

Intra-Cellular Therapies, Inc.
Form 10-Q
November 05, 2013
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2013

or

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

For the transition period from _____ to _____

Commission File Number: 000-54896

INTRA-CELLULAR THERAPIES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

36-4742850
(I.R.S. Employer
Identification No.)

3960 Broadway

New York, New York 10032
(Address of principal executive offices)

10032
(Zip Code)

(212) 923-3344

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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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.

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 4, 2013, the registrant had 22,134,647 shares of common stock outstanding.

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In this Quarterly Report on Form 10-Q, the terms we, us, our, and the Company mean Intra-Cellular Therapies, Inc. and our subsidiaries. ITI refers to our wholly-owned operating subsidiary ITI, Inc. and its subsidiary.

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Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	September 30, 2013	December 31, 2012
	<i>(Unaudited)</i>	<i>(Audited)</i>
Assets		
Current assets:		
Cash and cash equivalents	\$ 44,072,012	\$ 15,645,528
Certificates of deposit	2,000,000	3,500,000
Accounts receivable	251,291	300,429
Prepaid expenses and other current assets	806,288	188,702
Total current assets	47,129,591	19,634,659
Property and equipment, net	75,700	58,266
Other assets	130,755	130,755
Total assets	\$ 47,336,046	\$ 19,823,680
Liabilities, redeemable convertible preferred stock, and stockholders deficit		
Current liabilities:		
Accounts payable	\$ 4,027,097	\$ 41,608
Accrued and other current liabilities	2,571,126	404,656
Accrued employee benefits	759,757	726,657
Deferred revenue	416,682	1,666,674
Total current liabilities	7,774,662	2,839,595
Stockholders' equity (deficit):		
Common stock, \$.0001 par value: 100,000,000 shares authorized; 22,134,647 and 14,599,612 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	2,213	1,460
Additional paid-in capital	89,082,858	47,678,924
Accumulated deficit	(49,523,687)	(30,696,299)
Total stockholders' equity	39,561,384	16,984,085
Total liabilities and stockholders' equity	\$ 47,336,046	\$ 19,823,680

See accompanying notes.

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Intra-Cellular Therapies, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations

	Three-Months Ended September 30,		Nine-Months Ended September 30,	
	2013	2012	2013	2012
	<i>(Unaudited)</i>	<i>(Unaudited)</i>	<i>(Unaudited)</i>	<i>(Unaudited)</i>
Revenues	\$ 667,955	\$ 377,911	\$ 1,909,471	\$ 2,449,055
Costs and expenses:				
Research and development	4,157,742	1,797,429	16,897,903	14,969,710
General and administrative	1,295,571	802,053	3,245,585	2,916,139
Total costs and expenses	5,453,313	2,599,482	20,143,488	17,885,849
Loss from operations	(4,785,358)	(2,221,571)	(18,234,017)	(15,436,794)
Interest expense	(131,888)		(604,960)	
Interest income	5,626	6,656	11,589	29,730
Income taxes		(8,230)		(24,690)
Net loss	(4,911,620)	(2,223,145)	(18,827,388)	(15,431,754)
Net loss per common share:				
Basic	\$ (0.42)	\$ (0.40)	\$ (2.43)	\$ (2.75)
Dilutive	(0.42)	(0.40)	(2.43)	(2.75)
Weighted average number of common shares:				
Basic & Dilutive	11,779,745	5,607,022	7,737,250	5,603,575

See accompanying notes.

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Intra-Cellular Therapies, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

	Nine-Months Ended September 30	
	2013	2012
	<i>(Unaudited)</i>	<i>(Unaudited)</i>
Cash flows provided by (used in) operating activities		
Net loss	\$ (18,827,388)	\$ (15,431,754)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation	15,821	39,413
Share-based compensation expense	282,450	282,629
Changes in operating assets and liabilities:		
Accounts receivable	49,138	241,534
Prepaid expenses and other assets	(617,586)	2,099
Accounts payable	3,985,489	2,078,182
Accrued and other current liabilities and employee benefits	2,398,611	(738,321)
Deferred revenue	(1,249,992)	(1,249,995)
Net cash used in operating activities	(13,963,457)	(14,776,213)
Cash flows provided by (used in) investing activities		
Purchases of investments		(1,000,000)
Maturities of investments	1,500,000	5,950,123
Purchase of property and equipment	(33,255)	(38,957)
Net cash provided by investing activities	1,466,745	4,911,166
Cash flows provided by (used in) financing activities		
Proceeds from stock option exercises	316,827	7,022
Proceeds from stock subscription	109,834	
Gross proceeds of public offering	43,941,850	
Payment of costs of public offering	(3,445,315)	
Net cash provided by financing activities	40,923,196	7,022
Net increase (decrease) in cash and cash equivalents	28,426,484	(9,858,025)
Cash and cash equivalents at beginning of period	15,645,528	13,693,215
Cash and cash equivalents at end of period	\$ 44,072,012	\$ 3,835,190
Cash paid for interest	\$ 3,317	\$
Cash paid for taxes	\$ 13,437	\$ 13,857
<i>See accompanying notes.</i>		

