

STEMCELLS INC  
Form 10-Q  
November 05, 2007

**Table of Contents**

**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, 2007  
Commission File Number: 0-19871  
STEMCELLS, INC.  
(Exact name of registrant as specified in its charter)**

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)

94-3078125  
(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. Yes  No

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

At October 24, 2007, there were 80,681,087 shares of Common Stock, \$.01 par value, issued and outstanding.

---

STEMCELLS, INC.  
INDEX

	Page Number
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements (Unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets at September 30, 2007 and December 31, 2006</u>	3
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2007 and 2006</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2007 and 2006</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	26
<u>Item 4. Controls and Procedures</u>	26
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	27
<u>Item 1A. Risk Factors</u>	27
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	36
<u>Item 3. Defaults Upon Senior Securities</u>	36
<u>Item 4. Submission of Matters to a Vote of Security-Holders</u>	36
<u>Item 5. Other Information</u>	36
<u>Item 6. Exhibits</u>	36
<u>SIGNATURES</u>	
<u>Exhibit Index</u>	38
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	
<u>EXHIBIT 32.2</u>	



**Table of Contents****PART I FINANCIAL INFORMATION**

## ITEM 1. FINANCIAL STATEMENTS

## STEMCELLS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2007 (unaudited)	December 31, 2006
Assets		
Current assets:		
Cash and cash equivalents	\$ 17,529,201	\$ 51,795,529
Marketable securities, short term	25,765,004	4,132,646
Receivables	366,273	482,850
Other current assets	1,020,719	1,119,467
 Total current assets	 44,681,197	 57,530,492
Marketable securities	1,818,812	3,133,632
Property, plant and equipment, net	4,112,286	3,596,150
Other assets, net	2,516,915	2,596,543
 Total assets	 \$ 53,129,210	 \$ 66,856,817
 Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,537,858	\$ 620,765
Accrued expenses	2,049,989	2,053,902
Accrued wind-down expenses, current portion	1,306,625	1,252,483
Deferred revenue, current portion	54,065	16,826
Capital lease obligations, current portion	17,241	
Bonds payable, current portion	132,500	205,833
 Total current liabilities	 5,098,278	 4,149,809
Capital lease obligations, non-current portion	29,753	
Bonds payable, non-current portion	1,045,416	1,145,416
Deposits and other long-term liabilities	466,211	547,392
Accrued wind-down expenses, non-current portion	4,838,683	5,497,774
Deferred rent	789,066	959,732
Deferred revenue, non-current portion	168,072	180,691
 Total liabilities	 12,435,479	 12,480,814
Stockholders' equity:		
Common stock, \$.01 par value; 125,000,000 shares authorized; 80,068,593 and 78,046,304 shares issued and outstanding at	800,685	780,462

Edgar Filing: STEMCELLS INC - Form 10-Q

September 30, 2007 and December 31, 2006, respectively

Additional paid in capital	262,414,823	255,299,508
Accumulated deficit	(222,089,191)	(204,891,945)
Accumulated other comprehensive income (loss)	(432,586)	3,187,978

Total stockholders' equity	40,693,731	54,376,003
----------------------------	------------	------------

Total liabilities and stockholders' equity	\$ 53,129,210	\$ 66,856,817
--	---------------	---------------

See accompanying notes to condensed consolidated financial statements.

**Table of Contents**

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

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Revenue:				
Revenue from grants and licensing agreements	\$ 13,162	\$ 18,321	\$ 26,948	\$ 80,406
Total revenue	13,162	18,321	26,948	80,406
Operating expenses:				
Research and development	5,621,955	3,523,078	14,139,297	9,402,472
General and administrative	2,043,275	1,889,512	5,716,480	4,979,349
Wind-down expenses	83,661	168,168	439,471	499,186
Total operating expenses	7,748,891	5,580,758	20,295,248	14,881,007
Loss from operations	(7,735,729)	(5,562,437)	(20,268,300)	(14,800,601)
Other income (expense):				
License and settlement agreement, net			550,467	103,359
Realized gain on sale of marketable securities			717,621	
Interest income	617,616	735,652	1,926,753	1,779,016
Interest expense	(29,405)	(34,062)	(96,777)	(111,159)
Other	(5,985)	(2,362)	(27,009)	(16,309)
Total other income	582,226	699,228	3,071,055	1,754,907
Net loss	\$ (7,153,503)	\$ (4,863,209)	\$ (17,197,245)	\$ (13,045,694)
Net loss per share basic and diluted	\$ (0.09)	\$ (0.06)	\$ (0.22)	\$ (0.18)
Weighted average shares used to compute net loss per share basic and diluted	80,065,667	77,779,257	79,478,537	73,487,670
See accompanying notes to condensed consolidated financial statements.				

**Table of Contents**

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

	Nine months ended September 30,	
	2007	2006
Cash flows from operating activities:		
Net loss	\$ (17,197,245)	\$ (13,045,694)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	869,432	790,949
Stock-based compensation expense	2,276,026	1,812,962
Loss on disposal of fixed assets		1,197
Non-cash income from license and settlement agreement	(550,467)	(103,359)
Gain on sale of marketable securities	(717,621)	
Changes in operating assets and liabilities:		
Receivables	116,577	(243,449)
Other current assets	98,748	(720,066)
Other assets	14,395	106,271
Accounts payable and accrued expenses	913,180	(621,116)
Accrued wind-down expenses	(604,949)	(428,884)
Deferred revenue	24,620	248,274
Deferred rent	(170,666)	153,339
Deposits and other long-term liabilities	(81,181)	(27,624)
Net cash used in operating activities	(15,009,151)	(12,077,200)
Cash flows from investing activities:		
Purchases of short-term investments	(25,746,705)	
Proceeds from the sale of marketable securities	3,076,691	
Purchase of property, plant and equipment	(1,260,961)	(1,230,554)
Acquisition of other assets	(49,375)	(88,375)
Net cash provided (used in) investing activities	(23,980,350)	(1,318,929)
Cash flows from financing activities:		
Proceeds from issuance of common stock	3,545,489	33,421,534
Proceeds from the exercise of stock options	210,273	123,186
Proceeds from the exercise of warrants	1,093,750	994,896
Proceeds (repayments) of capital lease obligations	46,994	(54,676)
Repayment of debt obligations	(173,333)	(189,169)



Edgar Filing: STEMCELLS INC - Form 10-Q

Net cash provided by financing activities	4,723,173	34,295,771
Increase (decrease) in cash and cash equivalents	(34,266,328)	20,899,642
Cash and cash equivalents, beginning of period	51,795,529	34,540,908
Cash and cash equivalents, end of period	\$ 17,529,201	\$ 55,440,550

Supplemental disclosure of cash flow information:

Interest paid	\$ 96,777	\$ 111,159
Stock issued for licensing agreements	\$ 10,000(1)	\$ 10,000(1)

(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 StemCells holds a license from Cal Tech, payable in cash or stock at the Company's choice. The Company elected to pay the fees in stock and issued 3,865 and 3,848 unregistered shares to Cal Tech for the nine-month periods ended September 30, 2007 and 2006 respectively.

See accompanying notes to condensed consolidated financial statements

**Table of Contents**

**Notes to Condensed Consolidated Financial  
Statements(Unaudited)  
September 30, 2007 and 2006**

**NOTE 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The terms StemCells, the Company, our, we and us as used in this report refer to StemCells, Inc. The accompanying unaudited, condensed consolidated financial statements have been prepared by the Company in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, considered necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. Results of operations for the nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for the entire fiscal year ending December 31, 2007.

The balance sheet at December 31, 2006 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required for complete financial statements in accordance with accounting principles generally accepted in the United States of America. For the complete financial statements, see the audited financial statements and footnotes thereto as of December 31, 2006, included on Form 10-K.

The Company has incurred significant operating losses and negative cash flows since inception. It has not achieved profitability and may not be able to realize sufficient revenues to achieve or sustain profitability in the future. The Company has limited capital resources and will need to raise additional capital from time to time to sustain its product development efforts, acquisition of businesses, technologies and intellectual property rights, preclinical and clinical testing of 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. To fund its operations, the Company relies on cash balances, proceeds from equity and debt offerings, proceeds from the transfer or sale of intellectual property rights, equipment, facilities or investments, and on government grants and collaborative arrangements. The Company cannot be certain that such funding will be available when needed. 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.

**Use of Estimates**

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements. Actual results could differ from these estimates. Significant estimates include the following:

Accrued wind-down expenses (see Note 4).

The grant date fair value of share-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 *Stock-Based Compensation* below.

**Marketable securities**

In accordance with Statement of Financial Accounting Standards (SFAS) No. 115 *Accounting for Certain Investments in Debt and Equity Securities*, the Company has classified its investment in equity securities as available-for-sale marketable securities in the accompanying consolidated financial statements (see Note 2). The marketable securities are stated at fair market value, with unrealized gains and losses reported in other comprehensive income.

