Ocata Therapeutics, Inc.

Form 10-Q May 07, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON D.C. 20549
FORM 10-Q
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGI ACT OF 1934
ACI OF 1934
FOR THE QUARTERLY PERIOD ENDED March 31, 2015
OR
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGI ACT OF 1934
FOR THE TRANSITION PERIOD FROMTO
COMMISSION FILE NUMBER: 0-50295
OCATA THERAPEUTICS, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)
DELAWARE 87-0656515
(STATE OR OTHER JURISDICTION OF (I.R.S. EMPLOYER IDENTIFICATION NO.) INCORPORATION OR ORGANIZATION)

## 33 LOCKE DRIVE, MARLBOROUGH, MASSACHUSETTS 01752

(ADDRESS, INCLUDING ZIP CODE, OF PRINCIPAL EXECUTIVE OFFICES)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (508) 756-1212

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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 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 x 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 x

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

Class: Outstanding at April 30, 2015:

Common Stock, \$0.001 par value per share 35,667,442 shares

# OCATA THERAPEUTICS, INC. AND SUBSIDIARY

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## PART I – FINANCIAL INFORMATION

## **ITEM 1. Financial Statements**

# OCATA THERAPEUTICS, INC. AND SUBSIDIARY

## CONSOLIDATED BALANCE SHEETS

Commitments and contingencies (Note 2)

# AS OF MARCH 31, 2015 AND DECEMBER 31, 2014 (UNAUDITED)

	March 31, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$3,532,602	\$4,424,374
Other receivable	44,848	16,217
Prepaid expenses and other current assets	379,489	308,444
Total current assets	3,956,939	4,749,035
Property and equipment, net	788,253	832,963
Deferred royalty fees	92,170	107,779
Other assets	40,232	47,707
TOTAL ASSETS	\$4,877,594	\$5,737,484
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable	\$1,191,185	\$1,271,325
Accrued expenses	1,815,014	2,515,674
Accrued settlement	1,047,098	1,731,202
Deferred revenue, current portion	157,873	157,873
Total current liabilities	4,211,170	5,676,074
Warrant liabilities	10,252	16,255
Other liabilities	1,188,874	1,188,874
Deferred revenue, less current portion	1,552,358	1,591,826
Total liabilities	6,962,654	8,473,029

# STOCKHOLDERS' DEFICIT:

Common stock, \$0.001 par value; 60,000,000 shares authorized, 35,600,417 and 34,620,218 shares issued and outstanding	35,600	34,620
Additional paid-in capital	354,049,136	346,364,060
Accumulated deficit	(356,169,796)	(349,134,225)
Total stockholders' deficit	(2,085,060 )	(2,735,545)

TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT \$4,877,594 \$5,737,484

The accompanying notes are an integral part of these consolidated financial statements.

# OCATA THERAPEUTICS, INC. AND SUBSIDIARY

# CONSOLIDATED STATEMENTS OF OPERATIONS

# FOR THE THREE MONTHS ENDED MARCH 31, 2015 AND 2014 (UNAUDITED)

	Three Months Ended March 31,	
	2015	2014
Revenue (License fees and royalties)	\$39,468	39,468
Cost of revenue	15,609	15,609
Gross profit	23,859	23,859
Operating expenses:		
Research and development	3,377,573	2,507,844
General and administrative expenses	3,687,860	
Litigation settlement contingency	_	1,901,538
Total operating expenses	7,065,433	
Loss from operations	(7,041,574)	(7,698,086)
Non-operating income (expense):		
Interest income	_	54,890
Interest expense	_	(296,972)
Other loss	_	(50,726)
Adjustments to fair value of unsettled warrant obligation	_	(985,908)
Adjustments to fair value of derivatives	6,003	287,028
Total non-operating expense	6,003	(991,688 )
Loss before provision for income tax	(7,035,571)	(8,689,774)
Provision for income tax	_	_
Net loss	\$(7,035,571)	\$(8,689,774)
Preferred stock dividend	_	623,804
Net loss applicable to common stock	\$(7,035,571)	\$(9,313,578)
Weighted average shares outstanding: Basic and diluted	34,943,293	27,991,483
Net loss applicable to common share: Basic and diluted	\$(0.20)	\$(0.33)

The accompanying notes are an integral part of these consolidated financial statements

