STEMCELLS INC
Form 10-Q
November 04, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

For the quarter ended: September 30, 2008 **Commission File Number: 0-19871**

STEMCELLS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	94-3078125
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer identification No)

3155 PORTER DRIVE
PALO ALTO, CA 94304

(Address of principal executive offices including zip code)
(650) 475-3100

(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 twelve months (or for such shorter periods that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yesþ No o

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 o	Accelerated filer þ	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

At October 30, 2008, there were 81,145,499 shares of Common Stock, $.01 par value, issued and outstanding.

STEMCELLS, INC.
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NOTE REGARDING REFERENCES TO OUR COMMON STOCK

Throughout this Form 10-Q, the words we, us, our, and StemCells refer to StemCells, Inc., including StemCells California, Inc., our wholly-owned subsidiary, and the owner or licensee of most of our intellectual property. Common stock refers to our common stock, $.01 par value.

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

STEMCELLS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	September 30, 2008	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	$ 16,170,526	$ 9,759,169
Marketable securities, current	5,175,023	26,696,413
Other receivables	122,664	264,631
Note receivable		1,000,000
Prepaid assets	590,820	1,032,482
Total current assets	22,059,033	38,752,695
Marketable securities, non-current	321,936	3,150,971
Property, plant and equipment, net	3,379,952	3,905,404
Other assets, non-current	2,043,650	1,710,829
Intangible assets, net	678,570	762,667
Total assets	$ 28,483,141	$ 48,282,566
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 1,360,341	$ 1,813,595
Accrued expenses	1,500,038	2,462,252
Accrued wind-down expenses, current	1,338,344	1,374,632
Deferred rent, current	333,002	290,391
Deferred revenue, current	54,065	43,909
Capital lease obligation, current	18,430	17,530
Bonds payable, current	236,250	136,250
Total current liabilities	4,840,470	6,138,559
Capital lease obligation, non-current	11,331	25,269
Bonds payable, non-current	809,166	1,009,166
Deposits and other long-term liabilities	527,804	527,804
Accrued wind-down expenses, non-current	4,098,086	4,768,859
Deferred rent, non-current	180,429	437,144
Deferred revenue, non-current	151,245	163,865
Total liabilities	10,618,531	13,070,666
Commitment and contingencies (Note 6)		
Stockholders equity:		
Common stock, $.01 par value; 250,000,000 shares authorized; issued and outstanding 81,103,102 at September 30, 2008 and 80,681,087 at December 31, 2007	811,030	806,810

Additional paid-in capital	267,948,249	264,603,711
Accumulated deficit	(248,919,164)	(229,914,747)
Accumulated other comprehensive loss	(1,975,505)	(283,874)
Total stockholders equity	17,864,610	35,211,900
Total liabilities and stockholders equity	$ 28,483,141	$ 48,282,566

See Notes to Condensed Consolidated Financial Statements.

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STEMCELLS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Revenue:				
Revenue from licensing agreements	$ 12,379	$ 13,162	$ 59,561	$ 26,948
Operating expenses:				
Research and development	4,171,799	5,621,955	13,087,165	14,139,297
General and administrative	1,631,580	2,043,275	6,231,629	5,716,480
Wind-down expenses	53,636	83,661	381,136	439,471
Total operating expenses	5,857,015	7,748,891	19,699,930	20,295,248
Loss from operations	(5,844,636)	(7,735,729)	(19,640,369)	(20,268,300)
Other income (expense):				
License and settlement agreement, net				550,467
Realized gain on sale of marketable securities				717,621
Interest income	138,332	617,616	738,107	1,926,753
Interest expense	(26,849)	(29,405)	(84,010)	(96,777)
Other expense	(10,800)	(5,985)	(18,145)	(27,009)
Total other income, net	100,683	582,226	635,952	3,071,055
Net loss	$ (5,743,953)	$ (7,153,503)	$ (19,004,417)	$ (17,197,245)
Basic and diluted net loss per share	$ (0.07)	$ (0.09)	$ (0.24)	$ (0.22)
Shares used to compute basic and diluted loss per share	80,961,150	80,065,667	80,827,141	79,478,537

See Notes to Condensed Consolidated Financial Statements.

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STEMCELLS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	Nine months ended September 30,	
	2008	**2007**
Cash flows from operating activities:		
Net loss	$ (19,004,417)	$ (17,197,245)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	895,617	869,432
Share-based payment	3,021,444	2,276,026
Gain on sale of marketable securities		(717,621)
Non-cash income from license and settlement agreement, net		(550,467)
Changes in operating assets and liabilities:		
Accrued interest and other receivables	141,967	116,577
Prepaid and other assets, current	441,662	98,748
Other assets, non-current	(322,821)	14,395
Accounts payable and accrued expenses	(1,415,468)	913,180
Accrued wind-down expenses	(707,061)	(604,949)
Deferred revenue	(2,464)	24,620
Deferred rent	(214,104)	(170,666)
Deposits and other long-term liabilities		(81,181)
Net cash used in operating activities	(17,165,645)	(15,009,151)
Cash flows from investing activities:		
Proceeds from maturities of marketable securities, net	22,658,794	3,076,691
Purchases of marketable securities, net		(25,746,705)
Prepayment of advance	1,000,000	
Purchases of property, plant and equipment	(261,693)	(1,260,961)
Acquisition of other assets	(24,375)	(49,375)
Net cash provided by (used in) investing activities	23,372,726	(23,980,350)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	194,061	3,545,489
Proceeds from the exercise of stock options	123,253	210,273
Proceeds from the exercise of warrants		1,093,750
(Repayment) proceeds of capital lease obligations	(13,038)	46,994
Repayment of debt obligations	(100,000)	(173,333)
Net cash provided by financing activities	204,276	4,723,173
Increase (decrease) in cash and cash equivalents	6,411,357	(34,266,328)
Cash and cash equivalents, beginning of period	9,759,169	51,795,529
Cash and cash equivalents, end of period	$ 16,170,526	$ 17,529,201

Supplemental disclosure of cash flow information:				
Interest paid	$	84,010	$	96,777
Supplemental schedule of non-cash investing and financing activities:				
Stock issued for licensing agreement(1)	$	10,000	$	10,000

(1) Under terms of a license agreement with the California Institute of Technology (Cal Tech), annual fees of $5,000 were due on each of two patents to which we hold a license from Cal Tech, payable in cash or common stock at our choice. We elected to pay the fees in stock and issued 6,924 and 3,865 shares of our common stock in 2008 and 2007 respectively.

See Notes to Condensed Consolidated Financial Statements.

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Notes to Condensed Consolidated Financial Statements (Unaudited)
September 30, 2008 and 2007

Note 1. Summary of Significant Accounting Policies

Nature of Business

StemCells, Inc., a Delaware corporation, is a biopharmaceutical company that operates in one segment, the development of novel cell-based therapeutics designed to treat human diseases and disorders.

The accompanying financial data as of and for the three and nine months ended September 30, 2008 and 2007 has been prepared by us, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) have been condensed or omitted pursuant to such rules and regulations. The December 31, 2007 condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by US GAAP. However, we believe that the disclosures are adequate to make the information presented not misleading. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and the notes thereto, included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

We expect to incur additional operating losses over the foreseeable future. We have very limited liquidity and capital resources and must obtain significant additional capital and other resources in order to sustain our product development efforts, to provide funding for the acquisition of technologies, businesses and intellectual property rights, preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, general and administrative expenses and other working capital requirements. We rely on our cash reserves, proceeds from equity and debt offerings, proceeds from the transfer or sale of intellectual property rights, equipment, facilities or investments, government grants and funding from collaborative arrangements, to fund our operations. If we exhaust our cash reserves and are unable to obtain adequate financing, we may be unable to meet our operating obligations and we may be required to initiate bankruptcy proceedings. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of StemCells, Inc. and our wholly-owned subsidiary, StemCells California, Inc. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make judgments, assumptions and estimates that affect the amounts reported in our condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

Significant estimates include the following:

The grant date fair value of stock-based awards recognized as compensation expense in accordance with the provisions of Statement of Financial Accounting Standards No. 123 (Revised 2004) *Share Based Payment* (SFAS 123R). (See Note 4).

Accrued wind-down expenses. (See Note 5).

Reclassification

Certain reclassifications of prior year amounts have been made to conform to the current year presentation. Deferred rent of approximately $290,000 has been reclassified from Deferred rent, non-current to Deferred rent, current on the condensed consolidated balance sheet as of December 31, 2007 to conform to the current year presentation. The reclassifications had no effect on total assets, total liabilities, equity, or net loss previously reported.

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Financial Assets

Cash and Cash Equivalents

We consider money market accounts and investments with a maturity of 90 days or less from the date of purchase to be cash equivalents.

Marketable Securities

Our existing marketable debt and equity securities are designated as available-for-sale securities. These securities are carried at fair value (see Note 2, Financial Assets), with the unrealized gains and losses reported as a component of stockholders equity. The balance sheet classification of our marketable debt securities as current or non-current is based on their maturity dates. Investments with remaining maturities of 365 days or less not classified as cash equivalents are classified as Marketable securities, current. Investments with remaining maturities greater than 365 days are classified as Marketable securities, non-current. Management determines the appropriate designation of its investments in marketable debt and equity securities at the time of purchase and reevaluates such designation as of each balance sheet date. The cost of securities sold is based upon the specific identification method.

If the estimated fair value of a security is below its carrying value, we evaluate whether we have the intent and ability to retain our investment for a period of time sufficient to allow for any anticipated recovery to the cost of the investment, and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. Other-than-temporary declines in estimated fair value of all marketable securities are charged to Other income (expense), net. No such impairment was recognized during the three and nine months ended September 30, 2008 and 2007.

Other Receivables

Our receivables generally consist of interest income on our financial instruments, revenue from licensing agreements, and rent from our sub-lease tenants.

Revenue Recognition

We currently recognize revenue resulting from the licensing and use of our technology and intellectual property. Such licensing agreements may contain multiple elements, such as upfront fees, payments related to the achievement of particular milestones and royalties. Revenue from upfront fees for licensing agreements that contain multiple elements are generally deferred and recognized on a straight-line basis over the term of the agreement. Fees associated with substantive at risk performance-based milestones are recognized as revenue upon completion of the scientific or regulatory event specified in the agreement, and royalties received are recognized as earned. Revenue from collaborative agreements and grants are recognized as earned upon either the incurring of reimbursable expenses directly related to the particular research plan or the completion of certain development milestones as defined within the terms of the relevant collaborative agreement or grant.

Share-Based Payment

We account for share-based payment awards to employees in accordance with SFAS 123R. The compensation expense we record for these awards is based on their grant date fair value as calculated and amortized over their vesting period. See Note 4, Share-Based Payment for further information.

We account for stock-based awards granted to non-employees in accordance with SFAS 123 and Emerging Issues Task Force (EITF) 96-18, *Accounting For Equity Instruments That Are Issued To Other Than Employees For Acquiring, Or In Conjunction With Selling, Goods Or Services*, and accordingly, expense the estimated fair value of such options as calculated using the Black-Scholes-Merton (Black-Scholes) model. The estimated fair value is re-measured at each reporting date and is amortized over the remaining vesting period.

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Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed based on the weighted-average number of shares of common stock and other dilutive securities. To the extent these securities are anti-dilutive, they are excluded from the calculation of diluted earnings per share.

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per share computations:

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Net loss	$ (5,743,953)	$ (7,153,503)	$(19,004,417)	$(17,197,245)
Weighted average shares outstanding used to compute basic and diluted net loss per share	80,961,150	80,065,667	80,827,141	79,478,537
Basic and diluted net loss per share	$ (0.07)	$ (0.09)	$ (0.24)	$ (0.22)

The following outstanding potentially dilutive common stock equivalents were excluded from the computation of diluted net loss per share because the effect would have been anti-dilutive as of September 30:

	2008	2007
Options	8,471,887	9,033,794
Restricted stock units	1,650,000	
Warrants	1,255,000	1,355,000
Total	11,376,887	10,388,794

Comprehensive Loss

Comprehensive loss is comprised of net losses and other comprehensive loss (OCL). OCL includes certain changes in stockholders equity that are excluded from net losses. Specifically, we include in OCL changes in unrealized gains and losses on our marketable securities. Accumulated other comprehensive loss was $1,975,505 as of September 30, 2008 and $283,874 as of December 31, 2007.

