sales, net	$ 679	$ 315	$ 1,764	$ 1,459
Other revenues	1	38	4	82
	680	353	1,768	1,541
Cost and expenses:				
Cost of goods sold	372	219	863	552
Research and development	11,638	15,726	24,401	26,887
Selling, general and administrative	7,397	10,450	16,865	19,714
	19,407	26,395	42,129	47,153
Operating loss	(18,727)	(26,042)	(40,361)	(45,612)
Investment income (expense), net	(27)	411	(229)	1,364
Other expense, net	(36,055)	(162)	(36,168)	(312)
Loss before income taxes	(54,809)	(25,793)	(76,758)	(44,560)
Income tax benefit		(1,595)		(2,810)
Net loss	$ (54,809)	$ (24,198)	$ (76,758)	$ (41,750)
Loss per common share:				
Basic and diluted	$ (0.92)	$ (0.45)	$ (1.35)	$ (0.78)
Weighted-average number of common and common equivalent shares:				
Basic and diluted	59,594	53,542	56,804	53,409

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

SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS EQUITY
(Unaudited)
(In thousands)

	Common Stock				Accumulated Other	
	Shares	Par Value	Additional Paid-in-Capital	Accumulated Deficit	Comprehensive Income	Total Stockhold Equit
Balance, December 31, 2008	54,654	$ 547	$ 214,467	$ (151,614)	$ 24	$ 63,4
Comprehensive loss:						
Net loss				(76,758)		(76,7
Unrealized gain on marketable securities, net					436	4
Total comprehensive loss						(76,3
Restricted stock grants	446	4	(4)			
Amortization of deferred compensation			1,449			1,4
Forfeitures of restricted stock grants	(331)	(3)	3			
Issuance of common stock	67		252			2
Issuance of common stock for cash on registered direct offering, net of expenses	5,927	59	28,960			29,0
Issuance of warrants in connection with registered direct offering, net of expenses			(12,561)			(12,5
ESPP compensation expense			110			1
Stock option compensation			1,906			1,9

expense											
Exercise of stock options	613		6		3,619						3,6
Balance, June 30, 2009	61,376	$	613	$	238,201	$	(228,372)	$	460	$	10,9

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

SAVIENT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2009	**2008**
Cash flows from operating activities:		
Net loss	$ (76,758)	$ (41,750)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	237	223
Deferred income taxes	(601)	
Unrecognized tax benefit liability	(629)	148
Net realized losses	298	83
Change in valuation of warrant liability	35,881	
Amortization of deferred compensation related to restricted stock (including restricted stock awards that contain performance conditions)	1,449	2,583
Stock option and ESPP compensation expense	2,016	2,080
Changes in:		
Accounts receivable, net	24	799
Inventories, net	652	306
Recoverable income taxes	5,526	5,934
Prepaid expenses and other current assets	(273)	128
Accounts payable	(2,887)	(864)
Income taxes payable		(2)
Other current liabilities	(679)	7,066
Deferred revenues	(202)	(422)
Net cash used in operating activities	(35,946)	(23,688)
Cash flows from investing activities:		
Proceeds from sale of Delatestryl		644
Purchases of available-for-sale securities (restricted)	(22)	(205)
Proceeds from sale of available-for-sale securities (restricted)	1,541	8,835
Proceeds from sales of available-for-sale securities		131
Capital expenditures	(7)	(261)
Changes in other long-term assets	5	(30)
Net cash provided by investing activities	1,517	9,114
Cash flows from financing activities:		
Proceeds from issuance of common stock	3,877	2,263

Proceeds from issuance of common stock for cash on registered direct offering, net of expenses		29,019		
Changes in other long-term liabilities		(33)		(29)
Net cash provided by financing activities		32,863		2,234
Net decrease in cash and cash equivalents		(1,566)		(12,340)
Cash and cash equivalents at beginning of period		76,315		124,865
Cash and cash equivalents at end of period	$	74,749	$	112,525
Supplementary Information				
Other information:				
Income tax paid	$	1,237	$	44
Interest paid	$	345	$	16

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

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 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 (GAAP) 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 Savient Pharmaceuticals, Inc. s (Savient or the Company) financial position at June 30, 2009, the results of its operations for the three and six months ended June 30, 2009 and 2008 and cash flows for the six months ended June 30, 2009 and 2008. Interim financial statements are prepared on a basis consistent with the Company s annual financial statements. Results of operations for the three and six months ended June 30, 2009 are not necessarily indicative of the operating results that may be expected for the year ending December 31, 2009.

The consolidated balance sheet as of December 31, 2008 was derived from the audited financial statements at that date and does not include all of the information and notes required by GAAP in the United States of America for complete financial statements. The interim statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company s latest Annual Report on Form 10-K for the year ended December 31, 2008.

Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Savient Pharma Holdings, Inc. and Myelos Corporation. Certain prior period amounts have been reclassified to conform to current period presentations.

Use of estimates

The preparation of financial statements in conformity with GAAP in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Note 2 Summary of Significant Accounting Policies

In addition to the Company s significant accounting policies as set forth in the Company s Annual Report on Form 10-K for the year ended December 31, 2008, the following reflects a summary of material accounting policies that the Company has adopted as of June 30, 2009.

Derivative Instruments (Warrant Liability)

On April 8, 2009, the Company issued 5,927,343 shares of its common stock to existing and new institutional investors as part of a registered direct offering. The investors also received warrants to purchase up to 5,038,237 shares of the Company s common stock at an initial exercise price of $10.46 per share. The Company accounts for the warrants as a liability pursuant to the guidance provided in Emerging Issues Task Force (EITF) Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entities Own Stock,* EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock* and Statement of Financial Accounting Standards (SFAS) No. 133, *Accounting for Derivative Instruments and Hedging Activities.* SFAS No. 133 specifies that a contract that would otherwise meet the definition of a derivative under that Statement, issued or held by

the reporting entity that is both (a) indexed to its own stock and (b) classified in stockholders equity in its

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

statement of financial position, shall not be considered a derivative financial instrument for purposes of applying that Statement. EITF No. 07-05 provides a two-step method for determining whether an instrument is indexed to an entities own stock. Under the provisions of EITF No. 00-19, a contract designated as an asset or a liability must be carried at fair value until exercised or expired, with any changes in fair value recorded in results of operations. Also pursuant to EITF No. 00-19, the classification of a contract should be reassessed at each balance sheet date and should be reclassified as of the date of the event that caused the reclassification. There is no limit on the number of times a contract may be reclassified. If a contract is reclassified from permanent or temporary equity to an asset or a liability, the change in fair value of the contract during the period the contract was classified as equity should be accounted for as an adjustment to stockholders equity. If a contract is reclassified from an asset or a liability to equity, gains or losses recorded to account for the contract at fair value during the period that the contract was classified as an asset or a liability should not be reversed. The Company s warrant liability is marked-to-market each reporting period with the change in fair value recorded as a gain or loss within Other Expense, net on the Company s consolidated statement of operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified as an equity instrument. The fair value of the warrant liability is determined at each reporting period by utilizing a Monte Carlo simulation option pricing model that takes into account estimated probabilities of possible outcomes provided by the Company. See Note 10 to the Company s consolidated financial statements for further discussion of the warrants.

Note 3 Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued SFAS No. 168, *FASB Accounting Standards Codification (Codification)* as the single source of authoritative non-governmental United States GAAP to be launched on July 1, 2009. SFAS No. 168 replaces FASB Statement No. 162, *The Hierarchy of Generally Accepted Accounting Principles.* The Codification does not change current U.S. GAAP, but is intended to simplify user access to all authoritative U.S. GAAP by providing all the authoritative literature related to a particular topic in one place. All existing accounting standard documents will be superseded and all other accounting literature not included in the Codification will be considered non-authoritative. The Codification is effective for interim and annual periods ending after September 15, 2009. The Codification is for disclosure only and will not impact the Company s financial condition or results of operations. The Company is currently evaluating the impact to its financial reporting process of providing Codification references within its public filings.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events.* SFAS No. 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. SFAS No. 165 requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date and should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. SFAS No. 165 shall be applied to the accounting for and disclosure of subsequent events not addressed in other applicable GAAP. Other applicable GAAP may address the accounting treatment of events or transactions that occur after the balance sheet date but before the financial statements are issued. If an event or transaction is within the scope of other applicable GAAP, then an entity shall follow the guidance in that applicable GAAP, rather than the guidance in SFAS No. 165. SFAS No. 165 is effective for interim or annual financial periods ending after June 15, 2009, and is applied prospectively. The adoption of SFAS No. 165 did not have a material effect on the Company s recognition or disclosures in its consolidated financial statements. The Company evaluates all subsequent events as of the issuance date of its financial statements. The Company has evaluated subsequent events as of August 10, 2009, the date of filing

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

of the Company s report on this Form 10-Q. The Company has not evaluated subsequent events after such date.

In April 2009, FASB issued FASB Staff Position (FSP) SFAS No. 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly.* FSP SFAS No. 157-4 provides additional guidance for estimating fair value in accordance with SFAS No. 157, *Fair Value Measurements*, when the volume and level of activity for the asset or liability have significantly decreased. FSP SFAS No. 157-4 supersedes FSP SFAS No. 157-3. FSP No. 157-4 emphasizes that even if there has been a significant decrease in the volume and level of activity for the asset or liability and regardless of the valuation technique(s) used, the objective of a fair value measurement remains the same. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction (that is, not a forced liquidation or distressed sale) between market participants at the measurement date under current market conditions. The guidance included in FSP SFAS No. 157-4 addresses the recommendations of specific issues in the Securities and Exchange Commission s (SEC s) study on mark-to-market accounting and provides additional guidance on determining fair value when the volume and level of activity for the asset or liability has significantly decreased when compared with normal market activity for the asset or liability (or similar assets or liabilities). FSP SFAS No. 157-4 is effective for interim and annual reporting periods ending after June 15, 2009 and shall be applied prospectively. Early adoption is permitted for periods ending after March 15, 2009. Early adoption for periods ending before March 15, 2009 is not permitted. Additionally, if a reporting entity elects to adopt early, either FSP SFAS No. 115-2 and SFAS No. 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments,* or FSP No. 107-1 and Accounting Practice Bulletin (APB) No. 28-1, *Interim Disclosures about Fair Value of Financial Instruments,* the entity is also required to adopt early FSP SFAS No. 157-4. FSP SFAS No. 157-4 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP SFAS No. 157-4 requires comparative disclosures only for periods ending after initial adoption. The Company early adopted FSP SFAS No. 157-4 for the quarterly period ended March 31, 2009. The adoption of FSP SFAS No. 157-4 did not have a material effect on the Company s consolidated financial statements.

In April 2009, the FASB issued FSP SFAS No. 107-1 and APB No. 28-1, *Interim Disclosures about Fair Value of Financial Instruments.* FSP SFAS No. 107-1 and APB No. 28-1 amends SFAS No. 107, *Disclosures about Fair Value of Financial Instruments,* to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FSP SFAS No. 107-1 and APB No. 28-1 also amends APB Opinion No. 28, *Interim Financial Reporting,* to require those disclosures in summarized financial information at interim periods. FSP SFAS No. 107-1 and APB No. 28-1 is effective for interim and annual reporting periods ending after June 15, 2009 with early adoption permitted for periods ending after March 15, 2009. An entity may early adopt FSP SFAS No. 107-1 and APB No. 28-1 only if it also elects to early adopt FSP SFAS No. 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly* and FSP SFAS No. 115-2 and 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments.* FSP SFAS No. 107-1 and APB No. 28-1 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP SFAS No. 107-1 and APB No. 28-1 requires comparative disclosures only for periods ending after initial adoption. The Company early adopted FSP SFAS No. 107-1 and APB No. 28-1 for the quarterly period ended March 31, 2009. The adoption of FSP SFAS No. 107-1 and APB No. 28-1 did not have a material effect on the Company s consolidated financial statements.

In April 2009, the FASB issued FSP SFAS No. 115-2 and SFAS No. 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments.* FSP SFAS No. 115-2 and SFAS No. 124-2 amends the other-than-temporary impairment guidance in GAAP for debt securities to make the

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. FSP SFAS No. 115-2 and SFAS No. 124-2 does not amend existing recognition and measurement guidance related to other-than- temporary impairments of equity securities. FSP SFAS No. 115-2 and SFAS No. 124-2 expands and increases the frequency of existing disclosures about other-than-temporary impairments for debt and equity securities. It requires a more detailed, risk oriented breakdown by major security types and related information currently required by SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* In addition, FSP SFAS No. 115-2 and SFAS No. 124-2 requires that the annual disclosures in SFAS No. 115, and FSP SFAS No. 115-1 and SFAS No. 124-1, *The Meaning of Other- Than-Temporary Impairment and its Application to Certain Investments,* be made for interim periods. FSP SFAS No. 115-2 and SFAS No. 124-2 is effective for interim and annual reporting periods ending after June 15, 2009 with early adoption permitted for periods ending after March 15, 2009. Early adoption for periods ending before March 15, 2009, is not permitted. If an entity elects to adopt early either FSP SFAS No. 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly* or FSP SFAS No. 107-1 and APB No. 28-1, *Interim Disclosures about Fair Value of Financial Instruments,* the entity is also required to adopt early FSP SFAS No. 115-2 and SFAS No. 124-2. Additionally, if an entity elects to adopt early FSP SFAS No. 115-2 and SFAS No. 124-2, it is required to adopt FSP SFAS No. 157-4. FSP SFAS No. 115-2 and 124-2 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP SFAS No. 115-2 and 124-2 requires comparative disclosures only for periods ending after initial adoption. The Company early adopted FSP SFAS No. 115-2 and 124-2 for the quarterly period ended March, 2009. The adoption of FSP SFAS No. 115-2 and 124-2 did not have a material effect on the Company s consolidated financial statements.

In June 2008, the EITF ratified the consensus on Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entities Own Stock.* EITF No. 07-05 applies to any freestanding financial instrument or embedded feature that has all the characteristics of a derivative in paragraphs six through nine of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities,* for the purposes of determining whether that instrument or embedded feature qualifies for the first part of the scope exception in paragraph 11(a) of SFAS No. 133. EITF No. 07-05 also applies to any freestanding financial instrument that is potentially settled in an entities own stock, regardless of whether the instrument has all of the characteristics of a derivative in paragraphs six through nine of SFAS No. 133, for purposes of determining whether the instrument is within the scope of EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock.* In April 2009, the Company issued 5,927,343 shares of its common stock to existing and new institutional investors as part of a registered direct offering. The investors also received warrants to purchase up to 5,038,237 shares of its common stock at an initial exercise price of $10.46 per share. The Company accounts for these warrants as a liability pursuant to the guidance provided in EITF No. 07-05, EITF No. 00-19 and SFAS No. 133. The Company s warrant liability is marked-to- market each reporting period with the change in fair value recorded as a gain or loss within Other Expense, net on the Company s consolidated statement of operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified as an equity instrument. The value of the warrants are determined at each reporting period utilizing a Monte Carlo simulation option pricing model that takes into account estimated probabilities of possible outcomes provided by the Company. See Note 10 to the Company s consolidated financial statements for further discussion of the warrants.

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

Note 4 Fair Value of Financial Instruments and Investments

On January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements*, which clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. In February 2008, the FASB issued FSP SFAS No. 157-2 that deferred the effective date of SFAS No. 157 for one-year for non-financial assets and liabilities recorded at fair value on a non-recurring basis. In October 2008, the FASB issued FSP SFAS No. 157-3, which clarifies the application of SFAS No. 157 in a market that is not active. FSP SFAS No. 157-3 was effective for the Company during the fourth quarter of 2008, and the effect of adoption on the Company s financial position and results of operations was not material. In April 2009, the FASB issued FSP SFAS No. 157-4, which provides additional guidance for estimating fair value in accordance with SFAS No. 157 when the volume and level of activity for an asset or liability have significantly decreased. Additionally, FSP SFAS No. 157-4 supersedes FSP SFAS No. 157-3 and also addresses the identification of transactions that are not considered orderly. FSP SFAS No. 157-4 emphasizes that even if there has been a significant decrease in the volume and level of activity for the asset or liability and regardless of the valuation technique(s) used, the objective of a fair value measurement remains the same. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction (that is, not a forced liquidation or distressed sale) between market participants at the measurement date under current market conditions. FSP SFAS No. 157-4 was early adopted by the Company and was effective for the Company for the quarterly period ended March 31, 2009. The effect of adoption on the Company s financial position and results of operations was not material. SFAS No. 157 establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Pursuant to the provisions as prescribed in SFAS No. 157, the Company categorizes its financial instruments into a three-level fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). If the inputs used to measure fair value fall within different levels of the hierarchy, the category level is based on the lowest priority level input that is significant to the fair value measurement of the instrument.

Financial assets recorded at fair value on the Company s consolidated balance sheets are categorized as follows:

Level 1: Unadjusted quoted prices for identical assets in an active market.

Level 2: Quoted prices in markets that are not active or inputs that are observable either directly or indirectly for substantially the full-term of the asset. Level 2 inputs include the following:

Quoted prices for similar assets in active markets,

Quoted prices for identical or similar assets in non-active markets,

Inputs other than quoted market prices that are observable, and

Inputs that are derived principally from or corroborated by observable market data through correlation or other means.

Level 3: Prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. They reflect management s own assumptions about the assumptions a market participant would use in pricing the asset.

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

The following table presents the Company s hierarchy for its financial instruments measured at fair value on a recurring basis as of June 30, 2009:

	Level 1	Level 2	Level 3	Total
		(In thousands)		
Cash and cash equivalents (1)	$ 74,749	$	$	$ 74,749
Short-term investments (available-for-sale)		10		10
Restricted investments short-term (available-for-sale) (2)		1,796		1,796
Total cash and cash equivalents and short-term investments	74,749	1,806		76,555
Restricted cash (1)	1,280			1,280
Restricted investments long-term (available-for-sale) (2)		800		800
Total long-term investments	1,280	800		2,080
Total assets measured at fair value on a recurring basis	$ 76,029	$ 2,606	$	$ 78,635
Warrant liability			48,442	48,442
Total liabilities measured at fair value on a recurring basis	$	$	$ 48,442	$ 48,442

The cost and estimated fair value of the Company s available-for-sale investments at June 30, 2009 and December 31, 2008 were as follows:

	June 30, 2009			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(In thousands)		
Equity Securities	$	$ 10	$	$ 10
Columbia Strategic Cash Portfolio (restricted short-term portion) (2)	1,485	311		1,796
Total Short-term Investments	1,485	321		1,806
	661	139		800

Columbia Strategic Cash Portfolio (restricted long-term portion) (2)				
Total	$ 2,146	$ 460	$	$ 2,606

	December 31, 2008			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(In thousands)			
Equity Securities	$	$ 24	$	$ 24
Columbia Strategic Cash Portfolio (restricted short-term portion) (2)	2,258			2,258
Total Short-term Investments	2,258	24		2,282
Columbia Strategic Cash Portfolio (restricted long-term portion) (2)	1,705			1,705
Total	$ 3,963	$ 24	$	$ 3,987

(1) The estimated fair value of cash and cash equivalents and restricted cash approximates the carrying value.

