STEMCELLS INC Form 10-Q November 05, 2009

# 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, 2009 Commission File Number: 0-19871 STEMCELLS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE 94-3078125

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer identification No)

3155 PORTER DRIVE PALO ALTO, CA 94304

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

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding twelve months (or for such shorter periods that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes b No o

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

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

Large accelerated filer o

Accelerated filer b

Non-accelerated filer o

Smaller reporting company o

(Do not check if a smaller reporting company)

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

At November 2, 2009, there were 118,349,587 shares of Common Stock, \$.01 par value, issued and outstanding.

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# NOTE REGARDING REFERENCES TO US AND OUR COMMON STOCK

Throughout this Form 10-Q, the words we, us, our, and StemCells refer to StemCells, Inc., including our directly a indirectly wholly-owned subsidiaries. Common stock refers to the common stock, \$.01 par value, of StemCells, Inc.

# PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS STEMCELLS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

		September 30, 2009	D	ecember 31, 2008	
ASSETS					
Current assets:					
Cash and cash equivalents	\$	28,226,515	\$	30,042,986	
Marketable securities		5,175,739		4,181,592	
Other receivables		273,937		164,204	
Notes receivable				298,032	
Prepaid and other current assets		492,979		645,242	
Total current assets		34,169,170		35,332,056	
Property, plant and equipment, net		3,012,856		3,173,468	
Other assets, non-current		2,357,968		2,079,278	
Goodwill and other intangible assets, net		5,384,762		645,538	
Total assets	\$	44,924,756	\$	41,230,340	
LIABILITIES AND STOCKHOLD	ERS	EQUITY			
Current liabilities:					
Accounts payable	\$	1,362,407	\$	1,078,123	
Accrued expenses and other liabilities		2,306,007		2,261,245	
Accrued wind-down expenses, current		1,435,234		1,420,378	
Deferred revenue, current		147,678		43,909	
Capital lease obligation, current		71,337		18,739	
Deferred rent, current		180,429		346,930	
Bond payable, current		157,500		149,167	
Total current liabilities		5,660,592		5,318,491	
Capital lease obligation, non-current		101,757		6,529	
Bond payable, non-current		741,250		860,000	
Fair value of warrant liability		9,262,448		8,439,931	
Deposits and other long-term liabilities		458,032		466,211	
Accrued wind-down expenses, non-current		3,322,076		4,092,939	
Deferred rent, non-current				90,215	
Deferred revenue, non-current		158,736		147,039	
Total liabilities		19,704,891		19,421,355	
Commitments and contingencies (Note 6)					
Stockholders equity:					
Common stock, \$.01 par value; 250,000,000 shares authorized;					
issued and outstanding 108,319,091 at September 30, 2009 and					
94,945,603 at December 31, 2008		1,083,190		949,455	
Additional paid-in capital		305,244,263		279,868,802	

Accumulated deficit Accumulated other comprehensive loss	(280,794,177) (313,411)	(259,001,524) (7,748)
Total stockholders equity	25,219,865	21,808,985
Total liabilities and stockholders equity	\$ 44,924,756	\$ 41,230,340
See Notes to Condensed Consolidated Financial Statements.		

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

	Three months ended September 30,			Nine months ended September 30,				
_		2009		2008		2009		2008
Revenue:								
Revenue from licensing agreements and	ф	00.006	ф	10.070	Ф	200.260	ф	50.561
grants	\$	98,806	\$	12,379	\$	300,260	\$	59,561
Revenue from product sales		154,362				274,961		
Total Revenue		253,168		12,379		575,221		59,561
Cost of product sales		(141,453)		,		(200,979)		,
1		, , ,						
Gross Profit		111,715		12,379		374,242		59,561
Operating expenses:								
Research and development		4,988,569		4,171,799		14,278,958		13,087,165
Selling, general and administrative		2,111,838		1,631,580		6,852,724		6,231,629
Wind-down expenses		(5,679)		53,636		539,821		381,136
Total operating expenses		7,094,728		5,857,015		21,671,503		19,699,930
Loss from operations		(6,983,013)	(	(5,844,636)		(21,297,261)	(	19,640,369)
Other income (expense):		, , ,				. , , ,	`	, , ,
Realized gain on sale of marketable								
securities						397,866		
Change in fair value of warrant liability		1,830,414				(822,517)		
Interest income		5,531		138,332		55,816		738,107
Interest expense		(27,613)		(26,849)		(84,863)		(84,010)
Other income (expense)		29,940		(10,800)		(41,694)		(18,145)
Total other income (expense), net		1,838,272		100,683		(495,392)		635,952
Net loss	\$	(5,144,741)	\$ (	(5,743,953)	\$	(21,792,653)	\$(	19,004,417)
Basic and diluted net loss per share	\$	(0.05)	\$	(0.07)	\$	(0.21)	\$	(0.24)
Shares used to compute basic and diluted		,		. ,		. ,		, ,
loss per share		108,257,345	8	0,961,150	1	103,071,957	8	30,827,141
See Notes to Condensed Consolidated Finan	cial S	Statements.						
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STEMCELLS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)

	Nine mon Septem	
	2009	2008
Cash flows from operating activities: Net loss	\$ (21,792,653)	\$ (19,004,417)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,220,813	895,617
Stock-based compensation	3,174,945	3,021,444
Gain on sale of marketable securities	(397,866)	
Change in fair value of warrant liability	822,517	
Changes in operating assets and liabilities:		
Other receivables	398,742	141,967
Prepaid and other current assets	196,778	441,662
Other assets, non-current	(269,393)	(322,821)
Accounts payable and accrued expenses	(509,958)	(1,415,468)
Accrued wind-down expenses	(775,547)	(707,061)
Deferred revenue	(303,027)	(2,464)
Deferred rent	(256,715)	(214,104)
Net cash used in operating activities	(18,491,364)	(17,165,645)
Cash flows from investing activities:		
Proceeds from the sale of marketable securities	4,510,213	22,658,794
Purchase of marketable securities	(4,977,982)	
Repayment (payment) of advances under notes receivable	(79,829)	1,000,000
Purchases of property, plant and equipment	(485,750)	(261,693)
Acquisition of other assets	(15,000)	(24,375)
Net cash provided by (used in) investing activities	(1,048,348)	23,372,726
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	17,694,812	194,061
Proceeds from the exercise of stock options	252,984	123,253
Proceeds from the exercise of warrants	331,501	
Payments related to net share issuance of stock based awards	(380,548)	
Proceeds from (repayment of) capital lease obligations	147,825	(13,038)
Repayment of bonds payable	(110,417)	(100,000)
Net cash provided by financing activities	17,936,157	204,276
Increase (decrease) in cash and cash equivalents	(1,603,555)	6,411,357
Effects of foreign exchange rate changes on cash	(212,916)	
Cash and cash equivalents, beginning of period	30,042,986	9,759,169
Cash and cash equivalents, end of period	\$ 28,226,515	\$ 16,170,526

Supplemental disclosure of cash flow information:

Interest paid	\$ 84,863	\$ 84,010
Supplemental schedule of non-cash investing and financing activities:		
Stock issued as part of our acquisition of the operations of SCS Plc (1)	\$ 4,425,500	
Forgiveness of principal and accrued interest on notes receivable (1)	\$ 709,076	
Stock issued for licensing agreement (2)	\$ 10,000	\$ 10,000

(1) On April 1, 2009, we acquired the operations of Stem Cell Sciences Plc (SCS). As consideration, we issued to SCS 2,650,000 shares of common stock with a closing price of \$1.67 per share and waived certain commitments of SCS to repay approximately \$709,000 in principal and accrued interest owed to us.