**Table of Contents**

Management reviews securities with unrealized losses for other than temporary impairment. A decline in the fair value of securities that is deemed other than temporary is charged to earnings when so deemed.

**Net Loss Per Share**

The Company has computed net loss per common share according to SFAS No. 128 *Earnings Per Share*, which requires disclosure of basic and diluted earnings per share. Basic earnings per share excludes any dilutive effects of options, warrants and convertible securities, and is computed using the weighted average number of common shares outstanding during the period. Diluted earnings per share includes the impact of potentially dilutive securities and is computed using the weighted average of common and diluted equivalent stock options, warrants and convertible securities outstanding during the period. Stock options, warrants and convertible securities that are anti-dilutive are excluded from the calculation of diluted loss per common share.

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Net loss	\$ (7,153,503)	\$ (4,863,209)	\$ (17,197,245)	\$ (13,045,694)
Weighted average shares used in computing net loss per share, basic and diluted	80,065,667	77,779,257	79,478,537	73,487,670
Net loss per share, basic and diluted	\$ (0.09)	\$ (0.06)	\$ (0.22)	\$ (0.18)

The Company has excluded outstanding stock options and warrants from the calculation of diluted loss per common share because all such securities are anti-dilutive for all applicable periods presented. These outstanding securities consist of the following potential common shares:

	Outstanding at September 30,	
	2007	2006
Outstanding options	9,033,794	8,989,671
Outstanding warrants	1,355,000	1,930,658
Total	10,388,794	10,920,329

**Comprehensive Income (Loss)**

The only component of other comprehensive income is unrealized gains and losses on available for sale securities (see Note 2). The following table summarizes the components of the Company's comprehensive income for the three and nine months ended September 30, 2007 and 2006.

As of September 30,	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Net loss	\$ (7,153,503)	\$ (4,863,209)	\$ (17,197,245)	\$ (13,045,694)
Other comprehensive loss (unrealized loss on marketable securities)	(436,331)	(1,059,360)	(3,620,563)	(2,782,626)
Comprehensive income (loss)	\$ (7,589,834)	\$ (5,922,569)	\$ (20,817,808)	\$ (15,828,320)

**Stock-Based Compensation**

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS 123R. SFAS 123R requires all share-based payments to employees, or to non-employee directors as compensation for service on the Board of Directors, to be recognized as compensation expense in the consolidated financial statements based on the fair values of such payments. The Company maintains stockholder approved stock-based compensation plans,

**Table of Contents**

pursuant to which it grants stock-based compensation to its employees, consultants and to non-employee directors for Board service. These grants are primarily in the form of options that allow a grantee to purchase a fixed number of shares of the Company's common stock at a fixed exercise price equal to the market price of the shares at the date of the grant (qualified stock option grants) with a contractual term of ten years. The options may vest on a single date or in tranches over a period of time, but normally they do not vest unless the grantee is still employed by or a director of the Company on the vesting date. The compensation expense for grants to employees and directors will be recognized over the requisite service period, which is typically the period over which the stock-based compensation awards vest. In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 107 (SAB 107), which provides guidance on the implementation of SFAS 123R. The Company applied the principles of SAB 107 in conjunction with its adoption of SFAS 123R.

The Company adopted SFAS 123R effective January 1, 2006, using the modified-prospective transition method. Under this transition method, compensation expense will be recognized based on the grant date fair value estimated in accordance with the provisions of SFAS 123R for all new grants effective January 1, 2006, and for options granted prior to but not vested as of December 31, 2005. The following table summarizes the stock option related compensation expense recognized by the Company in accordance with SFAS 123R, for the three-and nine-month periods ended September 30, 2007 and 2006:

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Compensation expense for stock options granted	\$ 803,000	\$ 696,000	\$ 2,066,000	\$ 1,604,000

The stock option related compensation expense was recognized on a straight line basis over the vesting period of each grant net of estimated forfeitures. The Company's estimated forfeiture rates are based on its historical experience within separate groups of employees. The estimated fair value of the options granted during 2007 and prior years was calculated using a Black Scholes Merton option pricing model (Black Scholes model). The following summarizes the weighted average fair value per share of options granted during the period and assumptions used in the Black Scholes model to calculate the fair value:

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Weighted average fair value per share of options granted	\$ 1.74	\$ 1.69	\$ 1.87	\$ 2.02
Assumptions, weighted average:				
Risk free interest rate <sup>(1)</sup>	4.28%	4.68%	4.39%	4.73%
Volatility <sup>(2)</sup>	93.35%	106.60%	95.49%	94.97%
Dividend yield <sup>(3)</sup>	0%	0%	0%	0%
Expected term (years until exercise) <sup>(4)</sup>	6.25	6.25	6.25	6.25

**Table of Contents**

- (1) The risk-free interest rate is based on U.S. Treasury debt securities with maturities close to the expected term of the option.
- (2) Expected volatility is based on historical volatility of the Company's stock factoring in daily share price observations. In computing expected volatility, the length of the historical period used is equal to the length of the expected term of the option.
- (3) No cash dividends have been declared on the Company's common stock since the Company's inception, and the Company currently does not anticipate paying cash dividends over the expected term of the option.
- (4)

The expected term is equal to the average of the contractual life of the stock option and its vesting period.

At September 30, 2007, approximately \$7,600,000 of unrecognized compensation expense related to stock options is expected to be recognized over a weighted average period of approximately 1.7 years. 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 forfeiture rates, additional grants and subsequent periods of vesting.

The Company has four active stock option plans that were authorized to award 14,000,000 shares in aggregate. A total of 3,041,918 shares were available for grant from these four plans at September 30, 2007.

The following table summarizes information about stock option activity for the three months ended September 30, 2007:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value
Outstanding at June 30, 2007	9,037,194	\$ 2.86	6.1	\$3,211,096
Granted	1,496,600	\$ 2.21	9.89	\$ 28,485(1)
Exercised				
Forfeited	(1,500,000)	\$ 5.25		
Outstanding at September 30, 2007	9,033,794	\$ 2.36	7.49	\$2,349,173(1)
Exercisable at September 30, 2007	4,307,763	\$ 2.22	5.78	\$2,071,960(1)
Vested and expected to vest at September 30, 2007 (2)	8,343,643	\$ 2.34	7.52	\$2,333,579(1)

(1) The intrinsic values are calculated using the Company's closing stock price of \$2.11 on September 30, 2007.

(2) These calculations include options already vested at September 30, 2007 and options expected to vest net of estimated

forfeitures after  
September 30,  
2007.

**Table of Contents**

A summary of the changes to the Company's unvested options during the three-month period ended September 30, 2007 is presented below:

	Number of securities underlying unvested options	Weighted average grant date fair value
Unvested Options		
Unvested options at June 30, 2007	3,941,974	\$ 2.09
Granted this period	1,496,600	\$ 1.74
Vested this period	(712,543)	\$ 1.85
Forfeited this period		
Unvested options at September 30, 2007	4,726,031	\$ 2.01

The Company accounts for stock options 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, recognizes as expense the estimated fair value of such options as calculated using the Black Scholes model. The fair value is re-measured at each reporting date during the service period and is amortized over the vesting period of each option or the recipient's contractual arrangement, if shorter.

**Stock Appreciation Rights**

In July 2006, the Company, pursuant to the 2006 Equity Incentive Plan, granted cash-settled Stock Appreciation Rights (SARs) to certain employees. The SARs give the holder the right, upon exercise, to the difference between the price per share of the Company's common stock at the time of exercise and the exercise price of the SAR. The exercise price of the SARs is equal to the market price per share of the Company's common stock at the date of grant. The SARs vest on the same schedule as the Company's qualified options issued to employees, i.e., 25% on the first anniversary of the grant date and then 1/48<sup>th</sup> every month thereafter. The Company recognizes compensation expense for the SARs over the requisite service period which is typically the period over which the awards vest. Compensation expense is based on the fair value of SARs which is calculated using the Black Scholes model. The share-based compensation liability for the cost of the requisite service that has been rendered to the reporting date is re-measured at each reporting date through the date of settlement. The following table presents the activity of the Company's SARs awards for the nine-month periods ended September 30, 2007 and 2006.

	2007		2006	
	SARs	Weighted Average Exercise Price	SARs	Weighted Average Exercise Price
Outstanding at January 1	1,564,599	\$ 2.00		
Granted			1,564,599	\$ 2.00
Exercised				
Canceled				
Outstanding at September 30	1,564,599	\$ 2.00	1,564,599	\$ 2.00
SARs exercisable at September 30	456,337	\$ 2.00		

For the three-month period ended September 30, 2007, the Company recorded approximately \$76,000 as compensation expense related to SARs granted. At September 30, 2007, approximately \$1,369,000 of unrecognized





**Table of Contents**

compensation expense related to SARs is expected to be recognized over a weighted average period of approximately 1.5 years. 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.