(2) The Company s restricted investments consist of its investment in the Columbia Strategic Cash Portfolio (the Portfolio). During the fourth quarter of 2007, Columbia Management (Columbia), a unit of Bank

of America (BOA), closed the Portfolio to new investments and redemptions and began an orderly liquidation and dissolution of the Portfolio s assets for

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

distribution to the unit holders, thereby restricting the Company s potential to invest in and withdraw from the Portfolio. At June 30, 2009, approximately $16.3 million, or 81%, of the Company s original $20.0 million investment had been redeemed and re-invested in cash and cash equivalents and used to fund operations. The Company has realized investment losses of approximately $1.6 million, or 8% of its original investment in the Portfolio, from other-than-temporary impairment write-down s and redemptions. At June 30, 2009, the fair market value of restricted investment securities was $2.6 million, $1.8 million of which is reflected in the Company s consolidated balance sheets as a component of Short-Term Investments and $0.8 million of which is reflected in the Company s consolidated balance sheets as a component of Other Assets. At December 31, 2008, the fair market value of the Company s investment in the Portfolio was $4.0 million, $2.3 million of which is reflected in the Company s consolidated balance sheets as Short-Term Investments and $1.7 million of which is reflected as Other Assets. The fair value of the securities held within the Company s investment in the Portfolio are independently priced by third-party pricing services that also provide valuations of other Columbia funds. The Portfolio s valuation process is covered by Columbia s Mutual Fund Valuation Committee and its

Valuation Group and is subject to various reviews on a daily, monthly and ad- hoc basis.

Level 3 Valuation

Financial assets or liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable. The following table provides a summary of the changes in fair value of the Company s financial liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during 2009:

Warrant Liability	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
Balance, December 31, 2008	$
Valuation of warrant liability on April 8, 2009	12,561
Total realized loss included in net loss (mark-to-market of warrant liability at June 30, 2009)	35,881
Balance, June 30, 2009	$ 48,442

The warrant liability is marked-to-market each reporting period with the change in fair value recorded as a gain or loss within Other Expense, net on the Company s consolidated statement of operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified as an equity instrument. The fair value of the warrant liability is determined at each reporting period by utilizing a Monte Carlo simulation option pricing model that takes into account estimated probabilities of possible outcomes provided by the Company (unobservable inputs).

The Company does not carry any financial instruments or non-financial instruments that are measured at fair value on a non-recurring basis.

The carrying amounts of Accounts Receivable, Accounts Payable and Other Current Liabilities approximate fair value.

There were no securities in a continuous unrealized loss position for greater than twelve months at June 30, 2009.

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

Net unrealized losses included in accumulated other comprehensive income, net of taxes, at June 30, 2009 and December 31, 2008, were as follows:

	June 30, 2009	December 31, 2008
	(In thousands)	
Net unrealized gains (losses) arising during the period	$ 138	$ (2,179)
Reclassification adjustment for net (gains) losses included in earnings	298	889
Net unrealized gains (losses) included in accumulated other comprehensive income	$ 436	$ (1,290)

Proceeds from the sales of available-for-sale securities and the gross realized investment gains and losses on those sales reclassified out of accumulated other comprehensive income for the three and six months ended June 30, 2009 and 2008, were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands)		(In thousands)	
Proceeds	$ 386	$ 2,581	$ 1,541	$ 8,966
Gross realized investment gains				131
Gross realized investment losses	62	74	298	162

Other-than-temporary impairments

The Company regularly monitors its available-for-sale portfolio to evaluate the necessity of recording impairments for other-than-temporary (OTT) declines in the fair value of investments. Management makes this determination through the consideration of various factors such as management s intent and ability to retain an investment for a period of time sufficient to allow for any anticipated recovery in market value. OTT impairment losses result in a permanent reduction of the cost basis of an investment. The Company did not realize any investment losses due to OTT declines in fair value for the three and six months ended June 30, 2009 and for the three months ended June 30, 2008. For the six months ended June 30, 2008, the Company recorded realized investment losses due to OTT declines in fair value of approximately $0.1 million.

Note 5 Inventories

Inventories at June 30, 2009 and December 31, 2008 are summarized below:

	June 30, 2009	December 31, 2008
	(In thousands)	
Raw materials	$ 1,518	$ 2,340
Work-in-process	354	256

Finished goods		5,340		5,619
		7,212		8,215
Inventory reserves		(5,972)		(6,323)
Total	$	1,240	$	1,892

Inventories are stated at the lower of cost or market. Cost is determined based on actual cost. If inventory costs exceed expected market value due to obsolescence or quantities in excess of expected demand, reserves are recorded for the difference between the cost and market value. These reserves are based on estimates. The aggregate inventory valuation reserve was $6.0 million at June 30, 2009 and $6.3 million at December 31, 2008.

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

Note 6 Property and Equipment, Net

Property and equipment, net at June 30, 2009 and December 31, 2008 is summarized below:

	June 30, 2009	December 31, 2008
	(In thousands)	
Office equipment	$ 8,190	$ 8,190
Office equipment capital leases	313	313
Leasehold improvements	1,543	1,536
	10,046	10,039
Accumulated depreciation and amortization	(8,883)	(8,646)
Total	$ 1,163	$ 1,393

Depreciation and amortization expense was approximately $0.1 million for each three-month period ended June 30, 2009 and 2008, respectively, and $0.2 million for each six-month period ended June 30, 2009 and 2008, respectively.

Note 7 Revenue Recognition

Product sales

Product sales are generally recognized when title to the product has transferred to the Company s customers in accordance with the terms of the sale. Since December 2006, the Company has shipped oxandrolone to its distributor and has accounted for these shipments on a consignment basis until product is sold into the retail market. The Company has deferred the recognition of revenue related to these shipments until it confirms that the product has been sold into the retail market and all other revenue recognition criteria have been met. The Company recognizes revenue in accordance with the SEC Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements,* as amended by SAB No. 104 (together, SAB 104), and SFAS No. 48, *Revenue Recognition When Right of Return Exists.* SAB 104 states that revenue should not be recognized until it is realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met:

- Persuasive evidence of an arrangement exists,
- Delivery has occurred or services have been rendered,

- The seller s price to the buyer is fixed and determinable, and
- Collectability is reasonably assured.

SFAS No. 48 states that revenue from sales transactions where the buyer has the right to return the product shall be recognized at the time of sale only if:

- The seller s price to the buyer is substantially fixed or determinable at the date of sale,
- The buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product,
- The buyer s obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product,
- The buyer acquiring the product for resale has economic

substance apart from that provided by the seller,

The seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and

The amount of future returns can be reasonably estimated.

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

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

Allowance for returns In general, the Company provides credit for product returns that are returned six months prior to and up to twelve months after the product expiration date. Upon sale, the Company estimates an allowance for future product returns. The Company provides additional reserves for contemporaneous events that were not known and knowable at the time of shipment. In order to reasonably estimate future returns, the Company analyzes both quantitative and qualitative information, including, but not limited to, actual return rates by lot productions, the level of product manufactured by the Company, the level of product in the distribution channel, expected shelf life of the product, current and projected product demand, the introduction of new or generic products that may erode current demand, and general economic and industry-wide indicators. The Company also utilizes the guidance provided in SFAS No. 48 and SAB 104 in establishing its return estimates. SFAS No. 48 discusses potential factors that may impair the ability to make a reasonable estimate, including:

- the susceptibility of the product to significant external factors, such as technological obsolescence or changes in demand,
- relatively long periods in which a particular product may be returned,
- absence of historical experience with similar types of sales of similar products, or inability to apply such experience because of changing circumstances, for example, changes in the selling

enterprise s marketing policies or relationships with its customers, and

absence of a large volume of relatively homogeneous transactions.

SAB 104 provides additional factors that may impair the ability to make a reasonable estimate, including:

significant increases in or excess levels of inventory in a distribution channel,

lack of visibility into or the inability to determine or observe the levels of inventory in a distribution channel and the current level of sales to end users,

expected introductions of new products that may result in the technological obsolescence of and larger than expected returns of current products,

the significance of a particular

- distributor to the registrant s (or a reporting segment s) business, sales and marketing,
- the newness of a product,
- the introduction of competitors products with superior technology or greater expected market acceptance, and
- other factors that affect market demand and changing trends in that demand for the registrant s products.

The Company continually analyzes the impact of generic competition on product returns by considering the product at wholesalers and retailers, together with demand forecasts. The allowance for product returns was $1.1 million at June 30, 2009 and $1.2 million at December 31, 2008. This allowance is included in Other Current Liabilities on the Company s consolidated balance sheets.

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

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

experience. The allowance for rebates was $0.5 million at June 30, 2009 and $0.6 million at December 31, 2008. This allowance is included in Other Current Liabilities on the Company s consolidated balance sheets.

Commercial discounts The Company sells Oxandrin directly to drug wholesalers. Terms of these sales vary, but generally provide for invoice discounts for prompt payment. These discounts are recorded by the Company at the time of sale.

Distribution fees The Company records distribution fees associated with wholesaler distribution services from two of its largest customers.

Other revenues Other revenues primarily represent royalty income, which is recognized as earned upon receipt of confirmation of the income amount or payment from contracting third parties.

Note 8 Research and Development

In the first quarter of 2008, the Company adopted Emerging Issues Task Force (EITF) Issue No. 07-03, *Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF No. 07-03). EITF No. 07-03 affirmed as a consensus, that non-refundable advance payments for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the goods are delivered or the related services are performed. Consistent with the consensus, the Company defers these costs and amortizes them into expense based on services performed. All other research and development costs are charged to expense as incurred, including inventory purchases for the Company s product candidate, KRYSTEXXA (pegloticase). The net deferred balance, which is included in Prepaid Expenses and Other Current Assets on the Company s consolidated balance sheets was $0.2 million at June 30, 2009 and $0.7 million at December 31, 2008.

Note 9 Earnings (Loss) per Share of Common Stock

The Company accounts for and discloses net earnings (loss) per share using the treasury stock method under the provisions of SFAS No. 128, *Earnings Per Share.* Net earnings (loss) per common share, or basic earnings (loss) per share, is computed by dividing the Company s reported net earnings (loss) for the period by the weighted-average number of common shares outstanding at the end of the period. Net earnings (loss) per common share assuming dilutions, or diluted earnings (loss) per share, is computed by reflecting the potential dilution that could occur from the exercise of in-the-money stock options, unvested restricted stock and warrants.

The Company s basic and diluted weighted-average number of common shares outstanding as of June 30, 2009 and 2008, were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands)		(In thousands)	
Basic	59,594	53,542	56,804	53,409
Incremental common stock equivalents				
Diluted	59,594	53,542	56,804	53,409

At June 30, 2009 and 2008, all in-the-money stock options, unvested restricted stock and warrants were excluded from the computation of diluted earnings (loss) per share as their effect would have been anti-dilutive, since the Company reported a net loss for these periods.

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

Note 10 Stockholder s Equity

On April, 8 2009, the Company raised $31.0 million from a registered direct offering, which yielded approximately $29.0 million in cash net of approximately $2.0 million of offering costs, which were charged to additional paid-in-capital. The Company issued 5,927,343 shares of its common stock to existing and new institutional investors as part of the offering. The investors also received warrants to purchase up to 5,038,237 shares of its common stock at an initial exercise price of $10.46 per share.

The warrants are exercisable at any time on or after the date of issuance and expire on the earlier of November 2, 2010 and the date that is nine months after the date on which the Company publicly announces that it has addressed all items required by the FDA to be addressed before its BLA can be approved. Pursuant to the terms of the warrants, the exercise price for the warrants will, from and after August 17, 2009, be equal to the dollar volume weighted-average price of the Company s common stock for the five trading days immediately preceding such date. The exercise price per share may not exceed $10.46 or be less than $1.57. The Company may, at its or the warrant holder s election, issue net shares in lieu of a cash payment of the exercise price by the warrant holder upon exercise.

In the event that the Company enters into a merger or change of control transaction, the holders of the warrants will be entitled to receive consideration as if they had exercised the warrant immediately prior to such transaction, or they may require the Company to purchase the warrant at the Black-Scholes value of the warrant on the date of such transaction.

The Company accounts for the warrants as a liability pursuant to the guidance provided in EITF Issue No. 07-05, *Determining Whether and Instrument (or Embedded Feature) Is Indexed to an Entities Own Stock,* EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock* and SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities.* SFAS 133 specifies that a contract that would otherwise meet the definition of a derivative under that Statement, issued or held by the reporting entity that is both (a) indexed to its own stock and (b) classified in stockholders equity in its statement of financial position, shall not be considered a derivative financial instrument for purposes of applying that Statement. EITF No. 07-05 provides a two step method for determining whether an instrument is indexed to an entities own stock. Under the provisions of EITF No. 00-19, a contract designated as an asset or a liability must be carried at fair value until exercised or expired, with any changes in fair value recorded in results of operations. Also pursuant to EITF No. 00-19, the classification of a contract should be reassessed at each balance sheet date and should be reclassified as of the date of the event that caused the reclassification. There is no limit on the number of times a contract may be reclassified. If a contract is reclassified from permanent or temporary equity to an asset or a liability, the change in fair value of the contract during the period the contract was classified as equity should be accounted for as an adjustment to stockholders equity. If a contract is reclassified from an asset or a liability to equity, gains or losses recorded to account for the contract at fair value during the period that the contract was classified as an asset or a liability should not be reversed. The Company s warrant liability is marked-to-market each reporting period with the change in fair value recorded as a gain or loss within Other Expense, net on the Company s consolidated statement of operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified as an equity instrument. The fair value of the warrant liability is determined at each reporting period by utilizing a Monte Carlo simulation option pricing model that takes into account estimated probabilities of possible outcomes provided by the Company. At the date of the transaction, the fair value of the warrant liability was calculated to be $12.6 million.

At June 30, 2009, the fair value of the warrant liability determined utilizing a Monte Carlo simulation option pricing model was approximately $48.4 million. The increase in the fair value of

18

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

the warrants during the June 30, 2009 quarter mainly reflects the increase in the value of the Company s common stock price of $9.35 per share subsequent to the April 8, 2009 issuance of the warrants.

During the three months ended June 30, 2009, the Company recorded a loss of approximately $35.8 million within Other Expense, net on its consolidated statement of operations to reflect the increase in the valuation of the warrants.

Note 11 Share-Based Compensation

In 2001, the Company adopted the 2001 Stock Option Plan. The 2001 Stock Option Plan permits the granting of options to purchase up to an aggregate of 10 million shares of the Company s common stock to employees (including employees who are directors), Directors and consultants of the Company. Under the 2001 Stock Option Plan, the Company may grant either incentive stock options, at an exercise price of not less than 100% of the fair market value of the underlying shares on the date of grant, or non-qualified stock options, at an exercise price of not less than 85% of the fair market value of the underlying shares on the date of grant. Options generally become exercisable ratably over two or four-year periods, with unexercised options expiring after the earlier of ten years or shortly after termination of employment. Cancelled or previously expired options are available for reissuance.

In 2004, the Company adopted the 2004 Incentive Plan, which superseded the 2001 Stock Option Plan. The 2004 Incentive Plan allows the Compensation Committee to award stock appreciation rights, restricted stock awards, performance-based awards and other forms of equity-based and cash incentive compensation, in addition to stock options. Under this plan, 2.5 million shares remain available for future grant at June 30, 2009.

Total compensation cost that has been charged against income related to the above plans was $1.3 million and $2.0 million for the three months ended June 30, 2009 and 2008, respectively. Total compensation cost that has been charged against income related to the above plans was $3.4 million and $4.4 million for the six months ended June 30, 2009 and 2008, respectively.

The following table summarizes stock-based compensation related to the above plans by expense category for the three and six months ended June 30, 2009 and 2008:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Research and development	552	734	1,476	1,633
Selling, general and administrative	794	1,249	1,879	2,773
Total non-cash compensation expense related to share-based compensation included in operating expense	$ 1,346	$ 1,983	$ 3,355	$ 4,406

Stock Options

The Company grants stock options to employees and Directors with exercise prices equal to the fair market value of the underlying shares of the Company s common stock on the date that the options are granted. Options have a term of ten years from the grant date. Options granted to employees vest over a four-year

period and options granted to Directors vest in equal quarterly installments over a one-year period from the date of grant. Options to Directors are granted on an annual basis and represent compensation for service on the Company s Board of Directors. Compensation cost for stock options is charged against income on a straight-line basis between the grant date for the option and each vesting date. The Company estimates the fair value of all stock option awards by applying the Black-Scholes pricing valuation model. The application of this

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

valuation model involves assumptions that are highly subjective, judgmental and sensitive in the determination of compensation cost. The weighted-average key assumptions used in determining the fair value of options granted for the three months ended June 30, 2009 and 2008, are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Weighted-average volatility	76 %	60 %	76 %	60 %
Weighted-average risk-free interest rate	2.6 %	3.5 %	2.4 %	2.8 %
Weighted-average expected life in years	6.6	7.1	6.7	6.6
Dividend yield	0.0 %	0.0 %	0.0 %	0.0 %
Weighted-average grant date fair value	$ 4.38	$ 15.44	$ 3.89	$ 12.56

Historical information is the primary basis for the selection of the expected volatility and expected dividend yield. The expected terms of options granted prior to December 31, 2007 were based upon the simplified method as set forth by SAB No. 107. SAB No. 107 provides guidance in developing an estimate of the expected term of plain vanilla share options in accordance with SFAS 123(R), *Share-Based Payment.* The simplified method estimates the expected term as the midpoint between vesting and the grant contractual life. The expected terms of options granted subsequent to December 31, 2007 are based upon the Company s historical experience for similar types of stock option awards. The risk-free interest rate is selected based upon yields of U.S. Treasury issues with a maturity equal to the expected term of the option being valued.

During the six months ended June 30, 2009, the Company issued 613,000 shares of common stock upon the exercise of outstanding stock options and received proceeds of $3.6 million. For the three months ended June 30, 2009 and 2008, approximately $0.7 million of stock option compensation cost was charged against income in each respective period. For the six months ended June 30, 2009 and 2008, approximately $1.9 million and $1.8 million, respectively, of stock option compensation cost was charged against income. As of June 30, 2009, there was $3.4 million of unrecognized compensation cost, adjusted for estimated forfeitures, related to unamortized stock option compensation which is expected to be recognized over a weighted-average period of approximately 2.8 years. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures.

Stock option activity during the six months ended June 30, 2009, was as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in yrs)	Aggregate Intrinsic Value of In-the-Money Options
	(In thousands, except weighted-average data)			
Outstanding at December 31, 2008	3,563	$ 8.29	7.27	$ 3,242
Granted	733	5.77		

Exercised	(613)		5.91			
Cancelled	(496)		11.95			
Outstanding at June 30, 2009	3,187	$	7.60	7.75	$	21,463
Exercisable at June 30, 2009	1,470	$	8.16	6.11	$	9,248

The aggregate intrinsic value in the previous table reflects the total pre-tax intrinsic value (the difference between the Company s closing stock price on the last trading day of the period and the exercise price of the options, multiplied by the number of in-the-money stock options) that would have been received by the option holders had all option holders exercised their options on June 30, 2009. The intrinsic value of the Company s stock options changes based on the closing price of the Company s common stock. The total intrinsic value of options exercised (the difference in the

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

market price of the Company s common stock on the exercise date and the price paid by the optionee to exercise the option) for the six months ended June 30, 2009 and 2008 was approximately $3.2 million and $5.9 million, respectively. The closing price per share of the Company s common stock was $13.83 on June 30, 2009 and $25.30 on June 30, 2008, the last trading days of the respective quarters.