(2) Under terms of a license agreement with the California Institute of Technology (Cal Tech), annual fees of \$5,000 were due on each of two patents to which we hold a license from Cal Tech, payable in cash or common stock at our choice. We elected to pay the fees in stock

and issued 5,900

and 6,924 shares of our common stock in 2009 and 2008 respectively.

See Notes to Condensed Consolidated Financial Statements.

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# Notes to Condensed Consolidated Financial Statements (Unaudited) September 30, 2009 and 2008

# Note 1. Summary of Significant Accounting Policies

# **Nature of Business**

StemCells, Inc., a Delaware corporation, is a biopharmaceutical company that operates in one segment, the development and commercialization of cell-based technologies.

The accompanying financial data as of and for the three and nine months ended September 30, 2009 and 2008 has been prepared by us, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) have been condensed or omitted pursuant to such rules and regulations. The December 31, 2008 condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. However, we believe that the disclosures are adequate to make the information presented not misleading. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and the notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. Subsequent events have been evaluated through November 4, 2009, which represents the issuance date of these unaudited condensed consolidated financial statements.

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

### **Principles of Consolidation**

The condensed consolidated financial statements include the accounts of StemCells, Inc., and our wholly-owned subsidiaries, StemCells California, Inc., StemCells Property Holding LLC, Stem Cell Sciences Holdings Ltd; Stem Cell Sciences (UK) Ltd; and Stem Cell Sciences (Australia) Pty Ltd. All significant intercompany accounts and transactions have been eliminated.

### **Use of Estimates**

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

Significant estimates include the following:

the grant date fair value of stock-based awards recognized as compensation expense (see Note 4, Stock Based Compensation );

accrued wind-down expenses (see Note 5, Wind-Down Expenses );

the fair value of warrants recorded as a liability (see Note 7, Warrant Liability); and

the fair value of goodwill and other intangible assets (see Note 9, Acquisition of SCS Operations ).

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### **Financial Instruments**

Cash and Cash Equivalents

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

Marketable Securities

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

If the estimated fair value of a security is below its carrying value, we evaluate whether we have the intent and ability to retain our investment for a period of time sufficient to allow for any anticipated recovery to the cost of the investment, and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. Other-than-temporary declines in estimated fair value of all marketable securities are charged to Other income (expense), net. No such impairment was recognized during the nine months ended September 30, 2009 or 2008.

Other Receivables

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

### **Revenue Recognition**

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

# **Stock-Based Compensation**

Compensation expense for stock-based payment awards to employees is based on their grant date fair value as calculated and amortized over their vesting period. See Note 4, Stock-Based Compensation for further information.

Compensation expense for stock-based awards granted to non-employees is based on the estimated fair value of the award which is re-measured at each reporting date and is amortized over the remaining vesting period.

We use the Black-Scholes-Merton (Black-Scholes) model to calculate the fair value of stock-based awards.

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### **Net Loss per Share**

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

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

	T	Three months ended September 30,				Nine months ended September			
		2009		2008		2009		2008	
Net loss	\$	(5,144,741)	\$	(5,743,953)	\$	(21,792,653)	\$	(19,004,417)	
Weighted average shares									
outstanding used to compute basic									
and diluted net loss per share		108,257,345		80,961,150		103,071,957		80,827,141	
Basic and diluted net loss per share	\$	(0.05)	\$	(0.07)	\$	(0.21)	\$	(0.24)	

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

	2009	2008
Options	9,293,703	8,471,887
Restricted stock units	2,367,901	1,650,000
Warrants	10,344,828	1,255,000
Total	22,006,432	11,376,887

### **Comprehensive Loss**

Comprehensive loss is comprised of net losses and other comprehensive loss or income (OCL). OCL includes certain changes in stockholders—equity that are excluded from net losses. Specifically, we include in OCL changes in unrealized gains and losses on our marketable securities and unrealized gains and losses on foreign currency translations. Accumulated other comprehensive loss was \$313,411 as of September 30, 2009 and \$7,748 as of December 31, 2008.

The activity in OCL was as follows:

	Th	Three months ended September 30,			N	eptember 30,		
		2009		2008		2009		2008
Net loss Net change in unrealized gains and losses on marketable	\$	(5,144,741)	\$	(5,743,953)	\$	(21,792,653)	\$	(19,004,417)
securities Net change in unrealized gains and losses on foreign currency		(5,248)		(272,066)		128,512		(1,691,631)
translations		(208,537)				(434,175)		
Comprehensive loss	\$	(5,358,526)	\$	(6,016,019)	\$	(22,098,316)	\$	(20,696,048)

### **Recent Accounting Pronouncements**

In August 2009, the FASB issued an Accounting Standard Update (ASU) under the topic *Fair Value*Measurements and Disclosures Measuring Liabilities at Fair Value. This ASU provides amendments for fair value measurements of liabilities. It provides clarification that under circumstances in which, a quoted price in an active

market for the identical liability is not available, a reporting entity is required to measure fair value using one or more techniques prescribed in this update. This ASU also clarifies that when estimating a fair value of a liability, a reporting entity is not required to include a separate input or adjustment to other inputs relating to the existence of a restriction that prevents the transfer of the liability. This ASU is effective for the first reporting period (including interim periods) beginning after issuance or fourth quarter 2009. The Company is assessing the impact, if any, of this ASU on our condensed consolidated financial statements and disclosures.

### **Note 2. Financial Instruments**

The following table summarizes the fair value of our cash, cash equivalents and available-for-sale marketable securities held in our current investment portfolio:

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	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
<b>September 30, 2009</b>				
Cash	\$ 515,459	\$	\$	\$ 515,459
Cash equivalents (money market accounts) Marketable debt securities, current (maturity	27,711,056			27,711,056
within 1 year)	4,980,519		(711)	4,979,808
Marketable equity securities, current	74,456	121,475		195,931
Total cash, cash equivalents, and marketable				
securities	\$ 33,281,490	\$ 121,475	\$ (711)	\$ 33,402,254
December 31, 2008				
Cash	\$ 243,883	\$	\$	\$ 243,883
Cash equivalents (money market accounts)	29,799,103			29,799,103
Marketable debt securities, current (maturity				
within 1 year)	4,002,537		(7,748)	3,994,789
Marketable equity securities, current	186,803			186,803
Total cash, cash equivalents, and marketable				
securities	\$ 34,232,326	\$	\$ (7,748)	\$ 34,224,578

Gross unrealized gains and losses on cash equivalents were not material at September 30, 2009 and December 31, 2008. At September 30, 2009, our investment in marketable debt securities was composed primarily of U.S. Treasury securities.