Comprehensive loss was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Net loss	$ (5,743,953)	$ (7,153,503)	$ (19,004,417)	$ (17,197,245)
Net change in unrealized gains and losses on marketable securities	(272,066)	(436,331)	(1,691,631)	(3,620,563)
Comprehensive loss	$ (6,016,019)	$ (7,589,834)	$ (20,696,048)	$ (20,817,808)

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We adopted the provisions of SFAS 157 that became effective in our first quarter of 2008. See Note 3 Fair Value Measurement for further information about the adoption of the required provisions of SFAS 157.

In February 2008, the FASB issued FASB Staff Position (FSP) No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2). FSP 157-2 delays the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities, except for certain items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). We are currently evaluating the impact of SFAS 157 on our consolidated financial statements for items within the scope of FSP 157-2, which will become effective beginning with our first quarter of 2009.

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In October 2008, the FASB issued FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* (FSP 157-3). FSP 157-3 clarifies the application of SFAS 157, in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP shall be effective upon issuance, including prior periods for which financial statements have not been issued. Revisions resulting from a change in the valuation technique or its application shall be accounted for as a change in accounting estimate. Adoption of FSP 157-3 will not have a material impact on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS 159). Under SFAS 159, a company may choose, at specified election dates, to measure eligible items at fair value and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. SFAS 159 became effective beginning with our first quarter of 2008. At this time, we have chosen not to adopt the provisions of SFAS 159 for our existing financial instruments.

In April 2008, the FASB issued FSP No.142-3, *Determination of the Useful Life of Intangible Assets* (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). FSP 142-3 amends paragraph 11(d) of SFAS 142 to require an entity to use its own assumptions about renewal or extension of an arrangement, adjusted for the entity-specific factors in paragraph 11 of SFAS 142, even when there is likely to be substantial cost or material modifications. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, with early adoption prohibited. We expect to adopt FSP142-3 on January 1, 2009, and we do not expect the adoption to have a material effect on our consolidated financial condition and results of operations.

Note 2. Financial Assets

The following table summarizes our cash, cash equivalents and marketable securities:

	September 30, 2008	December 31, 2007
Cash and cash equivalents:		
Cash	$ 150,040	$ 549,544
Cash equivalents:		
Money market accounts	545,726	5,079,564
U.S. Treasury obligations and corporate debt securities (due within 90 days)	15,474,760	4,130,061
Total cash and cash equivalents	16,170,526	9,759,169
Marketable securities:		
Corporate debt securities, current (due within 1 year)	5,175,023	26,696,413
Corporate debt securities, non-current (due in 1 to 5 years)		1,189,503
Equity securities, non-current	321,936	1,961,468
Total marketable securities	5,496,959	29,847,384
Total cash, cash equivalents, and marketable securities, current and non-current	$ 21,667,485	$ 39,606,553

The following table summarizes unrealized gains and losses related to our investments in marketable securities designated as available-for-sale:

	As of September30, 2008			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated Fair value
Corporate debt securities	$ 5,202,766	$ 2,246	$ (29,989)	$ 5,175,023
Equity securities	2,269,698		(1,947,762)	321,936
Total marketable securities	$ 7,472,464	$ 2,246	$ (1,977,751)	$ 5,496,959

	As of December 31, 2007			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated Fair value
Corporate debt securities	$ 27,861,218	$ 28,246	$ (3,548)	$ 27,885,916
Equity securities	2,269,697		(308,229)	1,961,468
Total marketable securities	$ 30,130,915	$ 28,246	$ (311,777)	$ 29,847,384

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Gross unrealized gains and losses on cash equivalents were not material at September 30, 2008 and December 31, 2007. Our investments in marketable corporate debt securities consist primarily of commercial paper, corporate bonds, and asset-backed securities.

Our investment in marketable equity securities consists of shares in ReNeuron Group plc, a publicly listed UK corporation. In July 2005, we entered into a license and settlement agreement with ReNeuron Limited, a wholly-owned subsidiary of ReNeuron Group plc, (collectively referred to as ReNeuron). As part of the agreement, we granted ReNeuron a license that allows ReNeuron to exploit its c-mycER conditionally immortalized adult human neural stem cell technology for therapy and other purposes. In return for the license, we received a 7.5% fully-diluted equity interest in ReNeuron, subject to certain anti-dilution provisions, and a cross-license to the exclusive use of ReNeuron s technology for certain diseases and conditions, including lysosomal storage diseases, spinal cord injury, cerebral palsy, and multiple sclerosis. The agreement also provides for full settlement of any potential claims that either we or ReNeuron might have had against the other in connection with any putative infringement of certain of each party s patent rights prior to the effective date of the agreement. In February 2007, we sold 5,275,000 ordinary shares of ReNeuron for net proceeds of approximately $3,075,000 and we recognized a realized gain of approximately $716,000. In February 2007, as a consequence of certain anti-dilution provisions in the agreement, ReNeuron issued us an additional 822,000 shares of common stock net of approximately 12,000 shares which were transferred to NeuroSpheres Ltd. (NeuroSpheres), a Canadian corporation from which we have licensed some of the patent rights that are subject to the agreement with ReNeuron. We recorded approximately $550,000 as other income for the additional shares. We owned 4,821,924 ordinary shares of ReNeuron at September 30, 2008 and December 31, 2007 and the fair value of those shares was approximately $322,000 at September 30, 2008 and approximately $1,961,000 at December 31, 2007.

Changes in the market value of our ReNeuron shares as a result of changes in market price per share or the exchange rate between the US dollar and the British pound are accounted for under other comprehensive loss if deemed temporary and are not recorded as other income (expense), net until the shares are disposed of and a gain or loss realized.

Note 3. Fair Value Measurement

Effective January 1, 2008, we adopted SFAS 157, except as it applies to the nonfinancial assets and nonfinancial liabilities subject to FSP SFAS 157-2. SFAS 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, SFAS 157 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 Directly or indirectly observable inputs other than in Level 1, that include quoted prices for similar assets or liabilities in active markets or quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 Unobservable inputs which are supported by little or no market activity that reflects the reporting entity s own assumptions about the assumptions that market participants would use in pricing the asset or liability

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

In accordance with SFAS 157, we measure our financial assets and liabilities at fair value. Our cash equivalents and marketable securities are primarily classified within Level 1 or Level 2. This is because our cash equivalents and marketable securities are valued primarily using quoted market prices or alternative pricing sources and models utilizing market observable inputs. We currently do not have any Level 3 financial assets or liabilities.

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The following table presents assets and liabilities measured at fair value:

	Fair value measurement at reporting date using		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	As of September 30, 2008
Assets			
Cash Equivalents:			
Money market funds	$ 545,726	$	$ 545,726
U.S. Treasury obligations	15,474,760		15,474,760
Marketable Securities:			
Equity securities	321,936		321,936
Corporate bonds		2,779,553	2,779,553
Asset-Backed securities		2,395,470	2,395,470
Total assets	$ 16,342,422	$ 5,175,023	$ 21,517,445
Liabilities			
Bond obligation	$	$ 1,045,416	$ 1,045,416

Note 4. Share-Based Payment

We currently grant stock-based awards under three equity incentive plans. We had 15,227,244 shares authorized under the three plans as of September 30, 2008. Under these plans we may grant incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, and performance-based shares to our employees, directors and consultants, at prices determined by our Board of Directors. Incentive stock options may only be granted to employees under these plans with a grant price not less than the fair market value on the date of grant.

Our compensation expense for stock options and restricted stock units issued from our equity incentive plans for the three and nine months ended September 30 was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Research and development expense	$473,828	$418,764	$1,430,157	$ 986,366
General and administrative expense	465,351	385,285	1,443,788	1,080,205
Total employee stock based compensation expense and effect on net loss	$939,179	$804,049	$2,873,945	$2,066,571
Effect on basic and diluted net loss per common share	$ 0.01	$ 0.01	$ 0.04	$ 0.03

As of September 30, 2008, we have approximately $5,570,000 of total unrecognized compensation expense related to unvested options and restricted stock units granted under our various stock-based plans that we expect to recognize over a weighted-average vesting period of 2.3 years.

Incentive Stock Options

Generally, stock options granted to employees have a maximum term of ten years, and vest over a four year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. We may grant options with different vesting terms from time to time. Upon employee termination of service, any unexercised vested option will be forfeited three months following termination or the expiration of the option, whichever is earlier. Unvested options are forfeited on termination.

A summary of our stock option activity for the three months ended September 30, 2008 is as follows:

	Number of options	**Weighted-average exercise price**
Outstanding options at June 30, 2008	8,629,392	$ 2.36
Granted	210,000	$ 1.12
Exercised		
Cancelled	(367,505)	$ 2.37
Outstanding options at September 30, 2008	8,471,887	$ 2.33

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The estimated weighted-average fair value per share of options granted in the three months ended September 30, 2008 was approximately $0.93. The fair value of options granted is estimated as of the date of grant using the Black-Scholes option pricing model, which requires certain assumptions as of the date of grant. The weighted-average assumptions used as of September 30 were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2008	**2007**	**2008**	**2007**
Expected life (years)(1)	7.71	6.25	7.22	6.25
Risk-free interest rate(2)	3.56%	4.28%	3.32%	4.39%
Expected volatility(3)	93.78%	93.35%	93.81%	95.49%
Expected dividend yield(4)	0%	0%	0%	0%

(1) The expected term represents the period during which our stock-based awards are expected to be outstanding. In 2008 we estimated this amount based on historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements, and expectation of future employee behavior, including post-vesting terminations. In 2007 the expected term is equal to the average of the contractual life of the stock option and its vesting period as of the date of

grant.

(2) The risk-free interest rate is based on U.S. Treasury debt securities with maturities close to the expected term of the option as of the date of grant.

(3) Expected volatility is based on historical volatility over the most recent historical period equal to the length of the expected term of the option as of the date of grant.

(4) We have not historically issued any dividends and we do not expect to in the foreseeable future.

At the end of each reporting period, we estimate forfeiture rates based on our historical experience within separate groups of employees and adjust the share-based payment expense accordingly.

A summary of changes in unvested options for the three months ended September 30, 2008 is as follows:

	Number of options	Weighted-average grant date fair value
Unvested options at June 30, 2008	3,656,252	$ 1.95
Granted	210,000	$ 0.93
Vested	(672,085)	$ 1.91
Cancelled	(276,550)	$ 1.91
Unvested options at September 30, 2008	2,917,617	$ 1.89

The estimated fair value of options vested was approximately $1,284,000 for the three months ended September 30, 2008.

Restricted Stock Units

In March 2008, we granted restricted stock units to certain employees that entitle the holders to receive shares of our common stock upon vesting. These restricted stock units vest over a three-year period from the date of grant: one-third of the award will vest on each grant date anniversary over the following three years. The fair value of restricted stock units granted are based upon the market price of the underlying common stock as if it were vested and issued on the date of grant.

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A summary of our restricted stock unit activity for the three months ended September 30, 2008 is as follows:

	Number of RSUs	Weighted-average grant date fair value
Outstanding RSUs at June 30, 2008	1,650,000	$ 1.26
Granted		
Exercised		
Cancelled		
Outstanding RSUs at September 30, 2008	1,650,000	$ 1.26
RSUs exercisable at September 30, 2008		

Stock Appreciation Rights

In July 2006, we granted cash-settled Stock Appreciation Rights (SARs) to certain employees that give the holder the right, upon exercise, to the difference between the price per share of our common stock at the time of exercise and the exercise price of the SAR. The exercise price of the SAR is equal to the market price of our common stock at the date of grant. The SARs vest over a four year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. Compensation expense is based on the fair value of SARs, which is calculated using the Black-Scholes option pricing model. The share-based payment expense and liability are re-measured at each reporting date through the date of settlement.

A summary of the changes in SARs for the three months ended September 30, 2008 is as follows:

	Number of SARs	Weighted average exercise price
Outstanding at June 30, 2008	1,430,849	$ 2.00
Granted		
Exercised		
Cancelled		
Outstanding SARs at September 30, 2008	1,430,849	$ 2.00
SARs exercisable at September 30, 2008	775,043	$ 2.00

For the three months ended September 30, 2008, we re-measured the compensation expense and liability related to the SARs and recorded compensation expense of approximately $25,000. The total compensation expense related to SARs was approximately $76,000 for the three months ended September 30, 2007.

At September 30, 2008, approximately $241,000 of unrecognized compensation expense related to SARs is expected to be recognized over a weighted average vesting period of approximately 1.0 year. The resulting effect on net loss and net loss per share attributable to common stockholders is not likely to be representative of the effects in future periods, due to changes in the fair value calculation which is dependent on the stock price, volatility, interest and forfeiture rates, additional grants and subsequent periods of vesting.