Stock Options that Contain Performance and Market-Based Conditions

During the second quarter of 2009, the Company awarded a stock option grant that contains both performance and market conditions to certain members of the Company s executive management team. The vesting of the award is contingent on the occurrence of certain performance objectives or a market-based objective. Pursuant to the provisions of SFAS 123(R), the Company is required to calculate the fair value of an equity award with market-based vesting terms with a valuation model such as a lattice model or Monte Carlo simulation model. The Company utilized a Monte Carlo simulation model to measure the fair value of the options, which considers the estimated probabilities of possible outcomes provided by the Company. The final measure of compensation cost will be based on the amount estimated at the grant date for the condition or outcome that is actually satisfied. Based on the simulation, the grant date fair value of the award is $2.65 per share and compensation cost is being charged against income ratably over an 88 day derived service period, which is the shortest of the explicit, implicit and derived service periods. Regardless of the nature and number of conditions that must be satisfied, the existence of a market condition requires recognition of compensation cost if the requisite service is rendered, even if the market condition is never satisfied. The key assumptions used in determining the grant date fair value for this grant that contains both performance and market conditions are as follows:

	June 30, 2009
Volatility at expected term	169.2 %
Risk-free interest rate at expected term	0.47 %
Expected term (years)	0.62
Derived service period (years)	0.25
Dividend yield	0.00 %
Grant date fair value per share	$2.65

Volatility is based on the Company s historical volatility that corresponds to the expected term of the option calculated as the standard deviation of daily total continuous returns on the Company s common stock. The risk-free interest rate is consistent with the U.S. Treasury rate curve as of the grant date equal to the expected term of the option. The rate is a continuously compounded rate. The expected term was calculated using a Monte Carlo simulation model assuming that the options will be disposed after vesting. The stock price in the Monte Carlo simulation model grows at the cost of equity. The derived service period was also calculated using a Monte Carlo simulation model. To estimate the vesting period, a Monte Carlo simulation model is used to produce price paths for the Company s common stock. The vesting conditions are evaluated at the applicable time and the percentage of shares that vest is determined. The vesting period for the path is an average over all vesting dates where vesting occurs weighted by the probability that vesting occurred at that point. The derived service period shown is the median over all simulation vested paths.

Modifications of Stock Option Awards

In January 2009, the Company modified the terms of certain stock option awards previously granted to the Company s former President and Chief Executive Officer. The first modification extended the term of the exercisability of the vested portion of the options from three months following the separation from employment to six months subsequent to the separation of

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

employment. For the three months ended June 30, 2009, the Company recorded a stock-based compensation charge of $10,507 as a result of this modification. For the six months ended June 30, 2009 the Company recorded a stock-based compensation charge of $18,936 as a result of this modification. The second modification revised the terms of certain unvested stock option awards previously granted to the Company s former President and Chief Executive Officer allowing him to vest in awards through July 17, 2009 that otherwise would have been cancelled on his termination date of January 17, 2009. The Company accounted for this modification as a Type III improbable-to-probable modification per SFAS 123(R), *Share Based Payment.* A Type III modification can result in recognition of compensation cost that is less than the estimated fair value of the award. For the three months ended June 30, 2009, the Company recorded stock-based compensation expense of $6,219 as a result of this modification. For the six months ended June 30, 2009, the Company recorded share-based compensation income of $89,910 as a result of this modification. The Company did not have any share-based compensation expense related to modifications for the three and six months ended June 30, 2008.

Restricted Stock

The Company grants restricted stock awards to its employees and to its Directors. Restricted stock awards are recorded as deferred compensation and amortized into compensation expense on a straight-line basis over the vesting period, which ranges from one to four years in duration. Restricted stock awards to Directors are granted on a yearly basis and represent compensation for services performed on the Company s Board of Directors. Restricted stock awards to Directors vest in equal quarterly installments over a one-year period from the grant date. Compensation cost for restricted stock awards is based on the award s grant date fair value, which is the closing market price of the Company s common stock on the grant date, multiplied by the number of shares awarded. During the six months ended June 30, 2009, the Company issued 133,000 shares of restricted stock amounting to $0.8 million in total aggregate fair market value. For the three months ended June 30, 2009 and 2008, approximately $0.6 million and $0.9 million, respectively, of deferred restricted stock compensation cost was charged against income. For the six months ended June 30, 2009 and 2008, approximately $1.4 million and $1.7 million, respectively, of deferred restricted stock compensation cost was charged against income. At June 30, 2009, approximately 631,000 shares remained unvested and there was approximately $4.6 million of unrecognized compensation cost related to restricted stock. A summary of the status of the Company s unvested restricted stock as of December 31, 2008, and changes during the six months ended June 30, 2009, is presented below:

	Number of Shares	Weighted-Average Grant Date Fair Value
	(In thousands)	
Unvested at December 31, 2008	875	$ 11.24
Granted	133	5.78
Vested	(271)	11.18
Forfeited	(106)	12.76
Unvested at June 30, 2009	631	$ 9.85

The weighted-average grant date fair value for restricted stock awards granted during the six months ended June 30, 2009 and 2008 was $5.78 and $20.86, respectively. The total fair value of restricted shares vested

during the six months ended June 30, 2009 and 2008, was $1.7 million and $2.7 million, respectively.

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

Restricted Stock Awards that Contain Performance Conditions

The Company issues restricted stock awards that contain performance conditions to members of senior management. These awards contingently vest over a period of one to four years from the date of grant depending on the nature of the performance goal upon the achievement of specific strategic objectives associated with KRYSTEXXA-related developmental and sales milestones and other manufacturing, commercial operations and business development objectives. Compensation cost is based on the grant date fair value of the award, which is the closing market price of the Company s common stock on the date the award is issued multiplied by the number of shares awarded. Compensation expense is recorded over the implicit or explicit requisite service period based on management s best estimate as to whether it is probable that the shares awarded are expected to vest. Previously recognized compensation expense is fully reversed if performance targets are not satisfied.

The Company did not record any expense related to restricted stock awards that contain performance conditions for the three and six months ended June 30, 2009. For the three and six months ended June 30, 2008, approximately $0.4 million and $0.9 million, respectively, of compensation cost was charged against income related to restricted stock awards that contain performance conditions. The compensation cost for the six months ended June 30, 2008, includes approximately $0.4 million related to a market-based performance award that was subsequently reversed in December 2008 due to the derived service period not being met. At June 30, 2009, approximately 126,000 potential shares of restricted stock with performance conditions remained unvested. Restricted stock awards with performance conditions encompass performance targets set for senior management personnel through 2011 and could result in approximately $2.0 million of additional compensation expense if the performance targets are met or expected to be attained. A summary of the status of the Company s unvested restricted stock awards that contain performance conditions as of December 31, 2008, and changes during the six months ended June 30, 2009, is presented below:

	Number of Shares	Weighted-Average Grant Date Fair Value
	(Shares in thousands)	
Unvested at December 31, 2008	351	$ 15.68
Granted		
Vested		
Forfeited	(225)	15.56
Unvested at June 30, 2009	126	$ 15.89

The Company did not grant any restricted stock awards that contain performance conditions during the six months ended June 30, 2009. The weighted-average grant date fair value for restricted stock awards that contain performance conditions granted during the six months ended June 30, 2008 was $20.59. No vesting of restricted stock awards that contain performance conditions occurred during the six months ended June 30, 2009. The total fair value of restricted stock awards that contain performance conditions that vested during the six months ended June 30, 2008 was $1.7 million.

Employee Stock Purchase Plan

In April 1998, the Company adopted its 1998 Employee Stock Purchase Plan (the 1998 ESPP). The 1998 ESPP is qualified as an employee stock purchase plan under Section 423 of the Internal Revenue Code of 1986, as amended. Prior to the adoption of SFAS No. 123(R), *Share-Based Payment,* and under the accounting guidance that preceded SFAS No. 123(R), the 1998 ESPP

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

was considered to be non-compensatory. Under the 1998 ESPP, the Company grants rights to purchase shares of common stock (Rights) at prices not less than 85% of the lesser of (i) the fair market value of the shares on the date of grant of such Rights or (ii) the fair market value of the shares on the date such Rights are exercised. Therefore, the 1998 ESPP is considered compensatory under SFAS No. 123(R) since, along with other factors, it includes a purchase discount of greater than 5%. For the six months ended June 30, 2009 and 2008, approximately $0.1 million and $0.3 million, respectively, of compensation expense was charged against income related to participation in the 1998 ESPP.

Note 12 Other Current Liabilities

The components of Other Current Liabilities at June 30, 2009 and December 31, 2008, were as follows:

	June 30, 2009	December 31, 2008
	(In thousands)	
Severance	$ 3,880	$ 1,877
Salaries and related expenses	2,026	2,324
Clinical research organization expenses	1,685	2,121
Manufacturing and technology transfer services	1,669	3,339
Allowance for product returns	1,147	1,163
Litigation, legal and professional fees	1,004	1,456
Unrecognized tax benefit BTG tax assessment		1,565
Other	4,995	4,805
Total	$ 16,406	$ 18,650

Note 13 Other Liabilities

The components of Other Liabilities at June 30, 2009 and December 31, 2008, were as follows:

	June 30, 2009	December 31, 2008
	(In thousands)	
Unrecognized tax benefit (1)	$ 10,581	$ 9,645
Capital leases (2)	131	164
Total	$ 10,712	$ 9,809

(1) See Note 14 to the

Financial Statements for further discussion of unrecognized tax benefits resulting from FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes,* (FIN 48).

(2) The Company maintains capital leases for office equipment used at its corporate headquarters in East Brunswick, New Jersey. The leases range in terms from 36 to 60 months and were entered into between 2002 and 2007.

Note 14 Income Taxes

The Company did not have an income tax provision or benefit from operations for the six months ended June 30, 2009 due to the fact that the Company can no longer currently benefit from its net operating losses. The Company no longer has the ability to carry back losses to previous years to recover taxes paid. The Company has recorded at June 30, 2009, a deferred tax asset of

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

$27.5 million, reflecting the federal tax benefit of $78.5 million in tax loss carryforwards primarily from 2008 and 2009. Realization is dependent on generating sufficient taxable income in the future.

The Company adopted the provisions of FIN 48, on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes.* This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition of tax benefits, classification on the balance sheet, interest and penalties, accounting in interim periods, disclosure, and transition.

As a result of the implementation of FIN 48, the Company recorded in 2007, a $4.5 million increase in the liability for unrecognized tax benefits, which is included in Other Liabilities within the Company s consolidated balance sheets. This increase in the liability resulted in a corresponding increase to the balance of Accumulated Deficit for the cumulative effect of this change. The total amount of federal, state, local and foreign unrecognized tax benefits was $10.6 million at June 30, 2009 and $11.2 million at December 31, 2008, including accrued penalties and interest. The increase in the Company s liability for unrecognized tax benefits from the implementation of FIN 48 to June 30, 2009 is primarily the result of $4.8 million in research and development credits, $1.4 million in interest and penalties as discussed below offset by a $0.1 million net reduction in state income tax positions.

In accordance with FIN 48, paragraph 19, the Company recognized accrued interest and penalties related to unrecognized tax benefits as a component of Other Expense, net in its consolidated statements of operations, which is consistent with the recognition of these items in prior reporting periods. From inception to date, the Company has recorded a liability of approximately $1.0 million and $0.6 million for the payment of interest and penalties, respectively, which is included as a component of the liability for unrecognized tax benefits within Other Liabilities on its consolidated balance sheets. The accrued liability for interest and penalties for unrecognized tax benefits remained unchanged during the six months ended June 30, 2009. However, a reduction of $0.2 million in the liability resulted from a payment associated with the 2003-2005 Israel tax audit assessment relating to the Company s former subsidiary Bio-Technology General Israel Ltd. (BTG). Offsetting the reduction was an increase in the accrued interest and penalty liability for all other unrecognized tax benefits of approximately $0.2 million during the six-month period ended June 30, 2009.

The Company files income tax returns in the United States and various state jurisdictions. The Company s federal tax returns have been audited by the Internal Revenue Service through fiscal year ended December 31, 2003 and for the 2005 tax year. Currently, the Internal Revenue Service is in the process of examining the 2006 through 2008 tax years. The Company filed the 2008 Federal 1120 corporate income tax return during the second quarter of 2009.

State income tax returns are generally subject to examination for a period of three to five years subsequent to the filing of the respective tax return. The Company recently settled its income tax examination for the 2004 through 2006 tax years with the State of New York for no additional tax liability.

In connection with the 2005 sale agreement of BTG, the Company is responsible for the results of any examination of BTG by any taxing authority through July 18, 2005. During 2008, BTG settled its examination with the Israeli taxing authorities for the tax years 2003 through 2005. The result of this tax examination required the Company to pay the new owners of BTG, Ferring Pharmaceuticals, approximately $1.6 million, which includes interest. This liability was included in Other Current Liabilities within the Company s consolidated balance sheet as of December 31, 2008, and was paid to Ferring on March 30, 2009. The Company does not have any additional tax liability to the Israeli authorities as all tax years have been audited and closed.

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

In connection with the 2006 sale agreement of the Company s former United Kingdom subsidiary, Rosemont, the Company is responsible for the results of any examination of Rosemont by any taxing authority through August 4, 2006. As of the end of 2008, the statute of limitations has expired on the 2006 tax year and all previous tax years have been examined and closed.

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

At present, the likelihood of the Company being able to fully realize its deferred income tax benefits against future income is uncertain. Accordingly, at June 30, 2009 and December 31, 2008, the Company s valuation allowance against its deferred income tax assets was $112.8 million and $86.8 million, respectively. As of June 30, 2009 and December 31, 2008, $4.8 million and $4.2 million, respectively, of the net deferred tax assets remaining, were offset by an unrecognized tax benefit reserve recorded as components of Long-Term Liabilities on the Company s consolidated balance sheets.

Note 15 Commitments and Contingencies

The Company s administrative offices are located in East Brunswick, New Jersey, where it has leased approximately 53,000 square feet of office space. The lease has a base average annual rental expense of approximately $1.9 million and expires in March 2013. The lease provides the Company with two renewal options to extend the lease by five years each. In connection with this lease arrangement, the Company was required to provide a security deposit by way of an irrevocable letter of credit for $1.3 million, which is secured by a cash deposit of $1.3 million and is reflected in Other Assets (as restricted cash) on the Company s consolidated balance sheets at June 30, 2009 and December 31, 2008.

At June 30, 2009, the Company had employment agreements with three senior officers. Under these agreements, the Company has committed to total aggregate base compensation per year of approximately $1.5 million plus other normal customary fringe benefits and bonuses. These employment agreements generally have initial terms of two or three years and are automatically renewed thereafter for successive one-year periods unless either party gives the other notice of non-renewal. On January 17, 2009, the Company entered into a General Release and Separation agreement (the Agreement) with its former President and Chief Executive Officer. Pursuant to the Agreement, the Company is committed to approximately $1.9 million in severance costs which will be paid out over the course of 2009 and 2010 comprised of (i) two year s base salary to be paid over two years totaling approximately $1.0 million, (ii) cash bonus at 60% of two times base salary to be paid over two years in the amount of approximately $0.6 million, (iii) continuation of welfare benefits of healthcare, dental, life and accidental death and dismemberment, and disability insurance coverage for a period of twenty-four months totaling approximately $0.2 million and (iv) unused vacation days and outplacement assistance in the amount of $0.1 million. Additionally, the Company has also committed approximately $2.6 million for severance costs related to the resignations of the Company s former Senior Vice President of Quality and Regulatory Affairs and its former Senior Vice President, Chief Medical Officer and the termination of the Company s former Senior Vice President, Chief Financial Officer and Treasurer. These severance payments will be paid out over the course of 2009 and 2010 and are comprised of eighteen months of each former executive s base salary and bonus, unused vacation days, outplacement services and the continuation of healthcare, dental, life and other welfare-related insurance benefits.

In November 2008, Richard Sagall, an alleged stockholder, commenced an action in the U.S. District Court for the Southern District of New York seeking to certify a class of shareholders who

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

held Savient securities between December 13, 2007 and October 24, 2008. The suit alleges that the Company made false and misleading statements relating to the GOUT1 and GOUT2 Phase 3 clinical trials, and that the Company failed to disclose in a timely manner serious adverse events which occurred in five patients in these trials. A lead plaintiff was appointed in March 2009 resulting in the re-captioning of the action as *Lawrence J. Koncelik, Jr. vs. Savient Pharmaceuticals, et al.* An amended compliant was filed in this matter in April 2009 and the Company filed a motion to dismiss in June 2009. Plaintiff s opposition is due in August 2009. The Company intends to vigorously defend against this action.

In 2007, Joseph R. Berger filed a complaint against the Company in the Fayette County Circuit Court in Kentucky alleging breach of contract in connection with the assignment of certain inventions related to the method of using oxandrolone to treat HIV/AIDS patients. The complaint alleged several causes of action, each of which was premised on the existence of an oral agreement between the Company and Berger, which Berger alleges was breached. Berger sought, among other things, damages and rescission of the assignment of the inventions. In March 2008, Berger filed an amended complaint that abandoned several of his claims, but continued to seek damages and rescission of the invention assignments. In March 2008, the Court granted the Company s motion to limit discovery to liability issues for 150 days in contemplation of the Company s motion for summary judgment at the end of that period. Over the Company s objections in 2008, the Court granted a request by Berger to extend the discovery period by four months and, accordingly, discovery as to liability ended in December 2008. In March 2009, each party filed a separate Motion for Summary Judgment with the Court, after which each party filed responsive pleadings. Oral arguments on the cross-motions were held in April 2009, and a decision from the Court is expected in the near future. The Company intends to vigorously defend against this action.

In May 2007, the Company filed a notice of appeal with the New Jersey Division of Taxation contesting a New Jersey Sales & Use Tax assessment of $1.2 million for the tax periods 1999 through 2003. The Company believes it is not subject to taxes on services that were provided to the Company. An acknowledgement was received from The Conference and Appeals Branch and an appeal conference is expected to be scheduled in the future.

The Company is in the process of contesting a matter in which one of the Company s customers has requested a $1.2 million reimbursement for Oxandrin returned goods that were not in compliance with the Company s returned goods policy.

From time to time, the Company becomes subject to legal proceedings and claims in the ordinary course of business. Such claims, even if without merit, could result in the significant expenditure of the Company s financial and managerial resources. The Company is not aware of any legal proceedings or claims that it believes will, individually or in the aggregate, materially harm its business, results of operations, financial condition or cash flows.

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, 2009, the Company has not recorded a liability for any obligations arising as a result of these indemnification obligations.

SAVIENT PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

Note 16 Segment Information

The Company currently operates within one Specialty Pharmaceutical segment which includes sales of Oxandrin and oxandrolone, and the research and development activities of KRYSTEXXA.

Note 17 Investment Income (Expense), Net

The Company s Investment income (expense), net as of June 30, 2009 and 2008, was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Interest and dividend income from cash, cash equivalents and investments	$ 35	$ 485	$ 69	$ 1,447
Realized gains on sales of short-term investments				131
Realized losses on redemptions of short-term investments	(62)	(74)	(298)	(162)
Realized losses from impairment write-downs of short-term investments				(52)
Total investment income (expense), net	$ (27)	$ 411	$ (229)	$ 1,364

Note 18 Other Expense, Net

The Company s Other expense, net as of June 30, 2009 and 2008, was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Realized loss on change in valuation of warrant liability	$ (35,881)	$	$ (35,881)	$
Other non-operating expenses	(174)	(162)	(287)	(312)
Total expense, net	$ (36,055)	$ (162)	$ (36,168)	$ (312)

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

Our management s discussion and analysis of financial condition and results of operations contains statements which constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements that set forth anticipated results based on management s plans and assumptions. From time to time, we also provide forward-looking statements in other materials we release to the public as well as oral forward-looking statements. Such statements discuss our strategy, expected future financial position, results of operations, cash flows, financing plans, development of products, strategic alliances, intellectual property, competitive position, plans and objectives of management. We often use words such as anticipate, estimate, expect, project, intend, plan, believe, will and similar expressions to identify forward-looking statements. In particular, any statements regarding our efforts to reduce our burn rate and conserve cash, potential FDA marketing approval for KRYSTEXXA™ (pegloticase), a meeting with the FDA to discuss the complete response letter, the reversion to and revalidation of the Phase 3 manufacturing process, the terms of a REMS program, the timing of a resubmission to the FDA in response to the complete response letter and the efficacy and safety of KRYSTEXXA are forward-looking statements. Additionally, forward-looking statements include those relating to future actions, prospective products or product approvals, future performance, financing needs, liquidity or results of current and anticipated products, sales efforts, expenses, interest rates, foreign exchange rates and the outcome of contingencies, such as legal proceedings, and financial results.