# OCATA THERAPEUTICS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT

## FOR THE THREE MONTHS ENDED MARCH 31, 2015 (UNAUDITED)

	Common Sto	ock	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Deficit
Balance December 31, 2014	34,620,218	\$34,620	\$346,364,060	\$(349,134,225)	\$(2,735,545)
Shares issued for services	7,500	8	46,192	_	46,200
Stock based compensation	_	_	1,519,154	_	1,519,154
Issuance of common stock in financing arrangement	972,699	972	6,119,730	_	6,120,702
Net loss for the three months ended March 31, 2015	_	_	_	(7,035,571)	(7,035,571)
Balance, March 31, 2015	35,600,417	\$35,600	\$354,049,136	\$(356,169,796)	\$(2,085,060)

The accompanying notes are an integral part of these consolidated financial statements.

# OCATA THERAPEUTICS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF CASH FLOWS

# FOR THE THREE MONTHS ENDED MARCH 31, 2015 AND 2014 (UNAUDITED)

	Three Month March 31,	s Ended
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(7,035,571)	\$(8,689,774)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	65,144	30,960
Amortization of deferred charges	15,609	· ·
Deferred revenue	(39,468)	
Stock based compensation	1,519,154	346,595
Amortization of deferred issuance costs	_	65,903
Amortization of discounts on senior secured convertible debentures	_	154,648
Changes in fair value of warrant obligation	_	985,908
Changes in fair value of derivatives	(6,003)	(287,028)
Shares of common stock issued for services	46,200	92,475
Non-cash financing costs	_	1,952,264
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(92,201)	511,453
Accounts payable and other liabilities	(1,464,904)	(493,167)
Net cash used in operating activities	(6,992,040)	(5,353,622)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(20,434)	(91,402)
Net cash used in investing activities	(20,434)	(91,402 )
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock	6,120,702	7,706,756
Net cash provided by financing activities	6,120,702	7,706,756
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(891,772)	2,261,732
CASH AND CASH EQUIVALENTS, BEGINNING BALANCE	4,424,374	1,743,485
CASH AND CASH EQUIVALENTS, ENDING BALANCE	\$3,532,602	\$4,005,217
CASH PAID FOR:		
Interest	\$-	\$51,578
Income taxes	\$-	\$-

# SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES:

Accrued dividends on Series B and C Preferred Stock	\$-	\$623,804
Accretion of note receivable discount on Series B and C Preferred Stock	\$-	\$552,091
Issuance of 0 and 43,373,609 shares of common stock for accrued settlement	\$-	\$2,400,000

The accompanying notes are an integral part of these consolidated financial statements.

OCATA THERAPEUTICS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

#### 1. ORGANIZATIONAL MATTERS

#### **Organization and Nature of Business**

Ocata Therapeutics, Inc., and Subsidiary (the "Company") is a clinical stage biotechnology company focused on the development and commercialization of Regenerative Ophthalmology<sup>TM</sup> therapeutics. The most advanced products are in clinical trials for the treatment of Stargardt's macular degeneration, dry age-related macular degeneration, and myopic macular degeneration. The Company is also developing several pre-clinical terminally differentiated-cell therapies for the treatment of other ocular disorders. Additionally, the Company has a number of pre-clinical stage assets in disease areas outside the field of ophthalmology, including autoimmune, inflammatory and wound healing-related disorders. The Company's intellectual property portfolio includes pluripotent human embryonic stem cell, or hESC; induced pluripotent stem cell, or iPSC, platforms; and other cell therapy technologies. The Company has no therapeutic products currently available for sale and does not expect to have any therapeutic products commercially available for sale for a period of years, if at all. These factors indicate that the Company's ability to continue research and development activities is dependent upon the ability of management to obtain additional financing as required.

The Company pursues a number of approaches to generating transplantable tissues both in-house and through collaborations with other researchers who have particular interests in, and skills related to, cellular differentiation. The Company's research in this area includes projects focusing on the development of many different cell types that may be used to treat a range of diseases within ophthalmology and other therapeutic areas. Control of cellular differentiation and the culture and growth of stem and differentiated cells are important areas of research and development for the Company. Based on the success to date of the Phase 1 clinical trials and what the Company sees as favorable market dynamics of the ophthalmology sector, the Company has shifted its strategic priorities to focus primarily on the development, and ultimate commercialization of ophthalmology therapies. The largest indication involving macular degeneration is "age-related macular degeneration", or AMD. AMD is the leading cause of blindness and visual impairment in adults over fifty years of age. The Company is also pursuing a treatment for Stargardt's Maculuar Degeneration, or SMD, an inherited juvenile onset form of macular degeneration. The Company plans to initiate the Phase 2 clinical trial for dry AMD in the second quarter of this year.