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Note 5. Wind-down Expenses

In October 1999, we relocated to California from Rhode Island and established a wind-down reserve for the estimated lease payments and operating costs of the scientific and administrative facility in Rhode Island. Even though we intend to dispose of the facility at the earliest possible time, we cannot determine with certainty a fixed date by which such disposal will occur. In light of this uncertainty, we periodically re-evaluate and adjust the reserve. We consider various factors such as our lease payments through to the end of the lease, operating expenses, the current real estate market in Rhode Island, and estimated subtenant income based on actual and projected occupancy.

The summary of the changes to our wind-down reserve for the three month periods ended March 31, 2008, June 30, 2008 and September 30, 3008; the nine month period ended September 30, 2008 and for the year ended December 31, 2007 were as follows:

	January to March 31, 2008	April to June 30, 2008	July to September 30, 2008	January to September 30, 2008	January to December 31, 2007
Accrued wind-down reserve at beginning of period	$ 4,875,000	$ 4,704,000	$ 4,583,000	$ 4,875,000	$ 5,512,000
Less actual expenses recorded against estimated reserve during the period	(331,000)	(288,000)	(316,000)	(935,000)	(1,420,000)
Additional expense recorded to revise estimated reserve at period-end	160,000	167,000	54,000	381,000	783,000
Revised reserve at period-end	4,704,000	4,583,000	4,321,000	4,321,000	4,875,000
Add deferred rent at period-end	1,218,000	1,166,000	1,115,000	1,115,000	1,268,000
Total accrued wind-down expenses at period-end (current and non-current)	$ 5,922,000	$ 5,749,000	$ 5,436,000	$ 5,436,000	$ 6,143,000
Accrued wind-down expenses, current	$ 1,383,000	$ 1,379,000	$ 1,338,000	$ 1,338,000	$ 1,374,000
Accrued wind-down expenses, non-current	4,539,000	4,370,000	4,098,000	4,098,000	4,769,000
Total accrued wind-down expenses	$ 5,922,000	$ 5,749,000	$ 5,436,000	$ 5,436,000	$ 6,143,000

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Note 6. Commitments and Contingencies

Leases

Capital leases

We entered into direct financing transactions with the State of Rhode Island and received proceeds from the issuance of industrial revenue bonds totaling $5,000,000 to finance the construction of our pilot manufacturing facility in Rhode Island. The related lease agreements are structured such that lease payments fully fund all semiannual interest payments and annual principal payments through maturity in August 2014. The interest rate for the remaining bond series is 9.5%. The bond contains certain restrictive covenants which limit, among other things, the payment of cash dividends and the sale of the related assets. The outstanding principal was approximately $1,045,000 at September 30, 2008 and $1,145,000 at December 31, 2007.

Operating leases

We entered into a fifteen-year lease agreement for a scientific and administrative facility in Rhode Island in connection with a sale and leaseback arrangement in 1997. The lease term expires June 30, 2013. The lease contains escalating rent payments, which we recognize as operating lease expense on a straight-line basis. Deferred rent expense for this facility was approximately $1,115,000 at September 30, 2008 and $1,268,000 at December 31, 2007, and is included as part of the wind-down accrual on our condensed consolidated balance sheet.

We entered into and amended a lease agreement for an approximately 68,000 square foot facility located at the Stanford Research Park in Palo Alto, California. The facility includes space for laboratories, offices, and a GMP (Good Manufacturing Practices) suite. GMP facilities can be used to manufacture materials for clinical trials. The lease term expires March 31, 2010. Under the terms of the agreement we are required to provide a letter of credit for a total of approximately $778,000, which serves as a security deposit for the duration of the lease term. The letter of credit issued by our financial institution is collateralized by a certificate of deposit for the same amount, which is reflected as restricted cash in other assets, non-current on our condensed consolidated balance sheets. The lease contains escalating rent payments, which we recognize as operating lease expense on a straight-line basis. Deferred rent for this facility was approximately $513,000 at September 30, 2008 and $728,000 at December 31, 2007, and is reflected as deferred rent on our condensed consolidated balance sheet. At September 30, 2008, we had a space-sharing agreement covering approximately 10,451 square feet of this facility. We receive base payments plus a proportionate share of the operating expenses based on square footage over the term of the agreement.

Indemnification Agreement

On July 9, 2008, we amended our 1997 and 2000 license agreements with NeuroSpheres. NeuroSpheres is the holder of certain patents exclusively licensed by us, including the six patents that are the basis of our patent infringement suits against Neuralstem. As part of the amendment, we agreed to pay all reasonable litigation costs, expenses and attorney s fees incurred by NeuroSpheres in the declaratory judgment suit between us and Neuralstem. In return, we are entitled to off-set all litigation costs incurred in that suit against amounts that would otherwise be owed under the license agreements, such as annual maintenance fees, milestones and royalty payments. At this time, we cannot estimate the likely total costs of our pending litigation with Neuralstem, given the unpredictable nature of such proceedings, or the total amount we may ultimately owe under the NeuroSpheres license agreements. However, the ability to apply the offsets will run for the entire term of each license agreement. For these reasons, we have chosen to approximate the potential value of the offset receivable by assuming that all litigation charges actually incurred in the declaratory judgment action will ultimately be offset against royalties owed. Based on actual costs and other relevant factors, management will reevaluate this assumption on a quarterly basis.

Note 7. Subsequent Events

On October 2, 2008, we were awarded a $305,000 grant from the National Institute of Diabetes and Digestive and Kidney Diseases to research and develop a potential cell-based therapeutic for liver disease arising from infection by the hepatitis C virus (HCV). The award is a Phase I grant under the Small Business Innovation Research (SBIR) Program of the National Institutes of Health. Should the objectives of the research funded by this grant be met, we anticipate applying for Phase II and additional funding under the SBIR Program.

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Contingencies

In July 2006, we filed suit against Neuralstem, Inc. in the Federal District Court for the District of Maryland, alleging that Neuralstem s activities violate claims in four of the patents we exclusively licensed from NeuroSpheres. Neuralstem has filed a motion for dismissal or summary judgment in the alternative, citing Title 35, Section 271(e)(1) of the United States Code, which says that it is not an act of patent infringement to make, use or sell a patented invention solely for uses reasonably related to the development and submission of information to the FDA. Neuralstem argues that because it does not have any therapeutic products on the market yet, the activities complained of fall within the protection of Section 271(e)(1) that is, basically, that the suit is premature. This issue will be decided after discovery is complete. Subsequent to filing its motion to dismiss, in December 2006, Neuralstem petitioned the U.S. Patent and Trademark Office (PTO) to reexamine two of the patents in our infringement action against Neuralstem, namely U.S. Patent No. 6,294,346 (claiming the use of human neural stem cells for drug screening) and U.S. Patent No. 7,101,709 (claiming the use of human neural stem cells for screening biological agents). In April 2007, Neuralstem petitioned the PTO to reexamine the remaining two patents in the suit, namely U.S. Patent No. 5,851,832 (claiming methods for proliferating human neural stem cells) and U.S. Patent No. 6,497,872 (claiming methods for transplanting human neural stem cells). These requests were granted by the PTO and, in June 2007, the parties voluntarily agreed to stay the pending litigation while the PTO considers these reexamination requests. In October 2007, Neuralstem petitioned the PTO to reexamine a fifth patent, namely U.S. Patent No. 6,103,530, which claims a culture medium for proliferating mammalian neural stem cells. In April 2008, the PTO upheld the 832 and 872 patents, as amended, and issued Notices of Intent to Issue an *Ex Parte* Reexamination Certificate for both. In August 2008, the PTO upheld the 530 patent, as amended, and issued a Notice of Intent to Issue an *Ex Parte* Reexamination Certificate. The remaining two patents are still under review by the PTO.

In May 2008, we filed a second patent infringement suit against Neuralstem and its two founders, Karl Johe and Richard Garr. In this suit, which we filed in the Federal District Court for the Northern District of California, we allege that Neuralstem s activities infringe claims in two patents we exclusively license from NeuroSpheres, specifically U.S. Patent No. 7,361,505 (claiming composition of matter of human neural stem cells derived from any source material) and U.S. Patent No. 7,115,418 (claiming methods for proliferating human neural stem cells). In addition, we allege various state law causes of action against Neuralstem arising out of its repeated derogatory statements to the public about our patent portfolio. Also in May 2008, Neuralstem filed suit against us and NeuroSpheres in the Federal District Court for the District of Maryland seeking a declaratory judgment that the 505 and 418 patents are either invalid or are not infringed by Neuralstem and that Neuralstem has not violated California state law. In August 2008, the California court transferred our lawsuit against Neuralstem to Maryland for resolution on the merits. We anticipate that the Maryland District Court will consolidate these actions in some manner prior to trial.

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

This report contains forward looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act that involve substantial risks and uncertainties. Such statements include, without limitation, all statements as to expectation or belief and statements as to our future results of operations; the progress of our research, product development and clinical programs; the need for, and timing of, additional capital and capital expenditures; partnering prospects; costs of manufacture of products; the protection of, and the need for, additional intellectual property rights; effects of regulations; the need for additional facilities; and potential market opportunities. Our actual results may vary materially from those contained in such forward-looking statements because of risks to which we are subject, including uncertainty as to whether the U.S. Food and Drug Administration (FDA) or other regulatory authorities will permit us to proceed with clinical testing of proposed products despite the novel and unproven nature of our technologies; the risk that our initial clinical trial and any other clinical trials or studies could be substantially delayed beyond their expected dates or cause us to incur substantial unanticipated costs; uncertainties in our ability to obtain the capital resources needed to continue our current research and development operations and to conduct the research, preclinical development and clinical trials necessary for regulatory approvals; the uncertainty regarding our ability to obtain a corporate partner or partners, if needed, to support the development

and commercialization of our potential cell-based therapeutics products; the uncertainty regarding the outcome of our Phase I clinical trial in NCL and any other clinical trials or studies we may conduct in the future; the uncertainty regarding the validity and enforceability of our issued patents; the risk that we may not be able to manufacture additional master and working cell banks when needed; the uncertainty whether any products that may be generated in our cell-based therapeutics programs will prove clinically safe and effective; the uncertainty whether we will achieve revenue from product sales or become profitable; uncertainties regarding our obligations with respect to our former encapsulated cell therapy facilities in Rhode Island; obsolescence of our technologies; competition from third parties; intellectual property rights of third parties; litigation risks; and other risks to which we are subject. All forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by the cautionary statements and risk factors set forth in Risk Factors in Part II, Item 1A of this report and Part I, Item 1A included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

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Overview

The Company

Our research and development (R&D) programs are focused on identifying and developing potential cell-based therapeutics which can either restore or support organ function. Since we relocated our corporate headquarters and research laboratories to California in 1999, our R&D efforts have primarily been directed at refining our methods for identifying, isolating, culturing, and purifying the human neural stem cell (our HuCNS-SC cell population) and the human liver engrafting cells (our hLEC cell population) and developing these as potential cell-based therapeutics for the central nervous system (CNS) and the liver, respectively. In our CNS Program, we are in clinical development with our HuCNS-SC® product candidate. We have completed enrollment and dosing in a six-patient Phase I clinical trial of HuCNS-SC cells as an investigative treatment for infantile and late infantile neuronal ceroid lipofuscinosis (NCL), a fatal neurodegenerative disease often referred to as Batten disease. We expect this trial to be completed in January 2009. We are also continuing research and preclinical development work for the use of neural stem cells to treat other indications in the CNS field; and our goal is to initiate clinical trials of HuCNS-SC for a spinal cord indication, a myelin disorder in the brain, and a degenerative retinal disorder. In our Liver Program, we are in preclinical development with our human liver engrafting cells and are exploring their applicability as a cellular therapy to restore function to liver tissue by replacing dysfunctional or damaged cells. Our goal is to initiate a clinical study of our hLEC cells with the first indication anticipated to be a liver-based metabolic disorder. For a brief description of our significant research and development programs see Overview Research and Development Programs in the Business Section of Part I, Item 1 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007. We have also conducted research on several other cell types and in other areas, which could lead to other possible product candidates, process improvements or further research activities.

We have not derived any revenue or cash flows from the sale or commercialization of any products except for license revenue for certain of our patented cells and media for use in research. As a result, we have incurred annual operating losses since inception and expect to incur substantial operating losses in the future. Therefore, we are dependent upon external financing from equity and debt offerings, federal and state grants, and revenue from collaborative research arrangements with corporate sponsors to finance our operations. We have no such collaborative research arrangements at this time. External financing in the current financial environment may be particularly difficult, and there can be no assurance that such financing or partnering revenue will be available when needed or on terms acceptable to us.