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

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

Overview

We are a specialty biopharmaceutical company focused on developing and marketing pharmaceutical products that target unmet medical needs in both niche and broader specialty markets.

We are currently developing one product: KRYSTEXXA™ (pegloticase) for the treatment of chronic gout in patients refractory to conventional treatment. Chronic gout is gout refractory to conventional therapy occurring in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated. KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia. In our replicate randomized, double-blind, placebo- controlled, parallel-group Phase 3 clinical trials, KRYSTEXXA, a biologic PEGylated uricase enzyme, demonstrated the normalization of uric acid, complete resolution of tophi, improvement in chronic pain, improvement of physical functioning and decreased frequency of gout flares in patients with chronic gout.

In October 2007, we completed the treatment portion of our two replicate Phase 3 clinical trials of KRYSTEXXA and we are currently conducting an open label extension, or OLE, study in patients who completed the Phase 3 clinical trials. In October 2008, we submitted a Biologic License Application, or BLA, to the U.S. Food and Drug Administration, or FDA, for KRYSTEXXA, and in December 2008, the FDA notified us that the BLA was accepted for priority review with a Prescription Drug User Fee Act action, or PDUFA, date of April 30, 2009. The FDA notified us of the acceptance of the trade name KRYSTEXXA as the proprietary name for pegloticase in January 2009. Also in January 2009, we submitted to the FDA amendments to the KRYSTEXXA BLA to further clarify the BLA and to respond to FDA review-related

questions. The FDA determined that the additional information contained in the submissions constituted a major amendment to the BLA

and elected under applicable procedures to extend its review period by three months, establishing a revised target PDUFA date of August 1, 2009 for our BLA submission.

On July 31, 2009, the FDA issued a complete response letter notifying us that it would not approve the BLA as a treatment for chronic gout unless and until:

- deficiencies with the chemistry, manufacturing and controls, or CMC, section of the BLA are addressed,
- facility inspection observation remediation actions are adequately taken by our primary third-party manufacturer,
- we implement a Risk Evaluation and Mitigation Strategy, or REMS, (Medication Guide and Communication Plan), and
- we provide a follow-up safety update to the FDA.

The complete response letter also included draft label language. In response to the Type A meeting request filed by us, we have received notice from the FDA of a tentative meeting date scheduled for mid-September 2009 to discuss the complete response letter, and intend a resubmission once all of the issues raised by the letter have been adequately addressed or remediated.

Our strategic plan is to advance the development and regulatory review of KRYSTEXXA and continue to seek FDA approval of the BLA filing for this product. To fully optimize shareholder value through the full exploitation of the commercial prospects of KRYSTEXXA in the U.S., Europe and internationally, we continue to believe that a worldwide partnership for the commercialization of KRESTEXXA or broader strategic transaction is needed. If we are unsuccessful in consummating a worldwide partnership or broader strategic transaction, we intend to independently pursue the commercialization of KRYSTEXXA in the United States.

Currently, we sell and distribute branded and generic versions of oxandrolone, a drug used to promote weight

gain following involuntary weight loss. We distribute the branded version of oxandrolone in the United States under the name Oxandrin® directly through wholesalers, and our authorized generic version of oxandrolone through an agreement with Watson Pharma, Inc., or Watson. We launched our authorized generic version of oxandrolone in December 2006 in response to the approval and launch of generic competition to Oxandrin and currently have five competitors in the oxandrolone market. Our generic competitors are Sandoz Pharmaceuticals, Upsher-Smith Laboratories, Par Pharmaceuticals, Roxane Laboratories and Kali Laboratories.

The introduction of Oxandrin generics has led to significant decreases in demand for Oxandrin and our authorized generic version of oxandrolone. We believe that revenues from Oxandrin and our authorized generic version of oxandrolone will slightly decline or remain flat in future periods.

We currently operate within one Specialty Pharmaceutical segment, which includes sales of Oxandrin and oxandrolone and the research and development activities of KRYSTEXXA.

Results of Operations

Our revenues were derived from Oxandrin and oxandrolone for the six months ended June 30, 2009 and 2008. Our product revenues and expenses have in the past displayed, and may continue to display, significant variations. These variations may result from a variety of factors, including:

- the timing and amount of product sales,
- changing demand for our products,
- our inability to provide adequate supply for our products,
- changes in wholesaler buying patterns,
- returns of expired product,
- changes in government or private payor reimbursement policies for our products,
- increased competition

from new or existing products,

the timing of the introduction of new products,

- the timing and amount of expenses relating to our manufacturing activities, and
- the extent and timing of costs of obtaining, enforcing and defending intellectual property rights.

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

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

During 2009, we continue to expect the expenses associated with our regulatory, clinical, manufacturing and commercial development of KRYSTEXXA to be the most significant factors affecting our results of operations.

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

	Three months ended June 30,					Six months en
	2009		2008		2009	
Oxandrin	$ (264)	-38.9 %	$ (390)	-123.8 %	$ (126)	-7.1 %
Oxandrolone	943	138.9 %	705	223.8 %	1,890	107.1 %
	$ 679	100.0 %	$ 315	100.0 %	$ 1,764	100.0 %

Results of Operations for the Three Months Ended June 30, 2009 and June 30, 2008

Revenues

Total revenues increased $0.3 million, or 93%, to $0.7 million for the three months ended June 30, 2009, from $0.4 million for the three months ended June 30, 2008.

Gross sales of Oxandrin decreased $0.3 million, or 33%, to $0.6 million for the three months ended June 30, 2009, from $0.9 million for the three months ended June 30, 2008. The decrease was primarily attributable to lower overall demand for the product resulting from increased generic competition. We expect that gross sales will slightly decline or remain flat in future periods. The rate of decline will depend on various factors, including the pricing of competing generic products and the number of competing products and overall demand in the marketplace. Net sales of Oxandrin have increased slightly from period-to-period mainly due to higher prior year historical experience adjustments to our product return reserve and lower government and customer rebates during the current quarter.

Sales of oxandrolone, our Oxandrin generic, increased $0.2 million, or 34%, to $0.9 million for the three months ended June 30, 2009, from $0.7 million for the three months ended June 30, 2008. The higher net sales are mainly due to increased market share being achieved by Watson Pharmaceuticals, Inc., or Watson, our authorized generic distributor.

Cost of goods sold

Cost of goods sold increased $0.2 million, or 70%, to $0.4 million for the three months ended June 30, 2009, from $0.2 million for the three months ended June 30, 2008. The increase is primarily from higher gross sales of our authorized generic, oxandrolone. In addition, the prior year included an adjustment to our inventory obsolescence reserve, which reduced cost of goods sold by $0.1 million based on revised sales demand forecasts.

Research and development expenses

Research and development expenses decreased by $4.1 million, or 26%, to $11.6 million for the three months ended June 30, 2009, from $15.7 million for the three months ended June 30, 2008. The decrease was primarily due to lower technology transfer expenses of $2.1 million as we near the

completion of the technology transfer related to developing our secondary source supplier of pegloticase drug substance. In addition, manufacturing capacity reservation fees paid to our primary manufacturer, BTG-Israel, or BTG, clinical trial expenses and process development expenses were lower by $2.1 million $0.7 million, and $0.6 million, respectively, as the majority of our research and development activities associated with the development of KRYSTEXXA were incurred in prior years. Partially offsetting the lower costs was an increase in severance expense of $1.0 million recorded during the current quarter and $0.6 million in consulting expenses related to our preparation for the FDA Advisory Committee meeting held on June 16, 2009.

Selling, general and administrative expenses

Selling, general and administrative expenses decreased $3.1 million, or 29%, to $7.4 million for the three months ended June 30, 2009, from $10.5 million for the three months ended June 30, 2008. The decrease was primarily due to lower legal fees as the prior year results reflect expenses for Oxandrin-related patent infringement litigation.

Investment income (expense), net

Investment income decreased $0.4 million to an expense of $27,000 for the three months ended June 30, 2009, from income of $0.4 million for the three months ended June 30, 2008. The decrease was primarily attributable to lower dividend and interest income from lower cash, cash equivalent and investment balances and as a result of lower yields earned on these investments.

Other expense, net

Other expense, net increased $35.9 million as a result of the mark-to-market valuation adjustment to our warrant liability during the three months ended June 30, 2009. The increase in fair value of the warrants from their issue date to June 30, 2009 primarily reflects the increase in our common stock price of $9.35 per share during this period. During the three months ended June 30, 2009, we recorded a loss of approximately $35.8 million based upon the higher valuation of the warrants.

Income tax benefit

Our income tax benefit decreased $1.6 million to zero for the three months ended June 30, 2009, as we no longer have the ability to carry back losses to previous years to recover taxes paid and it is uncertain that we will be able to utilize these net operating losses against future income. The 2008 income tax benefit reflects the tax effects of the carryback of our 2008 net operating losses to the 2006 tax year to recover 2006 income taxes paid.

Results of Operations for the Six Months Ended June 30, 2009 and June 30, 2008

Revenues

Total revenues increased $0.3 million, or 15%, to $1.8 million for the six months ended June 30, 2009, from $1.5 million for the six months ended June 30, 2008.

Gross sales of Oxandrin decreased $0.8 million, or 33%, to $1.5 million for the six months ended June 30, 2009, from $2.3 million for the six months ended June 30, 2008. The decrease was primarily attributable to lower overall demand for the product resulting from increased generic competition. We expect that gross sales will slightly decline or remain flat in future periods. The rate of decline will depend on various factors, including the pricing of competing generic products and the number of competing products and overall demand in the marketplace. Net sales of Oxandrin have remained relatively consistent from year-to-year due to higher prior year historical experience adjustments to our product return reserves and lower customer rebates during in the current year.

Sales of oxandrolone, our Oxandrin generic, increased $0.2 million, or 13%, to $1.9 million for the three months ended June 30, 2009, from $1.7 million for the three months ended June 30, 2008.

The higher net sales are primarily due to increased market share being attained by Watson, our authorized generic distributor.

Cost of goods sold

Cost of goods sold increased $0.3 million, or 56%, to $0.9 million for the six months ended June 30, 2009, from $0.6 million for the six months ended June 30, 2008. The increase is primarily from higher gross sales of our authorized generic, oxandrolone. In addition, the prior year included adjustments to our inventory obsolescence reserve, which reduced cost of goods sold by approximately $0.2 million based on revised sales demand forecasts.

Research and development expenses

Research and development expenses decreased by $2.5 million, or 9%, to $24.4 million for the six months ended June 30, 2009, from $26.9 million for the six months ended June 30, 2008. The decrease was primarily due to lower technology transfer expenses of $2.4 million as we near the completion of the technology transfer related to developing our secondary source supplier of pegloticase drug substance. In addition, manufacturing capacity reservation fees paid to BTG, clinical trial expenses, and expenses related to the overall manufacturing of KRYSTEXXA were lower by $2.0 million, $0.9 million and $2.0 million, respectively, as the majority of our research and development activities associated with the development of KRYSTEXXA were incurred in prior years. Partially offsetting the decreases in research and development expenses were higher costs of $1.8 million associated with the production of commercial batches of pegloticase drug substance by BTG, severance expense of $1.8 million recorded during the current year related to the terminations and resignations of certain members of senior management and $0.9 million in consulting expenses related to our preparation for the FDA advisory committee meeting held on June 16, 2009.

Selling, general and administrative expenses

Selling, general and administrative expenses decreased $2.8 million, or 14%, to $16.9 million for the six months ended June 30, 2009, from $19.7 million for the six months ended June 30, 2008. The decrease was primarily due to lower legal fees of $2.9 million as the prior year results reflect expenses for Oxandrin-related patent infringement litigation and $2.0 million of lower compensation and benefits, including share-based compensation, due primarily to decreased headcount. Partially offsetting the lower expenses are higher severance expenses of $0.9 million recorded during the current year as a result of the termination of a former member of our senior management team and higher pre-launch marketing expenses of $1.1 million as we prepare for the launch of KRYSTEXXA.

Investment income (expense), net

Investment income decreased $1.6 million to an expense of $0.2 million for the six months ended June 30, 2009, from income of $1.4 million for the six months ended June 30, 2008. The decrease was primarily attributable to lower dividend and interest income from lower cash, cash equivalent and investment balances and as a result of lower yields earned on these investments.

Other expense, net

Other expense, net increased $35.9 million as a result of the mark-to-market valuation adjustment to our warrant liability in the current year. The increase in fair value of the warrants from their issue date to June 30, 2009 primarily reflects a higher common stock price of $9.35 per share during this period. During the six months ended June 30, 2009, we recorded a loss of approximately $35.8 million based upon the higher valuation of the warrants.

Income tax benefit

Our income tax benefit decreased $2.8 million to zero for the six months ended June 30, 2009, as we no longer have the ability to carry back losses to previous years to recover taxes paid and it is uncertain that we will be able to utilize these net operating losses against future income. The 2008

income tax benefit reflects the tax effects of the carryback of our 2008 net operating losses to the 2006 tax year to recover 2006 income taxes paid.

Liquidity and Capital Resources

At June 30, 2009, we had $76.6 million in cash, cash equivalents and short-term investments. Our current cash balance reflects $29.0 million in proceeds from our registered direct offering in April 2009, a $5.5 million federal income tax refund received in June 2009 and approximately $3.9 million in proceeds from the issuance of common stock, primarily due to the exercise of stock options during the six months ended June 30, 2009. We primarily invest our cash equivalents and short-term investments in highly liquid, interest-bearing, U.S. Treasury money market funds in order to preserve principal.

Although our strategic plan is to advance the development and regulatory review of KRYSTEXXA and to seek FDA approval of the BLA filing for this product, we believe that a worldwide partnership or strategic transaction is needed to fully optimize shareholder value through the full exploitation of the commercial prospects of KRYSTEXXA in the U.S., Europe and internationally. If we are unsuccessful in consummating a worldwide partnership or strategic transaction, we intend to independently pursue the commercialization of KRYSTEXXA in the U.S. and will make significant expenditures related to the launch of the product, which we anticipate will occur in 2010. We believe that our available cash and cash equivalents will be sufficient to fund anticipated levels of operations through at least August 2010. In addition, in light of the FDA s July 31, 2009 complete response letter to our KRYSTEXXA BLA, we are engaging in an active effort to reassess our expenditures and align our cash expenses more closely with the FDA approval process to conserve cash.

On April, 8 2009, we raised $31.0 million from a registered direct offering, which yielded approximately $29.0 million in cash net of approximately $2.0 million of offering costs, which were charged to additional paid-in-capital. We issued 5,927,343 shares of its common stock to existing and new institutional investors as part of the offering. The investors also received warrants to purchase up to 5,038,237 shares of its common stock at an initial exercise price of $10.46 per share. The warrants are exercisable at any time on or after the date of issuance and expire on the earlier of November 2, 2010, and the date that is nine months after the date on which we publicly announce that we have addressed all items required by the FDA to be addressed before our BLA can be approved. Pursuant to the terms of the warrants, the exercise price for the warrants will, from and after August 17, 2009, be equal to the dollar volume weighted-average price of our common stock for the five trading days immediately preceding such date. The exercise price per share may not exceed $10.46 or be less than $1.57. We may, at our or the warrant holder s election, issue net shares in lieu of a cash payment of the exercise price by the warrant holder upon exercise.

In the event that we enter into a merger or change of control transaction, the holders of the warrants will be entitled to receive consideration as if they had exercised the warrant immediately prior to such transaction, or they may require us to purchase the warrant at the Black-Scholes value at the time of such transaction.

In June 2009 we received a U.S. federal income tax refund of approximately $5.5 million which was reflected in Recoverable Income Taxes on our consolidated balance sheet as of December 31, 2008. The refund is the result of the carry back of our 2008 federal net operating losses against 2006 taxable income.

If the FDA does not approve our BLA, if we are not successful in commercializing KRYSTEXXA, or if the FDA further delays its approval of KRYSTEXXA, our cash needs will increase, our business will be materially harmed and we may need to curtail or cease operations. We may not be able to obtain additional funds or, if such funds are available, such funding may not be on terms that are acceptable to us, particularly in light of current macroeconomic conditions. If we raise additional funds by issuing equity securities, dilution to our then-existing security-holders 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 additional funds are not available on favorable terms, or at all, we may be required to curtail or cease operations.

Cash Flows

Cash used in operating activities of $35.9 million for the six months ended June 30, 2009, reflects our net operating loss for the period of $76.8 million partially offset by $5.5 million in cash received from our U.S. federal income tax refund as a result of the carry back of our 2008 federal net operating losses against 2006 taxable income and a non-cash charge of $35.9 million as a result of increased valuation of our warrant liability primarily due to the increase in our common stock price from the date of the warrant issuance through June 30, 2009. We received $1.5 million from investment activities resulting primarily from redemptions of our investment in the Columbia Strategic Cash Portfolio. The proceeds from the redemptions were re-invested in cash and cash equivalents and used to fund operations. We also received $32.9 million in cash from financing activities, $29.0 million resulting from net proceeds from our registered direct offering on April 8, 2009 and $3.9 million in proceeds from the issuance of common stock, primarily due to the exercise of stock options.

For the six months ended June 30, 2008, we used net cash of $23.7 million in operating activities, mainly to fund the research and development of KRYSTEXXA. We received $9.1 million in cash from investment activities, resulting primarily from redemptions of our investment in the Columbia Strategic Cash Portfolio. These proceeds were reinvested in cash and cash equivalents and used to fund operations. Cash received from financing activities of $2.2 million resulted from proceeds from the exercise of stock options.

Contractual Obligations

We have a liability for unrecognized tax benefits of $10.6 million as of June 30, 2009. We are unable to reasonably estimate the amount or timing of payments for this liability, if any. As of June 30, 2009, we have accrued $2.6 million in addition to our contractual obligations set forth in our Annual Report on Form 10-K for the year ended December 31, 2008 for severance expenses related to the resignations of our former Senior Vice President of Quality and Regulatory Affairs and Senior Vice President and Chief Medical Officer and the termination of our former Senior Vice President, Chief Financial Officer and Treasurer, which will be ratably paid out through 2011. The severance payments consist of eighteen months of base salary and bonus, unused vacation days, outplacement services and the continuation of health care, dental, life and accidental death and dismemberment and disability insurance coverage for a period of eighteen months. There have been no other material changes to our contractual obligations as presented in our Annual Report on Form 10-K for the year ended December 31, 2008.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

Critical Accounting Policies and Estimates

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

circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in Item 8 of our Annual Report on Form 10-K, we believe the following accounting policies are the most critical to our reported financial results:

Product revenue recognition. Product sales are generally recognized when title to the product has transferred to our customers in accordance with the terms of the sale. Since December 2006, we began shipping oxandrolone to our distributor and have accounted for this on a consignment basis until the product is sold into the retail market. We have deferred the recognition of revenue related to these shipments until we confirm that the product has been sold into the retail market and all other revenue recognition criteria have been met. We recognize revenue in accordance with the Securities and Exchange Commission s, or SEC s, Staff Accounting Bulletin, or SAB, No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, which we refer to together as SAB 104, and Statement of Financial Accounting Standards, or SFAS, No. 48 *Revenue Recognition When Right of Return Exists.* SAB 104 states that revenue should not be recognized until it is realized or realizable and earned.

