CELL THERAPEUTICS INC
Form 10-Q/A
February 06, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q/A

(Amendment No. 1)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended: September 30, 2006

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number 001-12465

CELL THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Washington	**91-1533912**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

501 Elliott Avenue West, Suite 400

Seattle, Washington	**98119**
(Address of principal executive offices)	**(Zip Code)**

(206) 282-7100

(Registrant s telephone number, including area code)

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 x No ¨

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

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

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

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

Class	**Outstanding at October 31, 2006**
Common Stock, no par value	144,652,751

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Explanatory Note:

Cell Therapeutics, Inc., or CTI, is filing this Amendment No. 1 on Form 10-Q/A to its Form 10-Q for the quarter ended September 30, 2006, to reflect the restatement of its previously issued financial statements to correct inadvertent errors in accounting for accounts payable and accrued expenses in our Italian subsidiary, Cell Therapeutics Europe, S.r.l., or CTI (Europe).

The information contained in this Amendment, including the financial statements and the notes hereto, amends only Items 1, 2 and 4 of Part I and Item 1A of Part 2 of our originally filed Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 and no other items in our originally filed Form 10-Q are amended hereby. In accordance with Rule 12b-15 of the Securities and Exchange Act of 1934, the complete text of those items in which amended language appears is set forth herein, including those portions of the text that have not been amended from that set forth in the original Form 10-Q. Except for the aforementioned adjustments, this Form 10-Q/A does not materially modify or update other disclosures in the original Form 10-Q, including the nature and character of such disclosure to reflect events occurring after November 9, 2006, the filing date of the original Form 10-Q. Accordingly this Form 10-Q/A should be read in conjunction with our filings made with the Securities and Exchange Commission. Currently dated certifications from the our Chief Executive Officer and Chief Financial Officer have been included as exhibits to this amendment.

Impact on Management s Assessment of Internal Control over Financial Reporting: In connection with the restatement, we reevaluated our disclosure controls and procedures in CTI (Europe). We concluded that our failure to correctly account for accounts payable and accrued expenses constituted a material weakness in our internal control over financial reporting. As a result of this material weakness, we concluded that our disclosure controls and procedures in relation thereto were not effective as of September 30, 2006.

Remediation of Material Weakness: In an effort to remediate the material weakness described above, we are currently implementing enhanced procedures that are designed to ensure that we will properly record accounts payable and accrued expenses in CTI (Europe). These enhanced procedures will provide for additional managerial oversight of accounts payable and accrued expense balances.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	September 30, 2006 (unaudited)	December 31, 2005
		(restated)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,128	$ 50,022
Restricted cash	57	25,596
Securities available-for-sale	51,329	18,858
Interest receivable	645	187
Accounts receivable, net	339	2,306
Prepaid expenses and other current assets	11,062	10,107
Total current assets	79,560	107,076
Property and equipment, net	9,013	12,278
Goodwill	17,064	17,064
Other intangibles, net	1,799	2,239
Other assets	13,550	16,783
Total assets	$ 120,986	$ 155,440
LIABILITIES AND SHAREHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 4,800	$ 3,370
Accrued expenses	22,201	17,558
Current portion of deferred revenue	80	80
Current portion of long-term obligations	2,701	2,880
Current portion of convertible senior notes		6,900
Total current liabilities	29,782	30,788
Deferred revenue, less current portion	498	558
Long-term obligations, less current portion	5,242	7,326
7.5% convertible senior notes	50,409	
6.75% convertible senior notes	6,954	72,146
Convertible senior subordinated notes	82,557	122,079
Convertible subordinated notes	28,490	29,640
Commitments and contingencies		
Shareholders deficit:		
Preferred stock, no par value:		
Authorized shares - 10,000,000		
Series C, 100,000 shares designated, none issued or outstanding		
Common stock, no par value:		
Authorized shares - 200,000,000		
Issued and outstanding shares - 137,073,731 (unaudited) and 73,421,721 at September 30, 2006 and December 31, 2005, respectively	843,600	721,544
Deferred stock-based compensation		(1,669)
Accumulated other comprehensive loss	(1,038)	(1,683)