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Intra-Cellular Therapies, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

September 30, 2013

1. Organization

Intra-Cellular Therapies, Inc. (the Company), through its wholly-owned operating subsidiary, ITI, Inc. (ITI), is a biopharmaceutical company focused on the discovery and clinical development of innovative, small molecule drugs that address underserved medical needs in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system (CNS). The Company's lead product candidate, ITI-007, is in Phase 2 clinical trials as a first-in-class treatment for schizophrenia.

ITI was incorporated in the State of Delaware on May 22, 2001 under the name Intra-Cellular Therapies, Inc. and commenced operations in June 2002. ITI was founded to discover and develop drugs for the treatment of neurological and psychiatric disorders.

On August 29, 2013, ITI completed a reverse merger (the Merger) with a public shell company named Oneida Resources Corp. (Oneida). Oneida was formed in August 2012 as a vehicle to investigate and, if such investigation warranted, acquire a target company or business seeking the perceived advantages of being a publicly held corporation. In the Merger, each outstanding share of capital stock of ITI was exchanged for 0.5 shares of common stock of Oneida, and each outstanding option and outstanding warrant of ITI was assumed by Oneida and became exercisable for 0.5 shares of Oneida common stock. As a result of the Merger and related transactions, ITI survived as a wholly-owned subsidiary of Oneida, Oneida changed its fiscal year end from March 31 to December 31, and Oneida changed its name to Intra-Cellular Therapies, Inc. (the Company). In addition, the Company began operating ITI and its business, and therefore ceased being a shell company. Following the Merger and the redemption of all then outstanding shares of Oneida at the closing of the Merger, the former shareholders of ITI owned 100% of the shares of the Company's outstanding capital stock.

Immediately prior to the Merger, on August 29, 2013, ITI sold to accredited investors approximately \$60.0 million of its shares of common stock, or 18,889,307 shares at a price of \$3.1764 per share (the Private Placement), which included \$15.3 million in principal and \$0.8 million in accrued interest from the conversion of ITI's then outstanding convertible promissory notes (the Notes).

In accordance with Financial Accounting Standards Board (FASB), Accounting Standards Codification (ASC) Topic 805, *Business Combinations*, ITI is considered the acquirer for accounting purposes, and will account for the transaction as a capital transaction, because ITI's former stockholders received 100% of the voting rights in the combined entity and ITI's senior management represents all of the senior management of the combined entity. Consequently, the assets and liabilities and the historical operations that will be reflected in our consolidated financial statements will be those of ITI and will be recorded at the historical cost basis of the Company. All share and per share amounts in the consolidated financial statements and related notes have been retrospectively adjusted to reflect the one for 0.5 shares common stock exchange as well as the conversion of the Notes and Redeemable Preferred Series A, B, and C convertible preferred stock.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Although actual results could differ from those estimates, management does not believe that such differences would be material.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents consist of money market investments and certificates of deposit with commercial banks and financial institutions. Certificates of deposit with a maturity date of more than three months are classified separately on the balance sheet. Their carrying values approximate the fair market value.

Fair Value Measurements

The Company applies the fair value method under ASC Topic 820, *Fair Value Measurements and Disclosures*. ASC Topic 820 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value and requires expanded disclosures about fair value measurements. The ASC Topic 820 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires assets and liabilities carried at fair value to be classified and disclosed in one of the following categories based on the lowest level input used that is significant to a particular fair value measurement:

Level 1 Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.

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Level 2 Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models, such as interest rates and yield curves that can be corroborated by observable market data.

Level 3 Fair value is determined by inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgments to be made by a reporting entity e.g., determining an appropriate adjustment to a discount factor for illiquidity associated with a given security.

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the ASC Topic 820 hierarchy.

The Company has no assets or liabilities that were measured using quoted prices for similar assets and liabilities or significant unobservable inputs (Level 2 and Level 3 assets and liabilities, respectively) as of September 30, 2013 and December 31, 2012. The carrying value of cash held in money market funds of approximately \$21.2 million as of September 30, 2013 and approximately \$1.2 million as of December 31, 2012, is included in cash and cash equivalents and approximates market value based on quoted market price or Level 1 inputs.