Before we can derive revenue or cash inflows from the commercialization of any of our product candidates, we will need to: (i) conduct substantial *in vitro* testing and characterization of our proprietary cell types, (ii) undertake preclinical and clinical testing for specific disease indications, (iii) develop, validate and scale-up manufacturing processes to produce these cell-based therapeutics, and (iv) pursue required regulatory approvals. These steps are risky, expensive and time consuming.

Overall, we expect our R&D expenses to be substantial and to increase for the foreseeable future as we continue the development and clinical investigation of our current and future product candidates. However, expenditures on R&D programs are subject to many uncertainties, including whether we develop our product candidates with a partner or independently. We cannot forecast with any degree of certainty which of our current product candidates will be subject to future collaboration, when such collaboration agreements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. In addition, there are numerous factors associated with the successful commercialization of any of our cell-based therapeutics, including future trial design and regulatory requirements, many of which cannot be determined with accuracy at this time given the stage of our development and the novel nature of stem cell technologies. The regulatory pathways, both in the United States and internationally, are complex and fluid given the novel and, in general, clinically unproven nature of stem cell technologies. At this time, due to such uncertainties and inherent risks, we cannot estimate in a meaningful way the duration of, or the costs to complete, our R&D programs or whether, when or to what extent we will generate revenues or cash inflows from the commercialization and sale of any of our product candidates. While we are currently focused on advancing each of our product development programs, our future R&D expenses will depend on the determinations we make as to the scientific and clinical prospects of each product candidate, as well as our

ongoing assessment of the regulatory requirements and each product candidate s commercial potential.

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Given the early stage of development of our product candidates, any estimates of when we may be able to commercialize one or more of these products would not be meaningful. Moreover, any estimate of the time and investment required to develop potential products based upon our proprietary HuCNS-SC and hLEC technologies will change depending on the ultimate approach or approaches we take to pursue them, the results of preclinical and clinical studies, and the content and timing of decisions made by the FDA and other regulatory authorities. For example, we cannot predict with any degree of certainty when the necessary regulatory and other approvals to initiate any of the various trials we are planning will be obtained, if at all. There can be no assurance that we will be able to develop any product successfully, or that we will be able to recover our development costs, whether upon commercialization of a developed product or otherwise. We cannot provide assurance that any of these programs will result in products that can be marketed or marketed profitably. If certain of our development-stage programs do not result in commercially viable products, our results of operations could be materially adversely affected.

Significant Events

In July 2008, at our Annual Meeting of Stockholders, our stockholders approved an increase to our authorized capital by an additional 125,000,000 shares of common stock, increasing the number of authorized shares of capital stock from 126,000,000 total shares to 251,000,000 total shares. We subsequently amended our restated certificate of incorporation to designate an additional 125,000,000 shares of common stock, bringing the total number of authorized shares of common stock to 250,000,000. These securities may be used to raise additional capital to fund the company s working capital and other corporate needs, for future acquisitions of assets, programs or businesses, and for other corporate purposes.

In September 2008, Stewart Craig, Ph.D., joined the Company as Senior Vice President, Development and Operations. Dr. Craig is responsible for process design and engineering, GMP manufacturing operations, regulatory affairs, quality assurance, facilities and supply chain management. Dr. Craig has over 25 years of experience in the biotechnology sector, the last 15 of which have been in the cell therapy field. Dr. Craig was most recently Vice President and Chief Technology Officer of Progenitor Cell Therapy, LLC (PCT), a contract provider of GMP cell processing and development services. Prior to joining PCT, Dr. Craig was chief operating officer of Xcyte Therapies, Inc., a publicly traded cell-based immunotherapy company. Dr. Craig has also held senior management positions with the stem cell companies Osiris Therapeutics, Inc. and SyStemix, Inc.

In October 2008, we were awarded a $305,000 grant from the National Institute of Diabetes and Digestive and Kidney Diseases to research and develop a potential cell-based therapeutic for liver disease arising from infection by the hepatitis C virus (HCV). Hepatitis C is a global health challenge, with approximately 170 million people affected worldwide and an estimated three million new infections each year. The virus targets liver cells and is a leading cause of end-stage liver disease. The grant will fund work over the next year to investigate whether our proprietary human liver engrafting cells (hLEC) can be made resistant to infection by the hepatitis C virus. This award is a Phase I grant under the Small Business Innovation Research (SBIR) Program of the National Institutes of Health. Should the objectives of the research funded by this grant be met, we anticipate applying for Phase II and additional funding under the SBIR Program.

In October 2008, we announced preclinical results which show that our proprietary HuCNS-SC® product candidate (purified human neural stem cells) can protect the retina from progressive degeneration. Retinal degeneration leads to loss of vision in diseases such as age-related macular degeneration and retinitis pigmentosa. In this study, our HuCNS-SC cells were transplanted into the Royal College of Surgeons (RCS) rat, a well established animal model of retinal degeneration, and were shown to have survived the transplant and engrafted, and the eyes transplanted with the cells showed preservation of photoreceptors and stabilization of visual function.

Critical Accounting Policies and the Use of Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed consolidated financial statements requires management to make estimates, assumptions, and judgments that affect the reported amounts in our condensed consolidated financial statements and accompanying notes. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments on

historical experience and on various other assumptions that we believe to be reasonable under the circumstances, and we have established internal controls related to the preparation of these estimates. Actual results and the timing of the results could differ materially from these estimates.

Share-Based Payment

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards 123 (revised 2004), *Share-Based Payment*, (SFAS 123R). SFAS 123R requires us to recognize expense related to the fair value of our share-based payment awards, including employee stock options. Under the provisions of SFAS 123R, employee share-based payment is estimated at the date of grant based on the award s fair value using the Black-Scholes-Merton (Black-Scholes) option-pricing model and is recognized as expense ratably over

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the requisite service period. The Black-Scholes option-pricing model requires the use of certain assumptions, the most significant of which are our estimates of the expected volatility of the market price of our stock and the expected term of the award. Our estimate of the expected volatility is based on historical volatility. The expected term represents the period during which our stock-based awards are expected to be outstanding. From January 1, 2006 to December 31, 2007, and in accordance with Staff Accounting Bulletin 107, *Share-Based Payment* (SAB 107), the expected term was equal to the average of the contractual life of the stock option and its vesting period as of the date of grant (the simplified method). In December 2007, the SEC issued Staff Accounting Bulletin 110, *Share-Based Payment* (SAB 110), extending the availability of SAB 107 beyond its original deadline of December 31, 2007. The extension is available for companies under specified conditions that include a lack of sufficient historical exercise data related to their stock based awards. Effective January 1, 2008, in accordance with SAB 110, we no longer use the simplified method and estimate the expected term based on historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements, and expectation of future employee behavior, including post-vesting terminations. The change of method in estimating the expected term did not have a material impact on our condensed consolidated financial statements.

As required under SFAS 123R, we review our valuation assumptions at each grant date and, as a result, our assumptions in future periods may change. As of September 30, 2008, total compensation cost related to unvested stock-based awards not yet recognized was approximately $5,570,000, which is expected to be recognized as expense over a weighted-average period of 2.3 years. See also Note 4, Share-Based Payment, in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.

Wind-down expenses

In connection with exiting our research and manufacturing operations in Lincoln, Rhode Island, and the relocation of our corporate headquarters and remaining research laboratories to California in October 1999, we provided a reserve for our estimate of the exit cost obligation in accordance with EITF 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (Including Certain Costs Incurred in a Restructuring)*. The reserve reflects estimates of the ongoing costs of our former scientific and administrative facility in Lincoln, which we hold on a lease that terminates on June 30, 2013. We are seeking to sublease, assign, sell, or otherwise divest ourselves of our interest in the facility at the earliest possible time, but we cannot determine with certainty a fixed date by which such events will occur, if at all.

In determining the facility exit cost reserve amount, we are required to consider our lease payments through to the end of the lease term and estimate other relevant factors such as facility operating expenses, real estate market conditions in Rhode Island for similar facilities, occupancy rates, and sublease rental rates projected over the course of the leasehold. We re-evaluate the estimate each quarter, taking account of changes, if any, in each underlying factor. The process is inherently subjective because it involves projections over time from the date of the estimate through the end of the lease and it is not possible to determine any of the factors, except the lease payments, with certainty over that period.

Management forms its best estimate on a quarterly basis, after considering actual sublease activity, reports from our broker/realtor about current and predicted real estate market conditions in Rhode Island, the likelihood of new subleases in the foreseeable future for the specific facility and significant changes in the actual or projected operating expenses of the property. We discount the projected net outflow over the term of the leasehold to arrive at the present value, and adjust the reserve to that figure. The estimated vacancy rate for the facility is an important assumption in determining the reserve because changes in this assumption have the greatest effect on estimated sublease income. In addition, the vacancy rate estimate is the variable most subject to change, while at the same time it involves the greatest judgment and uncertainty due to the absence of highly predictive information concerning the future of the local economy and future demand for specialized laboratory and office space in that area. The average vacancy rate of the facility over the last five years (2003 through 2007) was approximately 73%, varying from 66% to 89%. As of September 30, 2008, based on current information available to management, the vacancy rate is projected to be approximately 78% for 2008 and 2009, and approximately 70% from 2010 through the end of the lease. These estimates are based on actual occupancy as of September 30, 2008, predicted lead time for acquiring new subtenants, historical vacancy rates for the area, and assessments by our broker/realtor of future real estate market conditions. If

the assumed vacancy rate for 2009 to the end of the lease had been 5% higher or lower at September 30, 2008, then the reserve would have increased or decreased by approximately $180,000. Similarly, a 5% increase or decrease in the operating expenses for the facility from 2009 on would have increased or decreased the reserve by approximately $102,000, and a 5% increase or decrease in the assumed average rental charge per square foot would have increased or decreased the reserve by approximately $55,000. Management does not wait for specific events to change its estimate, but instead uses its best efforts to anticipate them on a quarterly basis. See Note 5 Wind-down expenses, in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.

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Results of Operations

Our results of operations have varied significantly from year to year and quarter to quarter and may vary significantly in the future due to the occurrence of material recurring and nonrecurring events, including without limitation the receipt and payment of recurring and nonrecurring licensing payments, the initiation or termination of research collaborations, unpredictable or unanticipated manufacturing and supply costs, developments in on-going patent protection and litigation, the on-going expenses to lease and maintain our Rhode Island facilities, and the increasing costs associated with operating our California facility.

Revenue

Revenue for the three months and nine months ended September 30, 2008, as compared with the same periods in 2007, is summarized in the table below:

	Three months ended, September 30		Change in 2008 versus 2007		Nine months ended, September 30		Change in 2008 versus 2007	
	2008	2007	$	%	2008	2007	$	%
Revenue:								
Licensing agreements	$ 12,379	$ 13,162	$ (783)	(6)%	$ 59,561	$ 26,948	$ 32,613	121%

The increase in revenue for the nine months ended September 30, 2008 from the comparable period in 2007 was primarily attributable to increased licensing fees from existing licensing agreements. Licensing revenue for the third quarter of 2008 as compared to the third quarter of 2007 was relatively flat.

Operating Expenses

Operating expenses for the three and nine month periods ended September 30, 2008, as compared with the same periods in 2007, are summarized in the table below:

	Three months ended, September 30		Change in 2008 versus 2007		Nine months ended, September 30		Change in 2008 versus 2007	
	2008	2007	$	%	2008	2007	$	%
Operating expenses:								
Research & development	$ 4,171,799	$ 5,621,955	$ (1,450,156)	(26)%	$ 13,087,165	$ 14,139,297	$ (1,052,132)	(7)%
General & administrative	1,631,580	2,043,275	(411,695)	(20)%	6,231,629	5,716,480	515,149	9%
Wind-down expenses	53,636	83,661	(30,025)	(36)%	381,136	439,471	(58,335)	(13)%
Total operating expenses	$ 5,857,015	$ 7,748,891	$ (1,891,876)	(24)%	$ 19,699,930	$ 20,295,248	$ (595,318)	(3)%

Research and Development Expenses

Our R&D expenses consist primarily of salaries and related personnel expenses; costs associated with clinical trials and regulatory submissions; costs associated with preclinical activities such as toxicology studies; certain patent-related costs such as licensing; facilities-related costs such as depreciation; and lab equipment and supplies. Clinical trial expenses include payments to vendors such as clinical research organizations, contract manufacturers, clinical trial sites, laboratories for testing clinical samples, and consultants. Cumulative R&D costs incurred since we

refocused our activities on developing cell-based therapeutics (fiscal years 2000 through the nine months ended 2008) were approximately $88 million. Over this period, the majority of these cumulative costs were related to: (i) characterization of our proprietary HuCNS-SC cell, (ii) expenditures for toxicology and other preclinical studies, preparation and submission of our Investigational New Drug (IND) application for our Phase I trial for NCL to the FDA, and obtaining FDA clearance; and (iii) expenditures in connection with our HuCNS-SC Phase I clinical trial.