**Revenue Recognition**

Revenues 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. The Company currently recognizes revenues 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 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.

**Recent Accounting Pronouncements**

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109* ( FIN 48 ). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*, and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Additionally, FIN 48 provides guidance on subsequent derecognition of tax positions, financial statement classification, recognition of interest and penalties, accounting in interim periods, and disclosure and transition requirements. The Company adopted the provisions of FIN 48 on January 1, 2007. Previously, the Company had accounted for tax contingencies in accordance with Statement of Financial Accounting Standards 5, *Accounting for Contingencies*. As required by FIN 48, the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. At the adoption date, the Company applied FIN 48 to all tax positions for which the statute of limitations remained open. The amount of unrecognized tax benefits as of January 1, 2007 was zero. There have been no material changes in unrecognized tax benefits since January 1, 2007. The Company is subject to income taxes in the U.S. federal jurisdiction and various state jurisdictions. As of January 1, 2007, due to the carry forward of unutilized net operating losses and research and development credits, the Company is subject to U.S. Federal income tax examinations for the tax years 1992 through 2006, and to state income tax examinations for the tax years 1999 through 2006. The Company's Federal income tax return for the year 2004 is currently under examination. The ultimate outcome of the examination by the Internal Revenue Service cannot be determined at this time.

The Company recognizes accrued interest related to unrecognized tax benefits in interest expense and penalties in operating expense. No amounts were accrued for the payment of interest and penalties at January 1, 2007. The Company's adoption of FIN 48 did not have a material effect on the Company's financial condition, results of operations or cash flows (see Note 7).

In September 2006, the FASB issued FASB Statement No. 157, *Fair Value Measurements* (SFAS 157), which defines fair value, establishes a framework for measuring fair value under GAAP, and expands disclosures about fair value measurements. SFAS 157 applies to other accounting pronouncements that require or permit fair value measurements. The new guidance is effective for financial statements issued for fiscal years beginning after November 15, 2007, and for interim periods within those fiscal years. The Company is currently evaluating the

**Table of Contents**

requirements of SFAS 157; however, it does not believe that its adoption will have a material effect on its consolidated financial statements.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. SFAS 159's objectives are to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. SFAS 159 is effective as of the beginning of an entity's first fiscal year beginning after November 15, 2007. The Company is currently evaluating the potential impact, if any, that the adoption of SFAS 159 will have on its condensed consolidated financial statements.

In June 2007, the Financial Accounting Standards Board ratified a consensus opinion reached by the Emerging Issues Task Force (EITF) on EITF Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*. The guidance in EITF Issue 07-3 requires the Company to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the services expected to be performed, the Company would be required to expense the related capitalized advance payments. The consensus in EITF Issue 07-3 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2007 and is to be applied prospectively to new contracts entered into on or after December 15, 2007. Early adoption is not permitted. Retrospective application of EITF Issue 07-3 is also not permitted. The Company intends to adopt EITF Issue 07-3 effective January 1, 2008. The impact of applying this consensus will depend on the terms of the Company's future research and development contractual arrangements entered into on or after December 15, 2007.

**NOTE 2. AVAILABLE FOR SALE SECURITIES**

The following table summarizes the Company's investments, which are all classified as available-for-sale:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>September 30, 2007</b>				
Short-term Investments				
Commercial paper	\$11,139,127	\$ 919		\$11,140,046
U.S. corporate debt	11,843,192	9,458		11,852,650
Asset backed	2,766,444	5,864		2,772,308
Total short-term investments	25,748,763	16,241		25,765,004
Long-term investments				
Investment in equity securities	2,269,697		(450,885)	1,818,812
Total long-term investments	2,269,697		(450,885)	1,818,812
Total investments	\$28,018,460	\$ 16,241	\$(450,885)	\$27,583,816
<b>December 31, 2006</b>				
Short-term Investments				
Investment in equity securities	\$ 2,319,505	\$1,813,141		\$ 4,132,646
Total short-term investments	2,319,505	1,813,141		4,132,646
Long-term Investments				
Investment in equity securities	1,758,795	1,374,837		3,133,632

Edgar Filing: STEMCELLS INC - Form 10-Q

Total long-term investments	1,758,795	1,374,837	3,133,632
Total investments	\$ 4,078,300	\$3,187,978	\$ 7,266,278

The investment in equity securities consists of shares of ReNeuron Group plc, a publicly listed UK corporation. In July 2005, the Company 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, the Company granted ReNeuron a license that allows ReNeuron to exploit their c-mycER conditionally immortalized adult

**Table of Contents**

human neural stem cell technology for therapy and other purposes. In return for the license, StemCells 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 StemCells 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. As of December 31, 2006, the Company held 9,274,837 shares of ReNeuron common stock with fair value of approximately \$7,266,000. In February 2007, the Company sold 5,275,000 ordinary shares of ReNeuron for net proceeds of approximately \$3,077,000. The Company recorded approximately \$718,000 as realized gain for this transaction. In February 2007, ReNeuron issued additional shares of common stock to the Company as a consequence of certain anti-dilution provisions in the agreement. StemCells was entitled to approximately 822,000 shares net of approximately 12,000 shares transferred to Neurospheres Ltd., (Neurospheres) an Alberta corporation from which StemCells has licensed some of the patent rights that are subject to the agreement with ReNeuron. The Company recorded approximately \$550,000 as other income for the additional shares. As of September 30, 2007, the Company owned approximately 4,822,000 ordinary shares of ReNeuron with a fair market value of approximately \$1,819,000.

Changes in market value 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 income (loss) if deemed temporary and are not recorded as other income or loss until the shares are disposed of and a gain or loss realized. The unrealized loss as of September 30, 2007 is approximately \$451,000. A decline in the fair value of securities that is deemed other than temporary would be charged to operations.

**NOTE 3. LEASES**

The Company had undertaken 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 a pilot manufacturing facility related to its former encapsulated cell technology. The related leases are structured such that lease payments will fully fund all semiannual interest payments and annual principal payments through maturity in August 2014. Interest rates vary with the respective bonds' maturities, ranging currently from 8.2% to 9.5%. The outstanding principal at September 30, 2007 was approximately \$1,178,000. The bonds contain certain restrictive covenants, which limit among other things, the payment of cash dividends and the sale of the related assets.

The Company entered into a fifteen-year lease for a laboratory facility in Rhode Island in connection with a sale and leaseback arrangement in 1997. The lease has escalating rent payments and accordingly, the Company is recognizing rent expense on a straight-line basis. At December 31, 2006 and September 30, 2007, the Company had deferred rent liability for this facility of approximately \$1,261,000 and \$1,253,000 respectively; the deferred rent liability is presented as part of the wind-down reserve.

Although the Company previously discontinued activities relating to encapsulated cell technology, the Company remains obligated under the leases for the pilot manufacturing facility and the laboratory facility. The Company is currently seeking to sublease the pilot manufacturing facility and part of the laboratory facility. The aggregate income received by the Company is significantly less than the Company's aggregate obligations under the leases, and the Company's continued receipt of rental income is dependent on the financial ability of the occupants to comply with their obligations under the subleases. The Company continues to seek to sublet the vacant portions of the Rhode Island facilities, to assign or sell its interests in all of these properties, or to otherwise arrange for the termination of its obligations under the lease obligations on these facilities. There can be no assurance, however, that the Company will be able to dispose of these properties in a reasonable time, if at all, or to terminate its lease obligations without the payment of substantial consideration.

As of February 1, 2001, the Company entered into a 5-year lease for 40,000 square feet of an approximately 68,000 square foot facility located in the Stanford Research Park in Palo Alto, California. The facility includes space for animals, laboratories and offices. On December 19, 2002, the Company negotiated an amendment to the lease, which resulted in reducing the average annual rent over the remaining term of the lease from approximately \$3.7 million to \$2.0 million. As part of the amendment, the Company issued a letter of credit on January 2, 2003 for \$503,079, which was an addition to the letter of credit in the amount of \$275,000 issued at commencement of the

lease, to serve as a deposit for the duration of the lease. The Company negotiated an

**Table of Contents**

amendment to the lease effective April 1, 2005, which extends the term of the lease through March 31, 2010, includes a reduction in the rent per square foot, and provides for an expansion of the leased premises by approximately 28,000 additional square feet. The average annual rent due from the Company under its lease for the period commencing April 1, 2005 to March 31, 2010 is approximately \$2 million before subtenant income. The lease has escalating rent payments, which the Company is recognizing on a straight-line basis. At September 30, 2007, the Company had deferred rent liability for this facility of approximately \$789,000. At September 30, 2007, the Company has a space-sharing agreement covering in total approximately 11,000 square feet of this facility. The Company receives the amount of base rent plus the proportionate share of the operating expenses that it pays for such space over the term of these agreements.