Accumulated deficit	(925,508)	(825,289)
Total shareholders deficit	(82,946)	(107,097)
Total liabilities and shareholders deficit	$ 120,986	$ 155,440

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006 (restated)	2005	2006 (restated)	2005
Revenues:				
Product sales	$	$ 1,190	$	$ 14,599
License and contract revenue	20	101	60	300
Total revenues	20	1,291	60	14,899
Operating expenses:				
Cost of product sold		60		518
Research and development	14,443	13,340	45,370	55,582
Selling, general and administrative	9,032	12,500	27,452	49,475
Amortization of purchased intangibles	200	236	588	731
Restructuring charges and related asset impairments	25	5,077	367	7,049
Gain on divestiture of TRISENOX		(30,500)		(30,500)
Total operating expenses	23,700	713	73,777	82,855
Income (loss) from operations	(23,680)	578	(73,717)	(67,956)
Other income (expense):				
Investment and other income	607	414	1,843	1,326
Interest expense	(3,552)	(2,955)	(16,888)	(10,842)
Foreign exchange gain (loss)	(115)	(104)	997	98
Make-whole interest expense	(213)		(24,753)	
Gain (loss) on derivative liabilities	(879)		5,204	
Gain on exchange of convertible notes			7,978	
Settlement expense			(883)	
Loss on extinguishment of royalty obligation		(6,437)		(6,437)
Other expense, net	(4,152)	(9,082)	(26,502)	(15,855)
Net loss	$ (27,832)	$ (8,504)	$ (100,219)	$ (83,811)
Basic and diluted net loss per share	$ (0.25)	$ (0.13)	$ (0.98)	$ (1.32)
Shares used in calculation of basic and diluted net loss per share	111,560	63,515	102,132	63,385

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2006 (restated)	2005
Operating activities		
Net loss	$ (100,219)	$ (83,811)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,850	7,426
Equity-based compensation expense	3,579	2,516
Loss on disposition of property and equipment	91	83
Amortization of investment premium	85	271
Non-cash gain on exchange of convertible notes	(7,978)	
Non-cash gain on derivative liabilities	(5,204)	
Non-cash interest expense	10,445	719
Asset impairments		2,563
Gain on divestiture of TRISENOX		(30,500)
Loss on extinguishment of royalty obligation		6,437
Non-cash rent (benefit) expense	(11)	135
Loss on sale of investment securities		14
Changes in operating assets and liabilities:		
Restricted cash	877	
Interest receivable	(458)	48
Accounts receivable, net	1,532	(1,855)
Inventory		4
Prepaid expenses and other current assets	3,182	1,443
Other assets	103	(1,029)
Accounts payable	(2,767)	(3,433)
Accrued expenses	2,189	(8,703)
Deferred revenue	(60)	1,568
Excess facilities obligations	(1,913)	4,675
Other long-term obligations	(416)	3,740
Total adjustments	8,126	(13,878)
Net cash used in operating activities	(92,093)	(97,689)
Investing activities		
Net proceeds from divestiture of TRISENOX		67,061
Purchases of securities available-for-sale	(57,635)	(26,922)
Proceeds from maturities of securities available-for-sale	25,113	13,494
Proceeds from sales of securities available-for-sale		15,815
Purchases of property and equipment	(472)	(1,946)
Proceeds from sale of property and equipment	511	
Net cash provided by (used in) investing activities	(32,483)	67,502