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Our investment in marketable equity securities consists of ordinary shares of ReNeuron Group Plc (ReNeuron), a publicly listed U.K. corporation. In July 2005, we entered into an agreement with ReNeuron under which we granted ReNeuron a license that allows ReNeuron to exploit their c-mycER conditionally immortalized adult human neural stem cell technology for therapy and other purposes. We received shares of ReNeuron common stock, as well as a cross-license to the exclusive use of ReNeuron stechnology for certain diseases and conditions, including lysosomal storage diseases, spinal cord injury, cerebral palsy, and multiple sclerosis. The agreement also provides for full settlement of any potential claims that either we or ReNeuron might have had against the other in connection with any putative infringement of certain of each party s patent rights prior to the effective date of the agreement. In July and August 2005, we received approximately 8,836,000 ordinary shares of ReNeuron common stock, net of approximately 104,000 shares that were transferred to NeuroSpheres, and subsequently, as a result of certain anti-dilution provisions in the agreement, we received approximately 1,261,000 more shares, net of approximately 18,000 shares that were transferred to NeuroSpheres. In February 2007, we sold 5,275,000 shares for net proceeds of approximately \$3,075,000. We recognized approximately \$716,000 as realized gain from this transaction. At December 31, 2008, we owned 4,821,924 shares of ReNeuron with a carrying and fair market value of approximately \$187,000. In the first quarter of 2009, we sold 2,900,000 shares of ReNeuron and received net proceeds of approximately \$510,000 for a realized gain of approximately \$398,000. As of September 30, 2009, we owned 1,921,924 shares of ReNeuron with a carrying and fair market value of approximately \$196,000.

Changes in the fair market value of our ReNeuron shares as a result of changes in market price per share or the exchange rate between the U.S. dollar and the British pound are accounted for as an unrealized gain or loss under other comprehensive income (loss) if deemed temporary and are not recorded as other income (expense), net until the shares are disposed of and a gain or loss realized. If the fair value of a security is below its carrying value, we evaluate whether we have the intent and ability to retain our investment for a period of time sufficient to allow for any anticipated recovery to the cost of the investment, and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. Other-than-temporary declines in estimated fair value of all marketable securities are charged to other income (expense), net. For the three months ended September 30, 2009, we recorded an unrealized gain of approximately \$5,000.

Notes Receivable

In December 2008 and March 2009, we made two secured loans to Stem Cell Sciences Plc (SCS) in connection with our acquisition negotiations with SCS. The loans accrued interest at 8% per annum and were repayable six months after the initial funding. At March 31, 2009, the principal and accrued interest for these two loans together totaled approximately \$709,000. On April 1, 2009, we closed the acquisition of the operations of SCS, and in connection with that transaction, we waived the obligation of SCS to repay the principal and accrued interest of these two loans.

### **Note 3. Fair Value Measurement**

The following tables present our assets and liabilities that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy. The fair value hierarchy has three levels based on the reliability of the inputs used to determine fair value

- Level 1 Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level 2 Directly or indirectly observable inputs other than in Level 1, that include quoted prices for similar assets or liabilities in active markets or quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3 Unobservable inputs which are supported by little or no market activity that reflects the reporting entity s own assumptions about the assumptions that market participants would use in pricing the asset or liability.

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

Our cash equivalents and marketable debt and equity securities are classified within Level 1 or Level 2. This is because our cash equivalents and marketable securities are valued primarily using quoted market prices or alternative pricing sources and models utilizing market observable inputs. We currently do not have any Level 3 financial assets or liabilities.

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

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	Fair Value M at Reporting Quoted			
A	Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	S	As of September 30, 2009
Assets				
Cash Equivalents:				
Money market funds	\$ 1,266,401	\$	\$	1,266,401
U.S. Treasury securities	31,424,463			31,424,463
Marketable Securities:				
Equity securities	195,931			195,931
Total assets	\$ 32,886,795			32,886,795
Liabilities				
Bond payable	\$	\$ 898,750	\$	898,750
Note 1 Steel Paged Companyation				

# **Note 4. Stock-Based Compensation**

We currently grant stock-based awards under three equity incentive plans. We had 19,025,067 shares authorized to be granted under the three plans as of September 30, 2009. Under these plans we may grant incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, and performance-based shares to our employees, directors and consultants, at prices determined by our Board of Directors. Incentive stock options may only be granted to employees under these plans with a grant price not less than the fair market value of the stock on the date of grant.

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

	Three months ended September 30,			Nine months ended September 30,			
	2009		2008		2009	_	2008
Research and development expense	\$ 555,450	\$	473,828	\$	1,542,023	\$	1,430,157
General and administrative expense	542,400		465,351		1,525,699		1,443,788
Total employee stock-based compensation expense and effect on net loss	\$ 1,097,850	\$	939,179	\$	3,067,722	\$	2,873,945
Effect on basic and diluted net loss per common share	\$ (0.01)	\$	(0.01)	\$	(0.03)	\$	(0.04)

As of September 30, 2009, we had approximately \$6,200,000 of total unrecognized compensation expense related to unvested awards of stock options and restricted stock units granted under our various stock-based plans that we expect to recognize over a weighted-average vesting period of 2.5 years.

Stock Options

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

A summary of our stock option activity for the three months ended September 30, 2009 is as follows:

	Number of options	Weighted-average exercise price (\$)
Balance at June 30, 2009	9,380,197	2.27
Granted	47,500	1.70
Exercised	(69,654)	1.11
Cancelled	(64,340)	1.93
Outstanding options at September 30, 2009	9,293,703	2.28

The estimated weighted-average fair value of options granted in the three months ended September 30, 2009 and 2008 was approximately \$1.38 and \$0.93 per share respectively. The fair value of options granted is estimated as of the date of grant using the Black-Scholes option pricing model, which requires certain assumptions as of the date of grant. The weighted-average assumptions used as of September 30, 2009 and 2008 were as follows:

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	Three mon	Nine months ended			
	Septemb	oer 30,	September 30,		
	2009	2008	2009	2008	
Expected life (years)(1)	7.59	7.71	7.38	7.22	
Risk-free interest rate(2)	3.22%	3.56%	2.79%	3.32%	
Expected volatility(3)	91.83%	93.78%	93.56%	93.81%	
Expected dividend yield(4)	0%	0%	0%	0%	

- (1) The expected term represents the period during which our stock-based awards are expected to be outstanding. We estimated this amount based on historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements, and expectation of future employee behavior, including post-vesting terminations.
- (2) The risk-free interest rate is based on U.S. Treasury debt securities with maturities close to the expected term of the option as of the date of grant.
- (3) Expected volatility is

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

### (4) We have not

historically

issued any

dividends, and

we do not

expect to in the

foreseeable

future.

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

A summary of changes in unvested options for the three months ended September 30, 2009 is as follows:

		Weighted-average grant
	Number of options	date fair value (\$)
Unvested options at June 30, 2009	3,265,484	1.62
Granted	47,500	1.38
Vested	(360,500)	1.95
Cancelled	(64,340)	1.45
Unvested options at September 30, 2009	2,888,144	1.58

The estimated fair value of shares vested were approximately \$703,000 in the three months ended September 30, 2009.

### Restricted Stock Units

We have granted restricted stock units (RSUs) to certain employees which entitle the holders to receive shares of our common stock upon vesting of the RSUs. The fair value of restricted stock units granted are based upon the market price of the underlying common stock as if it were vested and issued on the date of grant.