**NOTE 4. RELOCATION TO CALIFORNIA FROM RHODE ISLAND**

In October 1999, the Company relocated to California from Rhode Island and established a wind down reserve for the estimated lease payments and operating costs of the Rhode Island facilities through an expected disposal date of June 30, 2000. The Company did not fully sublet the Rhode Island facilities in 2000. Even though the Company intends to dispose of the facility at the earliest possible time, management cannot determine with certainty a fixed date by which such disposal will occur. In light of this uncertainty, the Company periodically re-evaluates and adjusts the reserve. The Company considers various factors such as the Company's 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. At December 31, 2006, the reserve was approximately \$5,512,000. For the three-and nine-month periods ended September 30, 2007, the Company incurred approximately \$344,000 and \$1,067,000, respectively, in operating expenses, which was recorded against the reserve. After evaluating the afore-mentioned factors, the Company re-valued the reserve to approximately \$4,884,000 at September 30, 2007 by recording an additional \$222,000, \$134,000 and \$83,000 at March 31, 2007, June 30, 2007 and September 30, 2007, respectively, as wind-down expenses.

**Wind-down reserve**

	January to March 31, 2007	April to June 30, 2007	July to September 30, 2007	January to September 30, 2007	January to December 31, 2006
Accrued wind-down reserve at beginning of period	\$5,512,000	\$5,353,000	\$5,145,000	\$ 5,512,000	\$ 6,098,000
Less actual expenses recorded against estimated reserve during the period	(381,000)	(342,000)	(344,000)	(1,067,000)	(1,295,000)
Additional expense recorded to revise estimated reserve at period-end	222,000	134,000	83,000	439,000	709,000
Revised reserve at period-end	5,353,000	5,145,000	4,884,000	4,884,000	5,512,000
Add deferred rent at period end (see Note 3)	1,246,000	1,253,000	1,261,000	1,261,000	1,238,000
Total accrued wind-down expenses at period-end (current and non current portion)	\$6,599,000	\$6,398,000	\$6,145,000	\$ 6,145,000	\$ 6,750,000

Accrued wind-down expenses					
Current portion	\$1,363,000	\$1,053,000	\$1,307,000	\$ 1,307,000	\$ 1,252,000
Non current portion	5,236,000	5,345,000	4,838,000	4,838,000	5,498,000
Total Accrued wind-down expenses	\$6,599,000	\$6,398,000	\$6,145,000	\$ 6,145,000	\$ 6,750,000

**NOTE 5. GRANTS**

In September 2004, the National Institutes of Health (NIH) awarded the Company a Small Business Technology Transfer grant of \$464,000 for studies in Alzheimer's disease, consisting of approximately \$308,000 for the first year and approximately \$156,000 for the remainder of the grant term, September, 2005 through June, 2006.



**Table of Contents**

The studies have been conducted by Dr. George A. Carlson of the McLaughlin Research Institute in Great Falls, Montana, which received approximately \$222,000 of the total award. The remaining \$242,000 has been recognized by the Company as grant revenue as and when resources were expended for this study. For the nine-month period ended September 30, 2006, the Company recognized approximately \$38,000, after which the Company had drawn down in full its share of the grant. The Company had no grant revenue for the nine-month period ended September 30, 2007.

**NOTE 6. STOCKHOLDERS EQUITY**

On December 29, 2006, the Company filed a Prospectus Supplement announcing the entry into a sales agreement with Cantor Fitzgerald & Co. (Cantor) under which up to 10,000,000 shares may be sold from time to time under a shelf registration statement. For the nine-month period ended September 30, 2007, the Company sold 1,217,000 shares under this sales agreement at an average price of \$3.13 per share and received net proceeds of approximately \$3,614,000. 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 the Company's common stock at \$1.90 per share. The Company issued 575,658 shares of its common stock and received proceeds of approximately \$1,094,000.

**NOTE 7. INCOME TAXES**

At December 31, 2006, the Company had net operating loss carryforwards for Federal income tax purposes of approximately \$118,560,000 expiring in the years 2007 through 2026 and net operating loss carry forwards for state income tax purposes of approximately \$11,747,000 which expire in the years 2009 through 2016. The Company did not provide for a tax benefit, because it is more likely than not that any such benefit would not be realized.

**NOTE 8. SUBSEQUENT EVENTS**

In connection with the sales agreement with Cantor, in October 2007, the Company sold 590,000 shares at an average price of \$2.25 per share and received net proceeds of approximately \$1,261,000.

**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion of our financial condition and the results of our operations for the three and nine-month periods ended September 30, 2007 and 2006 should be read in conjunction with the accompanying unaudited condensed consolidated financial statements and the related footnotes thereto.

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) will permit us to proceed with clinical testing of proposed products despite the novel and unproven nature of our technology; 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 regarding 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 cell-based therapeutics programs; 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 uncertainty whether any products that may be generated in our cell-based therapeutics programs will prove clinically effective and not cause tumors or other side effects; the uncertainty whether we will achieve revenues 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 Item 1A (Risk Factors) and elsewhere in our Form 10-K for the year ended December 31, 2006 and the risk factors set forth in Part II, Item 1A (Risk Factors) and elsewhere in this Form 10-Q.

**Overview**

Since our inception in 1988, we have been primarily engaged in research and development of human therapeutic products. Since the second half of 1999, our sole focus has been on developing cell-based therapeutics using our cellular technologies. We are currently conducting a Phase I clinical trial of our HuCNS-SC<sup>®</sup> product candidate (purified human neural stem cells) as a treatment for infantile and late infantile neuronal ceroid lipofuscinosis (NCL), a fatal neurodegenerative disease often referred to as Batten disease. As of October 2007, we have enrolled five of the six patients planned for this trial and we anticipate completing enrollment of all six patients by the end of 2007. Our Neural Program is also continuing basic research and preclinical development for additional potential indications in the Central Nervous System (CNS) field. We are targeting initiating clinical trials to test our HuCNS-SC product candidate as a treatment for spinal cord injury by mid-2008 and a myelin disorder in the brain by the end of 2008. In our Liver Program, we are engaged in preclinical development of our human liver engrafting cells (hLEC) and plan to initiate a clinical study to evaluate the hLEC as a cellular therapy for liver-based metabolic disease in early 2008. Our pancreas program is still in the discovery stage and further evaluation of the therapeutic potential of our candidate human pancreatic stem/progenitor cell will be required.

We have not derived any revenues from the sale of any products apart from license revenue for the research use of certain of our patented cells and media, and we do not expect to receive revenues from product sales for at least several years. We have not commercialized any product and in order to do so we must, among other things, substantially increase our research and development expenditures as research continues, product development efforts accelerate and clinical trials or similar studies are initiated. We had expenditures for screening and enrolling patients



**Table of Contents**

and for preparing HuCNS-SC doses for our Phase I clinical trial and will incur additional similar expenditures for any future clinical trials and similar studies. We previously had expenditures for toxicology and other studies in preparation for submitting the Investigational New Drug application (IND) for our Phase I trial for NCL to the FDA and getting it cleared by the FDA, and will incur additional similar expenditures for any future INDs or for the equivalent regulatory authorizations needed to conduct human clinical trials or similar studies outside the United States. We have incurred annual operating losses since inception and expect to incur substantial operating losses in the future. As a result, we are dependent upon external financing from equity and debt offerings and revenues from collaborative research arrangements with corporate sponsors to finance our operations. The Company has no such collaborative research arrangements at this time and there can be no assurance that such financing or partnering revenues will be available when needed or on terms acceptable to us.

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, the on-going expenses to lease and maintain our facilities in Rhode Island and the increasing costs associated with our facility in California. To expand and provide high quality systems and support to our Research and Development programs, as well as to enhance our internal controls over financial reporting, we will need to hire more personnel, which will lead to higher operating expenses.

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

**Use of Estimates**

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements. Actual results could differ from these estimates. The significant estimates include the accrued wind-down expenses related to our Rhode Island facilities and the grant date fair value of share based awards recognized as compensation expense in accordance with the provisions of SFAS 123R.

**Stock-Based Compensation**

In December 2004, FASB issued SFAS 123R *Share-Based Payment*, which is a revision of SFAS 123 *Accounting for Stock-Based Compensation* and amends SFAS No. 95 *Statement of Cash Flows*. SFAS 123R supersedes APB Opinion No. 25 *Accounting for Stock Issued to Employees* and its related implementation guidance. SFAS 123R covers a wide range of share-based compensation arrangements including stock options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. The new standard is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. We adopted SFAS 123R effective January 1, 2006. Adoption of the expensing requirements has increased our losses (see Note 1 under *Stock-Based Compensation* for assumptions used in calculating the fair value of stock-based compensation).