Revenue is realized or realizable and earned when all of the following criteria are met:

- persuasive evidence of an arrangement exists,
- delivery has occurred or services have been rendered,
- the seller s price to the buyer is fixed and determinable, and
- collectability is reasonably assured.

SFAS No. 48 states that revenue from sales transactions where the buyer has the right to return the product shall be recognized at the time of sale only if:

- the seller s price to the buyer is substantially fixed or determinable at the date of sale,

- the buyer has paid and the obligation is not contingent on resale of the product,
- the buyer s obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product,
- the buyer acquiring the product for resale has economic substance apart from that provided by the seller,
- the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and
- the amount of future returns can be reasonably estimated.

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

Allowances for returns. In general, we provide credit for product returns that are returned six months prior to or up to twelve months after the product expiration date. Our product sales in the U.S. primarily relate to the

following products:

Product	Expiration (in years)
Oxandrin and oxandrolone 2.5 mg	5
Oxandrin and oxandrolone 10 mg	3 and 4

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

Actual return rates We track actual returns by product and by batch produced and analyze historical return trends. We use these historical trends as part of our overall process of estimating future returns.

The level of product manufactured The level of product produced has an impact on the valuation of that product. For production that exceeds anticipated future demand, a valuation adjustment will be required. Generally, this valuation adjustment occurs as an offset to gross inventory. Currently, we have mandated that product with less than twelve months of expiry dating will not be sold into the distribution channel. However, beginning in April of 2008 and continuing for approximately

three months, we commenced shipment of a small amount of our 2.5 mg strength Oxandrin with less than twelve months of expiry dating into the distribution channel.

Level of product in the distribution channel We review wholesaler inventory and third-party prescription data to ensure that the level of product in the distribution channel is at a reasonable level. Currently, the level of product in the distribution channel appears reasonable for four-year and three- year expiration product. The five-year expiration product currently has higher levels of inventory in the distribution channel as compared to historical trends.

Estimated shelf life Product

returns generally occur due to product expiration. Therefore, it is important for us to ensure that product sold into the distribution channel has excess dating that will allow the product to be sold through the distribution channel without nearing its expiration date. Currently, we have mandated that product with less than twelve months of expiry dating will not be sold into the distribution channel. We have taken the appropriate measures to enforce this policy, including setting up certain controls with our third-party logistics provider. However, beginning in April of 2008 and continuing for approximately three months, we commenced shipment of a small amount of our 2.5 mg strength Oxandrin with

less than twelve months of expiry dating into the distribution channel. In addition, we entered into a distributor service agreement with two of our large wholesalers which limits the level of product at these wholesaler customers. The terms of these agreements are consistent with the industry s movement toward a fee-for-service approach which we believe has resulted in better distribution channel inventory management, higher levels of distribution channel transparency, and more consistent buying and selling patterns. Since a majority of our sales flow through three large wholesalers, we expect that these industry changes will have a direct impact on our future sales to wholesalers,

inventory management, product returns and estimation capabilities.

Current and projected demand We analyze prescription demand data provided by industry standard third-party sources. This data is used to estimate the level of product in the distribution channel and to determine future sales trends.

Product launches and new product introductions For future product launches, we will analyze projected product demand and production levels in order to estimate return and inventory reserve allowances. New product introductions, including generics, will be monitored for market erosion and adjustments to return reserve estimates will be made

accordingly.

We also utilize the guidance provided in SFAS No. 48 and SAB 104 in establishing our return estimates. SFAS No. 48 discusses potential factors that may impair the ability to make a reasonable estimate including:

- the susceptibility of the product to significant external factors, such as technological obsolescence or changes in demand,
- relatively long periods in which a particular product may be returned,
- absence of historical experience with similar types of sales of similar products, or inability to apply such experience because of changing circumstances, for example, changes in the selling enterprise s marketing policies or relationships with its customers, and
- absence of a large volume of relatively homogeneous transactions.

SAB 104 provides additional factors that may impair the ability to make a reasonable estimate including:

- significant increases in or excess levels of inventory in a distribution channel,
- lack of visibility into or the inability to determine or observe the levels of inventory in a distribution channel and the current level of sales to end users,
- expected introductions of new products that may result in the technological obsolescence of and larger than expected returns of current products,
- the significance of a particular distributor to the registrant s (or a reporting segment s) business, sales and marketing,
- the newness of a product,

- the introduction of competitors products with superior technology or greater expected market acceptance, and
- other factors that affect market demand and changing trends in that demand for the registrant s products.

The allowance for product returns was $1.1 million at June 30, 2009 and $1.2 million at December 31, 2008.

Allowances for Medicaid and other government rebates. Our contracts with Medicaid and other government agencies such as the Federal Supply System commit us to providing those agencies with our most favorable pricing. This ensures that our products remain eligible for purchase or reimbursement under these government-funded programs. Based upon our contracts and the most recent experience with respect to sales through each of these channels, we provide an allowance for rebates. We monitor the sales trends and adjust the rebate percentages on a regular basis to reflect the most recent rebate experience. The aggregate net rebate accrual balance was $0.5 million at June 30, 2009 and $0.6 million at December 31, 2008.

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

We continually analyze the impact of generic competition on our inventory reserves considering the Oxandrin inventory currently on hand, inclusive of raw materials and finished goods, and the current demand forecasts. The aggregate net inventory valuation reserves were $6.0 million at June 30, 2009 and $6.3 million at December 31, 2008.

Share-based compensation. We grant stock options to employees and non-employee Directors, or Directors, with exercise prices equal to the fair market value of the underlying shares of our common stock on the date that the options are granted. Options have a term of ten years from the grant date. Options granted to employees vest over a four-year period and options granted to Directors vest in equal quarterly installments over a one-year period from the date of grant. Options to Directors are granted on an annual basis and represent compensation for service on our Board. Compensation cost for stock options is charged against income on a straight-line basis between the grant date for the option and the vesting period. We estimate the fair value of all stock option awards by applying the Black-Scholes pricing valuation model. The application of this valuation model involves assumptions that are highly subjective, judgmental and sensitive in the determination of compensation cost. For the three months ended June 30, 2009 and 2008, approximately $0.7

million of stock option compensation expense has been charged against income in each respective period. For the six months ended June 30, 2009 and 2008, approximately $1.9 million and $1.8 million, respectively, of stock option compensation expense was charged against income. As of June 30, 2009, there was $3.4 million of unrecognized compensation cost, adjusted for estimated forfeitures, related to unamortized stock option compensation which is expected to be recognized over a weighted-average period of approximately 2.8 years. Total unrecognized compensation cost will be adjusted for future changes in estimated forfeitures. In addition, as future grants are made, we expect to incur additional compensation costs.

We grant restricted stock awards to our employees and to our Directors. Restricted stock awards are recorded as deferred compensation and amortized into compensation expense, on a straight-line basis over the vesting period, which ranges from one to four years in duration. Restricted stock awards to Directors are granted on an annual basis and represent compensation for services performed on our Board. Restricted stock awards to Directors vest in equal quarterly installments over a one-year period from the grant date. Compensation cost for restricted stock awards is based on the grant date fair value of the award, which is the closing market price of our common stock on the grant date multiplied by the number of shares awarded. For the six months ended June 30, 2009, we issued 133,000 shares of restricted stock at a weighted-average grant date fair value of $5.78 per share amounting to $0.8 million in total aggregate fair market value. For the three months ended June 30, 2009 and 2008, approximately $0.6 million and $0.9 million, respectively, of deferred restricted stock compensation cost was charged against income. For the six months ended June 30, 2009 and 2008, approximately $1.4 million and $1.7 million, respectively, of deferred restricted stock compensation cost was charged against income. At June 30, 2009, approximately 631,000 shares remained unvested and there was approximately $4.6 million of unrecognized compensation cost related to restricted stock.

We issue restricted stock awards that contain performance conditions to members of senior management. These awards may vest over a period of one to four years from the date of grant depending on the nature of the performance goal upon the achievement of specific strategic objectives associated with the achievement of KRYSTEXXA-related developmental and sales milestones and other manufacturing, commercial operations and business development objectives. Compensation cost is based on the grant date fair value of the award, which is the closing market price of our common stock on the date the award is granted multiplied by the number of shares awarded. Compensation expense is recorded over the implicit or explicit requisite service period based on management s best estimate as to whether it is probable that the shares awarded are expected to vest. Previously recognized compensation expense is fully reversed if performance targets are not satisfied.

We did not record any expense related to restricted stock awards that contain performance conditions for the three and six months ended June 30, 2009 based on our probability estimates after consideration of the FDA s complete response letter to us on July 31, 2009. For the three and six months ended June 30, 2008, approximately $0.4 million and $0.9 million, respectively, of compensation cost was charged against income related to restricted stock awards that contain performance conditions. At June 30, 2009, approximately 126,000 potential shares of restricted stock with performance conditions remained unvested. Restricted stock awards with performance conditions encompass performance targets set for senior management personnel through 2011and could result in approximately $2.0 million of additional compensation expense if the performance targets are met or expected to be attained.

Research and development. During the first quarter of 2008, we adopted Emerging Issues Task Force, or EITF, Issue No. 07-03, *Accounting for Non-refundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities.* The EITF affirmed as a consensus, that non-refundable advance payments for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the goods are delivered or the related services are performed. Consistent with the consensus, we defer these costs and amortize them into expense based on services performed. All other research and development costs are charged to expense as incurred, including KRYSTEXXA inventory purchaces. The net deferred balance, which is included in Prepaid Expenses and Other Current Assets on our consolidated balance sheets was $0.2 million at June 30, 2009 and $0.7 million at December 31, 2008.

Income taxes. We account for income taxes pursuant to the provisions prescribed under SFAS No. 109, *Accounting for Income Taxes* . Under SFAS No. 109, deferred income taxes are recognized at each year end for the future tax consequences of differences between the tax bases of assets and liabilities and their financial reporting amounts based on tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. We routinely assess the reliability of our deferred tax assets. We consider future taxable income in making such assessments. If we conclude that it is more likely than not that some portion or all of

the deferred tax assets will not be realized under accounting standards, it is reduced by a valuation allowance. However, despite our attempt to make an accurate estimate, the ultimate utilization of our deferred tax assets is highly dependent upon our actual results and the realization of taxable income in future periods. In July 2006, the Financial Accounting Standards Board, or FASB, issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, which we refer to as FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with SFAS No. 109. This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition of tax benefits, classification on the consolidated balance sheet, interest and penalties, accounting in interim periods, disclosure, and transition. We adopted FIN 48 effective January 1, 2007. As a result of the implementation of FIN 48 in 2007, we recorded a $4.5 million increase in the liability for unrecognized tax benefits, including $0.2 million of accrued interest and penalties, which is included in Other Liabilities on our consolidated balance sheets. This increase in liability resulted in a corresponding increase to Accumulated Deficit. The total amount of federal, state, local and foreign liabilities for unrecognized tax benefits was $10.6 million as of June 30, 2009, including accrued penalties and interest. The net increase of $6.1 million in the liability for unrecognized tax benefits subsequent to adoption resulted in a corresponding decrease to the income tax benefit within our consolidated statements of operations as well as an increase to the deferred tax asset for which no tax benefit will be recognized in our consolidated statements of operations.

Disclosures about fair values of financial instruments. On January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements*, which clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. In February 2008, the FASB issued FASB Staff Position, or FSP, SFAS No. 157-2 that deferred the effective date of SFAS No. 157 for one-year for non-financial assets and liabilities recorded at fair value on a non-recurring basis. In October 2008, the FASB issued FSP SFAS No. 157-3, which clarifies the application of SFAS No. 157 in a market that is not active. FSP SFAS No. 157-3 was effective during the fourth quarter of 2008, and the effect of adoption on our financial position and results of operations was not material. In April 2009, the FASB issued FSP SFAS No. 157-4, which provides additional guidance for estimating fair value in accordance with SFAS No.157 when the volume and level of activity for an asset or liability have significantly decreased. Additionally, FSP SFAS No. 157-4 supersedes FSP SFAS No. 157-3 and also addresses the identification of transactions that are not considered orderly. FSP No. 157-4 emphasizes that even if there has been a significant decrease in the volume and level of activity for the asset or liability and regardless of the valuation technique(s) used, the objective of a fair value measurement remains the same. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction (that is, not a forced liquidation or distressed sale) between market participants at the measurement date under current market conditions. FSP SFAS No. 157-4 was early adopted by us and was effective for us for the quarter ended March 31, 2009. The effect of adoption on our financial position and results of operations was not material. SFAS No. 157 establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Pursuant to the provisions as prescribed in SFAS No. 157, we categorize our financial instruments into a three-level fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). If the inputs used to measure fair value fall within different levels of the hierarchy, the category level is based on the lowest priority level input that is significant to the fair value measurement of the instrument. SFAS No. 107 requires all entities to disclose the fair value of financial instruments, both assets and liabilities recognized and not recognized in the statement of financial position, for which it is practicable to estimate fair value. In April 2009, the FASB issued FSP SFAS No. 107-1 and Accounting Practice Bulletin, or APB, No. 28-1, *Interim Disclosures about Fair Value of Financial Instruments.* FSP SFAS No. 107-1 and APB No. 28-1 amends SFAS No. 107, *Disclosures about Fair Value of Financial Instruments,* to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. We have elected to early adopt FSP SFAS No. 107-1 and APB No. 28-1 for the

quarter ended March 31, 2009. The carrying amounts of Notes Receivable, Accounts Receivable, Accounts Payable and Other Current Liabilities approximate fair value.

Other-than-temporary impairment losses on investments. We regularly monitor our available-for-sale portfolio to evaluate the necessity of recording impairments for other-than-temporary, or OTT, declines in the fair value of investments. Management makes this determination through the consideration of various factors such as management s intent and ability to retain an investment for a period of time sufficient to allow for any anticipated recovery in market value. OTT impairment losses result in a permanent reduction of the cost basis of an investment. We did not realize any investment losses due to OTT declines in fair value for the three and six months ended June 30, 2009 and for the three months ended June 30, 2008. For the six months ended June 30, 2008, we recorded realized investment losses due to OTT declines in fair value of approximately $0.1 million.

Derivative Instruments (Warrant Liability). In April 2009, we issued 5,927,343 shares of our common stock to existing and new institutional investors as part of a registered direct offering. The investors also received warrants to purchase up to 5,038,237 shares of our common stock at an initial exercise price of $10.46 per share. We account for the warrants as a liability pursuant to the guidance provided in EITF Issue No. 07-05, *Determining Whether and Instrument (or Embedded Feature) Is Indexed to an Entities Own Stock,* EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock* and SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities.* SFAS 133 specifies that a contract that would otherwise meet the definition of a derivative under that Statement, issued or held by the reporting entity that is both (a) indexed to its own stock and (b) classified in stockholders equity in its statement of financial position, shall not be considered a derivative financial instrument for purposes of applying that Statement. EITF No. 07-05 provides a two-step method for determining whether an instrument is indexed to an entities own stock. Under the provisions of EITF No. 00-19, a contract designated as an asset or a liability must be carried at fair value until exercised or expired, with any changes in fair value recorded in the results of operations. Also pursuant to EITF No. 00-19, the classification of a contract should be reassessed at each balance sheet date and should be reclassified as of the date of the event that caused the reclassification. There is no limit on the number of times a contract may be reclassified. If a contract is reclassified from permanent or temporary equity to an asset or a liability, the change in fair value of the contract during the period the contract was classified as equity should be accounted for as an adjustment to stockholders equity. If a contract is reclassified from an asset or a liability to equity, gains or losses recorded to account for the contract at fair value during the period that the contract was classified as an asset or a liability should not be reversed. Our warrant liability is marked-to-market each reporting period with the change in fair value recorded as a gain or loss within Other Expense, net on our consolidated statement of operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified as an equity instrument. The fair value of the warrant liability is determined at each reporting period by utilizing a Monte Carlo simulation option pricing model that takes into account estimated probabilities of possible outcomes provided by us.

Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board, or FASB, issued SFAS No. 168 *FASB Accounting Standards Codification*, or Codification, as the single source of authoritative non-governmental United States Generally Accepted Accounting Principles, or GAAP, to be launched on July 1, 2009. SFAS No. 168 replaces FASB Statement No. 162, *The Hierarchy of Generally Accepted Accounting Principles.* The Codification does not change current GAAP, but is intended to simplify user access to all authoritative GAAP by providing all the authoritative literature related to a particular topic in one place. All existing accounting standard documents will be superseded and all other accounting literature not included in the Codification will be considered non-authoritative. The Codification is effective for interim and annual periods ending after September 15, 2009. The Codification is for disclosure only and will not impact our financial condition or results of operations. We are currently evaluating the impact to our financial reporting process of providing Codification references in our public filings.

In May 2009, the FASB, issued SFAS No. 165, *Subsequent Events.* SFAS No. 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet data but before financial statements are issued. SFAS No. 165 requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date and should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. SFAS No. 165 shall be applied to the accounting for and disclosure of subsequent events not addressed in other applicable GAAP. Other applicable GAAP may address the accounting treatment of events or transactions that occur after the balance sheet date but before the financial statements are issued. If an event or transaction is within the scope of other applicable GAAP, then an entity shall follow the guidance in that applicable GAAP, rather than the guidance in SFAS No. 165. SFAS No. 165 is effective for interim or annual financial periods ending after June 15, 2009, and is applied prospectively. The adoption of FSP SFAS No. 165 did not have a material effect on our recognition or disclosure in our consolidated financial statements. We evaluate all subsequent events as of the issuance date of our financial Statements. We have evaluated subsequent events as of August 10, 2009, which is the date of filing of our report on this Form 10-Q. We have not evaluated subsequent events after such date.

In April 2009, the FASB issued FASB Staff Position, or FSP, SFAS No. 157-4, *Determining the Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly.* FSP SFAS No. 157-4 provides additional guidance for estimating fair value in accordance with SFAS No. 157, *Fair Value Measurements*, when the volume and level of activity for the asset of liability have significantly decreased. FSP SFAS No. 157-4 supersedes FSP SFAS No. 157-3. FSP No. 157-4 emphasizes that even if there has been a significant decrease in the volume and level of activity for the asset or liability and regardless of the valuation technique(s) used, the objective of a fair value measurement remains the same. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction (that is, not a forced liquidation or distressed sale) between market participants at the measurement date under current market conditions. The guidance included in FSP SFAS No. 157-4 addresses the recommendations of specific issues in the SEC s study on mark-to-market accounting and provides additional guidance on determining fair value when the volume and level of activity for the asset or liability have significantly decreased when compared with normal market activity for the asset or liability (or similar assets or liabilities). FSP SFAS No. 157-4 is effective for interim and annual reporting periods ending after June 15, 2009 and shall be applied prospectively. Early adoption is permitted for periods ending after March 15, 2009. Early adoption for periods ending before March 15, 2009 is not permitted. Additionally, if a reporting entity elects to adopt early either FSP SFAS No. 115- 2 and FAS No. 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments,* or FSP SAS No. 107-1 and APB No. 28-1, *Interim Disclosures about Fair Value of Financial Instruments,* the entity is also required to adopt early FSP SFAS No. 157-4. FSP SFAS No. 157-4 does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP SFAS No. 157-4 requires comparative disclosures only for periods ending after initial adoption. We early adopted FSP SFAS No. 157-4 for the quarterly period ended March 31, 2009. The adoption of FSP SFAS No. 157-4 did not have a material effect on our consolidated financial statements.