A summary of our restricted stock unit activity for the three months ended September 30, 2009 is as follows:

		Weighted-average grant
	Number of RSUs	date fair value (\$)
Balance at June 30, 2009 (1)	2,303,068	1.49
Granted (2)	103,333	1.70
Vested and converted to common shares		
Cancelled	(38,500)	1.26

Balance unvested at September 30, 2009

2,367,901

1.50

(1) 1,100,000 of these restricted stock units vest and convert into shares of our common stock over a three year period from the date of grant: one-third of the award will vest on each grant date anniversary over the following three years. 953,068 of these restricted stock units vest and convert into shares of our common stock over a four year period from the date of grant: one-fourth of the award will vest on each grant date anniversary over the following four years. 250,000 of these restricted stock units will vest and convert into shares of our common stock subject to attainment of certain performance criteria and will be forfeited if not met by March 31, 2011.

(2) 93,333 of these restricted stock units vest and convert into shares of our common stock over a four year period from the date of grant: one-fourth of the award will vest on each grant date anniversary over the following four years. 10,000 of these restricted stock units vest and convert into shares of our common stock after one year from the date of grant.

Stock Appreciation Rights

In July 2006, we granted cash-settled Stock Appreciation Rights (SARs) to certain employees that give the holder the right, upon exercise, to the difference between the price per share of our common stock at the time of exercise and the exercise price of the SARs.

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The SARs have a maximum term of ten years with an exercise price of \$2.00, which is equal to the market price of our common stock at the date of grant. The SARs vest 25% on the first anniversary of the grant date and 75% vest monthly over the remaining three-year service period. Compensation expense is based on the fair value of SARs which is calculated using the Black-Scholes option pricing model. The stock-based compensation expense and liability are re-measured at each reporting date through the date of settlement.

A summary of the changes in SARs for the three months ended September 30, 2009 is as follows:

Outstanding at June 30, 2009 Granted Exercised Forfeited and expired	Number of SARs 1,430,849
Outstanding SARs at September 30, 2009	1,430,849
SARs exercisable at September 30, 2009	1,132,755

For the three months ended September 30, 2009, we re-measured the liability related to the SARs and due to a decrease in our common stock price, the re-measured fair value of the liability reduced compensation expense by approximately \$5,000. For the same period in 2008, we recorded compensation expense of approximately \$25,000.

At September 30, 2009, approximately \$210,000 of unrecognized compensation expense related to SARs is expected to be recognized over a weighted average vesting period of approximately 1.0 year. The resulting effect on net loss and net loss per share attributable to common stockholders is not likely to be representative of the effects in future periods, due to changes in the fair value calculation which is dependent on the stock price, volatility, interest and forfeiture rates, additional grants and subsequent periods of vesting.

### **Note 5. Wind-Down Expenses**

Rhode Island

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

The summary of the changes to our wind-down reserve related to this facility as of September 30, 2009 and December 31, 2008 were as follows:

	January to	April to	July to September	January to September	January to December
	March 31, 2009	June 30, 2009	30, 2009	30, 2009	31, 2008
Accrued wind-down reserve at beginning of period Less actual expenses recorded	\$ 4,448,000	\$4,323,000	\$ 4,060,000	\$ 4,448,000	\$ 4,875,000
against estimated reserve during the period Additional expense recorded	(331,000)	(293,000)	(286,000)	(910,000)	(1,293,000)
to revise estimated reserve at period-end	206,000	30,000	(6,000)	230,000	866,000

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Revised reserve at period-end Add deferred rent at	4,323,000	4,060,000	3,768,000	3,768,000	4,448,000
period-end	1,014,000	962,000	911,000	911,000	1,065,000
Total accrued wind-down expenses at period-end (current and non current)	\$ 5,337,000	\$ 5,022,000	\$ 4,679,000	\$ 4,679,000	\$ 5,513,000
Accrued wind-down expenses, current Accrued wind-down expenses, non-current	\$ 1,496,000 3,841,000	\$ 1,438,000 3,584,000	\$ 1,357,000 3,322,000	\$ 1,357,000 3,322,000	\$ 1,420,000 4,093,000
Total accrued wind-down expenses	\$ 5,337,000	\$ 5,022,000	\$ 4,679,000	\$ 4,679,000	\$ 5,513,000

# Australia

On April 1, 2009, as part of our acquisition of the SCS operations, we acquired operations near Melbourne, Australia. In order to

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reduce operating complexity and expenses, we made the decision to close our site in Australia and consolidate personnel and programs to our Cambridge, U.K. and Palo Alto, California sites. U.S. GAAP requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. In accordance with U.S. GAAP requirements, at June 30, 2009, we established a short-term reserve of approximately \$310,000 for the estimated costs to close down and exit our Australia operations. The reserve reflects the estimated cost to terminate our facility lease in Australia (with an original termination date of December 31, 2010), employee termination benefits and other liabilities associated with the wind-down and relocation of our operations in Australia.

	July to tember 30, 2009
Accrued wind-down reserve at June 30, 2009 Less actual expenses recorded against estimated reserve during the period Additional expense recorded to revise estimated reserve at period-end Accrued wind-down reserve at September 30, 2009	\$ 310,000 (232,000)
Accrued wind-down reserve at September 30, 2009	\$ 78,000

# **Note 6. Commitments and Contingencies**

### Leases

Capital leases

We entered into direct financing transactions with the State of Rhode Island and received proceeds from the issuance of industrial revenue bonds totaling \$5,000,000 to finance the construction of our pilot manufacturing facility in Rhode Island. The related lease agreements are structured such that lease payments fully fund all semiannual interest payments and annual principal payments through maturity in August 2014. The interest rate for the remaining bond series is 9.5%. The bond contains certain restrictive covenants which limit, among other things, the payment of cash dividends and the sale of the related assets. The outstanding principal was approximately \$899,000 at September 30, 2009 and \$1,009,000 at December 31, 2008.

Operating leases

We entered into a fifteen-year lease agreement for a scientific and administrative facility in Rhode Island in connection with a sale and leaseback arrangement in 1997. The lease term expires June 30, 2013. The lease contains escalating rent payments, which we recognize on a straight-line basis. Deferred rent expense for this facility was approximately \$911,000 at September 30, 2009 and \$1,065,000 at December 31, 2008, and is included as part of the wind-down accrual on the accompanying condensed consolidated balance sheet.

We entered into and amended a lease agreement for an approximately 68,000 square foot facility located at the Stanford Research Park in Palo Alto, California. The facility includes space for animals, laboratories, offices, and a GMP (Good Manufacturing Practices) suite. GMP facilities can be used to manufacture materials for clinical trials. Under the term of the agreement we were required to provide a letter of credit for a total of approximately \$778,000, which serves as a security deposit for the duration of the lease term. The letter of credit issued by our financial institution is collateralized by a certificate of deposit for the same amount, which is reflected as restricted cash in other assets, non-current on our condensed consolidated balance sheets. The lease contains escalating rent payments, which we recognize as operating lease expense on a straight-line basis. Deferred rent was approximately \$180,000 as of September 30, 2009 and \$437,000 as of December 31, 2008, and is reflected as deferred rent on our condensed consolidated balance sheet. As of September 30, 2009, we had a space-sharing agreement covering approximately 10,451 square feet of this facility, under which we receive base payments plus a proportionate share of the operating expenses based on square footage over the term of the agreement. In October 2009, we amended the lease to extend the expiry date of the lease term from March 31, 2010 to August 31, 2011. The aggregate rent payment for the extended lease term is approximately \$3,100,000.