**Research and Development Costs**

We expense all research and development costs as incurred. Research and development costs include costs of personnel, external services, supplies, facilities and miscellaneous other costs.

**Wind-down and Exit Costs**

In connection with the wind-down of our former encapsulated cell technology operations, our research and manufacturing operations in Lincoln, Rhode Island, and the relocation of our remaining research and development activities and corporate headquarters to California in October 1999, we provided a reserve for our estimate of the exit cost obligation in accordance with EITF 94-3 *Other Cost to Exit an Activity*. The reserve reflects estimates of the ongoing costs of our former research 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

**Table of Contents**

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 the Company's 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 for years 2001 through 2006 was approximately 67%, varying from 49% to 80%. As of September 30, 2007, based on current information available to management, the vacancy rate is projected to be 89% for the remainder of 2007, and approximately 78% for 2008 and 70% from 2009 through the end of the lease. These estimates are based on actual occupancy in 2007, expiration of subleases in 2007 and 2008, predicted lead time for acquiring new subtenants, discussions with potential 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 2008 to the end of the Lease had been five percentage points higher or lower at September 30, 2007, then the reserve would have increased or decreased by approximately \$222,000. Similarly, a 5% increase or decrease in the operating expenses for the facility from 2007 would have increased or decreased the reserve by approximately \$113,000, and a 5% increase or decrease in the assumed average rental charge per square foot would have increased or decreased the reserve by approximately \$77,000. Management does not wait for specific events to change its estimate, but instead uses its best efforts to anticipate them on a quarterly basis.

The wind-down reserve at December 31, 2006 was \$5,512,000. For the three-and nine-month period ended September 30, 2007 we recorded actual expenses against this reserve of approximately \$344,000 and \$1,067,000 respectively. Based on management's evaluation of the factors mentioned, and particularly the projected vacancy rates described above, we adjusted the reserve to \$4,884,000 by recording an additional \$83,000 and \$439,000 for the three-and nine-month periods ended September 30, 2007.

**Recent Accounting Pronouncements**

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an *Interpretation of FASB Statement No. 109* ( FIN 48 ). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*, and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Additionally, FIN 48 provides guidance on subsequent derecognition of tax positions, financial statement classification, recognition of interest and penalties, accounting in interim periods, and disclosure and transition requirements. We adopted the provisions of FIN 48 on January 1, 2007. Previously, we had accounted for tax contingencies in accordance with Statement of Financial Accounting Standards 5, *Accounting for Contingencies* . As required by FIN 48, we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. At the adoption date, we applied FIN 48 to all tax positions for which the

statute of limitations remained open. The amount of unrecognized tax benefits as of January 1, 2007 was zero. There have been no material changes in

**Table of Contents**

unrecognized tax benefits since January 1, 2007. As of January 1, 2007, due to the carry forward of unutilized net operating losses and research and development credits, the Company is subject to U.S. Federal income tax examinations for the tax years 1992 through 2006, and to state income tax examinations for the tax years 1999 through 2006. Our Federal income tax return for the year 2004 is currently under examination. The ultimate outcome of the examination by the Internal Revenue Service cannot be determined at this time.

We recognize accrued interest related to unrecognized tax benefits in interest expense and penalties in operating expense. No amounts were accrued for the payment of interest and penalties at January 1, 2007. Our adoption of FIN 48 did not have a material effect on our financial condition, results of operations or cash flows (see Note 7).

In September 2006, the FASB issued FASB Statement No. 157, *Fair Value Measurements* (SFAS 157), which defines fair value, establishes a framework for measuring fair value under GAAP, and expands disclosures about fair value measurements. SFAS 157 applies to other accounting pronouncements that require or permit fair value measurements. The new guidance is effective for financial statements issued for fiscal years beginning after November 15, 2007, and for interim periods within those fiscal years. We are currently evaluating the requirements of SFAS 157; however, we do not believe that its adoption will have a material effect on our consolidated financial statements.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. SFAS 159's objectives are to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. SFAS 159 is effective as of the beginning of an entity's first fiscal year beginning after November 15, 2007. We are currently evaluating the potential impact, if any, that the adoption of SFAS 159 will have on our condensed consolidated financial statements.

In June 2007, the Financial Accounting Standards Board ratified a consensus opinion reached by the Emerging Issues Task Force (EITF) on EITF Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*. The guidance in EITF Issue 07-3 requires us to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the services expected to be performed, we would be required to expense the related capitalized advance payments. The consensus in EITF Issue 07-3 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2007 and is to be applied prospectively to new contracts entered into on or after December 15, 2007. Early adoption is not permitted. Retrospective application of EITF Issue 07-3 is also not permitted. We intend to adopt EITF Issue 07-3 effective January 1, 2008. The impact of applying this consensus will depend on the terms of our future research and development contractual arrangements entered into on or after December 15, 2007.

**RESULTS OF OPERATIONS****Three months ended September 30, 2007 and 2006****Revenue**

Revenue for the three-month period ended September 30, 2007, as compared with the same period in 2006, is summarized in the table below:

	2007	2006	Change from previous year	
			\$	%
Revenue:				
Revenue from licensing agreements	\$ 13,162	\$ 18,321	\$(5,159)	(28)%
Total revenue	\$ 13,162	\$ 18,321	\$(5,159)	(28)%

**Table of Contents**

Revenue for the three months ended September 30, 2007 and 2006 is solely comprised of amounts received from various licensees as part of our licensing agreements with them.

**Operating Expenses**

Operating expenses for the three-month period ended September 30, 2007, as compared with the same period in 2006, is summarized in the table below:

	2007	2006	Change from previous year	
			\$	%
Operating expenses:				
Research and development	\$5,621,955	\$3,523,078	\$2,098,877	60%
General and administrative	2,043,275	1,889,512	153,763	8%
Wind-down expenses	83,661	168,168	(84,507)	(50)%
<b>Total operating expenses</b>	<b>\$7,748,891</b>	<b>\$5,580,758</b>	<b>\$2,168,133</b>	<b>39%</b>

Research and development expenses totaled approximately \$5,622,000 for the three months ended September 30, 2007, compared with approximately \$3,523,000 for the same period in 2006. The increase of \$2,099,000, or approximately 60%, from 2006 to 2007 was primarily attributable to expansion of our operations in cell processing and clinical development, including an increase in personnel costs of approximately \$415,000, an increase in external services and clinical study costs of approximately \$1,428,000, and the remainder due to increases in supplies, rent and other operating expenses. At September 30, 2007, we had 49 full-time employees working in research and development and laboratory support services as compared to 37 at September 30, 2006.

General and administrative expenses were approximately \$2,043,000 for the three months ended September 30, 2007, compared with approximately \$1,890,000 for the same period in 2006. The increase of \$154,000, or approximately 8%, from 2006 to 2007 was primarily attributable to our patent related external legal fees.

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. At June 30, 2007, the reserve was approximately \$5,145,000. For the three months ended September 30, 2007, payments of approximately \$344,000 net of subtenant income were recorded against this reserve (see Note 4). At September 30, 2007, we re-evaluated the estimate and adjusted the reserve to approximately \$4,884,000 by recording an additional \$83,000 as wind-down expenses. Payments recorded against the reserve for the same period in 2006 were approximately \$368,000 and additional expenses recorded to adjust the reserve were approximately \$168,000. 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, we will periodically re-evaluate and adjust the reserve, as necessary.

**Other Income**

Other income for the three-month period ended September 30, 2007, as compared with the same period in 2006, is summarized in the table below:

	2007	2006	Change from previous year	
			\$	%
Other income (expense):				
License and settlement agreement, net				
Interest income	617,616	735,652	(118,036)	(16)%
Interest expense	(29,405)	(34,062)	4,657	(14)%
Other	(5,985)	(2,362)	(3,623)	153%



Edgar Filing: STEMCELLS INC - Form 10-Q

Total other income (expense)	\$582,226 20	\$699,228	(\$117,002)	(17)%
------------------------------	-----------------	-----------	-------------	-------

---

**Table of Contents**

Interest income for the three months ended September 30, 2007 and 2006 was approximately \$618,000 and \$736,000, respectively. The decrease in interest income for the 2007 period was primarily attributable to a lower average investment balance when compared to the three-month period in 2006.

Interest expense for the three months ended September 30, 2007 and 2006 was approximately \$29,000 and \$34,000, respectively. The decrease in interest expense in 2007 was attributable to lower outstanding debt and capital lease balances in 2007 compared to 2006. Other income (expense) comprises primarily of state franchise tax paid.