In April 2009, the FASB issued FSP SFAS No. 107-1 and APB No. 28-1, *Interim Disclosures about Fair Value of Financial Instruments.* FSP SFAS No. 107-1 and APB No. 28-1 amends SFAS No. 107, *Disclosures about Fair Value of Financial Instruments,* to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FSP SFAS No. 107-1 and APB No. 28-1 also amends APB Opinion No. 28, *Interim Financial Reporting,* to require those disclosures in summarized financial information at interim periods. FSP SFAS No. 107-1 and APB No. 28-1 is effective for interim and annual reporting periods ending after June 15, 2009 with early adoption permitted for periods ending after March 15, 2009. An entity may early adopt FSP SFAS No. 107-1 and APB No. 28-1 only if it also elects to early adopt FSP SFAS No. 157-4, *Determining the Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly,* and FSP SFAS Nos. 115-2 and 124-2, *Recognition and Presentation of Other-Than-*

Temporary Impairments. FSP SFAS No. 107-1 and APB No. 28-1 do not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP SFAS No. 107-1 and APB No. 28-1 require comparative disclosures only for periods ending after initial adoption. We have early adopted FSP SFAS No. 107-1 and APB No. 28-1 for the quarterly period ended March 31, 2009. The adoption of FSP SFAS No. 107-1 and APB No. 28-1 did not have a material effect on our consolidated financial statements.

In April 2009, the FASB issued FSP SFAS No. 115-2 and SFAS No. 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments.* FSP SFAS No. 115-2 and SFAS No.124-2 amends the OTT impairment guidance in GAAP for debt securities to make the guidance more operational and to improve the presentation and disclosure of OTT impairments on debt and equity securities in the financial statements. FSP SFAS No. 115-2 and SFAS No. 124-2 does not amend existing recognition and measurement guidance related to OTT impairments of equity securities. FSP SFAS No. 115-2 and SFAS No. 124-2 expands and increases the frequency of existing disclosures about OTT impairments for debt and equity securities. It requires a more detailed, risk oriented breakdown by major security types and related information currently required by SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* In addition, FSP SFAS No. 115-2 and SFAS No. 124-2 requires that the annual disclosures in SFAS No. 115, and FSP SFAS No. 115- 1 and SFAS No.124-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments,* be made for interim periods. FSP SFAS No. 115-2 and SFAS No. 124-2 is effective for interim and annual reporting periods ending after June 15, 2009 with early adoption permitted for periods ending after March 15, 2009. Early adoption for periods ending before March 15, 2009 is not permitted. If an entity elects to adopt early either FSP SFAS No. 157-4, *Determining the Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly* or FSP SFAS No. 107-1 and APB No. 28-1, *Interim Disclosures about Fair Value of Financial Instruments,* the entity is also required to adopt early FSP SFAS No. 115-2 and SFAS No. 124-2. Additionally, if an entity elects to adopt early FSP SFAS No. 115-2 and SFAS No. 124-2*,* it is required to adopt FSP SFAS No. 157-4. FSP SFAS Nos. 115-2 and 124-2 do not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, FSP SFAS Nos. 115-2 and 124-2 require comparative disclosures only for periods ending after initial adoption. We early adopted FSP SFAS Nos. 115-2 and 124-2 for the quarterly period ended March 31, 2009. The adoption of FSP SFAS Nos. 115-2 and 124-2 did not have a material effect on our consolidated financial statements.

In June 2008, the EITF ratified the consensus on Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entities Own Stock.* EITF No. 07-05 applies to any freestanding financial instrument or embedded feature that has all the characteristics of a derivative in paragraphs six through nine of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities,* for the purposes of determining whether that instrument or embedded feature qualifies for the first part of the scope exception in paragraph 11(a) of SFAS No. 133. EITF No. 07-05 also applies to any freestanding financial instrument that is potentially settled in an entities own stock, regardless of whether the instrument has all of the characteristics of a derivative in paragraphs six through nine of SFAS No. 133, for purposes of determining whether the instrument is within the scope of EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock.* In April 2009, we issued 5,927,343 shares of our common stock to existing and new institutional investors as part of a registered direct offering. The investors also received warrants to purchase up to 5,038,237 shares of our common stock at an initial exercise price of $10.46 per share. These warrants are being accounted for as a liability derivative instrument pursuant to the guidance provided in EITF No. 07-05, EITF No. 00-19 and SFAS No. 133. The warrant liability is marked-to- market each reporting period with the change in fair value recorded as a gain or loss within Other Expense, net on our consolidated statement of operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified as an equity instrument. The value of the warrants are determined at each reporting period utilizing the Black-Scholes option pricing model. See Note 10 to our consolidated financial statements for further discussion of the financial statement impact of the warrants.

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 any derivative financial instruments for trading or other speculative purposes.

Our material interest-bearing assets consist of cash and cash equivalents and short-term investments, including investments in U.S. Treasury and other money market funds. Our investment income is primarily sensitive to changes in U.S. Treasury security interest rates, general interest rates within the U.S. economy and other market conditions.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to management, including our President and our Chief Financial Officer, or CFO, as appropriate, to allow timely decisions regarding required disclosure.

We do not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within our company have been detected.

These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Our management, with the participation of our President and our CFO, evaluated the effectiveness of our disclosure controls and procedures. Based on this evaluation, as of the end of the period covered by this Quarterly report on Form 10-Q, our President and our CFO have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are effective.

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Intellectual Property-Related Litigation

We are aware of patent applications filed by, or patents issued to, other entities with respect to technology potentially useful to us and, in some cases, related to products and processes being developed by us. We cannot presently assess the effect, if any, that these patents may have on our operations. The extent to which efforts by other researchers have resulted or will result in patents and the extent to which the issuance of patents to others would have a materially adverse effect on us or would force us to obtain licenses from others is currently unknown. See Item 1A. Risk Factors Risks Relating to Intellectual Property for further discussion.

In 2007, Joseph R. Berger filed a complaint against us in the Fayette County Circuit Court in Kentucky alleging breach of contract in connection with the assignment of certain inventions related to the method of using oxandrolone to treat HIV/AIDS patients. The complaint alleged several causes of action, each of which was premised on the existence of an oral agreement between us and Berger, which Berger alleges we breached. Berger sought, among other things, damages and rescission of the assignment of the inventions. In March 2008, Berger filed an amended complaint that abandoned several of his claims, but continued to seek damages and rescission of the invention assignments. In March 2008, the Court granted our motion to limit discovery to liability issues for 150 days in contemplation of our bringing a motion for summary judgment at the end of that period. Over our objection in 2008, the Court granted a request by Berger to extend the discovery period by four months and, accordingly, discovery as to liability ended in December 2008. On or about March 13, 2009, each party filed a Motion for Summary Judgment and thereafter filed corresponding responsive pleadings. Oral arguments on the motions were held on April 24, 2009 and a decision is expected in the near future. We intend to vigorously defend against this action.

Other Litigation

In November 2008, Richard Sagall, an alleged stockholder, commenced an action in the U.S. District Court for the Southern District of New York seeking to certify a class of shareholders who held Savient securities between December 13, 2007 and October 24, 2008. The suit alleges that we made false and misleading statements relating to the GOUT1 and GOUT2 Phase 3 clinical trials and that we failed to disclose in a timely manner serious adverse events which occurred in five patients in these trials. A lead plaintiff was appointed in March 2009 resulting in the re-captioning of the action as *Lawrence J. Koncelik, Jr. vs. Savient Pharmaceuticals, et al.* An amended compliant was filed in this matter in April 2009 and the Company filed a motion to dismiss in June 2009. Plaintiff s opposition is due in August 2009. We intend to vigorously defend against this action.

From time to time we become subject to legal proceedings and claims in the ordinary course of business. Such claims, even if without merit, could result in the significant expenditure of our financial and managerial resources.

ITEM 1A. RISK FACTORS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. All statements, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future results of operations, future cash flows, projected costs, financing plans, product development, possible strategic alliances, competitive position, prospects, plans and objectives of management, are forward- looking statements. We often use words such as anticipate, estimate, expect, project, intend, plan, believe, may, predict, will, and would, and similar expressions, to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- *our efforts to reduce our burn rate and conserve cash,*
- *potential FDA marketing approval for KRYSTEXXA (pegloticase),*
- *a meeting with the FDA to discuss the complete response letter,*
- *the reversion to and revalidation of the Phase 3 manufacturing process,*
- *the terms of a REMS program,*
- *the timing of a resubmission to the FDA in response to the complete response letter, and*
- *the efficacy and safety of KRYSTEXXA.*

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 various cautionary statements in this Quarterly Report on Form 10-Q 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 undertake no obligation to publicly update forward-looking statements. We provide the following cautionary discussion of risks, uncertainties and possibly inaccurate assumptions relevant to our businesses.

These are important factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.

You should carefully consider the following risk factors in addition to other information included in this Quarterly Report on Form 10-Q, and in our Annual Report on Form 10-K, in evaluating us and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected. The following risk factors restate and supersede the risk factors previously disclosed in Item 1A. of our Annual Report on Form 10-K for the year ended December 31, 2008.

The following risk factors have been updated to reflect developments subsequent to the filing of our Annual Report on Form 10-K for the year ended December 31, 2008, and we have denoted with an asterisk (*) in the following discussion those risk factors that are new or materially revised.

Risks Relating to Development of KRYSTEXXA and Our Ability to Accomplish Our Future Business Objectives

**** Our business depends on our success in gaining approval of KRYSTEXXA, which requires that we and our third-party manufacturer address several deficiencies raised by the FDA. If these issues are not addressed, we will not gain approval of KRYSTEXXA, and our business will be materially harmed.***

On July 31, 2009, the FDA notified us that it would not approve the BLA for KRYSTEXXA unless and until:

- deficiencies with the chemistry, manufacturing and controls, or CMC, section of the BLA are addressed,
- facility inspection observation remediation actions are adequately taken by our primary third-party manufacturer,
- we implement a Risk Evaluation and Mitigation Strategy, or REMS, and
- we provide a follow-up safety update to the FDA.

In particular, the FDA concluded that the comparability data we submitted for the material manufactured using the proposed commercial manufacturing process for KRYSTEXXA was not adequate to demonstrate that it was representative of the material used to establish the safety and efficacy of KRYSTEXXA in the Phase 3 clinical trials. The FDA stated that we have the option of either reverting to and validating the manufacturing process used to produce pegloticase for the Phase 3 clinical trials or conducting additional comparability clinical trials to support the use of pegloticase in KRYSTEXXA manufactured using the proposed commercial manufacturing process. We currently expect that we will address this issue by reverting to and revalidating the manufacturing process used to produce pegloticase in KRYSTEXXA for the Phase 3 clinical trials.

The FDA also requested that we tighten manufacturing parameters and narrow analytical specifications associated with the commercial production processes. Many of these additional requests were previously

discussed with the FDA during the review and inspection process and were to be addressed as post-approval commitments if approval was granted on or before August 1, 2009. However, given the delay, these additional matters have now been incorporated into the complete response letter and will be addressed in our resubmission of the BLA.

In addition, the FDA is requiring that our third-party pegloticase drug substance manufacturer, BTG-Israel, or BTG, correct certain deficiencies noted in the FDA s inspection of its manufacturing facility, and be reinspected before KRYSTEXXA can be approved. BTG has issued a work plan and timeline to the FDA to address these concerns.

Addressing each of these issues will require additional expenditures of funds and time to complete, and there can be no guarantee that we, or BTG, as the case may be, will adequately address the FDA s concerns such that our BLA is ultimately approved without further delays, if at all. If our BLA is not approved, our business will be materially harmed.

**** The manufacture and packaging of pharmaceutical products such as KRYSTEXXA are subject to the requirements of the FDA and similar foreign regulatory bodies. If we or our third-party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be materially harmed.***

The manufacture and packaging of pharmaceutical products, such as KRYSTEXXA, are regulated by the FDA and similar foreign regulatory bodies and must be conducted in accordance with the FDA s cGMP and comparable requirements of foreign regulatory bodies. Failure by us or our third- party manufacturers 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.

Our third-party manufacturers and testing facilities, including BTG, Enzon and PPD, underwent pre-approval inspections by the FDA. As a result of these pre-approval inspections, the FDA identified deficiencies in its pre-approval inspection of our pegloticase drug substance manufacturer, BTG, and has required that these deficiencies be corrected prior to the approval of the

KRYSTEXXA BLA. BTG has submitted a work plan and a timeline to the FDA for correction of these deficiencies cited by the FDA, and some of these items have already been corrected and the remainder are expected to be addressed in the third quarter of 2009. However, a reinspection of the BTG facility and satisfactory inspection report for the remediation of such deficiencies is required prior to the approval of the KRYSTEXXA BLA. Failure by BTG to adequately and timely remediate these deficiencies may delay the issuance of the regulatory approvals that are necessary to market KRYSTEXXA. If BTG, or any of our third-party manufacturers do not pass such FDA or other regulatory inspections for any reason, including equipment failures, labor difficulties, failure to meet stringent manufacturing, quality control or quality assurance practices, or natural disaster, our ability to commercialize KRYSTEXXA will be jeopardized.

In addition, changes in the manufacturing process or procedure, including a change in the location where KRYSTEXXA is manufactured or a change of a third-party manufacturer, may require prior FDA review or approval or revalidation of the manufacturing process and procedures in accordance with the FDA s cGMP. There may be comparable foreign requirements. This review or revalidation may be costly and time consuming and could delay or prevent the launch of KRYSTEXXA. In particular, the FDA concluded in its complete response letter the comparability data submitted for the material manufactured using the proposed commercial manufacturing process for pegloticase drug substance in KRYSTEXXA was not adequate to demonstrate that it was representative of the material used to establish the safety and efficacy of KRYSTEXXA in the Phase 3 clinical trials. The FDA stated that we have the option of either reverting to and validating the manufacturing process used to produce pegloticase in KRYSTEXXA for the Phase 3 clinical trials or conducting additional comparability clinical trials to support the use of KRYSTEXXA manufactured using the proposed commercial manufacturing process. We currently expect that we will address this issue by reverting to and revalidating the manufacturing process used to produce pegloticase drug substance in KRYSTEXXA for the Phase 3 clinical trials. If the revalidation is not successful or proves to be more difficult than we expect, we may have to conduct the comparability clinical trials, which will result in further significant delays and expenses.

In addition, we have engaged Diosynth, which is located in North Carolina, as a secondary source supplier of the pegloticase drug substance used in KRYSTEXXA. As a result, we and BTG have begun to transfer the relevant manufacturing technology to Diosynth. This is a detailed, expensive and time consuming process that we have not completed. In connection with this technology transfer, Diosynth will be required to produce validation batches of pegloticase drug substance to demonstrate that the materials produced at Diosynth are of the same quality as those produced at BTG. If the FDA approves BTG as a manufacturer of pegloticase drug substance in KRYSTEXXA, and if we cannot establish that the pegloticase drug substance manufactured at Diosynth is equivalent to the drug substance manufactured at BTG to the satisfaction of the FDA, we may not be permitted to use pegloticase drug substance manufactured by Diosynth in the formulation of KRYSTEXXA. We do not expect this technology transfer process and the subsequent FDA approval of the Diosynth manufacturing facility to be completed until the second half of 2010 at the earliest.

If we elect to manufacture products in our own facility or at the facility of another third-party, we would need to ensure that the new facility and the manufacturing process are in substantial compliance with cGMP. Any such new facility would also be subject to a pre-approval inspection by the FDA and would necessitate a successful technology transfer and subsequent validation by the FDA. Any delays or failures to satisfy these requirements would harm our business.

Even if the FDA approves KRYSTEXXA for marketing, our success will depend on our ability to commercialize it. If we are unable to commercialize KRYSTEXXA, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of KRYSTEXXA. Other than Oxandrin and oxandrolone sales, which have significantly declined in recent years and which we expect to remain flat or continue to decline, our ability to generate near- term revenue depends on the success of our KRYSTEXXA product candidate. The commercial success of KRYSTEXXA will depend on many factors, including:

the successful resolution of the issues raised by the FDA regarding our BLA,

receipt and timing of marketing approvals and final product labeling from the FDA and similar foreign regulatory authorities,

receiving FDA and other foreign regulatory approvals of the third-party manufacturing facilities used to produce pegloticase drug substance and other ingredients used in KRYSTEXXA, as well as for facilities used by our third-party fill and finish service provider,

successful completion of our OLE study and any other clinical trials we may undertake, or are requested by the FDA,

producing batches of pegloticase drug substance and other ingredients used in KRYSTEXXA in commercial quantities

- through a validated process,
- maintaining and, as appropriate, entering into, additional commercial manufacturing arrangements for KRYSTEXXA,
- launching commercial sales of the product, whether alone or in collaboration with others,
- acceptance of the product by physicians, patients, health care payors and others in the medical community, and
- our ability to raise substantial additional capital.

Prescription pharmaceutical products may not be commercially marketed in the United States without prior approval from the FDA, and then can only be marketed for the indications and claims approved by the FDA, which may effect the commercial potential of such products.

Based on the results of our Phase 3 clinical trials for the use of KRYSTEXXA, we filed a BLA with the FDA seeking marketing approval for KRYSTEXXA for the treatment of patients with chronic gout refractory to conventional treatment. We believe that the Phase 3 results warranted this filing and proposed indication. Clinical data are difficult to interpret and are susceptible to varying interpretations. For example, we have conducted extended multi-faceted reviews of our Phase 3 data in recent months which have led to continued evaluations of the relative safety and efficacy of KRYSTEXXA and further clarification on its most appropriate uses. As a result, we filed major amendments to our previously submitted BLA, and in turn one was considered by the FDA as a major amendment which led to a delay by three months to August 1, 2009, its consideration of the BLA. On June 16, 2009, the FDA-appointed Arthritis Advisory Committee recommended by a vote of 14 to 1 that KRYSTEXXA be granted marketing approval by the FDA for the treatment of chronic gout in patients refractory to conventional treatment. On July 31, 2009, the FDA notified us that it would not approve the BLA for KRYSTEXXA unless and until the issues discussed above are adequately addressed. While we intend to address each of the issues, and in some cases have already begun to do so, the

FDA and similar foreign regulatory authorities may not grant marketing approval for KRYSTEXXA. If we are not successful in obtaining regulatory approvals for and commercializing KRYSTEXXA, or are significantly delayed in doing so, our business will be materially harmed and we may need to curtail or cease operations.

Even if the FDA approves KRYSTEXXA for marketing, it may only be approved for indications that are not as broad as we intend, and the FDA may require us to conduct supplemental large post-marketing clinical trials. In addition, we may elect to perform additional clinical trials for other indications or in support of applications for regulatory marketing approval in jurisdictions outside the United States. These supplemental trials could be costly and could result in findings inconsistent with or contrary to our historic United States clinical trials.