Financing activities		
Sale of common stock, net of offering costs	37,903	
Proceeds from issuance of 7.5% convertible senior notes, net	31,177	
Release of restricted cash related to 6.75% convertible senior notes	24,712	
Mandatory redemptions of 6.75% convertible senior notes	(2,655)	
Repayment of royalty obligation		(39,388)
Proceeds from common stock options exercised and stock sold via the employee stock purchase plan	17	218
Repayment of long-term obligations	(122)	(1,074)
Net cash provided by (used in) financing activities	91,032	(40,244)
Effect of exchange rate changes on cash and cash equivalents	(350)	(1,917)
Net decrease in cash and cash equivalents	(33,894)	(72,348)
Cash and cash equivalents at beginning of period	50,022	105,033
Cash and cash equivalents at end of period	$ 16,128	$ 32,685
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 29,281	$ 7,714
Cash paid for taxes	$	$
Supplemental disclosure of noncash financing and investing activities		
Conversion of 6.75% convertible senior notes to common stock	$ 69,345	$
Conversion of 7.5% convertible senior notes to common stock	$ 15,902	$
Conversion of convertible senior subordinated notes to common stock	$ 4	$
Extinguishment of 5.75% convertible senior subordinated notes in exchange for 7.5% convertible senior notes	$ 39,518	$
Extinguishment of 5.75% convertible subordinated notes in exchange for 7.5% convertible senior notes	$ 1,150	$
Issuance of 7.5% convertible senior notes in exchange for 5.75% subordinated and senior subordinated notes	$ 33,156	$

See accompanying notes.

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CELL THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Description of Business and Summary of Significant Accounting Policies

Description of Business

Cell Therapeutics, Inc., or CTI or the Company, focuses on the development, acquisition and commercialization of drugs for the treatment of cancer. Our principal business strategy is focused on cancer therapeutics, an area with significant market opportunity that we believe is not adequately served by existing therapies. Our operations are primarily conducted in the United States and Italy. Our Italian operations commenced on January 1, 2004, the effective date of our merger with Novuspharma S.p.A., or Novuspharma, an Italian biopharmaceutical company focused on cancer therapeutics.

Basis of Presentation

The accompanying unaudited financial information of CTI as of September 30, 2006 and for the three and nine months ended September 30, 2006 and 2005 has been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, such financial information includes all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the Company s financial position at such date and the operating results and cash flows for such periods. Operating results for the three and nine month periods ended September 30, 2006 are not necessarily indicative of the results that may be expected for the entire year. These financial statements and the related notes should be read in conjunction with our audited annual financial statements for the year ended December 31, 2005 included in our Form 10-K/A.

The balance sheet at December 31, 2005 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by generally accepted accounting principles in the United States for complete financial statements.

Liquidity

Cash and cash equivalents, restricted cash, securities available-for-sale and interest receivable are approximately $68.2 million as of September 30, 2006, approximately $3.0 million of which was used to repurchase shares of our common stock and warrants exercisable for our common stock in October 2006 (see Note 7, *Common Stock Offering*). In addition we received $15.0 million of cash from an offering of our common stock in October 2006 (see Note 6, *Agreements with Novartis International Pharmaceutical Ltd.*) We expect that this amount will not be sufficient to fund our operations for the next 12 months. Accordingly, we will need to raise additional funds and are currently exploring alternative sources of equity or debt financing. Additional funding may not be available on favorable terms or at all. If we are unable to raise additional capital in the near term, we have developed a plan to further curtail operations significantly, by delaying, modifying, or canceling selected aspects of research and development programs related to XYOTAX, pixantrone and other products we may be developing. The plan contains reductions in operating expenditures related to certain research and development and general and administrative activities including compensation and benefits, corporate costs and clinical trial costs, which are designed to allow the company to continue to operate on a going concern basis.

Product Sales

Because we sold our only commercial product, TRISENOX, to Cephalon on July 18, 2005, there have been no product sales subsequent to this date. Prior to this, we recognized revenue from product sales when there was persuasive evidence that an arrangement existed, title had passed and delivery had occurred, the price was fixed and determinable, and collectability was reasonably assured. Product sales were generally recorded upon shipment net of

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an allowance for returns and discounts. Customers were able to return damaged or expired inventory for up to one year after the expiration date. Estimated returns were based on historical returns and sales patterns. If we were unable to reasonably estimate returns related to a particular customer or market, we deferred revenue recognition until return rights had expired. There was no allowance for returns, discount and bad debts at September 30, 2006 or December 31, 2005 as all trade receivables were sold in connection with the divestiture of TRISENOX to Cephalon.

License and Contract Revenue

We may generate revenue from technology licenses, collaborative research and development arrangements, cost reimbursement contracts and research grants. Revenue under technology licenses and collaborative agreements typically consists of nonrefundable and/or guaranteed technology license fees, collaborative research funding, and various milestone and future product royalty or profit-sharing payments.