**Nine months ended September 30, 2007 and 2006****Revenue**

Revenue for the nine-month period ended September 30, 2007, as compared with the same period in 2006, is summarized in the table below:

	2007	2006	Change from previous year	
			\$	%
Revenue:				
Revenue from grants and licensing agreements	\$26,948	\$80,406	(\$53,458)	(66%)
Total revenue	\$26,948	\$80,406	(\$53,458)	(66%)

For the nine months ended September 30, 2007 and 2006, revenue from grants and licensing agreements totaled approximately \$27,000 and \$80,000 respectively. The decrease in revenue from 2006 to 2007 was primarily attributable to the completed draw down in 2006 of a September 2004 Small Business Technology Transfer grant for studies in Alzheimer's disease. The grant of \$464,000 for studies in Alzheimer's disease consisted of approximately \$308,000 for the first year and approximately \$156,000 for the remainder of the grant term, September, 2005 through June, 2006.

**Operating Expenses**

Operating expenses for the nine-month period ended September 30, 2007, as compared with the same period in 2006, is summarized in the table below:

	2007	2006	Change from previous year	
			\$	%
Operating expenses:				
Research and development	\$14,139,297	\$9,402,472	\$4,736,825	50%
General and administrative	5,716,480	4,979,349	737,131	15%
Wind-down expenses	439,471	499,186	(59,715)	(12)%
Total operating expenses	\$20,295,248	\$14,881,007	\$5,414,241	36%

Research and development expenses totaled approximately \$14,139,000 for the nine months ended September 30, 2007, compared with approximately \$9,402,000 for the same period in 2006. The increase of \$4,737,000, or approximately 50%, from 2006 to 2007 was primarily attributable to expansion of our operations in cell processing and clinical development, including an increase in personnel costs of approximately \$1,119,000, an increase in external services and clinical study costs of approximately \$2,792,000, with the remainder due to

**Table of Contents**

increases in supplies, rent and other operating expenses. At September 30, 2007, we had 49 full-time employees working in research and development and laboratory support services as compared to 37 at September 30, 2006.

General and administrative expenses were approximately \$5,716,000 for the nine months ended September 30, 2007, compared with approximately \$4,979,000 for the same period in 2006. The increase of \$737,000, or approximately 15%, from 2006 to 2007 was primarily attributable to an increase in personnel costs of approximately \$579,000, of which approximately \$427,000 was attributable to an increase in stock based compensation expense for grant of stock options and stock appreciation rights. The increase was also attributable to an increase in external services of approximately \$571,000 primarily attributable to an increase in patent related external legal fees. The increase in the afore mentioned expenses was partially offset by a net decrease in other operating 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. At December 31, 2006, the reserve was approximately \$5,512,000. For the nine months ended September 30, 2007, payments of \$1,067,000 net of subtenant income were recorded against this reserve (see Note 4). In the nine-month period ended September 30, 2007, we re-evaluated the estimate at September 30, 2007 and adjusted the reserve to approximately \$4,884,000 by recording in aggregate, an additional \$439,000 as wind-down expenses. Payments recorded against the reserve for the same period in 2006 were approximately \$950,000 and additional expenses recorded to adjust the reserve were approximately \$499,000. 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.

**Other Income**

Other income for the nine-month period ended September 30, 2007, as compared with the same period in 2006, is summarized in the table below:

	2007	2006	Change from previous year	
			\$	%
Other income (expense):				
License and settlement agreement, net	\$ 550,467	\$ 103,359	\$ 447,108	433%
Realized gain on sale of marketable securities	717,621		717,621	*
Interest income	1,926,753	1,779,016	147,737	8%
Interest expense	(96,777)	(111,159)	14,382	(13)%
Other	(27,009)	(16,309)	(10,700)	66%
<b>Total other income (expense)</b>	<b>\$3,071,055</b>	<b>\$1,754,907</b>	<b>\$1,316,148</b>	<b>75%</b>

\* Percentage change cannot be calculated

Income under licenses and settlement agreement for the nine months ended September 30, 2007 were for the value of additional shares received from ReNeuron (see Note 2). As a consequence of the anti-dilution provisions included in the agreement between StemCells and ReNeuron, StemCells was entitled to approximately 822,000 shares, net of approximately 12,000 shares to Neurospheres. We recorded approximately \$550,000 as other income for the fair value of the additional shares received. For the nine months ended September 30, 2006, we recorded approximately \$103,000 as other income for approximately 439,000 additional shares received from ReNeuron as a

consequence of the anti-dilution provisions in the agreement and net of shares due to Neurospheres. In February 2007, we sold 5,275,000 ordinary shares of ReNeuron for net proceeds of approximately \$3,077,000. We recorded approximately \$718,000 as realized gain for this transaction.

Interest income for the nine months ended September 30, 2007 and 2006 was approximately \$1,927,000 and \$1,779,000, respectively. The increase in interest income in 2007 was primarily attributable to a higher yield on a higher average investment balance in 2007 when compared to the nine-month period in 2006.

**Table of Contents**

Interest expense for the nine months ended September 30, 2007 and 2006 was approximately \$97,000 and \$111,000 respectively. The decrease in interest expense in 2007 was attributable to lower outstanding debt and capital lease balances in 2007 compared to 2006. Other income (expense) comprises primarily of state franchise tax paid.

**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, revenues from collaborative agreements, research grants and interest income.

We had cash, cash equivalents and short-term investments totaling \$43,294,205 at September 30, 2007. Short-term investments include securities (commercial paper, corporate bonds and asset backed securities) with days to maturity of 365 days or less, and excludes securities with an original holding period of 90 days or less, which securities are treated as cash equivalents. Cash equivalents are invested in US Treasury debt securities and commercial paper with maturities of 90 days or less. The table below summarizes our cash flows for the respective nine-month periods.

	2007	2006	Change from previous year	
			\$	%
Net cash used in operating activities	\$(15,009,151)	\$(12,077,200)	\$ (2,931,951)	24%
Net cash used in investing activities	(23,980,350)	\$ (1,318,929)	(22,661,421)	1,718%
Net cash provided by financing activities	4,723,173	34,295,771	(29,572,598)	(86)%
Increase (decrease) in cash and cash equivalents	\$(34,266,328)	\$ 20,899,642	\$(55,165,970)	(264)%

The increase of approximately \$2,932,000, or 24%, in cash used in operating activities from 2006 to 2007, was primarily attributable to the expansion of our operations in cell processing and clinical operations including an increase in personnel costs, an increase in external services and clinical study costs, increases in supplies other operating expenses.

Cash used in investing activities in 2007, was primarily for the purchase of short-term investments. Cash used in investing activities in 2006 was primarily for capital expenditures.

Net cash provided by financing activities in 2007 was primarily attributable to sales of shares of our common stock under our sales agreement with Cantor. From January 1, 2007 to September 30, 2007, we sold a total of 1,217,000 shares of our common stock under this agreement for gross proceeds of approximately \$3,805,000. Net cash provided by financing activities in 2006 was primarily attributable to the sale of 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. See the following discussion for more on our financing activities.

**Major sources of cash inflow for the nine months ended September 30, 2007 include the following:**

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. We issued 575,658 shares of our common stock and received proceeds of approximately \$1,094,000

In February 2007, we sold 5,275,000 ordinary shares of ReNeuron for net proceeds of approximately \$3,077,000. After this sale, as of September 30, 2007, we owned approximately 4,822,000 ordinary shares of ReNeuron with a fair market value of approximately \$1,819,000.

**Table of Contents**

On December 29, 2006, we filed a Prospectus Supplement announcing the entry of a sales agreement with Cantor under which up to 10,000,000 shares may be sold from time to time under a shelf registration statement. From January 1, 2007 to September 30, 2007, we sold a total of 1,217,000 shares of our common stock under this agreement for gross proceeds of approximately \$3,805,000. Subsequently, in October 2007, we sold an additional 590,000 shares of our common stock under this agreement for gross proceeds of approximately \$1,328,000. Cantor is paid compensation equal to 5.0% of the gross proceeds pursuant to the terms of the agreement.

**Major sources of cash inflow for the previous three years include the following:**

On April 6, 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 SEC. 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.

In 2005, an aggregate of 2,958,348 warrants were exercised. For the exercise of these warrants, we issued 2,842,625 shares of our common stock and received proceeds of approximately \$5,939,000.

On October 26, 2004, we entered into an agreement with institutional investors with respect to the registered direct placement of 7,500,000 shares of our common stock at a purchase price of \$3.00 per share, for gross proceeds of \$22,500,000. C.E. Unterberg, Towbin LLC (Unterberg) and Shoreline Pacific, LLC (Shoreline) served as placement agents for the transaction. We sold these shares under a shelf registration statement previously filed with and declared effective by the SEC. For acting as our placement agent Unterberg and Shoreline received fees of approximately \$1,350,000 and expense reimbursement of approximately \$40,000. No warrants were issued as part of this financing transaction.