On April 1, 2009, as part of our acquisition of the operations of SCS, we acquired operations in Cambridge, U.K.. Our wholly-owned subsidiary, Stem Cell Sciences UK Ltd, has two lease agreements with Babraham Bioscience

Technologies Ltd., for approximately 3,900 square feet in total of office and lab space in Cambridge, U.K. The lease term for one ends on February 28, 2010, and the other on March 26, 2011, with annual lease payments of approximately 59,000 U.K. pounds (GBP) and 51,000 GBP, respectively.

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On April 1, 2009, as part of our acquisition of the operations of SCS, we acquired operations near Melbourne, Australia. Our wholly-owned subsidiary, Stem Cell Sciences (Australia) Pty Ltd, is in a lease agreement with Monash University for approximately 1,938 square feet of office and lab space in Victoria, Australia. The lease term ends on December 31, 2010. In order to reduce operating complexity and expenses, we made the decision to close our site in Australia and consolidate personnel and programs to our Cambridge, U.K. and Palo Alto, California sites. We paid approximately \$86,000 for an early termination of the lease which cost is included as part of our wind-down expenses in the accompanying condensed consolidated financial statements.

# **Contingencies**

In July 2006, we filed suit against Neuralstem, Inc. in the Federal District Court for the District of Maryland, alleging that Neuralstem s activities violate claims in four of the patents we exclusively licensed from NeuroSpheres. In December 2006, Neuralstem petitioned the U.S. Patent and Trademark Office (PTO) to reexamine two of the patents in our infringement action against Neuralstem, namely U.S. Patent No. 6,294,346 (claiming the use of human neural stem cells for drug screening) and U.S. Patent No. 7,101,709 (claiming the use of human neural stem cells for screening biological agents). In April 2007, Neuralstem petitioned the PTO to reexamine the remaining two patents in the suit, namely U.S. Patent No. 5,851,832 (claiming methods for proliferating human neural stem cells) and U.S. Patent No. 6,497,872 (claiming methods for transplanting human neural stem cells). These requests were granted by the PTO and, in June 2007, the parties voluntarily agreed to stay the pending litigation while the PTO considered these reexamination requests. In April 2008, the PTO upheld the 832 and 872 patents, as amended, and issued Notices of Intent to Issue an Ex Parte Reexamination Certificate for both. In May 2009, the PTO upheld the 346 and 709 patents, as amended, and issued Notices of Intent to Issue an Ex Parte Reexamination Certificate for both.

In May 2008, we filed a second patent infringement suit against Neuralstem and its two founders, Karl Johe and Richard Garr. In this suit, which we filed in the Federal District Court for the Northern District of California, we allege that Neuralstem's activities infringe claims in two patents we exclusively license from NeuroSpheres, specifically U.S. Patent No. 7,361,505 (claiming composition of matter of human neural stem cells derived from any source material) and U.S. Patent No. 7,115,418 (claiming methods for proliferating human neural stem cells). In addition, we allege various state law causes of action against Neuralstem arising out of its repeated derogatory statements to the public about our patent portfolio. Also in May 2008, Neuralstem filed suit against us and NeuroSpheres in the Federal District Court for the District of Maryland seeking a declaratory judgment that the 505 and 418 patents are either invalid or are not infringed by Neuralstem and that Neuralstem has not violated California state law. In August 2008, the California court transferred our lawsuit against Neuralstem to Maryland for resolution on the merits. In July 2009, the Maryland District Court granted our motion to consolidate these two cases with the litigation we initiated against Neuralstem in 2006. In August 2009, the Maryland District Court approved a scheduling order submitted by the parties for discovery and trial.

# **Indemnification Agreement**

In July 2008, we amended our 1997 and 2000 license agreements with NeuroSpheres. NeuroSpheres is the holder of certain patents exclusively licensed by us, including the six patents that are the basis of our patent infringement suits against Neuralstem. As part of the amendment, we agreed to pay all reasonable litigation costs, expenses and attorney is fees incurred by NeuroSpheres in the declaratory judgment suit between us and Neuralstem. In return, we are entitled to off-set all litigation costs incurred in that suit and any successor suit against amounts that would otherwise be owed under the license agreements, such as annual maintenance fees, milestones and royalty payments. At this time, we cannot estimate the likely total costs of our pending litigation with Neuralstem, given the unpredictable nature of such proceedings, or the total amount we may ultimately owe under the NeuroSpheres license agreements. However, the ability to apply the offsets will run for the entire term of each license agreement. For these reasons, we have chosen to approximate the potential value of the offset receivable by assuming that all litigation charges actually incurred in the consolidated cases, as of September 30, 2009, will ultimately be offset against royalties owed. Management will reevaluate this assumption on a quarterly basis based on actual costs and other relevant factors.

### Note 7. Warrant Liability

In November 2008, we sold 13,793,104 units to institutional investors at a price of \$1.45 per unit, for gross proceeds of \$20,000,000. The units, each of which consisted of one share of common stock and a warrant to purchase 0.75 shares of common stock at an exercise price of \$2.30 per share, 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 \$18,637,000. We recorded the fair value of the warrants to purchase 10,344,828 shares of our common stock as a liability. The fair value of the warrant liability is revalued at the end of each reporting period, with the change in fair value of the warrant liability recorded as a gain or loss in our Consolidated Statements of Operations. We used the Black-Scholes option pricing

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model to estimate the fair value of these warrants. In using this model, we make certain assumptions about risk-free interest rates, dividend yields, volatility and expected term of the warrants. Risk-free interest rates are derived from the yield on U.S. Treasury debt securities. Dividend yields are based on our historical dividend payments, which have been zero to date. Volatility is derived from the historical volatility of our common stock as traded on Nasdaq. The expected term of the warrants is based on the time to expiration of the warrants from the date of measurement.

The assumptions used for the Black-Scholes option pricing model at September 30, 2009 are as follows:

Expected life (years)	4.62
Risk-free interest rate	2.39%
Expected volatility	77.85%
Expected dividend yield	0%

					Change in value for the
	At	September			
		30,	At June 30,	qu	arter ended
				Se	ptember 30,
		2009	2009		2009
Fair value of warrant liability	\$	9,262,448	\$11,092,862	\$	(1,830,414)

The fair value of the warrants will continue to be classified as a liability until such time as the warrants are exercised, expire or an amendment of the warrant agreement renders these warrants to be no longer classified as a liability.

### **Note 8. Common Stock**

On June 8, 2009, we filed a prospectus supplement that relates to the issuance and sale, from time to time, of up to \$30,000,000 of our common stock, through our sales agent Cantor Fitzgerald & Co (Cantor). These sales will be made pursuant to the terms of a sales agreement with Cantor, under which we will pay Cantor a fee of 3.0% of the gross proceeds. The prospectus is a part of a registration statement that we filed with the SEC on June 25, 2008, using a shelf registration process. Under this shelf registration process, we may offer to sell in one or more offerings up to a total dollar amount of \$100,000,000. Under our sales agreement with Cantor, in the three-month period ended September 30, 2009, we sold 1,555,000 shares of common stock at a price of approximately \$1.80 per share for gross proceeds of approximately \$2,800,000.