Revenue associated with up-front license fees and research and development funding payments under collaborative agreements is recognized ratably over the relevant periods specified in the agreement, generally the research and development period. If the time period is not defined in the agreement, we calculate the revenue recognition period based on our current estimate of the research and development period considering experience with similar projects, level of effort and the stage of development. Should there be a change in our estimate of the research and development period, we will revise the term over which the initial payment is recognized. Revenue from substantive at-risk milestones and future product royalties is recognized as earned based on the completion of the milestones and product sales, as defined in the respective agreements. Revenue under cost reimbursement contracts and research grants is recognized as the related costs are incurred. Payments received in advance of recognition as revenue are recorded as deferred revenue.

We evaluate multiple element arrangements pursuant to Emerging Issues Task Force, or EITF, 00-21, *Revenue Arrangements with Multiple Deliverables.* For multiple element arrangements that have continuing performance obligations, we recognize contract, milestone or license fees together with any up-front payments over the term of the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin 104, or SAB 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangement.

Research and Development Expenses

Research and development expenses include related salaries and benefits, clinical trial and related manufacturing costs, contract and other outside service fees, and facilities and overhead costs related to our research and development efforts. Research and development expenses also consist of costs incurred for proprietary and collaboration research and development and include activities such as product registries and investigator-sponsored trials. Research and development costs are expensed as incurred. Generally, in instances where we enter into agreements with third parties for research and development activities, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed unless there is an alternative future use of the funds in other research and development projects. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

Impairment of Long-lived Assets

We review our long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted future cash flows to the recorded value of the asset. If an impairment is indicated, the asset is written down to its estimated fair value based on quoted fair market values.

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Value Added Tax Receivable

Our European subsidiary is subject to Value Added Tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable is approximately $9.8 million and $8.9 million as of September 30, 2006 and December 31, 2005, respectively, of which $9.2 million and $8.3 million is included in *other assets* as of September 30, 2006 and December 31, 2005, respectively and $0.6 million is included in *prepaid expenses and other current assets* as of both dates. This receivable balance typically has a three to five year collection period. We review our VAT receivable balance for impairment whenever events or changes in circumstances indicate the carrying amount might not be recoverable.

Net Loss Per Share

Basic net loss per share is calculated based on the net loss divided by the weighted average number of shares outstanding for the period excluding any dilutive effects of options, warrants, unvested share awards and convertible securities. Diluted earnings per share assumes the conversion of all dilutive convertible securities, such as convertible debt using the if-converted method, and assumes the exercise or vesting of other dilutive securities, such as options, warrants and share awards using the treasury stock method. As of September 30, 2006 and 2005, options, warrants, unvested share awards and rights and convertible debt aggregating 48,338,717 and 23,390,105, common equivalent shares, respectively, prior to the application of the treasury stock method for options and warrants, were not included in the calculation of diluted net loss per share as they are anti-dilutive.

Derivatives Embedded in Certain Debt Securities

We evaluate financial instruments for freestanding or embedded derivatives in accordance with Statement of Financial Accounting Standards, or SFAS, No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and related guidance. Derivative instruments are recorded at fair value with changes in value recognized in the period of change.

Our 6.75% convertible senior notes, or 6.75% notes, and our 7.5% convertible senior notes, or 7.5% notes, contain certain features providing for payments in cash or common stock to be made in the event of certain conversions or repurchases of the debt. In the event of any conversion of our 6.75% notes to common stock, the feature calls for make-whole payments equal to the interest on the debt over its term less any amounts paid prior to the date of the conversion. Our 7.5% notes include a feature that calls for make-whole payments in the event of automatic conversion or if the holder requires us to repurchase the notes upon certain non-stock changes in control. This payment is equal to $225 per $1,000 principal amount of the notes less any interest amounts paid prior to the date of conversion or repurchase.