On June 16, 2004, we entered into a definitive agreement with institutional and other accredited investors with respect to the private placement of approximately 13,160,000 shares of our common stock at a purchase price of \$1.52 per share, for gross proceeds of approximately \$20,000,000. Investors also received warrants exercisable for five years to purchase approximately 3,290,000 shares of common stock at an exercise price of \$1.90 per share. Unterberg served as placement agent for the transaction. For acting as our placement agent, Unterberg received fees totaling \$1,200,192, expense reimbursement of approximately \$25,000 and a five year warrant to purchase 526,400 shares of our common stock at an exercise price of \$1.89 per share.

**Future Contractual Cash Obligations**

We continue to have outstanding obligations in regard to our former facilities in Lincoln, Rhode Island, and expect to pay in 2007, based on past experience and current assumptions, approximately \$1,500,000 in lease payments and other operating expenses net of sub-tenant income. We have subleased a portion of these facilities and are actively seeking to sublease, assign or sell our remaining interests in these facilities. Failure to do so within a reasonable period of time will have a material adverse effect on our liquidity and capital resources.

The following table summarizes our future contractual cash obligations (including both Rhode Island and California leases, but excluding interest income and sub-lease income):

**Table of Contents**

	Total	Payable October to December 2007	Payable in 2008	Payable in 2009	Payable in 2010	Payable in 2011	Payable in 2012 and beyond
Capital lease payments	\$ 1,649,944	\$ 60,850	\$ 244,531	\$ 244,572	\$ 242,560	\$ 242,321	\$ 615,110
Operating lease payments	12,644,814	795,478	3,469,017	3,536,843	1,767,304	1,171,875	1,904,297
Total contractual cash obligations	\$ 14,294,758	\$ 856,328	\$ 3,713,548	\$ 3,781,415	\$ 2,009,864	\$ 1,414,196	\$ 2,519,407

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 revenues 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 businesses, 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. We have a shelf registration statement which, as of October 31, 2007, covered shares of our common stock up to a value of approximately \$59 million that could be available for financings. On December 29, 2006, we filed a Prospectus Supplement announcing the entry of a sales agreement with Cantor Fitzgerald & Co. under which up to 10,000,000 shares may be sold from time to time under the shelf registration statement. As of October 31, 2007, we have sold 1,807,000 of these shares for gross proceeds of approximately \$5,133,000. 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 research, preclinical and 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 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.

With the exception of operating leases for facilities, 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.

**Table of Contents****ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

In July 2005, the Company entered into a license and settlement agreement with ReNeuron Limited, a wholly owned subsidiary of ReNeuron Group plc, a publicly listed UK corporation (collectively referred to as ReNeuron). As part of the agreement, the Company 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. In return for the license, StemCells 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 StemCells 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. The agreement is Exhibit 10.71 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005. An amendment to the agreement was entered on April 3, 2006, a copy of which was attached as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006. As of December 31, 2006, the Company held 9,274,837 shares of ReNeuron common stock with fair value of approximately \$7,266,000. In February 2007, the Company sold 5,275,000 ordinary shares of ReNeuron for net proceeds of approximately \$3,077,000. The Company recorded approximately \$718,000 as realized gain for this transaction. In February 2007, ReNeuron issued additional shares of common stock as a consequence of certain anti-dilution provisions in the agreement. StemCells was entitled to approximately 822,000 shares net of approximately 12,000 shares to be transferred to Neurospheres. The Company recorded approximately \$550,000 as other income for the fair value of the additional shares received. As of September 30, 2007, the Company owned approximately 4,822,000 ordinary shares of ReNeuron with a fair market value of approximately \$1,819,000.

Changes in market value 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 income (loss) if deemed temporary and are not recorded as other income or loss until the shares are disposed of and a gain or loss realized. The unrealized loss as of September 30, 2007 is approximately \$451,000. A decline in the fair value of securities that is deemed other than temporary would be charged to earnings.

Company/Stock		Exchange	Associated Risks	No. of Shares at September 30, 2007	Share price at September 30, 2007 in GBP (£)	Exchange Rate at September 30, 2007 1 GBP = USD	Market Value in USD at September 30, 2007	Expected Future Cash Flows
ReNeuron Group plc/RENE	AIM (AIM is the London Stock Exchange's Alternative Investment Market)	- Lower share price - Foreign currency translation - Liquidity - Bankruptcy	4,821,924	0.1850	2.0389	\$ 1,818,813	(1)	



- (1) It is our intention to liquidate this investment when we can do so at prices acceptable to us. Although we are not legally restricted from selling the stock, the share price is subject to change and the volume traded has often been very small since the stock was listed on the AIM on August 12, 2005. The performance of ReNeuron Group plc stock since its listing does not predict its future value.

Other than the above, no significant changes have occurred in our quantitative and qualitative information about market risks disclosed in our Annual Report on Form 10-K for the fiscal year ending December 31, 2006.

#### 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

**Table of Contents**

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 its activities violate claims in four of our patents. Neuralstem has filed a motion for dismissal or summary judgment, 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.

In January 2007, Neuralstem petitioned the U.S. Patent and Trademark Office (PTO) to reexamine two of the patents in our infringement action against Neuralstem. In April 2007, Neuralstem petitioned the U.S. PTO to reexamine the remaining two patents in the suit. These requests were granted and, in June 2007, the parties voluntarily agreed to stay the pending litigation while the U.S. PTO considers these reexaminations. In October 2007, Neuralstem petitioned the U.S. PTO to reexamine a fifth patent (6,103,530), which claims a culture medium for proliferating mammalian neural stem cells. The Company expects all five patents to reissue in 2008.

**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 in the initial clinical trial for our first product candidate developed from our cellular technologies could substantially depress our stock price and prevent us from raising additional capital.***

Our ability to progress as a company is significantly dependent 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 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 by investors 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.

***We have limited capital resources and, based on currently estimated operating expenses, our existing capital resources may not be sufficient to fund our operations beyond the next twelve months.***

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 revenues to achieve or sustain profitability in the future. We do

**Table of Contents**

not expect to become profitable within the next several years, but rather expect to incur additional and increasing operating losses. 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 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. If we exhaust our cash reserves and are unable to realize adequate financing, we may be unable to meet operating obligations and be required to initiate bankruptcy proceedings. Our existing capital resources may not be sufficient to fund our operations beyond the next twelve months. The expansion of our clinical and other product development activities or the acquisition of additional technologies or businesses could cause us to need significant additional funds sooner than anticipated. We intend to pursue opportunities to obtain additional financing in the future through equity and debt financings, corporate alliances or combinations, grants and collaborative research arrangements. 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 research, preclinical and 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 to delay, scale back or eliminate some or all of our research and product development programs and/or our capital expenditures or to license our potential products or technologies to third parties.

***We have limited liquidity and capital resources and may not obtain the significant capital resources we will need to sustain our research and development efforts.***

We have limited liquidity and capital resources and must obtain substantial additional capital to support our research and development programs and to acquire businesses, technology or intellectual property rights we might consider necessary, useful or complementary to our current efforts. If we do not obtain the necessary capital resources, we may have to delay, reduce or eliminate some or all of our research and development programs or license our technology or any potential products to third parties rather than commercialize them ourselves. We intend to pursue our needed capital resources through equity and debt financings, corporate alliances or combinations, grants and collaborative research arrangements. We may fail to obtain the necessary capital resources from any such sources when needed or on terms acceptable to us. Our ability to complete successfully any such arrangements will depend upon market conditions and, more specifically, on continued progress with our potential products and cellular technologies.

***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 regards to product development and optimization, manufacturing, government regulation, third party reimbursement, and market acceptance. For example, the U.S. Food and Drug Administration (FDA) has relatively little experience with cell-based therapeutics, and the pathway to regulatory approval for our product candidates may accordingly be more complex and lengthy than the pathway for new conventional drugs. These challenges may prevent us from developing and commercializing products on a timely or profitable basis or at all.

***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 yet to develop any products that have been approved for marketing. 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 our product candidate is safe and effective. Except for the NCL trial currently being conducted at the 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.



**Table of Contents**

Our programs are still at the preclinical phase for our human liver engrafting cells, and at the discovery phase for our candidate human pancreas stem cell. While the FDA has permitted us to initiate our Phase I clinical trial of our proprietary HuCNS-SC product candidate (purified human neural stem cells) in NCL, and the Institutional Review Board of OHSU has approved the protocol, there can be no assurance that the clinical investigators will be able to identify suitable candidates for completion of the trial (which is planned to enroll six patients only five of whom have received transplants of HuCNS-SC cells so far), or of a successful outcome of the trial if candidates are enrolled. We may fail to discover the cells we are seeking, to develop any products, to obtain regulatory approvals, to enter clinical trials, or to commercialize any products. We may elect to delay or discontinue preclinical 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;

properly 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. 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. Furthermore, because transplantation of cells is a new form of therapy, the marketplace may not accept any products we may develop. If we do succeed in developing products, we will face many potential obstacles such as the need to obtain regulatory approvals and to develop or obtain manufacturing, marketing and distribution capabilities. In addition, we will face substantial additional risks such as product liability claims.