### **Note 9. Acquisition of SCS Operations**

On April 1, 2009, we acquired the operations of SCS for an aggregate purchase price of approximately \$5,135,000. The acquired operations includes proprietary cell technologies relating to embryonic stem cells, induced pluripotent stem (iPS) cells, and tissue-derived (adult) stem cells; expertise and infrastructure for providing cell-based assays for drug discovery; a media formulation and reagent business; and an intellectual property portfolio with claims relevant to cell processing, reprogramming and manipulation, as well as to gene targeting and insertion. These acquired operations will help us pursue applications of our cell technologies to develop cell-based research tools, which we believe represent nearer-term commercial opportunities.

As consideration for the acquired operations, we issued to SCS 2,650,000 shares of common stock and waived certain commitments of SCS to repay approximately \$709,000 in principal and accrued interest owed to us. The closing price of our common stock on April 1, 2009 was \$1.67 per share.

This transaction has been accounted for as a business purchase. We have evaluated the acquired assets and liabilities and believe that the historical cost of the net tangible assets acquired approximated fair market value. The primary method used to calculate the fair value of the intangible assets was the Excess Earnings Method. These intangible assets will be amortized over their estimated lives.

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The purchase price has been allocated as follows:

		<b>Estimated life of</b>
	Allocated purchase price	intangible assets in years
Net tangible assets	\$ 36,000	
Intangible assets:		
Customer relationships and developed technology	1,310,000	6 to 9
In process research and development	1,340,000	13 to 19
Trade name	310,000	15
Goodwill	2,139,000	N/A
Total	\$ 5 135 000	

In connection with our acquisition of the operations of SCS, and in accordance with U.S. GAAP, our acquisition costs of approximately \$692,000, which primarily consisted of legal and other professional fees, were expensed in the nine-month period ended September 30, 2009. These costs were reported in our condensed consolidated statements of operations as part of our selling, general & administrative expense.

# **Note 10. Subsequent Events**

Subsequent events have been evaluated through November 4, 2009, which represents the issuance date of these unaudited condensed consolidated financial statements.

In November 2009, we raised gross proceeds of \$12,500,000 through the sale to certain institutional investors of 10,000,000 shares of common stock and warrants to purchase 4,000,000 shares of common stock. The common stock and warrants were sold in units, with each unit consisting of (i) one share of common stock and (ii) a warrant to purchase 0.4 of a share of common stock at an exercise price of \$1.50 per share, and the purchase price was \$1.25 per unit. The warrants will generally be exercisable for a period of five years beginning six months after the date of issuance. The shares and warrants were offered as a registered direct offering under our effective shelf registration statement previously filed with the SEC. We received total proceeds, net of offering expenses and placement agency fees, of approximately \$11,900,000. The net proceeds of the financing will be used for general corporate purposes, including working capital, product development and capital expenditures, as well as for other strategic purposes.

In October 2009, we amended the lease agreement for our facility located at the Stanford Research Park in Palo Alto, California, to extend the expiry date of the lease term from March 31, 2010 to August 31, 2011. The aggregate rent payment for the extended lease term is approximately \$3,100,000.

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

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 the fact that additional trials will be required to confirm the safety and demonstrate the efficacy of the Company s HuCNS-SC cells for the treatment of neuronal ceroid lipofuscinosis (NCL, also known as Batten disease) or any other disease; uncertainty as to whether the U.S. Food and Drug Administration (FDA) or other regulatory authorities will permit us to proceed with clinical testing of proposed products despite the novel and unproven nature of our technologies; the risk that one or more of our clinical trials or studies could be substantially delayed beyond their expected dates or cause us to incur substantial unanticipated costs; uncertainties in our ability to obtain the capital resources needed to continue our current research and development operations and to conduct the research, preclinical development and clinical trials necessary for regulatory approvals;

uncertainties about the design of future clinical trials and whether the Company will receive the necessary support of a clinical trial site and its institutional review board to pursue future clinical trials in NCL, PMD or in proposed therapies for other diseases or conditions; the uncertainty regarding our ability to obtain a corporate partner or partners, if needed, to support the development and commercialization of our potential cell-based therapeutics products; the uncertainty regarding the outcome of our clinical trials or studies we may conduct in the future; the uncertainty regarding the validity and enforceability of our issued patents; the risk that we may not be able to manufacture additional master and working cell banks when needed; the uncertainty whether any products that may be generated in our cell-based therapeutics programs will prove clinically safe and effective; the uncertainty whether we will achieve significant revenue from product sales or become profitable; uncertainties regarding our obligations with respect to our former encapsulated cell therapy facilities in Rhode Island; obsolescence of our technologies; competition from third parties; intellectual property rights of third parties; litigation risks; and other risks to which we are subject. All forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by the cautionary statements and risk factors set forth in Risk Factors in Part II, Item 1A of this report and Part I, Item 1A included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

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### Overview

# The Company

We are focused on developing and commercializing cell-based technologies. Our research and development (R&D) programs are primarily focused on identifying and developing potential cell-based therapeutics which can either restore or support organ function. In particular, since we relocated our corporate headquarters to California in 1999, our R&D efforts have been directed at refining our methods for identifying, isolating, culturing, and purifying the human neural stem cell and human liver engrafting cells (hLEC) and developing these as potential cell-based therapeutics for the central nervous system (CNS) and the liver, respectively. In our CNS Program, our HuCNS-SC® product candidate (purified human neural stem cells) is in clinical development for two indications. In January 2009, we completed a six patient Phase I clinical trial of HuCNS-SC cells in infantile and late infantile neuronal ceroid lipofuscinosis (NCL), two forms of a group of disorders often referred to as Batten disease. The data from this Phase I trial showed that the HuCNS-SC cells were well tolerated, and there was evidence that the donor cells engrafted and survived. In December 2008, the FDA approved our IND to initiate a Phase I clinical trial of HuCNS-SC cells in a second indication, Pelizeaus-Merzbacher Disease (PMD), a fatal myelination disorder in the brain. In September 2009, we announced that we plan to initiate the PMD trial at University of California-San Francisco Children s Hospital. We expect to begin enrolling patients by the end of 2009 and that the trial will take 12-18 months to complete. In addition, our HuCNS-SC cells are in preclinical development for spinal cord injury and retinal disorders. In our Liver Program, we are in preclinical research and development with our human liver engrafting cells and we plan to seek the necessary approvals to initiate a clinical study to evaluate hLEC as a potential cellular therapy, with the initial indication likely to be liver-based metabolic disorders. For a brief description of our significant therapeutic research and development programs see Overview Research and Development Programs in the Business Section of Part I, Item 1 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. We have also conducted research on several other cell types and in other areas, which could lead to other possible product candidates, process improvements or further research activities.

On April 1, 2009, we acquired the operations of Stem Cell Sciences Plc (SCS). The acquired business includes proprietary cell technologies relating to embryonic stem cells, induced pluripotent stem (iPS) cells, and tissue-derived (adult) stem cells; expertise and infrastructure for providing cell-based assays for drug discovery; a media formulation and reagent business; and an intellectual property portfolio with claims relevant to cell processing, reprogramming and manipulation, as well as to gene targeting and insertion. These acquired operations will help us pursue applications of our cell technologies to develop cell-based research tools, which we believe represent nearer-term commercial opportunities. See Note 9 Acquisition of SCS Operations in the notes to condensed financial statements of Part I, Item 1 of this form 10-O for further information.