These make-whole features represent embedded derivatives which are required to be accounted for separately from the related debt securities. The fair value of the derivative for the 6.75% notes is calculated based on a discounted cash flow model. The fair value of the derivative related to the 7.5% notes is calculated using a Monte Carlo simulation model that incorporates factors such as the current price of our common stock, its volatility, and time to expiration of the make-whole feature. Changes in the estimated fair value of the liabilities are included in *gain (loss) on derivative liabilities* and will be calculated until the relevant feature expires or all of the relevant notes are converted or repurchased.

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Foreign Currency Translation

For our operations that have a functional currency other than the U.S. dollar, gains and losses resulting from the translation of the functional currency into U.S. dollars for financial statement presentation are not included in determining net loss but are accumulated in the cumulative foreign currency translation adjustment account as a separate component of shareholders deficit in accordance with SFAS 52, Foreign Currency Translation.

Recently Issued Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157, which provides guidance on how to measure assets and liabilities that use fair value. This Statement clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS 157 will apply whenever another generally accepted accounting principle requires, or permits, assets or liabilities to be measure at fair value but does not expand the use of fair value to any new circumstances. This statement will also require additional disclosures in both annual and quarterly reports. SFAS 157 is effective for fiscal years beginning after November 2007, and will be adopted by us beginning January 1, 2008. We are currently evaluating the potential impact this statement may have on our financial statements, but do not believe the impact of adoption will be material.

In September 2006, the SEC staff issued Staff Accounting Bulletin, or SAB, No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, or SAB 108. SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of determining whether the current year s financial statements are materially misstated. SAB 108 is effective for fiscal years ending after November 15, 2006. We will initially apply the provisions of SAB 108 in connection with the preparation of our annual financial statements for the year ending December 31, 2006. We have evaluated the potential impact that SAB 108 may have on our financial statements and do not believe the impact of the application of this guidance will be material.

In September 2006, the FASB issued SFAS No. 158, *Employers Accounting for Defined Benefit Pension and Other Postretirement Plans*, or SFAS 158. This Statement requires companies to recognize in their statement of financial position an asset for a plan s overfunded status or a liability for a plan s underfunded status and to measure a plan s assets and its obligations that determine its funded status as of the end of the company s fiscal year. Additionally, SFAS 158 requires companies to recognize changes in the funded status of a defined benefit postretirement plan in the year that the changes occur and those changes will be reported in comprehensive income. The provisions of SFAS 158 are effective as of the end of fiscal year 2006 and we are currently in the process of quantifying the impact to the financial statements.

2. Restatement

In the fourth quarter of 2006, we discovered the following errors in CTI (Europe):

A $1.0 million accounts payable balance to Micromet AG, or Micromet, which had been recorded by CTI (Europe) prior to its acquisition by the Company in January 2004. In May 2006, we settled a dispute with Micromet whereby we paid Micromet $1.9 million to settle all outstanding claims between the two companies. Accordingly, the outstanding payable balance should have been reversed with a corresponding offset to settlement expense at the time we recorded the settlement charge in the first quarter of 2006.

In March 2006, CT (Europe) received a $251,000 payment from a clinical trial vendor. The payment represented a settlement of prior amounts paid to the vendor for which the company claimed it had not received services. The Company made the claim in December 2005 and at December 31, 2005 the claim represented a gain contingency and was not recorded due to significant uncertainty around receipt of payment. Upon receipt of payment in March 2006 the payment was inadvertently recorded as accounts payable rather than a reduction of research and development expense.

In the second and third quarters of 2006 CTI (Europe) inadvertently continued to record accruals for clinical trial activities that had been transferred to CTI Seattle in the first quarter of 2006. These accruals amounted to approximately $912,000 as of September 30, 2006.

The following tables summarize the effect of the restatement adjustments on the financial statements as of and for the three and nine months ended September 30, 2006.