Financial Instruments

The Company considers the recorded costs of its financial assets and liabilities, which consist of cash equivalents, accounts receivable, accounts payable and accrued liabilities, to approximate their fair value because of their relatively short maturities at September 30, 2013 and December 31, 2012. Management believes that the risks associated with its financial instruments are minimal as the counterparties are financial institutions of high credit standing.

Concentration of Credit Risk

Cash equivalents are held with major financial institutions in the United States. Certificates of deposit held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

Accounts Receivable

Accounts receivable that management has the intent and ability to collect are reported in the balance sheets at outstanding amounts, less an allowance for doubtful accounts. The Company writes off uncollectible receivables when the likelihood of collection is remote.

The Company evaluates the collectability of accounts receivable on a regular basis. The allowance, if any, is based upon various factors including the financial condition and payment history of customers, an overall review of collections experience on other accounts and economic factors or events expected to affect future collections experience. No allowance was recorded as of September 30, 2013 and December 31, 2012, as the Company has a history of collecting on all accounts including, but not limited to, collaborations funding its research.

Property and Equipment

Property and equipment is stated at cost and depreciated on a straight-line basis over estimated useful lives ranging from three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the assets or the term of the related lease. Expenditures for maintenance and repairs are charged to operations as incurred.

When indicators of possible impairment are identified, the Company evaluates the recoverability of the carrying value of its long-lived assets based on the criteria established in ASC Topic 360, *Property, Plant and Equipment*. The Company considers historical performance and anticipated future results in its evaluation of potential impairment. The Company evaluates the carrying value of those assets in relation to the operating performance of the business and undiscounted cash flows expected to result from the use of those assets. Impairment losses are recognized when carrying value exceeds the undiscounted cash flows then management must determine the fair value of the underlying asset. No such impairment losses have been recognized to date.

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Revenue Recognition

The Company earns its license and collaboration revenue from its significant partnership with Takeda Pharmaceutical Company Limited (Takeda). In order to further its research projects and support its collaborations, the Company will require additional financing until such time that revenue streams are sufficient to generate consistent positive cash flow from operations. Possible sources of funds include strategic alliances, additional equity offerings, grants and contracts, and research and development funding from third parties.

Revenue is recognized when all terms and conditions of the agreements have been met, including persuasive evidence of an arrangement, delivery has occurred or services have been rendered, price is fixed or determinable and collectability is reasonably assured. The Company is reimbursed for certain costs incurred on specified research projects under the terms and conditions of grants, collaboration agreements, and awards. The Company records the amount of reimbursement as revenues on a gross basis in accordance with ASC Topic 605-45, *Revenue Recognition/Principal Agent Considerations*. The Company is the primary obligor with respect to purchasing goods and services from third-party suppliers, is obligated to compensate the service provider for the work performed, and has discretion in selecting the supplier. Provisions for estimated losses on research grant projects and any other contracts are made in the period such losses are determined.

The Company engages in transactions with delivery of more than one element. Each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. For the Company, this determination is generally based on whether the deliverable has stand-alone value to the customer. The Company adopted accounts for all Multiple-Deliverable Revenue Arrangements (MDRAs) in accordance with ASC Topic 605-25, *Revenue Recognition Multiple Element Arrangements*.

The Company accounts for milestone revenue in accordance with ASC Topic 605-28, *Milestone Method*. Under this guidance, the Company recognizes revenue contingent upon the achievement of a substantive milestone in its entirety in the period the milestone is achieved. Substantive milestone payments are recognized upon achievement of the milestone only if all of the following conditions are met:

The milestone payments are non-refundable;

Achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;

Substantive effort on our part is involved in achieving the milestone;

The amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and

A reasonable amount of time passes between the up-front license payment and the first milestone payment, as well as between each subsequent milestone payment.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore, the resulting payment would be considered part of the consideration for the single unit of accounting and be recognized as revenue in accordance with the revenue models described above. In addition, the determination that one such payment was not a substantive milestone could prevent us from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments could also be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the proportional performance or straight-line methods, as applicable.

Deferred Revenue

Cash received as prepayment on future services is deferred and recognized as revenue as the services are performed. The Company must remit interest on any deferred revenue related to a governmental agency. As of September 30, 2013 and December 31, 2012, no interest was due as the Company did not have any deferred revenue from a government agency.

Research and Development

Except for payments made in advance of services, the Company expenses its research and development costs as incurred. For payments made in advance, the Company recognizes research and development expense as the services are rendered. Research and development costs primarily consist of salaries and related expenses for personnel and resources and the costs of clinical trials. Other research and development expenses include preclinical analytical testing, outside services, providers, materials and consulting fees.

Income Taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and its respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled.

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The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce net deferred tax assets to the amount expected to be realized. Income tax expense is the tax payable for the period and the change during the period in deferred tax assets and liabilities.