Draft label language was included in the FDA s July 31, 2009 complete response letter for our KRYSTEXXA BLA. However, this language is subject to final approval, and in the event that the FDA provides marketing approval for KRYSTEXXA, final approval may not be for indications that are as broad as set forth in the draft language. Additionally, the final label could prescribe safety limits or warnings that reduce the market for the product or increase the costs associated with the marketing and sale of the product. We may be required, or we may elect, to conduct additional clinical trials or pre-clinical animal studies for such narrow indications or for other indications. In addition, we may seek marketing approval from regulatory authorities in jurisdictions outside the United States, such as the EMEA, and they may require us to submit data from supplemental large clinical trials or pre- clinical animal studies in addition to data from the clinical trials that supported

our United States filings with the FDA. Any requirements to conduct supplemental trials would add to the cost of developing KRYSTEXXA and we may not be able to complete such supplemental trials. Additional trials could also produce findings that are inconsistent with the trial results we have previously submitted to the FDA, in which case we would be obligated to report those findings to the FDA. This could result in additional restrictions on KRYSTEXXA marketing approval or, if and when it is approved, could force us to stop selling KRYSTEXXA altogether. Inconsistent trial results could also lead to delays in obtaining marketing approval in the United States for other indications for KRYSTEXXA, could cause regulators to impose restrictive conditions on marketing approvals and could even make it impossible for us to obtain marketing approval. Any of these results could materially impair our ability to generate revenues and to achieve or maintain profitability.

In addition, if the FDA approves our BLA we will be required to implement a REMS program to minimize the potential risks of KRYSTEXXA treatment, which includes a medication guide for patients and a communication plan for health care providers, and an assessment plan to monitor and assess their effectiveness. The REMS program is subject to further negotiation and final approval by the FDA, and may impose significant additional obligations and commitments on us in the future, thereby limiting the commercial success of KRYSTEXXA and resulting in lower than expected future revenues.

We have limited marketing and sales capabilities. If we are unable to expand our sales and marketing capabilities or enter into sales and marketing agreements with third parties, we may be unable to generate product sales revenue from sales to customers.

To achieve commercial success for KRYSTEXXA, we must either develop a sales and marketing organization, outsource these functions to third parties, enter into a collaboration with a third-party to jointly commercialize KRYSTEXXA or enter into a worldwide partnership with a third party to commercialize KRYSTEXXA. We currently have limited marketing and sales capabilities. Because we intend to minimize our pre-approval sales and marketing expenditures, if we obtain marketing approval for KRYSTEXXA, and if we independently launch and market KRYSTEXXA in the United States, we will need to rapidly expand our sales and marketing organization. This will be difficult, expensive and time consuming, and we may not be able to attract, hire, train and retain qualified sales and marketing personnel to build a significant or effective marketing and sales force for sales of KRYSTEXXA. Alternatively, we may seek to enter into sales and marketing arrangements with third parties, which may not be on terms favorable to us. In addition, such third parties may not successfully perform such functions for us.

If we are not successful in our efforts to rapidly expand our internal sales and marketing capability or to enter into third-party sales and marketing arrangements, our ability to market and sell KRYSTEXXA will be impaired. If we do establish sales and marketing capabilities and the commercial launch of KRYSTEXXA is delayed as a result of FDA requirements or other reasons, we would incur related expenses too early relative to the product launch. This may be costly, and our sales and marketing investment could be lost.

The commercial success of KRYSTEXXA will depend upon the degree of market acceptance by physicians, patients, health care payors and others in the medical community.

Even if we are able to bring KRYSTEXXA to market, it may not gain or maintain market acceptance by physicians, patients, health care payors or others in the medical community. We believe the degree of market acceptance of KRYSTEXXA, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects,
- the efficacy and

potential advantages over alternative treatments,

the ability to offer KRYSTEXXA for sale at competitive prices,

the final labeling language,

the terms of the final REMS program,

- the relative convenience and ease of administration of KRYSTEXXA compared with other alternatives,
- the timing of the release of KRYSTEXXA to the public compared to alternative products or treatments,
- the willingness of the target patient population to try KRYSTEXXA and of physicians to prescribe it,
- the strength of marketing and distribution support, and
- the level of third-party coverage or reimbursement.

For example, Uloric (febuxostat) is a new treatment for gout that received FDA approval in February 2009. Febuxostat lowers uric acid levels by inhibiting uric acid formation through the same mechanism of action as allopurinol. While febuxostat is labeled for the chronic management of hyperurecemia in patients with gout, we may experience delayed uptake of KRYSTEXXA in the event febuxostat is used to treat patients who failed on or contraindicated to allopurinol, or if patients are otherwise treated with febuxostat prior to being treated with KRYSTEXXA. If KRYSTEXXA does not achieve an adequate level of acceptance, we may not generate sufficient additional revenues to achieve or maintain profitability, and we may be required to curtail or cease operations.

Our business may be harmed if we do not adequately predict the market size or customer demand for KRYSTEXXA.

The market size, and the timing and amount of customer demand, for KRYSTEXXA will be difficult to predict. Based on the results of our Phase 3 trials and interim OLE study data and the draft labeling for KRYSTEXXA, we have conducted internal and commissioned external market research to forecast the size of

the market for KRYSTEXXA. Ultimately, if we are able to bring KRYSTEXXA to market, the size of the market and demand for KRYSTEXXA will be based on the final approved label language, which may be different than the draft language provided by the FDA. If the FDA provides marketing approval for KRYSTEXXA, but with labeling that is materially different than the current draft labeling, the market for KRYSTEXXA could be significantly smaller than we expect. In addition, our REMS program is subject to final approval, and could limit our commercial success and result in lower than expected future revenues.

In addition, demand for KRYSTEXXA may be harmed as a result of the introduction of new products in the field of gout. Moreover, if the actual rate at which physicians prescribe KRYSTEXXA is lower than we have forecasted, our revenues would also be lower than expected.

If we overestimate market size or customer demand, we could incur significant unrecoverable costs from creating excess capacity. In addition, if we do not successfully develop and commercialize KRYSTEXXA, we may never require the production capacity that we currently have available. In this case, we would not be excused from our existing product production commitments. In addition, KRYSTEXXA will have a limited shelf life at the time of the product launch and we will incur lost revenues to the extent that any manufactured product is not sold and administered prior to its expiration.

**** We face substantial competition, and our competitors may develop or commercialize alternative technologies or products more successfully than we do.***

The pharmaceutical and biotechnology industries are intensely competitive. We face competition with respect to our product candidate, KRYSTEXXA, as well as for Oxandrin and oxandrolone, from major pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions and other public and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than any

products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

We are seeking approval for KRYSTEXXA for the treatment of chronic gout in patients refractory to conventional therapy, an orphan segment of the broader gout patient population. By far the most prevalent treatment for gout today is allopurinol, which can lower uric acid values by inhibiting uric acid formation. A small number of gout patients are treated with probenecid, which can lower uric acid values by promoting excretion of uric acid. Neither of these products is actively promoted at this time. Because the anticipated approved label for KRYSTEXXA will target only chronic gout patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum appropriate dose or for whom these drugs are contraindicated, we do not expect KRYSTEXXA to face competition from these existing treatments.

While febuxostat is labeled for the chronic management of hyperuricemia in patients with gout, we may experience delayed uptake of KRYSTEXXA in the event febuxostat is used to treat patients who failed on or contraindicated to allopurinol.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring products, product candidates and technologies complementary to, or necessary for, our programs or advantageous to our business.

**** Unless we are successful in consummating a worldwide partnership for the commercialization of KRYSTEXXA or a broader strategic transaction, we may need to raise substantial additional capital to develop and commercialize KRYSTEXXA. Such financing may only be available on terms unacceptable to us, or not at all. If we are unable to obtain financing on favorable terms, our business, results of operations and financial condition may be materially adversely affected.***

As of June 30, 2009, we had $76.6 million in cash, cash equivalents and short-term investments (including restricted investments), as compared to $78.6 million as of December 31, 2008. As of June 30, 2009, we had an accumulated deficit of $228.4 million. On April 8, 2009, we completed an offering of our common stock and warrants to purchase our common stock for net proceeds to us of approximately $29.0 million. However, the development and commercialization of pharmaceutical products requires substantial funds and we currently have no committed external sources of capital. In recent periods, we have satisfied our cash requirements primarily through product sales and the divestiture of assets that were not core to our strategic business plan. However, our product sales of Oxandrin have decreased significantly in recent years and they continue to decrease as a result of generic competition. Although we may consider divesting Oxandrin, any proceeds of that divestiture would not significantly improve our capital position, and we do not have further non-core assets to divest. Historically, we have also obtained capital through collaborations with third parties, contract fees, government funding and equity financings. These financing alternatives might not be available in the future to satisfy our cash requirements.

Although our strategic plan is to advance the development and regulatory review of KRYSTEXXA and to seek FDA approval of the BLA filing for this product, we believe that a worldwide partnership for the commercialization of KRYSTEXXA or a broader strategic transaction is needed to fully optimize shareholder value through the full exploitation of the commercial prospects of KRYSTEXXA in the U.S., Europe and internationally. If we are unsuccessful in consummating a worldwide partnership for the commercialization of KRYSTEXXA or broader strategic transaction, we intend to independently pursue the commercialization of KRYSTEXXA in the United States and will incur significant expenditures related to the launch of the product. Our future capital requirements will depend on many factors, including:

the timing of, and the costs involved in, obtaining regulatory approvals for KRYSTEXXA,

the cost of manufacturing activities,

- the cost of commercialization activities, including product marketing, sales and distribution, and
- our ability to establish and maintain additional collaborative arrangements relating to the commercialization of KRYSTEXXA in the United States and internationally.

If the FDA does not approve our BLA, if the FDA materially delays its approval of KRYSTEXXA, or if we are not successful in consummating a worldwide partnership for the commercialization of KRYSTEXXA or a broader strategic transaction, our cash needs will increase, our business will be materially harmed and we may need to curtail or cease operations. If the FDA does approve our BLA, unless we have been successful in consummating a worldwide partnership for the commercialization of KRYSTEXXA or a broader strategic transaction, we will be required to make significant disbursements from our existing capital resources in connection with the commercialization of KRYSTEXXA, and we likely would be required to seek additional funding.

We may not be able to obtain additional funds or, if such funds are available, such funding may not be on terms that are acceptable to us, particularly in light of current macroeconomic conditions. If we raise additional funds by issuing equity securities, or if our outstanding warrants are exercised, dilution to our then-existing stockholders will result. If we issue preferred stock, it would likely include a liquidation preference and other terms that would adversely affect our securityholders. 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 additional funds are not available on favorable terms, or at all, we may be required to curtail or cease operations.

**** If we fail to attract and retain senior management and other key personnel, we may not be able to successfully develop or commercialize KRYSTEXXA.***

We are dependent on key members of our management team. As a result of recent changes in our senior management, including the resignation of our former President and Chief Executive Officer on mutually agreed terms, the termination of our former Chief Financial Officer, and the resignation of our Senior Vice President, Chief Medical Officer, we are also dependent on our Board of Directors with respect to ongoing operational matters, particularly our Chairman, Stephen O. Jaeger, and Lee S. Simon. Since November 2008, Dr. Simon has been providing consulting services to us and chairs our BLA Oversight Committee, which has assumed oversight of all of our activities related to the FDA s BLA review process, including the resubmission of the BLA which will incorporate responses to the FDA s July 31, 2009 complete response letter. The loss of the services of any of these persons would harm our ability to develop and commercialize KRYSTEXXA and it might be difficult to recruit a replacement for any of their positions. We have employment agreements with the key members of our management team and a consulting agreement with Dr. Simon, but these agreements are terminable by the individuals on short or no notice at any time without

penalty. In addition, we do not maintain, and have no current intention of obtaining, key man life insurance on any member of our management team.

Recruiting and retaining qualified scientific and commercial personnel, including clinical development, regulatory, and marketing and sales executives and field personnel, is also critical to our success. If we fail to recruit and then retain these personnel, our ability to pursue the development and commercialization of KRYSTEXXA may be compromised. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions.

**** If it is approved for sale, KRYSTEXXA could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with the product.***

If we obtain marketing approval for KRYSTEXXA, it, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities, and REMS program, will

be subject to continual requirements of, and review by the FDA and other regulatory authorities, including thorough inspections of third-party manufacturing facilities.

These requirements include submission of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. The FDA enforces its cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect manufacturing facilities without a warrant at reasonable times and in a reasonable manner.

If, in connection with any future inspection, the FDA finds that we or any of our third-party manufacturers are not in substantial compliance with cGMP requirements, the FDA may undertake enforcement action against us.

Even if regulatory approval of KRYSTEXXA is granted, the approval may be subject to limitations on the indicated uses for which it may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor its safety or efficacy. Later discovery of previously unknown problems with KRYSTEXXA or its manufacturing processes, or failure to comply with regulatory requirements, may result in:

- restrictions on the marketing or manufacturing of KRYSTEXXA,
- costly corrective advertising,
- warning letters,
- withdrawal of KRYSTEXXA from the market,
- refusal to approve pending applications or supplements to approved applications,
- voluntary or mandatory product recall,
- fines or disgorgement of profits or revenue,
- suspension or

- withdrawal of regulatory approvals, including license revocation,
- shutdown, or substantial limitations on the operations, of manufacturing facilities,
- refusal to permit the import or export of products,
- product seizure, and
- injunctions or the imposition of civil or criminal penalties.

If any of these events were to occur, our business would be materially harmed.

**** We may not be able to commercialize KRYSTEXXA if the FDA does not accept that our clinical trials demonstrate safety and efficacy, or if we are required to conduct additional clinical trials.***

The FDA will continue its evaluation of the safety data from our clinical trials before granting regulatory approval for the sale of KRYSTEXXA, and may conclude that additional clinical trials are necessary to demonstrate its safety and efficacy. Moreover, we must provide similar foreign regulatory authorities with clinical data to demonstrate that KRYSTEXXA is safe and effective. Clinical trials of KRYSTEXXA must comply with regulation by numerous federal, state and local government authorities in the United States, principally the FDA, and by similar agencies in other countries. We may decide, or be required by regulators, to conduct additional clinical trials or testing of KRYSTEXXA. Clinical testing is expensive, difficult to design and implement, can take many years to complete, is uncertain as to outcome and results are subject to differing interpretations. Success in pre-clinical testing and early 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.

If we decide, or are required by regulators, to conduct additional clinical trials or other testing of KRYSTEXXA beyond those that we have completed and 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, we may:

- be delayed in obtaining marketing approval for KRYSTEXXA,
- not be able to obtain marketing approval,
- be subject to safety considerations that are more stringent than those that we have proposed, or
- obtain approval for indications that are not as broad as intended.

Our product development costs will also increase if we experience delays in testing or approvals. Such delays could also allow our competitors to bring products to market before we do and impair our ability to commercialize KRYSTEXXA. If any of these events occur, our business will be materially harmed and we may need to curtail or cease operations.

If we are unable to obtain adequate reimbursement from third-party payors, or acceptable prices, for KRYSTEXXA, our revenues and prospects for profitability will suffer.

Our future revenues and ability to become profitable will depend heavily upon the availability of adequate reimbursement for the use of KRYSTEXXA from governmental and other third-party payors. Reimbursement by a third-party payor may depend upon a number of factors, including the third- party payor s determination that use of a product is:

- a covered benefit under its health plan,
- safe, effective and medically necessary,
- appropriate for the specific patient,
- cost effective, and

neither
experimental
nor
investigational.

Obtaining reimbursement approval for KRYSTEXXA from each government or other third-party payor will be a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for KRYSTEXXA s use to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement.

Even when a payor determines that a product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some product uses that are approved by the FDA or similar authorities. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. If we are not able to obtain coverage and profitable reimbursement promptly from government-funded and private third-party payors for our products, our ability to generate revenues and become profitable will be compromised.

Federal legislation enacted in December 2003 has altered the way in which physician-administered drugs and biologics covered by Medicare are reimbursed. Under the new reimbursement methodology, physicians are reimbursed based on a product s average sales price . This new reimbursement methodology has generally led to lower reimbursement levels. The new federal legislation also has added an outpatient prescription drug benefit to Medicare, which went into effect in January 2006. These benefits will be provided primarily through private entities, which we expect will attempt to negotiate price concessions from pharmaceutical manufacturers.

Moreover, the Congress and state legislatures may propose changes to the regulation of the health care system, which, if enacted, could, among other things, increase pressure on drug pricing or make it more costly for patients to gain access to prescription drugs like KRYSTEXXA at affordable prices. This could lead to fewer prescriptions for KRYSTEXXA and could force individuals who are prescribed KRYSTEXXA to pay significant out-of-pocket costs or pay for the prescription entirely by themselves. As a result of such initiatives, market acceptance and commercial success of our product may be limited and our business may be harmed.

If the FDA provides marketing approval for KRYSTEXXA, this product may also be eligible for reimbursement under Medicaid. If state-specific Medicaid programs do not provide adequate coverage and reimbursement for KRYSTEXXA or any products we may develop in the future, it may have a negative impact on our operations.

The scope of coverage and payment policies varies among third-party private payors, including indemnity insurers, employer group health insurance programs and managed care plans. These third-party carriers may base their coverage and reimbursement on the coverage and reimbursement rate paid by carriers for Medicare beneficiaries. Furthermore, many such payors are investigating or implementing methods for reducing health care costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by health care providers. If third-party payors do not provide adequate coverage or reimbursement for KRYSTEXXA or any products we may develop in the future, it could have a negative effect on our revenues and results of operations.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products abroad.

We intend to have our products marketed outside the United States. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. While we have been unable to do so to date, if we are able to establish a development and commercialization partnership for KRYSTEXXA for markets outside of the United States, third parties may have responsibility to obtain regulatory approvals outside of the United States, and we will depend on them to obtain these approvals. The approval procedure varies among countries and can involve additional testing or pre-filing requirements such as a pediatric investigational plan, which we have been informed by the EMEA we must file prior to the filing of our Marketing Authorization Application. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We and our collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

Foreign governments tend to impose strict price controls, which may adversely affect our revenues.

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 an additional six to twelve months after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval for KRYSTEXXA in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. The conduct of such a clinical trial would be expensive and result in delays in commercialization of KRYSTEXXA in such markets. If reimbursement is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Legislation has been introduced in the U.S. Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the United States, which may include reimportation from foreign countries where the drugs are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could decrease the revenue we receive for any approved products, which, in turn, could adversely affect our operating results and our overall financial condition.

Product liability lawsuits could cause us to incur substantial liabilities.

We face an inherent risk of product liability exposure related to the sale of Oxandrin and oxandrolone, as well as the testing and, if approved by the FDA, future sale of KRYSTEXXA and any other products that we may develop. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for KRYSTEXXA, Oxandrin, oxandrolone or any product candidates or products that we may develop,

injury to our reputation,

withdrawal of clinical trial participants,

withdrawal or recall of a product from the market,

modification to product labeling which may be unfavorable to us,

a requirement to conduct additional clinical trials which may be expensive and time consuming,

costs to defend the related litigation,

substantial monetary awards to trial participants or patients,

loss of revenue, and

the inability to commercialize any products

that we may develop in the future.

We currently have product liability insurance coverage in place, which is subject to coverage limits and deductibles. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Product liability insurance is difficult to obtain and increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage with policy limits that will be adequate to satisfy any liability that may arise.

**** Our net operating loss carryforward may be limited if an ownership change is deemed to have occurred pursuant to Section 382 of the Internal Revenue Code.***

In the event that it is determined that we have undergone an ownership change pursuant to Section 382 of the Internal Revenue Code, we may be limited in the amount of net operating loss carryforwards that we can use on an annual basis.