	September 30, 2006 (in thousands)		
	As Filed	Adjustments	Restated
Accounts payable	$ 6,087	$ (1,287)	$ 4,800
Accrued expenses	23,113	(912)	22,201
Total current liabilities	31,981	(2,199)	29,782
Accumulated other comprehensive loss	(1,055)	17	(1,038)
Accumulated deficit	(927,690)	2,182	(925,508)
Total shareholders deficit	(85,145)	2,199	(82,946)

	Three Months Ended September 30, 2006 (in thousands)		
	As Filed	Adjustments	Restated
Research and development	$ 14,809	$ (366)	$ 14,443
Total operating expenses	24,066	(366)	23,700
Loss from operations	(24,046)	366	(23,680)
Net loss	(28,198)	366	(27,832)

	Nine Months Ended September 30, 2006 (in thousands, except per share data)		
	As Filed	Adjustments	Restated
Research and development	$ 46,516	$ (1,146)	$ 45,370
Total operating expenses	74,923	(1,146)	73,777
Loss from operations	(74,863)	1,146	(73,717)
Settlement expense	(1,919)	1,036	(883)
Other expense, net	(27,538)	1,036	(26,502)
Net loss	(102,401)	2,182	(100,219)
Basic and diluted net loss per share	$ (1.00)	$ 0.02	$ (0.98)

The adjustments to the balance sheet and income statement as of and for the three and nine months ended September 30, 2006 had no impact on total cash flows from operating, investing and financing activities.

3. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income or loss. SFAS 130, *Reporting Comprehensive Income*, provides for unrealized gains and losses on our securities available-for-sale and our former interest rate swap agreement which was designated as a cash flow hedge, to be included in other comprehensive loss. Also included are net exchange gains or losses resulting from the translation of assets and liabilities of foreign subsidiaries. Total comprehensive loss was $27.8 million and $8.4 million for the three month periods ended September 30, 2006 and 2005, respectively. Total comprehensive loss was $99.6 million and $87.1 million for the nine month periods ended September 30, 2006 and 2005, respectively.

Information regarding the components of accumulated other comprehensive loss is as follows (in thousands):

	September 30, 2006 (restated)	December 31, 2005
Foreign currency translation adjustment	$ (1,052)	$ (1,663)
Net unrealized gain (loss) on securities available-for-sale	14	(20)
Accumulated other comprehensive loss	$ (1,038)	$ (1,683)

4. Stock-Based Compensation Expense

On January 1, 2006, we adopted SFAS 123(R), *Share-Based Payment (Revised 2004)*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options, share awards, and employee stock purchases related to the Employee Stock Purchase Plan, or employee stock purchases, based on estimated fair values. SFAS 123(R) supersedes our

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previous accounting under Accounting Principles Board Opinion, or APB, No. 25, Accounting for Stock Issued to Employees, for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin, or SAB, No. 107 relating to SFAS 123(R). We have applied the provisions of SAB 107 in our adoption of SFAS 123(R).

We adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006. Our Condensed Consolidated Financial Statements as of and for the three and nine months ended September 30, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, our Condensed Consolidated Financial Statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). Stock-based compensation expense recognized under SFAS 123(R) for the three months ended September 30, 2006 was $1.1 million, which consisted of $0.6 million of stock-based compensation expense related to employee stock options and employee stock purchases and $0.5 million of stock-based compensation expense related to share awards. Stock-based compensation expense recognized for the nine months ended September 30, 2006 was $3.6 million, which consisted of $2.2 million related to employee stock options and employee stock purchases and $1.4 million related to share awards. Stock-based compensation expense recognized for share awards was $0.9 million and $2.6 million during the three and nine months ended September 30, 2005, respectively. There was no stock-based compensation expense related to employee stock options and employee stock purchases recognized during the three and nine months ended September 30, 2005.

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our Condensed Consolidated Statement of Operations. Prior to the adoption of SFAS 123(R), we accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under SFAS 123, *Accounting for Stock-Based Compensation*. Under the intrinsic value method, no employee stock-based compensation expense related to stock options had been recognized in our Condensed Consolidated Statement of Operations because the exercise price of our stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant.

Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized in our Condensed Consolidated Statement of Operations for the three and nine months ended September 30, 2006 included 1) compensation expense for share-based payment awards granted prior to, but not yet vested as of December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and 2) compensation expense for the share-based payment awards granted subsequent to January 1, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). We use the straight-line single-option method to recognize the value of stock-based compensation expense for all share-based payment awards granted after January 1, 2006. Expense is recognized using the graded-vesting multiple-option method for options granted prior to January 1, 2006. As stock-based compensation expense recognized in the Condensed Consolidated Statement of Operations for the three and nine months ended September 30, 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In our pro forma information required under SFAS 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

The following table summarizes stock-based compensation expense related to employee stock options, employee stock purchases, and share awards under SFAS 123(R) for the three and nine months ended September 30, 2006, which was allocated as follows (in thousands):

	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Research and development	$ 314	$ 1,393
Selling, general and administrative	763	2,186
Stock-based compensation expense included in operating expenses	$ 1,077	$ 3,579

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Stock-based compensation had a $1.1 million and $3.6 million effect on our net loss and a $(0.01) and $(0.04) effect on basic and diluted net loss per share for the three and nine month periods ending September 30, 2006, respectively. There was no effect on cash flows from operations or financing activities for the periods presented. The weighted average fair value of employee stock options granted in the three months ended September 30, 2006 and 2005 was $0.89 and $1.57, respectively. The weighted average fair value of employee stock options granted in the nine months ended September 30, 2006 and 2005 was $0.89 and $3.34, respectively.

SFAS 123(R) requires the disclosure of pro-forma information for periods prior to the adoption. The following table illustrates the effect on net loss and net loss per share for the three and nine months ended September 30, 2005 if we had recognized compensation expense for all share-based payments to employees based on their fair values (in thousands, except per share amounts):

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss, as reported	$ (8,504)	$ (83,811)
Add: Stock-based employee compensation included in reported net loss (share awards)	872	2,563
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(1,300)	(5,430)
Pro forma net loss	$ (8,932)	$ (86,678)
Basic and diluted net loss per share:		
As reported	$ (0.13)	$ (1.32)
Pro forma	$ (0.14)	$ (1.37)

Fair value was estimated at the date of grant using the Black-Scholes pricing model, with the following weighted average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Risk-free interest rates	4.7%	4.0%	4.9%	4.0%
Expected dividend yield	None	None	None	None
Expected life (in years)	2.7	3.6	2.8	3.6
Volatility	74%	96%	74%	96%

The risk-free interest rate used in the Black-Scholes valuation method is based on the implied yield currently available in U.S. Treasury securities at maturity with an equivalent term. We have not declared or paid any dividends and do not currently expect to do so in the future. The expected term of options represents the period that our stock-based awards are expected to be outstanding and was determined based on historical weighted average holding periods and projected holding periods for the remaining unexercised shares. Consideration was given to the contractual terms of our stock-based awards, vesting schedules and expectations of future employee behavior. Expected volatility is based on the annualized daily historical volatility, including consideration of the implied volatility and market prices of traded options for comparable entities within our industry.

Our stock price volatility and option lives involve management s best estimates, both of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. SFAS 123(R) also requires that we recognize compensation expense for only the portion of options expected to vest. Therefore, we applied an estimated forfeiture rate that we derived from historical employee termination behavior. If the actual number of forfeitures differs from our estimates, additional adjustments to compensation expense may be required in future periods.

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Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123 and EITF 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of options granted to non-employees is periodically remeasured as the underlying options vest.

No tax benefits were attributed to the stock-based compensation expense because a valuation allowance was maintained for substantially all net deferred tax assets.

Stock Option Plans

During 2003, shareholders approved the 2003 Equity Incentive Plan, or 2003 Plan, which replaced the 1994 Equity Incentive Plan, or 1994 Plan. The 1994 Plan has since been terminated, except with respect to outstanding awards previously granted thereunder. The 2003 Plan provides for (a) the grant of nonqualified and/or incentive stock options, stock appreciation rights and share awards, (b) annual, automatic, non-discretionary grants of non-qualified stock options and share awards to non-employee members of our board of directors and (c) the award of stock-based performance bonuses. There are 6,443,289 shares authorized under the 2003 Plan including the authorization for issuance of an additional 5,000,000 shares of common stock as set forth in an August 2004 amendment to the 2003 Plan approved by our shareholders at our 2004 Annual Meeting of Shareholders and 293,289 shares which had been reserved but not granted under the 1994 Plan.

The Novuspharma S.p.A. Stock Option Plan, or 2004 Plan, authorized 350,000 shares and provides for the grant of nonqualified and/or incentive stock options and share awards to employees, consultants and directors in Italy.