We have not derived any revenue or cash flows from the sale or commercialization of any therapeutic products. Through our acquisition of the SCS operations, we have derived revenue from sales and royalties on sales of cell culture media. We have also derived revenue from licensing rights to our intellectual property. To date, all such revenue has been limited and there can be no assurance that these revenues will increase. As a result, we have incurred annual operating losses since inception and expect to incur substantial operating losses in the future. Therefore, we are dependent upon external financing from equity and debt offerings and revenue from collaborative research arrangements with corporate sponsors to finance our operations. We have no such collaborative research arrangements at this time and there can be no assurance that such financing or partnering revenue will be available when needed or on terms acceptable to us.

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

Overall, we expect our R&D expenses to be substantial and to increase for the foreseeable future as we continue the development and clinical investigation of our current and future therapeutic product candidates. In addition, we expect our expenses and expenditures to increase as we begin to develop and commercialize non-therapeutic

applications of our cell-based technologies. However, expenditures on R&D programs are subject to many uncertainties, including whether we develop our product candidates with a partner or independently. We cannot forecast with any degree of certainty which of our product candidates or technologies will be subject to future collaboration, when such collaboration agreements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. In addition, there are numerous factors associated with the successful commercialization of any of our cell-based products, including future regulatory requirements and legal restrictions on the procurement of human tissue for medical research, many of which cannot be determined with accuracy at this time given the stage of

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our development and the novel nature of stem cell technologies. The regulatory pathways, both in the United States and internationally, are complex and fluid given the novel and, in general, clinically unproven nature of stem cell technologies. At this time, due to such uncertainties and inherent risks, we cannot estimate in a meaningful way the duration of, or the costs to complete, our R&D programs or whether, when or to what extent we will generate revenues or cash inflows from the commercialization and sale of any of our therapeutic product candidates or any non-therapeutic applications of our cell-based technologies. While we are currently focused on advancing each of our product development programs, our future R&D expenses will depend on the determinations we make as to the scientific and clinical prospects of each product candidate, as well as our ongoing assessment of the regulatory requirements and each product candidate s commercial potential.

There can be no assurance that we will be able to develop any product successfully, or that we will be able to recover our development costs, whether upon commercialization of a developed product or otherwise. We cannot provide assurance that any of these programs will result in products that can be marketed or marketed profitably. If certain of our development-stage programs do not result in commercially viable products, our results of operations could be materially adversely affected.

# Significant Events

In November 2009, we raised gross proceeds of \$12,500,000 through the sale to certain institutional investors of 10,000,000 shares of common stock and warrants to purchase 4,000,000 shares of common stock. The common stock and warrants were sold in units, with each unit consisting of (i) one share of common stock and (ii) a warrant to purchase 0.4 of a share of common stock at an exercise price of \$1.50 per share, and the purchase price was \$1.25 per unit. The warrants will generally be exercisable for a period of five years beginning six months after the date of issuance. The shares and warrants were offered as a registered direct offering under our effective shelf registration statement previously filed with the SEC. We received total proceeds, net of offering expenses and placement agency fees, of approximately \$11,900,000. The net proceeds of the financing will be used for general corporate purposes, including working capital, product development and capital expenditures, as well as for other strategic purposes.

In October 2009, we announced new preclinical data showing that our human neural stem cells protect cone photoreceptors (cones) in the eye from progressive degeneration and preserve visual function long term. Cones are light sensing cells that are highly concentrated within the macula of the human eye, and the ability to protect these cells suggests a promising approach to treating age-related macular degeneration (AMD), the leading cause of vision loss and blindness in people over the age of 55. These findings were presented at the Society for Neuroscience 2009 Annual Meeting.

In September 2009, we announced the publication of preclinical data demonstrating for the first time that transplantation of our proprietary, purified human neural stem cells delays the loss of motor function in a mouse model of infantile neuronal ceroid lipofuscinosis (NCL). NCL, commonly referred to as Batten disease, is a fatal neurodegenerative disorder in children. This paper, Neuroprotection of Host Cells by Human Central Nervous System Stem Cells in a Mouse Model of Infantile Neuronal Ceroid Lipofuscinosis, was featured in the September 2009 edition of the peer-reviewed journal *Cell Stem Cell*.

In September 2009, we announced that we plan to initiate with the University of California, San Francisco (UCSF) Children's Hospital a Phase I clinical trial to evaluate the therapeutic potential of our proprietary HuCNS-Se product candidate (purified human neural stem cells) to treat Pelizaeus-Merzbacher Disease (PMD), a myelination disorder that primarily affects infants and young children. In this trial, patients with a fatal form of PMD will be transplanted with our HuCNS-SC cells to evaluate safety and to explore the ability of the cells to myelinate the patients nerve axons.

### **Critical Accounting Policies and the Use of Estimates**

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

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

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### Stock-Based Compensation

U.S. GAAP requires us to recognize expense related to the fair value of our stock-based payment awards, including employee stock options. Under the provisions of U.S. GAAP, employee stock-based payment is estimated at the date of grant based on the award s fair value using the Black-Scholes-Merton (Black-Scholes) option-pricing model and is recognized as expense ratably over the requisite service period. The Black-Scholes option-pricing model requires the use of certain assumptions, the most significant of which are our estimates of the expected volatility of the market price of our stock and the expected term of the award. Our estimate of the expected volatility is based on historical volatility. The expected term represents the period during which our stock-based awards are expected to be outstanding. We estimate the expected term based on historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements, and expectation of future employee behavior, including post-vesting terminations.

We review our valuation assumptions at each grant date and, as a result, our assumptions in future periods may change. As of September 30, 2009, total compensation cost related to unvested stock-based awards not yet recognized was approximately \$6,200,000, which is expected to be recognized as expense over a weighted-average period of 2.5 years. See also Note 4, Stock-Based Compensation, in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-O for further information.

### Wind-down expenses Rhode Island

In connection with exiting our research and manufacturing operations in Lincoln, Rhode Island, and the relocation of our corporate headquarters and remaining research laboratories to California in October 1999, we provided a reserve for our estimate of the exit cost obligation. The reserve reflects estimates of the ongoing costs of our former scientific and administrative facility in Lincoln, which we hold on a lease that terminates on June 30, 2013. We are seeking to sublease, assign, sell, or otherwise divest ourselves of our interest in the facility at the earliest possible time, but we cannot determine with certainty a fixed date by which such events will occur, if at all.