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 such as cyclosporine, FK506, or others to prevent rejection of the cells. 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. Immunosuppression is currently being tested with our therapeutic product candidate in our Phase I clinical trial for NCL (Batten disease).

***Our success will depend in large part on our ability to develop and commercialize products that treat diseases other than 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, if at all, we will 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 we believe to be necessary, useful or complementary to our current product development efforts and cell-based therapeutics business. Any such acquisition may require assimilation of the operations, products or product candidates and personnel of the acquired business and the training and integration of its employees, and could substantially increase our costs of operation, without any offsetting increase in revenues. 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 will 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

**Table of Contents**

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 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 \$1,550,000 in 2006; 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 \$450,000 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 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, 2006 and September 30, 2007, the reserve was \$6,750,000 and \$6,145,000, respectively. For the year 2006 and the nine-month period ending September 2007, we incurred \$1,295,000 and \$1,067,000 respectively, 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. If we enter collaboration agreements and any of our collaborators terminates its relationship with us or fails to perform its obligations in a timely manner, the development or commercialization of our technology and potential products may be adversely affected.

***Because the patient populations for many diseases of the central nervous system and the liver are very small, we may encounter difficulties in enrolling subjects in our clinical trials.***





**Table of Contents**

The first clinical application we are pursuing NCL (also known as Batten disease) has a very small patient population. From this small population, we must locate and enroll patients that satisfy the specific enrollment criteria for our clinical trials for this indication. This clinical trial may be delayed significantly or terminated if we are unable to enroll a sufficient number of qualified patients. Likewise, many of the other diseases of interest which may benefit from our investigative cell-based therapeutic products have equally small or smaller patient populations. Conducting clinical studies in such populations may be unexpectedly lengthy, difficult or costly because of enrollment delays or because of a lack of medical information about the particular disease states.

***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 license a number of patents and pending patent applications related to various stem and progenitor cells and methods of deriving and using them, including human neural stem cell cultures. 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 a 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. 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. Third parties may challenge our patents or governmental authorities may declare them invalid or reduce their scope. 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 challenges to the validity or enforceability of our intellectual property, which could result in the loss of these rights. In July 2006, we brought a patent infringement action against Neuralstem, Inc., which was stayed in June 2007 after Neuralstem petitioned the U.S. PTO to reexamine the four patents that are the subject of that litigation. Those reexamination proceedings are ongoing. In October 2007, Neuralstem petitioned the U.S. PTO to reexamine a fifth patent (6,103,530), which claims a culture medium for proliferating mammalian neural stem cells. In general litigation proceedings may also be 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. See Part II, Item 1. Legal 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 others are first to discover and patent the stem and progenitor cells we are seeking to discover, we could be blocked from further work on those cells.***

Because the first person or entity to discover and obtain a valid patent to a particular stem or progenitor cell may effectively block all others, it will be important for us to be the first to discover the cells we are seeking. Failure to be the first could prevent us from effectively commercializing these cells, which may prove more effective than our own proprietary cells in treating specific diseases.



**Table of Contents*****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 alternate 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. Also, if we use alternative non-infringing technology, we may need to demonstrate comparability in subsequent clinical trials.

We have obtained rights from 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. Many of the world's large pharmaceutical companies, including Merck, Pfizer, Abbott, Bristol-Myers Squibb, Novartis, and GlaxoSmithKline, have made significant commitments to the CNS field. Any cell-based therapeutic to treat diseases of, or injuries to, the CNS is likely to face intense competition from the small molecule sector. In addition, a number of biotechnology companies with resources far greater than ours may also emerge as competitors. These include Genzyme, Amgen, Cephalon, Shire Pharmaceuticals, BioMarin, Celgene, Biogen Idec, and Titan Pharmaceuticals/Schering AG. Finally, we also expect to compete with a host of smaller biotechnology companies, some of which are privately owned.

We believe that our human neural stem cells may have application to many or most of the Lysosomal Storage Diseases (LSDs) with CNS involvement. We are currently conducting a Phase I clinical trial at Oregon Health & Safety University to treat infantile and late infantile NCL (also known as Batten disease), which are among the LSDs that affect the CNS. There can be no assurance that the trial will demonstrate either safety or efficacy of our HuCNS-SC product candidate. There are, so far as we know, no approved therapies for NCL or any of the other CNS-specific LSDs. But other companies, including Genzyme, BioMarin and Shire, have products approved to treat peripheral aspects of some of the other LSDs, and other products are in clinical trials.

**Table of Contents**

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. In addition, new therapies may become available before we successfully develop a cell-based therapeutic for liver disease.

In the field of diabetes, a number of major companies currently market products for the treatment of diabetes and are also engaged in the research and development of new therapies. Such companies include Eli Lilly, Novo Nordisk, J&J, Amylin, ViaCell, and Serono. Consequently, should we successfully develop a cell-based therapy for diabetes, we would expect to face severe competition from these and similar companies.

***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 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.

Although we do not use embryonic stem cells, U.S. government regulation and potential regulation of embryonic tissue may lead top researchers to leave the field of stem cell research or the country altogether. Similarly, these factors may induce the best graduate students to choose other fields less vulnerable to changes in regulatory oversight, thus exacerbating the risk, discussed below, 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. In addition, we cannot be certain that constraints on the use of embryonic stem cells will not be extended to use of fetal stem or progenitor cells. Moreover, it is possible that concerns regarding research using embryonic stem cells will negatively impact our stock price and our ability to attract collaborators and investors.

We may apply for status under the Orphan Drug Act for some of our therapies to gain a seven-year period of marketing exclusivity for those therapies. The U.S. Congress in the past has considered, and in the future may again consider, legislation that would restrict the extent and duration of the market exclusivity of an orphan drug. If enacted, such legislation could prevent us from obtaining some or all of the benefits of the existing statute even if we were to apply for and obtain orphan drug status with respect to a potential product.

***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 chief operating officer, our vice presidents, and the heads of key departments or functions within the company. Although

**Table of Contents**

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

By developing, manufacturing and, ultimately, commercializing medical products, we are exposed to the risk of product liability claims. Product liability claims against us could entail 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 materials.***

The proliferation and manufacture of cell-based therapeutic products is a complicated and difficult process, dependent upon substantial know-how and subject to the need for continual process improvements. Our manufacturing experience is limited and the technologies are comparatively new. In addition, our ability to scale-up manufacturing to satisfy the requirements of our planned clinical trials is uncertain. Manufacturing disruptions may occur. In addition, 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 and available from a limited number of suppliers. At present, some of our process materials are single sourced, and the loss of one or more of these sources may adversely affect our business if we are unable to obtain 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

**Table of Contents**

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, and 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 has not 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 federal and state proposals to implement government control over health care costs. Efforts at health care reform 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 payers for health care goods and services may take in response to health care reform proposals or legislation. We cannot predict the effect government control and other health care reforms may have 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.***

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. Government regulation and threatened regulation of embryonic tissue could also harm our ability to attract and retain qualified scientific personnel by causing top researchers to leave the country or the field of stem cell research altogether; and by encouraging the best graduate students to choose other fields that are less vulnerable to changes in regulatory oversight.

***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 shareholders.***

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 shareholder approval. In addition, we have adopted a rights plan that generally permits our existing shareholders to acquire additional shares at a substantial discount to the market price in the event of certain attempts by third parties to acquire us. These rights, along with certain provisions in our corporate documents and 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 shareholders.

**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 of our 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;

**Table of Contents**

competition in our industry;

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, 2007, the trading price of our common stock as reported on the Nasdaq Global Market ranged from a high of \$6.77 to a low of \$1.77. 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 shareholders.***

As of September 30, 2007, there were outstanding warrants to purchase 1,355,000 shares of our common stock, at a weighted average exercise price of \$1.85 per share. As of September 30, 2007, there were also outstanding options to purchase 9,033,794 shares of our common stock, at a weighted average exercise price of \$2.36 per share. 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 businesses or technologies, to pay for services, or for other corporate purposes. Any such issuances will have the effect of diluting the interest of current shareholders.

**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**

None

**ITEM 5. OTHER INFORMATION**

There were no matters required to be disclosed in a current report on Form 8-K during the fiscal quarter covered by this report that were not so disclosed.

**ITEM 6. EXHIBITS**

**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



**Table of Contents**

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)

November 1, 2007

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

37

---

**Table of Contents**

Exhibit Index

- 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