We use and manage our R&D resources, including our employees and facilities, across various projects rather than on a project-by-project basis for the following reasons. The allocations of time and resources change as the needs and priorities of individual projects and programs change, and many of our researchers are assigned to more than one project at any given time. Furthermore, we are

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exploring multiple possible uses for each of our proprietary cell types, so much of our R&D effort is complementary to and supportive of each of these projects. Lastly, much of our R&D effort is focused on manufacturing processes, which can result in process improvements useful across cell types. We also use external service providers to assist in the conduct of our clinical trials, to manufacture certain of our product candidates and to provide various other R&D related products and services. Many of these costs and expenses are complementary to and supportive of each of our programs. Because we do not have a development collaborator for any of our product programs, we are currently responsible for all costs incurred with respect to our product candidates.

R&D expenses totaled approximately $4,172,000 in the third quarter of 2008 compared with $5,622,000 in the third quarter of 2007, and $13,087,000 for the nine month period ended September 30, 2008 compared with $14,139,000 for the nine month period ended September 30, 2007.

Third quarter ended September 30, 2008 versus third quarter ended September 30, 2007. R&D expenses decreased by approximately $1,450,000, or 26%, in the third quarter of 2008 from the third quarter of 2007. The decrease was primarily attributable to a decrease in external services of approximately $1,358,000, including costs related to manufacturing and testing of our cells and the enrollment and dosing of patients. The decrease in external services was due mainly to the completed enrollment and dosing of our six-patient Phase I clinical trial in January 2008. The decrease in R&D expenses, was also attributable to a net decrease in other operating expenses, primarily attributable to personnel and business travel. At September 30, 2008, we had 43 full-time employees working in research and development and laboratory support services as compared to 49 at September 30, 2007.

Nine month period ended September 30, 2008 versus nine month period ended September 30, 2007. R&D expenses decreased by approximately $1,052,000, or 7%, for the nine month period ended September 30, 2008 from the comparable period in 2007. The decrease was primarily attributable to a decrease in external services of approximately $1,986,000, including costs related to manufacturing and testing of our cells and the enrollment and dosing of patients. The decrease in clinical external services was due mainly to the completed enrollment and dosing of our six-patient Phase I clinical trial in January 2008. The decrease was also attributable to a decrease in business travel expenses of approximately $177,000. These decreased expenses were partially offset by an increase in other operating expenses primarily attributable to (i) an increase in personnel costs of approximately $592,000 to support expanded operations in cell processing and our product development programs, and (ii) an increase in other operating expenses of approximately $519,000, primarily attributable to supplies. For the nine month period ended September 30, 2008, we had an average weighted headcount of 45 full-time employees working in research and development and laboratory support services as compared to an average weighted head count of 41 full-time employees in the comparable period of 2007.

General and Administrative Expenses

General and Administrative (G&A) expenses totaled approximately $1,632,000 in the third quarter of 2008 compared with $2,043,000 in the third quarter of 2007, and $6,232,000 for the nine-month period ended September 30, 2008 compared with $5,716,000 for the nine-month period ended September 30, 2007.

Third quarter ended September 30, 2008 versus third quarter ended September 30, 2007. G&A expenses decreased by approximately $412,000, or 20%, in the third quarter of 2008 from the third quarter of 2007. The decrease was primarily attributable to (i) a decrease in external services of approximately $486,000, primarily due to a decrease in legal fees and external consultants, and (ii) a decrease in net other operating expenses of approximately $21,000. These decreased expenses were partially offset by an increase in personnel costs of approximately $95,000, primarily due to an increase in headcount and share-based payment expense.

Nine-month period ended September 30, 2008 versus nine month period ended September 30, 2007. G&A expenses increased by approximately $515,000, or 9%, for the nine-month period ended September 30, 2008 from the nine-month period ended September 30, 2007. The increase was primarily attributable to an increase in personnel costs of approximately $193,000, due to an increase in headcount and an increase in share-based payment expense. In addition, operating expenses for our vacant pilot manufacturing facility in Rhode Island increased approximately $454,000 for the nine month period in 2008 to the comparable period in 2007, primarily attributable to the loss of tenant income to offset operating expenses. These increased expenses were partially offset by a decrease in external fees of $95,000, including legal and recruiting fees, and a decrease in other operating expenses of approximately

$37,000.

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Wind-down Expenses

In 1999, in connection with exiting our former research facility in Rhode Island, we created a reserve for the estimated lease payments and operating expenses related to it. The reserve has been re-evaluated and adjusted based on assumptions relevant to real estate market conditions and the estimated time until we could either fully sublease, assign or sell our remaining interests in the property. The reserve was approximately $6,143,000 at December 31, 2007. Payments net of subtenant income of approximately $316,000 for the third quarter and $935,000 for the nine months ended September 30, 2008 were recorded against this reserve. At September 30, 2008, we re-evaluated the estimate and adjusted the reserve to approximately $5,436,000 by recording in aggregate, additional wind-down expenses of approximately $54,000 in the third quarter of 2008, for a total of approximately $381,000 for the nine months ended September 30, 2008. Payments recorded against the reserve were approximately $344,000 in the third quarter and $1,067,000 for the nine months ended September 30, 2007 and additional expenses recorded to adjust the reserve were approximately $83,000 in the third quarter and $439,000 for the nine months ended September 30, 2007. Expenses for this facility will fluctuate based on changes in tenant occupancy rates and other operating expenses related to the lease. Even though it is our intent to sublease, assign, sell, or otherwise divest ourselves of our interests in the facility at the earliest possible time, we cannot determine with certainty a fixed date by which such events will occur. In light of this uncertainty, based on estimates, we will periodically re-evaluate and adjust the reserve, as necessary. See Note 5 Wind-down expenses, in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.

Other Income

Other income totaled approximately $101,000 in the third quarter of 2008 compared with $582,000 of 2007, and $636,000 for the nine months ended 2008 compared with $3,071,000 for the nine months ended 2007.

	Three months ended, September 30		Change in 2008 versus 2007		Nine months ended, September 30		Change in 2008 versus 2007	
	2008	2007	$	%	2008	2007	$	%
Other income (expense):								
License and settlement agreement, net	$	$	$	%	$	$ 550,467	$ (550,467)	*
Gain on sale of marketable securities						717,621	(717,621)	*
Interest income	138,332	617,616	(479,284)	(78)%	738,107	1,926,753	(1,188,646)	(62)%
Interest expense	(26,849)	(29,405)	2,556	(9)%	(84,010)	(96,777)	12,767	(13)%
Other expense, net	(10,800)	(5,985)	(4,815)	80%	(18,145)	(27,009)	8,864	(33)%
Total other income	$ 100,683	$ 582,226	$ (481,543)	(83)%	$ 635,952	$ 3,071,055	$ (2,435,103)	(79)%

* Calculation is not meaningful.

License and Settlement Agreement

In July 2005, we entered into an agreement with ReNeuron Limited, a wholly-owned subsidiary of ReNeuron Group plc, a listed UK corporation (collectively referred to as ReNeuron). As part of the agreement, we granted

ReNeuron a license that allows ReNeuron to exploit their c-mycER conditionally immortalized adult human neural stem cell technology for therapy and other purposes. We received a 7.5% fully-diluted equity interest in ReNeuron, subject to certain anti-dilution provisions, and a cross-license to the exclusive use of ReNeuron s technology for certain diseases and conditions, including lysosomal storage diseases, spinal cord injury, cerebral palsy, and multiple sclerosis. The agreement also provides for full settlement of any potential claims that either we or ReNeuron might have had against the other in connection with any putative infringement of certain of each party s patent rights prior to the effective date of the agreement.

Other income from the license and settlement agreement totaled approximately $550,000 for the nine months ended 2007, which was the fair value of the ReNeuron shares we received under such agreement, net of legal fees and the value of the shares that were transferred to NeuroSpheres, a Canadian corporation from which we have licensed some of the patent rights that are the subject of the

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agreement with ReNeuron. See Note 2 Financial Assets, in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information regarding this transaction.

Gain on Sale of Marketable Equity Securities

The gain on sale of marketable equity securities of approximately $716,000 for the nine months ended 2007 was attributable to sales of ReNeuron shares. See Note 2 Financial Assets, in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information on this transaction.

Interest Income

Interest income for the three months ended September 30, 2008, decreased by approximately $479,000, or 78%, compared to the similar period in 2007. For the nine months ended September 30, 2008, interest income decreased by approximately $1,189,000, or 62%, compared to the similar period in 2007. The decreases in 2008 were primarily due to a lower average yield and lower average investment balances. See Cash Used in Investing Activities, in Liquidity and Capital Resources below for further information.

Interest Expense

Interest expense for the three months ended September 30, 2008, decreased by approximately $3,000, or 9%, compared to the similar period in 2007. For the nine months ended September 30, 2008, interest expense decreased by approximately 13,000, or 13%, compared to the similar period in 2007. The decreases were primarily attributable to lower outstanding debt and capital lease balances. See Note 6 Commitment and Contingencies, in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.

Liquidity and Capital Resources

Since our inception, we have financed our operations through the sale of common and preferred stock, the issuance of long-term debt and capitalized lease obligations, revenue from collaborative agreements, research grants, license fees, and interest income. We have very limited liquidity and capital resources and must obtain significant additional capital and other resources in order to sustain our product development efforts, to provide funding for the acquisition of technologies, businesses and intellectual property rights, preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, general and administrative expenses and other working capital requirements.

	September 30, 2008	December 31, 2007	Change in 2008 Versus 2007 $	%
Cash, cash equivalents and marketable debt securities	$21,345,548	$37,645,085	$(16,299,537)	(43)%

Total cash, cash equivalents and marketable debt securities were approximately $21,346,000 at September 30, 2008, compared with approximately $37,645,000 at December 31, 2007. The decrease in our cash, cash equivalents and marketable debt securities of approximately 43%, or $16,299,000, from December 31, 2007 to September 30, 2008 was primarily attributable to cash used in operating activities.

In summary, our cash flows were:

	Nine months ended September 30,		Change in 2008 Versus 2007	
	2008	2007	$	%
Net cash used in operating activities	$ (17,165,645)	$ (15,009,151)	$ (2,156,494)	14%
Net cash provided by (used in) investing activities	$ 23,372,726	$ (23,980,350)	$ 47,353,076	(197)%
Net cash provided by financing activities	$ 204,276	$ 4,723,173	$ (4,518,897)	(96)%

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Net Cash Used in Operating Activities

Net cash used in operating activities is primarily driven by increases in our net loss. However, operating cash flows differ from net loss as a result of non-cash charges or differences in the timing of cash flows and expense recognition.

In our operating activities we used approximately $17,166,000 in cash for the nine months ended 2008, compared with $15,009,000 for the same period in 2007. The increase in cash used in operating activities in 2008 as compared to 2007 was primarily attributable to the continued expansion of our operations in cell processing and our product development programs, including increases in headcount and headcount related expenses and external services.

Net Cash Provided by (Used in) Investing Activities

The increase from 2007 to 2008 of approximately $47,353,000 for net cash provided by investing activities was primarily attributable to the maturity of marketable debt securities held to maturity, which were used to fund operating activities for the nine months ended 2008. In the nine months ended September 30, 2007, we invested approximately $25,747,000 in net purchases of marketable debt securities as compared to net proceeds of approximately $22,659,000 from the maturity of marketable debt securities for the similar period in 2008. Also, in April 2008, Progenitor Cell Therapy, LLC prepaid a $1.0 million loan that we had advanced to them in connection with discussions about the possible acquisition of PCT.

In February 2007, we sold 5,275,000 ordinary shares of ReNeuron for net proceeds of approximately $3,075,000.

Net Cash Provided by Financing Activities

The decrease from 2007 to 2008 of approximately $4,519,000 for net cash provided by financing activities was primarily attributable to the following financing transactions for the nine months ended 2007: (i) the sale of approximately 1,217,000 shares of our common stock at an average price of $3.13 per share for net proceeds (i.e, net of equity expense) of approximately $3,545,000, sold under a sales agreement with Cantor Fitzgerald & Co. (Cantor), and (ii) on April 26, 2007, a warrant issued as part of a June 16, 2004 financing arrangement, was exercised to purchase an aggregate of 575,658 shares of our common stock at $1.90 per share for net proceeds of approximately $1,094,000. The sales agreement with Cantor permits us to sell up to 10,000,000 shares of registered common stock, from time to time, under a shelf registration statement filed with the SEC. In 2008, under the sales agreement with Cantor, we sold 205,600 shares of our common stock at an average price of $1.26 per share for net proceeds (net of equity expenses) of approximately $194,000.