Risks Relating to Our Reliance on Third Parties

We have no manufacturing capabilities and limited manufacturing personnel. We depend on third parties to manufacture KRYSTEXXA. If these manufacturers fail to meet our market requirements at acceptable quality levels and at acceptable cost, and if we are unable to identify suitable replacements, our product development and commercialization efforts may be materially harmed.

We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. We depend on third parties to manufacture KRYSTEXXA. We have entered into commercial supply agreements with third-party manufacturers, NOF, BTG and Enzon respectively, to supply mPEG-NPC, a key raw material in the manufacture of the pegloticase drug substance, and to produce the pegloticase drug substance and KRYSTEXXA drug product. These companies represent single source of supply for the mPEG-NPC, the pegloticase drug substance and the drug product.

Although we have commenced the manufacture of launch quantities of pegloticase drug substance and finished drug, and have such quantities in the United States, our suppliers have not yet manufactured KRYSTEXXA on a consistent basis at the manufacturing intensity to support our market forecasts. In addition, in order to produce KRYSTEXXA in the quantities necessary to meet anticipated market demand if the product is approved, we and our contract manufacturers will need to increase the overall manufacturing capacity for the pegloticase drug substance. If we are unable to increase our manufacturing capacity or qualify an additional supplier, or if the cost of the increased capacity is uneconomical to us, we may not be able to produce KRYSTEXXA in a sufficient quantity to meet future demand, adversely affecting our projected revenues and gross margins.

BTG underwent a pre-approval inspection by the FDA in June 2009, as a result of which the FDA identified certain deficiencies and has required that these deficiencies be corrected prior to the approval of the KRYSTEXXA BLA. BTG has submitted a work plan and a timeline to the FDA

for correction of these deficiencies cited by the FDA, and some of these items have already been corrected and the remainder are expected to be addressed this fall. A reinspection of the BTG facility and satisfactory inspection report for the remediation of such deficiencies is required prior to the approval of the KRYSTEXXA BLA. Failure by BTG to adequately and timely remediate these deficiencies may delay the issuance of the regulatory approvals that are necessary to market KRYSTEXXA, or they may not be obtained at all.

Although the recent hostilities involving Israel have not adversely affected BTG s ability to supply us with adequate quantities of pegloticase drug substance for KRYSTEXXA, future hostilities in Israel could harm BTG s ability to supply us with pegloticase drug substance and could harm our commercialization efforts.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance,
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control, and
- the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

We may in the future elect to manufacture pegloticase drug substance in KRYSTEXXA in our own manufacturing facilities. We would need to invest substantial additional funds and recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

If the company on which we plan to rely for fill and finish services for KRYSTEXXA is unable to perform these services for us, our business may suffer.

We have outsourced the operation for KRYSTEXXA fill and finish services to a single company, Enzon. We have not established internal redundancy for our fill and finish functions and currently have no substitute that

can provide these services. If we successfully commercialize KRYSTEXXA and if Enzon is unable to perform these services for us, we would need to identify and engage an alternative company or develop our own fill and finish capabilities. Any new contract fill and finish company or capabilities that we acquire or develop will need to obtain FDA approval. Identifying and engaging a new contract fill and finish company or developing our own capabilities and obtaining FDA approval could involve significant cost and delay. As a result, we might not be able to deliver KRYSTEXXA orders on a timely basis and our business would be harmed.

We rely on third parties to conduct our clinical development activities for KRYSTEXXA and those third parties may not perform satisfactorily.

We do not independently conduct clinical development activities for KRYSTEXXA, including any additional clinical trials that may be required, or we may elect, to conduct in the future. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators to perform this function. We use multiple contract research organizations to coordinate the efforts of our clinical investigators and to accumulate the results of our trials. Our reliance on these third parties for clinical development activities reduces our control over these activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us and third parties acting on our behalf to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors.

If these third parties do not successfully carry out their contractual obligations, meet expected deadlines or conduct our clinical development activities in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory

approvals for KRYSTEXXA and may not be able to, or may be delayed in our efforts to, successfully commercialize KRYSTEXXA.

We also rely on third parties to store and distribute drug supplies for our clinical development activities. Any performance failure on the part of such third parties could delay regulatory approval or commercialization of KRYSTEXXA, causing us to incur additional expenses and harming our ability to generate additional revenue.

We are seeking a worldwide partner for the further development and commercialization of KRYSTEXXA, and we expect to continue to depend on collaborations with third parties. If we are not successful in these efforts, we may fail to meet our business objectives.

We currently depend on third parties in many aspects of the development and commercialization of KRYSTEXXA. Although we are seeking to establish a development and commercialization partnership for KRYSTEXXA as part of our strategic business plan, to date, we have not been able to enter into such a partnership. If we are unable to reach agreements with suitable partners, we may fail to meet our business objectives for KRYSTEXXA.

In addition, seeking new collaborations with corporate and academic collaborators for the research, development and commercialization of additional product candidates are important elements of our business strategy. We face significant competition in seeking appropriate partners. These arrangements may not be scientifically or commercially successful. The termination of any of these arrangements might adversely affect our ability to develop, commercialize and market our products.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations. The risks that we face in connection with these collaborations include the following:

- collaboration agreements are generally for fixed terms and subject to termination under various circumstances, including, in many cases, on short notice without cause,

- we expect to be required in our collaboration agreements not to conduct specified types of research and development in the field that is the subject of the collaboration. These agreements may have the

effect of limiting the areas of research and development that we may pursue, either alone or in cooperation with third parties,

collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with our products that are the subject of the collaboration with us, and

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 spending related to such products.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Such terminations or expirations can adversely affect us financially as well as harm our business reputation.

Risks Relating to Intellectual Property

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are party to various license agreements and we intend to enter into additional license agreements in the future. For example, we licensed exclusive worldwide rights to patents and pending patent applications that constitute the fundamental composition of matter and underlying manufacturing patents for KRYSTEXXA from Mountain View Pharmaceuticals, Inc., or Mountain View, and Duke University, or Duke. Under the agreement, we are required to use best efforts to bring to market and diligently market products that use the licensed technology. We also must

provide Mountain View and Duke with specified information relating to the development of KRYSTEXXA. The agreement requires us to pay to Mountain View and Duke quarterly royalty payments within sixty days after the end of each quarter based on net sales we make in that quarter. The royalty rate for a particular quarter ranges between 8% and 12% of net sales based on the amount of cumulative net sales made by us or our sub-licensees. Under the agreement, we are also required to pay royalties of 20% of any revenues or other consideration we receive from sub-licensees during any quarter. As of June 30, 2009, we have made aggregate payments of approximately $1.7 million to Mountain View and Duke for the achievement of milestones under this agreement, and if we obtain regulatory approval in one of five major global markets, which includes FDA approval in the United States, we will be required to make aggregate milestone payments of approximately $0.8 million.

The agreement remains in effect, on a country-by-country basis, for the longer of ten years from the date of first sale of KRYSTEXXA in such country, or the date of expiration of the last-to-expire patent covered by the agreement in such country. The licensors may terminate the agreement with respect to the countries affected upon our material breach, if not cured within a specified period of time, or immediately after our third or subsequent material breach of the agreement or our fraud, willful misconduct or illegal conduct. The licensors may also terminate the agreement for our bankruptcy or insolvency. Upon a termination of the agreement in one or more countries, all intellectual property rights conveyed to us with respect to the terminated countries under the agreement, including regulatory applications and pre-clinical and clinical data, revert to Mountain View and Duke and we are permitted to sell off any remaining inventory of KRYSTEXXA for such countries.

If we fail to comply with our obligations under this agreement, we could lose the ability to develop and commercialize KRYSTEXXA, which could require us to curtail or cease our operations.

We expect that future licenses that we may enter into would impose additional requirements on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

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 or term of patent protection we may have for our products. Generic forms of our product Oxandrin were introduced to the market in late 2006. As a result, our results of operations have been harmed. The patents and, if issued, patent applications related to KRYSTEXXA, would expire between 2019 and 2028, unless patent term extensions are obtained. 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 numerous competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen 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. In addition, patents generally expire, regardless of their date of issue, twenty years from the earliest claimed non-provisional filing date. As a result, the time required to obtain regulatory approval for a product candidate may consume

part or all of the patent term. We are not able to accurately predict the remaining length of the applicable patent term following regulatory approval of any of our product candidates.

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 through 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 and any remedies we may seek may prove costly. In addition, our trade secrets may otherwise become known or be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely affect our business.

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

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or patent applications under which we do not hold licenses or other rights. We are aware of patent applications filed by, or patents issued to, other entities with respect to technology potentially useful to us and, in some cases, related to products and processes being developed by us. 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, our licensors or our collaborators that would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, our licensors 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, our licensors or our collaborators may choose or be required to seek a license from the third party and be required to pay license fees, royalties, or both. These licenses may not be available on acceptable terms, or at all. Even if we, our licensors or our collaborators were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

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

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

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

Litigation is inherently uncertain and an adverse outcome could subject us to significant liability for damages

or invalidate our proprietary rights and adversely impact our ability to develop and market KRYSTEXXA and any future product candidates. Legal proceedings that we initiate to

protect our intellectual property rights could also result in counterclaims or countersuits against us. Any litigation, regardless of its outcome, could be time-consuming and expensive to resolve and could divert our management s time and attention. Any intellectual property litigation also could force us to take specific actions, including:

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

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

Risks Relating to Our Results of Operations and Your Investment in Our Common Stock

**** We may not be able to achieve profitability. We have incurred operating losses from continuing operations since 2004 and anticipate that we will incur operating losses from continuing operations for the foreseeable future, particularly as a result of increasing expenses related to our development and, if our BLA is approved by the FDA, commercialization of KRYSTEXXA.***

We continue to incur substantial operating losses from continuing operations. Our operating losses from continuing operations were $40.4 million for the six months ended June 30, 2009 and $89.0 million and $69.2 million for the years ended December 31, 2008 and 2007, respectively. Our operating losses from continuing operations are the result of two factors: increasing operating costs and decreasing product revenues. We have incurred and expect to continue to incur significant costs in connection with our research and development activities, including clinical trials, and from selling, general and administrative expenses associated with our operations. We have experienced and expect to continue to experience decreasing revenues from sales of Oxandrin and our authorized generic Oxandrin brand equivalent product, oxandrolone, on which our continuing operations have been substantially dependent. Sales of Oxandrin and, since December 2006, oxandrolone, accounted for 100% of our continuing net product sales. If the FDA does not approve our BLA, if we are not successful in commercializing KRYSTEXXA, or if the FDA materially delays its approval of KRYSTEXXA, our revenues will continue to decline significantly, and our results of operations will be materially adversely affected.

Our ability to achieve operating profitability in the future depends on the successful commercialization of KRYSTEXXA. If we do not receive regulatory approval for and are unable to successfully commercialize KRYSTEXXA or any other product candidate, or if we experience significant delays or unanticipated costs in doing so, or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never achieve operating profitability. If we do receive regulatory approval for KRYSTEXXA and have not been successful in consummating a worldwide partnership for the commercialization of KRYSTEXXA or broader strategic transaction, we expect to incur significant expenditures in connection with its commercialization. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. If we are unable to successfully commercialize KRYSTEXXA or any other product candidate, or if we experience significant delays or unanticipated costs in doing so, or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never achieve operating profitability. If we are not successful in consummating a significant collaboration or broader strategic transaction for the commercialization of KRYSTEXXA, we expect to incur

significant expenditures in connection with its commercialization. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

We expect sales of Oxandrin and oxandrolone to remain flat or continue to decrease.

In addition to market erosion due to generic competition, our sales of Oxandrin and oxandrolone in the United States are affected by fluctuations in the buying patterns of the three major drug wholesalers to which we principally sell these products. In the past, wholesalers have reduced their inventories of Oxandrin and we expect that they may continue to reduce inventories as a result of generic competition, further decreasing our revenues from these products.

Sales of Oxandrin and oxandrolone have also decreased as a result of the elimination of reimbursement, or limited reimbursement practices, by some states under their AIDS Drug Assistance Programs via their state Medicaid programs for HIV/AIDS prescription drugs, including Oxandrin and oxandrolone. Other state formularies may follow suit. In addition, the implementation of the Medicare Part D program has created disruption in the market as patients switch to a variety of new prescription coverage programs in all states across the United States, further decreasing demand for Oxandrin and oxandrolone.

We have considered the demand deterioration of Oxandrin and oxandrolone in estimating future product returns, however, our demand forecasts are based upon management s best estimates. Future product returns in excess of our historical reserves could reduce our revenues even further and adversely affect our results of operations.

In addition, we do not have the ability to independently distribute our authorized generic version of oxandrolone tablets and depend on our distribution partner, Watson, to distribute this product for us. If Watson fails to carry out its contractual obligations, does not devote sufficient resources to the distribution of oxandrolone, or does not carry out its responsibilities in the manner we expect, our oxandrolone product may not compete successfully against other generics, and our results of operations could be further harmed.

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

Our stock price has been, and is likely to continue to be, volatile. Since January 1, 2008, our common stock has traded as high as $28.42 per share and as low as $2.80 per share. The stock market in general and the market for biotechnology companies in particular have recently experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including:

- our ability to sustain our operations with our existing cash reserves,
- whether we obtain regulatory approval for KRYSTEXXA, and the timing of such approval,
- if we obtain regulatory approval of

KRYSTEXXA, whether it achieves market acceptance,

whether KRYSTEXXA achieves market acceptance,

the nature of post-marketing commitments,

the disclosure of information relating to the efficacy or safety of KRYSTEXXA,

announcements of technological innovations or developments relating to competitive products or product candidates,

the costs of commercialization activities, including product marketing, manufacturing, sales and distribution,

our ability to obtain adequate capital resources to execute our business strategy,

market conditions in the pharmaceutical and biotechnology sectors and the issuance of new or changed securities analysts reports or recommendations,

period-to-period fluctuations in our financial results,

regulatory developments in the United States and foreign countries,

- our issuance of additional shares of common stock in capital raising transactions, or upon the exercise of warrants to purchase shares of our common stock,
- general economic, industry and market conditions, and
- other factors described in this Risk Factors section.

The volatility of our common stock imposes a greater risk of capital losses on our stockholders than a less volatile stock would. In addition, volatility makes it difficult to ascribe a stable valuation to a stockholder s holdings of our common stock.

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

Our revenues from product sales of Oxandrin and oxandrolone 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:

- increased competition from new or existing products, including generic products,
- the amount and timing of product sales,
- changing

demand for our products,

our inability to provide adequate supply for our products,

changes in wholesaler buying patterns,

returns of expired product,

changes in government or private payor reimbursement policies for our products,

the timing of the introduction of new products,

the timing and realization of milestone and other payments to licensees,

the timing and amount of expenses relating to research and development, product development and manufacturing activities,

the timing and amount of expenses relating to sales and marketing,

- the timing and amount of expenses relating to general and administrative activities,
- the extent and timing of costs of obtaining, enforcing and defending intellectual property rights, and
- any charges related to acquisitions.

In addition, our expenses have fluctuated and are likely to increase significantly in the near future in connection with our development and commercialization efforts related to KRYSTEXXA. As a result, any decrease in revenues or increase in expenses will be likely to adversely affect our earnings in a significant manner until revenues can be increased or expenses reduced. We expect that our revenues and earnings from sales of Oxandrin and oxandrolone will continue to decline. 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.

**** Our outstanding warrants may be exercised in the future, which would increase the number of shares in the public market and result in dilution to our stockholders.***

In connection with the registered direct offering we completed on April 8, 2009, we issued warrants to purchase up to 5,038,237 shares of our common stock.

The warrants are exercisable at any time on or after the date of issuance and expire on the earlier of November 2, 2010, and the date that is nine months after the date on which we publicly announce that we have addressed all items required by the FDA to be addressed before our BLA can be approved.

Pursuant to the terms of the warrants, the exercise price for the warrants will, from and after August 17, 2009, be equal to the dollar volume weighted-average price of the Company s common

stock for the five trading days immediately preceding such date. The exercise price per share may not exceed $10.46 or be less than $1.57. The Company may, at its or the warrant holder s election, issue net shares in lieu of a cash payment of the exercise price by the warrant holder upon exercise.

In the event that we enter into a merger or change of control transaction, the holders of the warrants will be entitled to receive consideration as if they had exercised the warrant immediately prior to such transaction, or they may require us to purchase the warrant at the Black-Scholes value of the warrant on the date of such transaction.

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 a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include the requirements of Section 203 of the Delaware General Corporation Law. Section 203 prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person that, together with its affiliates, owns or within the last three years has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- our Board of Directors approves the transaction before the third party acquires 15% of our stock,
- the third party acquires at least 85% of our stock at the time its ownership exceeds 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.

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. Although 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.

**** We are a party to a shareholder lawsuit regarding the adequacy of our public disclosure, which could have a material adverse affect on our business, results of operations and financial condition.***

In November 2008, Richard Sagall, an alleged shareholder, commenced an action in the U.S. District Court for the Southern District of New York to certify a class of Shareholders who held Savient Securities between December 13, 2007 and October 24, 2008. The suit alleges that we made false and misleading statements relating to the GOUT1 and GOUT2 Phase 3 clinical trials and that we failed to disclose in a timely manner serious adverse events which occurred in five patients in these trials. A lead plaintiff was appointed in March 2009 resulting in the re-captioning of the action as *Lawrence J. Koncelik, Jr. vs. Savient Pharmaceuticals, et al* and an amended complaint was filed in this matter in April 2009. In June 2009 we filed a motion to dismiss the action. We intend to vigorously defend against this action.

We expect that the costs related to this suit will be significant and we can provide no assurance as to its outcome. If we are not successful in defending this action, we may be required to pay substantial damages to the plaintiffs and our business, results of operations and financial condition could be materially adversely affected. In addition, even if we are successful, the defense of these actions will continue to divert the attention of our management and other resources that would otherwise be engaged in operating our business.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

We held our 2009 Annual Meeting of Stockholders on May 5, 2009 at which our stockholders elected all of the Director nominees to serve as our Directors until 2010 Annual Meeting of Stockholders and until his or her successor is elected and qualified, and ratified the appointment of McGladrey & Pullen, LLP as our independent auditor for the fiscal year ending December 31, 2009.

The matters acted upon at the 2009 Annual Meeting of Stockholders, and the voting tabulations for each matter, are as follows:

Item No. 1: To elect six Directors for terms of one-year each:

Nominee	Votes For	Votes Withheld
Herbert Conrad	44,154,198	1,557,171
Alan L. Heller	44,256,025	1,455,344
Stephen O. Jaeger	43,858,545	1,852,824
Joseph Klein III	44,252,705	1,458,664
Lee S. Simon, M.D.	42,748,133	2,963,236
Virgil Thompson	43,991,327	1,720,042

Item No. 2: To ratify the appointment of McGladrey & Pullen, LLP as our independent auditor for the fiscal year ending December 31, 2009.

Votes For	Votes Against	Abstain
45,123,235	451,887	136,250

ITEM 6. EXHIBITS

a) Exhibits

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

SIGNATURES

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

SAVIENT PHARMACEUTICALS, INC.
(Registrant)

By: /s/ PAUL HAMELIN

Paul Hamelin
President
(Principal Executive Officer)

By: /s/ DAVID G. GIONCO

David G. Gionco
Group Vice President, Chief Financial Officer & Treasurer
(Principal Financial Officer)

Dated: August 10, 2009

EXHIBIT INDEX

Exhibit No.	Description
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