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

Management forms its best estimate on a quarterly basis, after considering actual sublease activity, reports from our broker/realtor about current and predicted real estate market conditions in Rhode Island, the likelihood of new subleases in the foreseeable future for the specific facility and significant changes in the actual or projected operating expenses of the property. We discount the projected net outflow over the term of the leasehold to arrive at the present value, and adjust the reserve to that figure. The estimated vacancy rate for the facility is an important assumption in determining the reserve because changes in this assumption have the greatest effect on estimated sublease income. In addition, the vacancy rate estimate is the variable most subject to change, while at the same time it involves the greatest judgment and uncertainty due to the absence of highly predictive information concerning the future of the local economy and future demand for specialized laboratory and office space in that area. The average vacancy rate of the facility over the last six years (2003 through 2008) was approximately 74%, varying from 66% to 89%. As of September 30, 2009, based on current information available to management, the vacancy rate is projected to be approximately 77% for 2009, approximately 73% for 2010 and approximately 70% from 2011 through the end of the lease. These estimates are based on actual occupancy as of September 30, 2009, predicted lead time for acquiring new subtenants, historical vacancy rates for the area, and assessments by our broker/realtor of future real estate market conditions. If the assumed vacancy rate from 2010 to the end of the lease had been 5% higher or lower at September 30, 2009, then the reserve would have increased or decreased by approximately \$146,000. Similarly, a 5% increase or decrease in the operating expenses for the facility from 2010 on would have increased or decreased the reserve by approximately \$93,000, and a 5% increase or decrease in the assumed average rental charge per square foot would have increased or decreased the reserve by approximately \$43,000. Management does not wait for specific

events to change its estimate, but instead uses its best efforts to anticipate them on a quarterly basis. See Note 5 Wind-down expenses, in the notes to condensed consolidated financial statements of Part I, Item 1 of this Form 10-Q for further information.

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### Wind-down expenses Australia

On April 1, 2009, as part of our acquisition of the SCS operations, we acquired operations near Melbourne, Australia. In order to reduce operating complexity and expenses, we made the decision to close our site in Australia and consolidate personnel and programs to our Cambridge, U.K. and Palo Alto, California sites. U.S. GAAP requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. In accordance with U.S. GAAP requirements, at June 30, 2009, we established a short-term reserve of approximately \$310,000 for the estimated costs to close down and exit our Australia operations. The reserve reflects the estimated cost for an early termination of our facility lease in Australia (with an original termination date of December 31, 2010), employee termination benefits and other liabilities associated with the wind-down and relocation of our operations in Australia.

### **Business Combinations**

The operating results of acquired companies or operations are included in our consolidated financial statements starting on the date of acquisition. Goodwill is recorded at the time of an acquisition and is calculated as the difference between the aggregate consideration paid for an acquisition and the fair value of the net tangible and intangible assets acquired. Accounting for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired, including in-process research and development (IPR&D). Goodwill and intangible assets deemed to have indefinite lives are not amortized but are subject to annual impairment tests. If the assumptions and estimates used to allocate the purchase price are not correct, or if business conditions change, purchase price adjustments or future asset impairment charges could be required. We test goodwill for impairment on an annual basis or more frequently if we believe indicators of impairment exist. Impairment evaluations involve management estimates of asset useful lives and future cash flows. Significant management judgment is required in the forecasts of future operating results that are used in the evaluations. It is possible, however, that the plans and estimates used may be incorrect. If our actual results, or the plans and estimates used in future impairment analysis, are lower than the original estimates used to assess the recoverability of these assets, we could incur additional impairment charges in a future period.

# **Results of Operations**

Our results of operations have varied significantly from year to year and quarter to quarter and may vary significantly in the future due to the occurrence of material recurring and nonrecurring events, including without limitation the receipt and payment of recurring and nonrecurring licensing payments, the initiation or termination of clinical studies, research collaborations and development programs for both cell-based therapeutic products and research tools, unpredictable or unanticipated manufacturing and supply costs, unanticipated capital expenditures necessary to support our business, expenses arising out of the integration of the acquired SCS operations, developments in on-going patent protection and litigation, the on-going expenses to lease and maintain our Rhode Island facilities, and the increasing costs associated with operating our California and Cambridge, U.K. facilities.

### Revenue and Cost of Product Sales

Revenue for the three and nine month periods ended September 30, 2009, as compared with the same periods in 2008, is summarized in the table below:

		Three n				N	line mont	hs ended,			
	September 30			Change in 2009 versus 2008			September 30		Change in 2009 versus 2008		08
		2009	2008	<b>\$</b>	<b>%</b>		2009	2008		\$	<b>%</b>
Revenue:											
Licensing											
agreements and											
grants	\$	98,806	\$12,379	\$ 86,427	698%	\$	300,260	\$ 59,561	\$	240,699	404%
Product sales		154,362		154,362	*		274,961			274,961	*

Total revenues	253,168	12,379	240,789	1,945%	575,221	59,561	515,660	866%
Cost of product sales	(141,453)		(141,453)	*	(200,979)		(200,979)	*
Gross Profit	\$ 111.715	\$ 12.379	\$ 99,336	802%	\$ 374,242	\$ 59.561	\$ 314.681	528%

# Calculation is not meaningful

Total revenue in the third quarter of 2009 was approximately \$253,000, which was 698% higher than total revenue in the third quarter of 2008. The increase in 2009 compared to 2008 was primarily attributable to consolidation of revenues from the acquired SCS operations in the third quarter of 2009, which were not part of our operations in the same period in 2008.

Third quarter ended September 30, 2009 versus third quarter ended September 30, 2008. Licensing and grant revenue for the third quarter of 2009 were approximately \$86,000, or 698%, higher as compared to the same period in 2008. This increase was primarily attributable to approximately \$44,000 in grant and licensing revenue recognized and consolidated as part of our acquisition of the SCS operations, revenue of approximately \$37,000 from an existing grant which we were awarded in October 2008 from the National Institute of Diabetes and Digestive and Kidney Diseases to research and develop a potential cell-based therapeutic for liver disease, and an increase of approximately \$5,000 in licensing revenue from existing licensing agreements. In the third quarter of 2009, we

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recognized approximately \$154,000 and \$141,000 as revenue from product sales and cost of product sales, respectively, in connection with our acquisition of the SCS operations, compared to none in the same period of 2008.

Nine-month period ended September 30, 2009 versus nine-month period ended September 30, 2008. Licensing and grant revenue for the nine-month period ended September 30, 2009 were approximately \$241,000, or 404%, higher as compared to the same period in 2008. This increase was primarily attributable to approximately \$136,000 in grant and licensing revenue recognized and consolidated as part of our acquisition of the SCS operations, Revenue of approximately \$89,000 from an existing grant which we were awarded in October 2008 from the National Institute of Diabetes and Digestive and Kidney Diseases to research and develop a potential cell-based therapeutic for liver disease, and an increase of approximately \$16,000 in licensing revenue from existing licensing agreements. For the nine months ended September 30, 2009, we recognized and consolidated approximately \$275,000 and \$201,000 as revenue from product sales and cost of product sales, respectively, in connection with of our acquisition of the SCS operations, compared to none in the same period of 2008.

# **Operating Expenses**

Operating expenses for the three and nine month periods ended September 30, 2009, as compared with the same periods in 2008, are summarized in the table below:

	Three months ended, September 30		Change in 2009 versus 2008		Nine months ended, September 30		Change in 2009 versus 2008		
	2009	2008		\$	<b>%</b>	2009	2008	\$	%
Operating expenses:									
Research &									
development	\$4,988,569	\$4,171,799	\$ 8	816,770	20%	\$ 14,278,958	\$13,087,165	\$ 1,191,793	9%
Selling, general &									
administrative	2,111,838	1,631,580	4	480,258	29%	6,852,724	6,231,629	621,095	10%
Wind-down									
expenses	(5,679)	53,636		(59,315)	(111)%	539,821	381,136	158,685	42%
Total operating									
expenses	\$7,094,728	\$5,857,015	\$ 1,2	237,713	21%	\$21,671,503	\$ 19.699,930	\$ 1,971,573	10%

Research and Development Expenses