On June 25, 2008 we filed with the SEC a universal shelf registration statement, declared effective July 18, 2008, which permits us to issue up to $100 million worth of registered debt and equity securities. Under this effective shelf registration, we have the flexibility to issue registered securities, from time to time, in one or more separate offerings or other transactions with the size, price and terms to be determined at the time of issuance. Registered securities issued using this shelf may be used to raise additional capital to fund our working capital and other corporate needs, for future acquisitions of assets, programs or businesses, and for other corporate purposes. In July 2008, we deregistered the remaining unissued shares (approximately $59 million worth of common stock) available under the shelf registration statement we had filed in October 2005. The 2005 shelf permitted the issuance of up to $100 million of registered shares of common stock.

Listed below are key financing transactions entered into by us in the last three years:

In August and September 2008, we sold a total of 205,600 shares of our common stock pursuant to the sales agreement we entered into with Cantor at an average price per share of $1.26 for gross proceeds of approximately $259,000. Cantor is paid compensation equal to 5.0% of the gross proceeds pursuant to the terms of the agreement.

In April 2007, a warrant issued as part of a June 16, 2004 financing arrangement, was exercised to purchase an aggregate of 575,658 shares of our common stock at $1.90 per share. We issued 575,658 shares of our common stock and received proceeds of approximately $1,094,000.

In January, April and October 2007, under the sales agreement with Cantor, we sold a total of 1,807,000 shares of our common stock at an average price per share of $2.84 for gross proceeds of approximately $5,133,000.

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In April 2006, we sold 11,750,820 shares of our common stock to a limited number of institutional investors at a price of $3.05 per share, for gross proceeds of approximately $35,840,000. The shares were offered as a registered direct offering under an effective shelf registration statement previously filed with and declared effective by the Securities and Exchange Commission. We received total proceeds, net of offering expenses and placement agency fees, of approximately $33,422,000. No warrants were issued as part of this financing transaction.

In March 2006, a warrant issued as part of a June 16, 2004 financing arrangement was exercised to purchase an aggregate of 526,400 shares of our common stock at $1.89 per share. We issued 526,400 shares of our common stock and received proceeds of approximately $995,000.

We have incurred significant operating losses and negative cash flows since inception. We have not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. We have limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain our product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, for general and administrative expenses and other working capital requirements. We rely on cash balances and proceeds from equity and debt offerings, proceeds from the transfer or sale of our intellectual property rights, equipment, facilities or investments, and government grants and funding from collaborative arrangements, if obtainable, to fund our operations.

We intend to pursue opportunities to obtain additional financing in the future through equity and debt financings, grants and collaborative research arrangements. On December 29, 2006, we filed a Prospectus Supplement announcing the entry of a sales agreement with Cantor under which up to 10 million shares may be sold from time to time under the shelf registration statement (discussed above), of which approximately 8 million shares remain available at September 30, 2008. The source, timing and availability of any future financing will depend principally upon market conditions, interest rates and, more specifically, on our progress in our exploratory, preclinical and future clinical development programs. Funding may not be available when needed at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our research and product development programs, planned clinical trials, and/or our capital expenditures or to license our potential products or technologies to third parties.

Commitments

See Note 6, Commitments and Contingencies in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.

Off-Balance Sheet Arrangements

We have certain contractual arrangements that create potential risk for us and are not recognized in our condensed consolidated balance sheets. Discussed below are those off-balance sheet arrangements that have, or are reasonably likely to have, a material current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

Operating Leases

We lease various real properties under operating leases that generally require us to pay taxes, insurance, maintenance, and minimum lease payments. Some of our leases have options to renew.

We entered into and amended a lease agreement for an approximately 68,000 square foot facility located at the Stanford Research Park in Palo Alto, California. At September 30, 2008, we had a space-sharing agreement covering approximately 10,451 square feet of this facility. We receive base payments plus a proportionate share of the operating expenses based on square footage over the term of the agreement. We expect to receive, in aggregate, approximately $144,000 as part of the space-sharing agreement, inclusive of estimated operating expenses, for the remainder of 2008. As a result of the above transactions, our estimated net cash outlay for rent and estimated operating expenses will be approximately $770,000 for the remainder of 2008.

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We continue to have outstanding obligations in regard to our former facilities in Lincoln, Rhode Island. In 1997, we had entered into a fifteen-year lease for a scientific and administrative facility (the SAF) in a sale and leaseback arrangement. The lease includes escalating rent payments. We expect to pay approximately $293,000 in operating lease payments and estimated operating expenses of approximately $137,000, before receipt of sub-tenant income, for the remainder of 2008. We expect to receive, in aggregate, approximately $80,000 in sub-tenant rent and operating expense for the remainder of 2008. As a result of the above transactions, our estimated cash outlay net of sub-tenant rent for the SAF will be approximately $350,000 for the remainder of 2008.

With the exception of leases discussed above, we have not entered into any off balance sheet financial arrangements and have not established any special purpose entities. We have not guaranteed any debts or commitments of other entities or entered into any options on non-financial assets.

Contractual Obligations

During the nine months ended September 30, 2008, we believe that there have been no significant changes in our payments due under contractual obligations, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2007.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We adopted the provisions of SFAS 157 that became effective January 1, 2008. See Note 3 Fair Value Measurement, in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information about the adoption of the required provisions of SFAS 157.

In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2). FSP 157-2 delays the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities, except for certain items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). We are currently evaluating the impact of SFAS 157 on our consolidated financial statements for items within the scope of FSP 157-2, which will become effective beginning with our first quarter of 2009.

In October 2008, the FASB issued FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active.* FSP 157-3 clarifies the application of SFAS 157, in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP shall be effective upon issuance, including prior periods for which financial statements have not been issued. Revisions resulting from a change in the valuation technique or its application shall be accounted for as a change in accounting estimate. Adoption of FSP 157-3 will not have a material impact on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS 159). Under SFAS 159, a company may choose, at specified election dates, to measure eligible items at fair value and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. SFAS 159 became effective beginning with our first quarter of 2008. At this time, we have chosen not to adopt the provisions of SFAS 159 for our existing financial instruments.

In April 2008, the FASB issued FSP No.142-3, *Determination of the Useful Life of Intangible Assets* (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, Goodwill and Other Intangible Assets (SFAS 142). FSP 142-3 amends paragraph 11(d) of SFAS 142 to require an entity to use its own assumptions about renewal or extension of an arrangement, adjusted for the entity-specific factors in paragraph 11 of SFAS 142, even when there is likely to be substantial cost or material modifications. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal

years, with early adoption prohibited. We expect to adopt FSP142-3 on January 1, 2009, and we do not expect the adoption to have a material effect on our consolidated financial condition and results of operations.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks at September 30, 2008 have not changed materially from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2007 on file with the U.S. Securities and Exchange Commission.

See also Note 2, Financial Assets, in the notes to condensed consolidated financial statements in Part I, Item 1 of this Form 10-Q.

ITEM 4. CONTROLS AND PROCEDURES

In response to the requirement of the Sarbanes-Oxley Act of 2002, as of the end of the period covered by this report, our chief executive officer and chief financial officer, along with other members of management, reviewed the effectiveness of the design and operation of our disclosure controls and procedures. Such controls and procedures are designed to ensure that information required to be disclosed in the Company s Exchange Act reports 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 the chief executive officer and the chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, the chief executive officer and chief financial officer have concluded that the Company s disclosure controls and procedures are effective.

During the most recent quarter, there were no changes in internal controls over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, these controls of the Company.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In July 2006, we filed suit against Neuralstem, Inc., in the Federal District Court for the District of Maryland, alleging that Neuralstem s activities violate claims in four of the patents we exclusively licensed from NeuroSpheres. Neuralstem has filed a motion for dismissal or summary judgment in the alternative, citing Title 35, Section 271(e)(1) of the United States Code, which says that it is not an act of patent infringement to make, use or sell a patented invention solely for uses reasonably related to the development and submission of information to the FDA. Neuralstem argues that because it does not have any therapeutic products on the market yet, the activities complained of fall within the protection of Section 271(e)(1) that is, basically, that the suit is premature. This issue will be decided after discovery is complete. Subsequent to filing its motion to dismiss, in December 2006, Neuralstem petitioned the U.S. Patent and Trademark Office (PTO) to reexamine two of the patents in our infringement action against Neuralstem, namely U.S. Patent No. 6,294,346 (claiming the use of human neural stem cells for drug screening) and U.S. Patent No. 7,101,709 (claiming the use of human neural stem cells for screening biological agents). In April 2007, Neuralstem petitioned the PTO to reexamine the remaining two patents in the suit, namely U.S. Patent No. 5,851,832 (claiming methods for proliferating human neural stem cells) and U.S. Patent No. 6,497,872 (claiming methods for transplanting human neural stem cells). These requests were granted by the PTO and, in June 2007, the parties voluntarily agreed to stay the pending litigation while the PTO considers these reexamination requests. In October 2007, Neuralstem petitioned the PTO to reexamine a fifth patent, namely U.S. Patent No. 6,103,530, which claims a culture medium for proliferating mammalian neural stem cells. In April 2008, the PTO upheld the 832 and 872 patents, as amended, and issued Notices of Intent to Issue an *Ex Parte* Reexamination Certificate for both. In August 2008, the PTO upheld the 530 patent, as amended, and issued a Notice of Intent to Issue an *Ex Parte* Reexamination Certificate. The remaining two patents are still under review by the PTO.

In May 2008, we filed a second patent infringement suit against Neuralstem and its two founders, Karl Johe and Richard Garr. In this suit, which we filed in the Federal District Court for the Northern District of California, we allege that Neuralstem s activities infringe claims in two patents we exclusively license from NeuroSpheres, specifically U.S. Patent No. 7,361,505 (claiming composition of matter of human neural stem cells derived from any source material) and U.S. Patent No. 7,115,418 (claiming methods for proliferating human neural stem cells). In addition, we allege various state law causes of action against Neuralstem arising out of its repeated derogatory statements to the public about our patent portfolio. Also in May 2008, Neuralstem filed suit against us and NeuroSpheres in the Federal District Court for the District of Maryland seeking a declaratory judgment that the 505 and 418 patents are either invalid or are not infringed by Neuralstem and that Neuralstem has not violated California

state law. In August 2008, the California court transferred our lawsuit against Neuralstem to Maryland for resolution on the merits. We anticipate that the Maryland District Court will consolidate these actions in some manner prior to trial.

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ITEM 1A. RISK FACTORS

This quarterly report on Form 10-Q contains forward looking statements that involve risks and uncertainties. Our business, operating results, financial performance, and share price may be materially adversely affected by a number of factors, including but not limited to the following risk factors, any one of which could cause actual results to vary materially from anticipated results or from those expressed in any forward-looking statements made by us in this quarterly report on Form 10-Q or in other reports, press releases or other statements issued from time to time. Additional factors that may cause such a difference are set forth elsewhere in this quarterly report on Form 10-Q.

Risks Related to our Business

Any adverse development relating to our HuCNS-SC product candidate, such as a significant clinical trial failure, could substantially depress our stock price and prevent us from raising additional capital.

At present our ability to progress as a company is significantly dependent on a single product candidate, our HuCNS-SC cells (purified human neural stem cells), and on a single early stage clinical trial, our Phase I clinical trial for neuronal ceroid lipofuscinosis (NCL, also often referred to as Batten disease). Any clinical, regulatory or other development that significantly delays or prevents us from completing this trial, any material safety issue or adverse side effect to any study participant in this trial, or the failure of this trial to show the results expected would likely depress our stock price significantly and could prevent us from raising the substantial additional capital we will need to further develop our cellular technologies. Moreover, any material adverse occurrence in our first clinical trial for Batten disease could substantially impair our ability to initiate clinical trials to test our HuCNS-SC cells in patients with spinal cord injuries, myelin disorders or other potential indications. This, in turn, could adversely impact our ability to raise additional capital and pursue our planned research and development efforts in both our CNS and liver programs.

We have limited capital resources and we may not obtain the significant additional capital needed to sustain our research and development efforts.

We have limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain our product development efforts, acquire businesses, technologies and intellectual property rights which may be important to our business, continue preclinical and clinical testing of our investigative products, pursue regulatory approvals, acquire capital equipment, laboratory and office facilities, establish production capabilities, maintain and enforce our intellectual property portfolio, and support our general and administrative expenses and other working capital requirements. We rely on cash reserves and proceeds from equity and debt offerings, proceeds from the transfer, license, lease, or sale of our intellectual property rights, equipment, facilities, or investments, and government grants and funding from collaborative arrangements, if obtainable, to fund our operations.