The Company accounts for uncertain tax positions pursuant to ASC Topic 740 (previously included in FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109*). Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more-likely-than-not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

Comprehensive Income (Loss)

ASC Topic 220-10, *Reporting Comprehensive Income*, requires the presentation of the comprehensive income or loss and its components as part of the financial statements if comprehensive income (loss) differs from net income (loss). For the three- and nine-months ended September 30, 2013 and the year ended December 31, 2012, the Company's net loss equals comprehensive loss.

Share-Based Compensation

Share-based payments are accounted for in accordance with the provisions of ASC Topic 718, *Compensation – Stock Compensation*. The fair value of share-based payments is estimated, on the date of grant, using the Black-Scholes-Merton option-pricing model (the Black-Scholes model). The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option.

For all time vesting awards granted, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. As share-based compensation expense recognized in the statements of operations for the three- and nine-months ended September 30, 2013 and 2012 and the year ended December 31, 2012, is based on share-based awards ultimately expected to vest, it has been reduced for estimated forfeitures.

ASC Topic 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures are based on the Company's historical experience for the three- and nine-months ended September 30, 2013 and 2012 and the year ended December 31, 2012, and have not been material.

The Company utilizes the Black-Scholes model for estimating fair value of its stock options granted. Option valuation models, including the Black-Scholes model, require the input of subjective assumptions, and changes in the assumptions used can materially affect the grant date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

Expected volatility rates are based on historical volatility of the common stock of comparable publicly traded entities and other factors due to the lack of historic information of the Company's common stock. The expected life of stock-based options is the period of time for which the stock-based options are expected to be outstanding. Given the lack of historic exercise data, the expected life is determined using the simplified method which is defined as the midpoint between the vesting date and the end of the contractual term.

The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception and does not plan to pay cash dividends in the foreseeable future. Therefore, the Company has assumed an expected dividend rate of zero.

Given the absence of an active market for the Company's common stock, the exercise price of the stock options on the date of grant was determined and approved by the board of directors using several factors, including progress and milestones achieved in the Company's business development and performance, the price per share of its convertible preferred stock offerings and general industry and economic trends. In establishing the estimated fair value of the common stock, the Company considered the guidance set forth in American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

Under ASC Topic 718, the cumulative amount of compensation cost recognized for instruments classified as equity that ordinarily would result in a future tax deduction under existing tax law shall be considered to be a deductible difference in applying ASC Topic 740, *Income Taxes*. The deductible temporary difference is based on the compensation cost recognized for financial reporting purposes; however, these provisions currently do not impact the Company, as all the deferred tax assets have a full valuation allowance.

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Since the Company had net operating loss carryforwards as of September 30, 2013 and December 31, 2012, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations.

Equity instruments issued to non-employees are accounted for under the provisions of ASC Topic 718 and ASC Topic 505-50, *Equity/Equity-Based Payments to Non-Employees*. Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services required are completed and are marked to market during the service period.

Loss Per Share

Loss per share is calculated under the two-class method under which all earnings (distributed and undistributed) are allocated to each class of common stock and participating securities based on their respective rights to receive dividends.

Basic net loss per common share is determined by dividing the net loss allocable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing the net loss allocable to common stockholders by the weighted-average number of common stock equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company's stock option grants.

The following common stock equivalents were excluded in the calculation of diluted loss per share because their effect would be anti-dilutive as applied to the loss from operations as of the three- and nine- months ended September 30, 2013 and 2012:

	Three-Months Ended		Nine-Months Ended	
	September 30		September 30	
	2013	2012	2013	2012
Stock options	712,525	901,210	710,819	901,210

Recently Issued Accounting Pronouncements

In April 2013, FASB issued Accounting Standards Update (ASU) 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*, which amended interim and annual reporting requirements about accumulated other comprehensive income (AOCI). In interim periods, companies are required to report information about reclassifications out of AOCI and changes in AOCI balances. The provision of ASU 2013-02 became effective for the first quarter of 2013. The adoption of ASU 2103-02 did not have a material effect on the Company's consolidated results of operations, financial position or liquidity.

3. Property and Equipment

Property and equipment consist of the following:

	September 30, 2013	December 31, 2012
Computer equipment	\$ 93,915	\$ 92,318
Furniture and fixtures	46,523	42,736
Scientific equipment	2,851,947	2,824,076
Leasehold improvements	319,553	319,553
	3,311,938	3,278,683
Less accumulated depreciation	(3,236,238)	(3,220,417)
	\$ 75,700	\$ 58,266

Depreciation expense for the three- and nine-months ended September 30, 2013 was \$4,729, and \$15,821 respectively.

4. Share-Based Compensation