The Plans are administered by the Compensation Committee of the Board of Directors which has the discretion to determine which employees, consultants and directors shall be granted options. The options are typically exercisable ratably over a four-year period commencing one year from the date of grant, and expire not more than 10 years from the date of grant. As of September 30, 2006, approximately 558,000 shares of common stock were available for future grants.

The following table summarizes stock option activity for all of stock option plans during the nine months ended September 30, 2006:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (Thousands)
Outstanding December 31, 2005	6,115,000	$ 10.95		
Granted	905,000	$ 1.75		
Exercised		$		
Forfeited	(363,000)	$ 4.35		
Expired	(395,000)	$ 13.45		
Outstanding September 30, 2006	6,262,000	$ 9.85	7.1	$ 76
Vested or expected to vest at September 30, 2006	5,956,826	$ 10.17	7.0	$ 74
Exercisable at September 30, 2006	4,462,784	$ 12.40	6.4	$ 48

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A summary of the status of nonvested share awards as of September 30, 2006 and changes during the period then ended, is presented below:

	Nonvested Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested at December 31, 2005	1,608,000	$ 4.92
Granted	76,000	$ 1.76
Vested	(518,000)	$ 3.56
Forfeited	(134,000)	$ 2.79
Nonvested at September 30, 2006	1,032,000	$ 5.65

The total fair value of share awards vested during the nine months ended September 30, 2006 was $884,000.

As of September 30, 2006, the total remaining unrecognized compensation cost related to unvested stock options and share awards amounted to $1.8 million, which will be amortized over the weighted-average remaining requisite service period of 1.2 years. This amount does not include unrecognized compensation cost related to 525,000 shares of contingent share awards granted during 2005.

5. Convertible Senior Notes

6.75% Convertible Senior Notes

As of September 30, 2006, $72.3 million of our 6.75% notes due 2010 had been converted into 27.5 million shares of common stock, resulting in cumulative make-whole interest payments of $24.1 million which was paid in cash. In addition, certain holders of the notes exercised their right to redeem up to 30% aggregate principal of their notes, and on April 30, 2006, we redeemed approximately $2.7 million in aggregate principal of these notes. Subsequent to this date the mandatory redemption right expired and the remaining cash which we held in escrow to fund the potential redemptions was returned to us. As of September 30, 2006, we had $7.0 million principal amount of 6.75% notes outstanding.

The interest make-whole provision of the 6.75% notes represents an embedded derivative which is required to be accounted for separate from the underlying notes and was recorded as a derivative liability and a discount to the carrying value of the notes. The resulting discount to the notes is being accreted over the life of the notes as additional interest expense using the effective interest method. Accordingly, we recorded interest expense of $0.1 million and $4.0 million for the three and nine months ended September 30, 2006, respectively, primarily in connection with the note conversions. The estimated fair value of the derivative liability was $0.3 million at September 30, 2006 and was recorded in *6.75% convertible senior notes*. The change in the estimated fair value for the three and nine months ended September 30, 2006 was a gain of $0.1 million and $4.1 million, respectively, and is recorded in *gain (loss) on derivative liabilities.*

7.5% Convertible Senior Notes

In April 2006, we issued approximately $66.3 million aggregate principal amount of our 7.5% notes, approximately $33.2 million of which was issued in a registered offering for cash with net proceeds of approximately $31.2 million, after deducting expenses and the initial purchaser s discounts and commissions. Approximately $33.2 million was issued in a private exchange for approximately $39.5 million aggregate principal amount of our 5.75% convertible senior subordinated notes and approximately $1.2 million aggregate principal amount of our 5.75% convertible subordinated notes. We recognized a net gain of $8.0 million on the early extinguishment and exchange of these notes which is based on the carrying value of the exchanged notes less the fair value of the new notes, net of issuance costs of $0.4 million and accrued interest of $0.9 million attributable to the exchanged notes. We recorded issuance costs related to 7.5% notes of approximately $2.0 million which are recorded in *other assets* and are being amortized to interest expense using the effective interest method over the five-year life of the notes.

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