We intend to pursue opportunities for additional fundraising in the future through equity or debt financings, corporate alliances or combinations, grants or collaborative research arrangements, or any combination of these. However, external financing in the current financial environment may be particularly difficult, and the source, timing and availability of any future fundraising will depend principally upon market conditions, interest rates and, more specifically, on progress in our research, preclinical and clinical development programs. Funding may not be available when needed at all or on terms acceptable to us. While we actively manage our programs and resources in order to conserve cash between fundraising opportunities, we believe we will need to secure additional capital in order to conduct our operations beyond 2009. If we exhaust our cash reserves and are unable to realize adequate additional fundraising, we may be unable to meet operating obligations and be required to initiate bankruptcy proceedings or delay, scale back or eliminate some or all of our research and product development programs.

Our product development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of these therapies creates significant challenges in regard to product development and optimization, manufacturing, government regulation, third party reimbursement, and market acceptance. For example, the pathway to regulatory approval for cell-based therapies, including our product candidates, may be more complex and lengthy than the pathway for conventional drugs. These challenges may prevent us from developing and commercializing products on a timely or profitable basis or at all.

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Our technology is at an early stage of discovery and development, and we may fail to develop any commercially acceptable or profitable products.

We have incurred significant operating losses and negative cash flows since inception. We have not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. We have yet to develop any products that have been approved for marketing, and we do not expect to become profitable within the next several years, but rather expect to incur additional and increasing operating losses. Before commercializing any medical product, we will need to obtain regulatory approval from the FDA or from equivalent foreign agencies after conducting extensive preclinical studies and clinical trials that demonstrate that the product candidate is safe and effective. Except for the NCL trial currently being conducted at Oregon Health & Science University (OHSU), we have had no experience conducting human clinical trials. We expect that none of our cell-based therapeutic product candidates will be commercially available for several years, if at all.

While the FDA has permitted us to initiate our Phase I clinical trial of our proprietary HuCNS-SC product candidate in NCL, and the Institutional Review Board of OHSU has approved the protocol and we have completed dosing the six patients planned for the trial, there can be no assurance that the trial will be completed or result in a successful outcome. We may elect to delay or discontinue other studies or clinical trials based on unfavorable results. Any product developed from, or based on, cellular technologies may fail to:

survive and persist in the desired location;

provide the intended therapeutic benefit;

engraft into existing tissue in the desired manner; or

achieve therapeutic benefits equal to, or better than, the standard of treatment at the time of testing.

In addition, our products may cause undesirable side effects. Results of preclinical research in animals may not be indicative of future clinical results in humans.

Ultimately if regulatory authorities do not approve our products or if we fail to maintain regulatory compliance, we would be unable to commercialize our products, and our business and results of operations would be harmed. Even if we do succeed in developing products, we will face many potential obstacles such as the need to develop or obtain manufacturing, marketing and distribution capabilities. Furthermore, because transplantation of cells is a new form of therapy, the marketplace may not accept any products we may develop.

Moreover, because our cell-based therapeutic products will be derived from tissue of individuals other than the patient (that is, they will be non-self or allogeneic transplant products), patients will likely require the use of immunosuppressive drugs. While immunosuppression is now standard in connection with allogeneic transplants of various kinds, such as heart or liver transplants, long-term maintenance on immunosuppressive drugs can result in complications such as infection, cancer, cardiovascular disease, and renal dysfunction. An immunosuppression regimen is currently being used with our therapeutic product candidate in our Phase I clinical trial for NCL.

Our success will depend in large part on our ability to develop and commercialize products that treat diseases other than neuronal ceroid lipofuscinosis (Batten disease).

Although we have initially focused on evaluating our neural stem cell product for the treatment of infantile and late infantile NCL (Batten disease), this disease is rare and the market for treating this disease is small. Accordingly, even if we obtain marketing approval for our HuCNS-SC product candidate for infantile and late infantile NCL, in order to achieve profitability, we will likely need to obtain approval to treat additional diseases that present more significant market opportunities.

Acquisitions of companies, businesses or technologies may substantially dilute our stockholders and increase our operating losses.

We may make acquisitions of businesses, technologies or intellectual property rights or otherwise modify our business model in ways we believe to be necessary, useful or complementary to our current product development efforts and cell-based therapeutics business. Any such acquisition or change in business activities may require assimilation of the operations, products or product candidates and

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personnel of the acquired business and the training and integration of its employees, and could substantially increase our operating costs, without any offsetting increase in revenue. Acquisitions may not provide the intended technological, scientific or business benefits and could disrupt our operations and divert our limited resources and management s attention from our current operations, which could harm our existing product development efforts. We would likely issue equity securities to pay for any future acquisitions. The issuance of equity securities for an acquisition could be substantially dilutive to our stockholders. In addition, our results of operations may suffer because of acquisition-related costs or the post-acquisition costs of funding the development of an acquired technology or product candidates or operation of the acquired business, or due to amortization or impairment costs for acquired goodwill and other intangible assets. Any investment made in, or funds advanced to, a potential acquisition target could also significantly adversely affect our results of operation and could further reduce our limited capital resources. Any acquisition or action taken in anticipation of a potential acquisition or other change in business activities could substantially depress the price of our stock.

We have payment obligations resulting from real property owned or leased by us in Rhode Island, which diverts funding from our cell-based therapeutics research and development.

Prior to our reorganization in 1999 and the consolidation of our business in California, we carried out our former encapsulated cell therapy programs in Lincoln, Rhode Island, where we also had our administrative offices. Although we have vacated the Rhode Island facilities, we remain obligated to make lease payments and payments for operating costs for our former science and administrative facility, which we have leased through June 30, 2013. These costs, before sub-tenant rental income, amounted to approximately $1,523,000 in 2007; our rent payments will increase over the term of the lease, and our operating costs may increase as well. In addition to these costs of our former science and administrative facility, we are obligated to make debt service payments and payments for operating costs of approximately $400,000 per year for our former encapsulated cell therapy pilot manufacturing facility, which we own. We have currently subleased a portion of the science and administrative facility, and we are seeking to sublease the remaining portion, but we cannot be sure that we will be able to keep any part of the facility subleased for the duration of our obligation. We are currently seeking to sublease the pilot manufacturing facility, but may not be able to sublease or sell the facility in the future. These continuing costs significantly reduce our cash resources and adversely affect our ability to fund further development of our cellular technologies. In addition, changes in real estate market conditions and assumptions regarding the length of time it may take us to either fully sublease, assign or sell our remaining interest in the our former research facility in Rhode Island may have a significant impact on and cause large variations in our quarter to quarter results of operations. In 1999, in connection with exiting our former research facility in Rhode Island, we created a reserve for the estimated lease payments and operating expenses related to it. The reserve is periodically re-evaluated and adjusted based on assumptions relevant to real estate market conditions and the estimated time until we can either, fully sublease, assign or sell our remaining interests in the property. At December 31, 2007, the reserve was $6,143,000. For the year 2007, we incurred $1,420,000 in operating expenses net of sub-tenant income for this facility. Expenses for this facility will fluctuate based on changes in tenant occupancy rates and other operating expenses related to the lease. Even though it is our intent to sublease, assign, sell, or otherwise divest ourselves of our interests in the facility at the earliest possible time, we cannot determine with certainty a fixed date by which such events will occur. In light of this uncertainty, based on estimates, we will periodically re-evaluate and adjust the reserve, as necessary, and we may make significant adverse adjustments to the reserve in the future.

We may be unable to obtain partners to support our cell-based therapeutic product development efforts when needed to commercialize our technologies.

Equity and debt financings alone may not be sufficient to fund the cost of developing our cellular technologies, and we may need to rely on partnering or other arrangements to provide financial support for our cellular discovery and development efforts. In addition, in order to successfully develop and commercialize our technologies, we may need to enter into various arrangements with corporate sponsors, pharmaceutical companies, universities, research groups, and others. While we have engaged, and expect to continue to engage, in discussions regarding such arrangements, we have not reached any agreement, and we may fail to obtain any such agreement on terms acceptable to us. Even if we enter into such arrangements, we may not be able to satisfy our obligations under them or renew or replace them after

their original terms expire. Furthermore, these arrangements may require us to grant rights to third parties, such as exclusive marketing rights to one or more products, may require us to issue securities to our collaborators and may contain other terms that are burdensome to us or result in a decrease in our stock price.

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If we are unable to protect our patents and proprietary rights, our business, financial condition and results of operations may be materially harmed.

We either own or exclusively license a number of patents and pending patent applications related to various stem and progenitor cells, including human neural stem cell cultures, as well as methods of deriving and using them. The process of obtaining patent protection for products such as those we propose to develop is highly uncertain and involves complex and continually evolving factual and legal questions. The governmental authorities that consider patent applications can deny or significantly reduce the patent coverage requested in an application either before or after issuing the patent. For example, under the procedures of the European Patent Office, third parties may oppose our issued European patents during the relevant opposition period. These proceedings and oppositions could result in substantial uncertainties and cost for us, even if the eventual outcome is favorable to us, and the outcome might not be favorable to us. In the United States, third parties may seek to invalidate issued patents through a U.S. PTO reexamination process or through the courts. In addition, changes to the laws protecting intellectual property rights could adversely impact the perceived or actual value of our Company. Consequently, we do not know whether any of our pending applications will result in the issuance of patents, whether any of our issued patents will be invalidated or restricted, whether any existing or future patents will provide sufficient protection or significant commercial advantage, or whether others will circumvent these patents, whether or not lawfully. In addition, our patents may not afford us adequate protection from competing products. Moreover, because patents issue for a limited term, our patents may expire before we can commercialize a product covered by the issued patent claims or before we can utilize the patents profitably. Some of our most important patents begin to expire in 2015.

If we learn of third parties who infringe our patent rights, we may decide to initiate legal proceedings to enforce these rights. Patent litigation is inherently unpredictable and highly risky and may result in unanticipated challenges to the validity or enforceability of our intellectual property, which could result in the loss of these rights. Litigation proceedings are also very costly and the parties we bring actions against may have significantly greater financial resources than our own. We may not prevail in these proceedings.

Proprietary trade secrets and unpatented know-how are also important to our research and development activities. We cannot be certain that others will not independently develop the same or similar technologies on their own or gain access to our trade secrets or disclose such technology or that we will be able to meaningfully protect our trade secrets and unpatented know-how. We require our employees, consultants and significant scientific collaborators and sponsored researchers to execute confidentiality agreements upon the commencement of an employment or consulting relationship with us. These agreements may, however, fail to provide meaningful protection or adequate remedies for us in the event of unauthorized use, transfer or disclosure of such information or technology.

If we are unable to obtain necessary licenses to third-party patents and other rights, we may not be able to commercially develop our expected products.

A number of pharmaceutical, biotechnology and other companies, universities and research institutions have filed patent applications or have received patents relating to cell therapy, stem and progenitor cells and other technologies potentially relevant to, or necessary for, our expected products. We cannot predict which, if any, of these applications will issue as patents or how many of these issued patents will be found valid and enforceable. There may also be existing issued patents which we are currently unaware of which would be infringed by the commercialization of one or more of our product candidates. If so, we may be prevented from commercializing these products unless the third party is willing to grant a license to us. We may be unable to obtain licenses to the relevant patents at a reasonable cost, if at all, and may also be unable to develop or obtain alternative non-infringing technology. If we are unable to obtain such licenses or develop non-infringing technology at a reasonable cost, our business could be significantly harmed. Also, any infringement lawsuits commenced against us may result in significant costs, divert our management s attention and result in an award against us for substantial damages, or potentially prevent us from continuing certain operations.

We are aware of intellectual property rights held by third parties that relate to products or technologies we are developing. For example, some aspects of our cell-based therapeutic product candidates involve the use of growth factors, antibodies and other reagents that may, in certain cases, be the subject of third party rights. Before we commercialize any product using these growth factors, antibodies or reagents, we may need to obtain license rights

from third parties or use alternative growth factors, antibodies and reagents that are not then the subject of third party patent rights. We currently believe that the commercialization of our products as currently planned will not infringe these third party rights, or, alternatively, that we will be able to obtain necessary licenses or otherwise use alternative non-infringing technology. However, third parties may nonetheless bring suit against us claiming infringement. If we are unable to prove that our technology does not infringe their patents, or if we are unable to obtain necessary licenses or otherwise use alternative non-infringing technology, we may not be able to commercialize any products.

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We have obtained rights from companies, universities and research institutions to technologies, processes and compounds that we believe may be important to the development of our products. These licensors, however, may cancel our licenses or convert them to non-exclusive licenses if we fail to use the relevant technology or otherwise breach these agreements. Loss of these licenses could expose us to the risk that our technology infringes the rights of third parties. We can give no assurance that any of these licenses will provide effective protection against our competitors.

We compete with companies that have significant advantages over us.

The market for therapeutic products to treat diseases of, or injuries to, the central nervous system (CNS) is large and competition is intense. The majority of the products currently on the market or in development are small molecule pharmaceutical compounds, and many pharmaceutical companies have made significant commitments to the CNS field. We believe cellular therapies, if proven safe and effective, will have unique properties that will make them desirable over small molecule drugs, none of which currently replace damaged tissue. However, any cell-based therapeutic to treat diseases of, or injuries to, the CNS is likely to face intense competition from the small molecule sector, biologics, as well as medical devices. We expect to compete with a host of companies, some of which are privately owned and some of which have resources far greater than ours.

In the liver field, there are no broad-based therapies for the treatment of liver disease at present. The primary therapy is liver transplantation, which is limited by the availability of matched donor organs. Liver-assist devices, when and if they become available, could also be used to help patients while they await suitably matched organs for transplantation. Liver transplantation may remain the standard of care even if we successfully develop a cellular therapy. In addition, new therapies may become available before we successfully develop a cell-based therapy for liver disease.

Development of our technologies is subject to, and restricted by, extensive government regulation, which could impede our business.

Our research and development efforts, as well as any future clinical trials, and the manufacturing and marketing of any products we may develop, will be subject to, and restricted by, extensive regulation by governmental authorities in the United States and other countries. The process of obtaining FDA and other necessary regulatory approvals is lengthy, expensive and uncertain. We or our collaborators may fail to obtain the necessary approvals to commence or continue clinical testing or to manufacture or market our potential products in reasonable time frames, if at all. In addition, the U.S. Congress and other legislative bodies may enact regulatory reforms or restrictions on the development of new therapies that could adversely affect the regulatory environment in which we operate or the development of any products we may develop.

We base our research and development on the use of human stem and progenitor cells obtained from human tissue, including fetal tissue. The federal and state governments and other jurisdictions impose restrictions on the use of fetal tissue, including those incorporated in federal Good Tissue Practice, or cGTP, regulations. These regulatory and other constraints could prevent us from obtaining cells and other components of our products in the quantity or quality needed for their development or commercialization. These restrictions change from time to time and may become more onerous. Additionally, we may not be able to identify or develop reliable sources for the cells necessary for our potential products that is, sources that follow all state and federal guidelines for cell procurement. Certain components used to manufacture our stem and progenitor cell product candidates will need to be manufactured in compliance with the FDA s Good Manufacturing Practices, or cGMP. Accordingly, we will need to enter into supply agreements with companies that manufacture these components to cGMP standards.

We are dependent on the services of key personnel.

We are highly dependent on the principal members of our management and scientific staff and some of our outside consultants, including the members of our scientific advisory board, our chief executive officer, our vice presidents, and the heads of key departments or functions within the company. Although we have entered into employment agreements with some of these individuals, they may terminate their agreements at any time. In addition, our operations are dependent upon our ability to attract and retain additional qualified scientific and management personnel. We may not be able to attract and retain the personnel we need on acceptable terms given the competition for experienced personnel among pharmaceutical, biotechnology and health care companies, universities and research

institutions.

Our activities involve hazardous materials and experimental animal testing; improper handling of these animals and materials by our employees or agents could expose us to significant legal and financial penalties.

Our research and development activities involve the controlled use of test animals as well as hazardous chemicals and potentially hazardous biological materials such as human tissue. Their use subjects us to environmental and safety laws and regulations such as

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those governing laboratory procedures, exposure to blood-borne pathogens, use of laboratory animals, and the handling of biohazardous materials. Compliance with current or future laws and regulations may be expensive and the cost of compliance could adversely affect us.

Although we believe that our safety procedures for using, handling, storing, and disposing of hazardous and potentially hazardous materials comply with the standards prescribed by California and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident or of any violation of these or future laws and regulations, state or federal authorities could curtail our use of these materials; we could be liable for any civil damages that result, the cost of which could be substantial; and we could be subjected to substantial fines or penalties. In addition, any failure by us to control the use, disposal, removal, or storage, or to adequately restrict the discharge, or to assist in the cleanup, of hazardous chemicals or hazardous, infectious or toxic substances could subject us to significant liability. Any such liability could exceed our resources and could have a material adverse effect on our business, financial condition and results of operations. Moreover, an accident could damage our research and manufacturing facilities and operations and result in serious adverse effects on our business.

The development, manufacturing and commercialization of cell-based therapeutic products expose us to product liability claims, which could lead to substantial liability.

By developing and, ultimately, commercializing medical products, we are exposed to the risk of product liability claims. Product liability claims against us could result in substantial litigation costs and damage awards against us. We have obtained liability insurance that covers our clinical trials, and we will need to increase our insurance coverage if and when we begin commercializing products. We may not be able to obtain insurance on acceptable terms, if at all, and the policy limits on our insurance policies may be insufficient to cover our liability.

The manufacture of cell-based therapeutic products is novel, highly regulated, critical to our business, and dependent upon specialized key materials.

The proliferation and manufacture of cell-based therapeutic products are complicated and difficult processes, dependent upon substantial know-how and subject to the need for continual process improvements to be competitive. Our manufacturing experience is limited and the technologies are comparatively new. In addition, our ability to scale-up manufacturing to satisfy the various requirements of our planned clinical trials, such as GTP, GMP and release testing requirements, is uncertain. Manufacturing disruptions may occur and despite efforts to regulate and control all aspects of manufacturing, the potential for human or system failure remains. Manufacturing irregularities or lapses in quality control could have a serious adverse effect on our reputation and business, which could cause a significant loss of stockholder value. Many of the materials that we use to prepare our cell-based products are highly specialized, complex and available from only a limited number of suppliers or derived from a biological origin. At present, some of our material requirements are single sourced, and the loss of one or more of these sources may adversely affect our business if we are unable to obtain alternatives or alternative sources at all or upon terms that are acceptable to us.

Because health care insurers and other organizations may not pay for our products or may impose limits on reimbursements, our ability to become profitable could be adversely affected.

In both domestic and foreign markets, sales of potential products are likely to depend in part upon the availability and amounts of reimbursement from third-party health care payor organizations, including government agencies, private health care insurers and other health care payors, such as health maintenance organizations and self-insured employee plans. There is considerable pressure to reduce the cost of therapeutic products. Government and other third party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing, in some cases, to provide any coverage for uses of approved products for disease indications for which the FDA or other relevant authority has not granted marketing approval. Moreover, in some cases, government and other third party payors have refused to provide reimbursement for uses of approved products for disease indications for which the FDA or other relevant authority *has* granted marketing approval. Significant uncertainty exists as to the reimbursement status of newly approved health care products or novel therapies such as ours. Even if we obtain regulatory approval to market our products, we can give no assurance that reimbursement will be provided by such payors at all or without substantial delay or, if such

reimbursement is provided, that the approved reimbursement amounts will be sufficient to enable us to sell products we develop on a profitable basis. Changes in reimbursement policies could also adversely affect the willingness of pharmaceutical companies to collaborate with us on the development of our cellular technologies. In certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. We also expect that there will continue to be a number of

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federal and state proposals to implement government control over health care costs. Efforts to change regulatory and reimbursement standards are likely to continue in future legislative sessions. We do not know what legislative proposals federal or state governments will adopt or what actions federal, state or private payors for health care goods and services may take in response to such proposals or legislation. We cannot predict the effect of government control and health care reimbursement practices on our business.

Ethical and other concerns surrounding the use of stem or progenitor-based cell therapy may negatively affect regulatory approval or public perception of our product candidates, which could reduce demand for our products or depress our stock price.

The use of stem cells for research and therapy has been the subject of debate regarding related ethical, legal and social issues. Although these concerns have mainly been directed to the use of embryonic stem cells, which we do not use, the distinction between embryonic and non-embryonic stem cells is frequently overlooked; moreover, our use of human stem or progenitor cells from fetal sources might raise these or similar concerns. Negative public attitudes toward stem cell therapy could result in greater governmental regulation of stem cell therapies, which could harm our business. For example, concerns regarding such possible regulation could impact our ability to attract collaborators and investors. Also, existing regulatory constraints on the use of embryonic stem cells may in the future be extended to use of fetal stem cells, and these constraints might prohibit or restrict us from conducting research or from commercializing products. Existing and potential U.S. government regulation of embryonic tissue may lead researchers to leave the field of stem cell research or the country altogether, in order to assure that their careers will not be impeded by restrictions on their work. Similarly, these factors may induce graduate students to choose other fields less vulnerable to changes in regulatory oversight, thus exacerbating the risk that we may not be able to attract and retain the scientific personnel we need in face of the competition among pharmaceutical, biotechnology and health care companies, universities and research institutions for what may become a shrinking class of qualified individuals.

Our corporate documents and Delaware law contain provisions that could make it difficult for us to be acquired in a transaction that might be beneficial to our stockholders.

Our board of directors has the authority to issue shares of preferred stock and to fix the rights, preferences, privileges, and restrictions of these shares without stockholder approval. These provisions in our corporate documents, along with certain provisions under Delaware law, may make it more difficult for a third party to acquire us or discourage a third party from attempting to acquire us, even if the acquisition might be beneficial to our stockholders.

Risks Related to the Securities Market

Our stock price has been, and will likely continue to be, highly volatile, which may negatively affect our ability to obtain additional financing in the future.

The market price per share of our common stock has been and is likely to continue to be highly volatile due to the risks and uncertainties described in this section of this Quarterly Report on Form 10-Q, as well as other factors, including:

- our ability to develop and test our technologies;
- our ability to patent or obtain licenses to necessary technologies;
- conditions and publicity regarding the industry in which we operate, as well as the specific areas our product candidates seek to address;
- competition in our industry;
- economic and other external factors or other disasters or crises;
- price and volume fluctuations in the stock market at large that are unrelated to our operating performance; and
- comments by securities analysts, or our failure to meet market expectations.

Over the two-year period ended September 30, 2008, the trading price of our common stock as reported on the Nasdaq Global Market

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ranged from a high of $3.63 to a low of $1.00. As a result of this volatility, your investment in our stock is subject to substantial risk. Furthermore, the volatility of our stock price could negatively impact our ability to raise capital or acquire businesses or technologies.

We are contractually obligated to issue shares in the future, diluting the interest of current stockholders.

As of September 30, 2008, there were outstanding warrants to purchase 1,255,000 shares of our common stock, at a weighted average exercise price of $1.90 per share. Also as of September 30, 2008, there were outstanding options to purchase 8,471,887 shares of our common stock, at a weighted average exercise price of $2.33 per share, and 1,650,000 restricted stock units. Moreover, we expect to issue additional options to purchase shares of our common stock to compensate employees, consultants and directors, and may issue additional shares to raise capital, to acquire other companies or technologies, to pay for services, or for other corporate purposes. Any such issuances will have the effect of diluting the interest of current stockholders.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

Information about our Annual Meeting of Stockholders, which was held on July 22, 2008, was disclosed in our quarterly report for the quarter ended June 30, 2008,on Form 10-Q, under Part II, Item 4.

ITEM 5. OTHER INFORMATION

On July 9, 2008, we amended our 1997 and 2000 license agreements with NeuroSpheres. NeuroSpheres is the holder of certain patents exclusively licensed by us, including the six patents that are the basis of our patent infringement suits against Neuralstem. As part of the amendment, we agreed to pay all reasonable litigation costs, expenses and attorney s fees incurred by NeuroSpheres in the declaratory judgment suit between us and Neuralstem. In return, we are entitled to off-set all litigation costs incurred in that suit against amounts that would otherwise be owed under the license agreements, such as annual maintenance fees, milestones and royalty payments.

ITEM 6. EXHIBITS

Exhibit 10.1 Indemnification Agreement, dated July 9, 2008, by and between registrant and NeuroSpheres Holdings, LTD

Exhibit 31.1 Certification of Martin McGlynn under Section 302 of the Sarbanes-Oxley Act of 2002

Exhibit 31.2 Certification of Rodney K. B. Young under Section 302 of the Sarbanes-Oxley Act of 2002

Exhibit 32.1 Certification of Martin McGlynn Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Exhibit 32.2 Certification of Rodney K. B. Young Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURE

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

STEMCELLS, INC.
(name of Registrant)

October 31, 2008

/s/ Rodney K. B. Young
Rodney K. B. Young
Chief Financial Officer

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