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation — The Company follows accounting standards set by the Financial Accounting Standards Board ("FASB"). The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, GAAP. References to GAAP issued by the FASB in these footnotes are to the FASB Accounting Standards Codification, TM sometimes referred to as the Codification or "ASC." Although the Company believes that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information normally included in the footnotes prepared in accordance with GAAP has been omitted as permitted by the rules and regulations of the Securities and Exchange Commission ("SEC"). The accompanying financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10–K for the fiscal year ended December 31, 2014 filed with the SEC on March 16, 2015. The results for the three month period ended March 31, 2015 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2015, or any future period.

The accompanying consolidated financial statements have been prepared in conformity with GAAP which contemplate continuation of the Company as a going concern. However, as of March 31, 2015, the Company has an accumulated deficit of \$356.2 million, recurring losses from operations, and negative working capital which raise substantial doubt about the ability of the Company to continue as a going concern. The ability to continue as a going concern is dependent upon many factors, including the Company's ability to raise additional capital in a timely manner. The Company has no expectation of generating any meaningful revenues from our product candidates for a substantial period of time and must rely on raising funds in capital transactions to finance our research and development programs. Our future cash requirements will depend on many factors, including the pace and scope of our research and development programs, the costs involved in filing, prosecuting and enforcing patents, and other costs associated with commercializing our potential products. Accordingly, management's plans to continue as a going concern contemplate raising additional capital including the prior execution of an agreement for a \$30 million equity line in late June 2014, of which approximately \$12.5 million remains available as of March 31, 2015. There can be no assurances that management can raise the necessary additional capital on favorable terms or at all. The accompanying financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

On August 28, 2014, the Company effected a 100-to-1 reverse stock split of its common stock. Unless otherwise noted, all references in these financial statements to number of shares, price per share and weighted average number of shares outstanding of common stock have been adjusted to reflect the reverse stock split on a retroactive basis. The split was also applied to any outstanding equity-based awards.

**Principles of Consolidation** — The accounts of the Company and its wholly-owned subsidiary Mytogen, Inc. are included in the accompanying consolidated financial statements. All intercompany balances and transactions were eliminated in consolidation.

**Segment Reporting** — ASC 280, Segment Reporting requires use of the "management approach" model for segment reporting. The management approach model is based on the way a company's management organizes segments within the company for making operating decisions and assessing performance. The Company determined it has one operating segment.

Use of Estimates — These consolidated financial statements have been prepared in accordance with GAAP and, accordingly, require management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Specifically, the Company's management has estimated loss contingencies related to outstanding litigation. In addition, management has estimated variables used to calculate the Black-Scholes option pricing model used to value derivative instruments and the Company estimates the fair value of the embedded conversion option associated with the senior secured convertible debentures using a binomial lattice model as discussed below under "Fair Value Measurements." Also, management has estimated the expected economic life and value of the Company's licensed technology, the Company's net operating loss for tax purposes, share-based payments for compensation to employees, directors, consultants and investment banks, and the useful lives of the Company's fixed assets. Actual results could differ from those estimates.

**Reclassifications** — Certain prior period financial statement balances have been reclassified to conform to the current period presentation. Items include the presentation of net loss applicable to common stock and net loss applicable to common share on the face of the statement of operations.

On August 28, 2014, the Company effected a 100-to-1 reverse stock split of its common stock. As such, the Company determined that current year presentation of net loss applicable to common stock and net loss applicable to common share was appropriate. The Company retroactively adjusted the presentation for net loss applicable to common stock and net loss applicable to common share for prior periods on the statement of operations to conform to the current year's presentation.

Cash and Cash Equivalents — Cash equivalents are comprised of certain highly liquid investments with maturities of three months or less when purchased. The Company maintains its cash in bank deposit accounts, which at times, may exceed federally insured limits. The Company has not experienced any losses related to this concentration of risk. As of March 31, 2015 and December 31, 2014, the Company had deposits in excess of federally-insured limits totaling \$3,728,776 and \$4,325,886, respectively.

**Commitments and Contingencies** — The Company is subject to various claims and contingencies related to lawsuits as well as commitments under contractual and other obligations. The Company recognizes liabilities for contingencies and commitments when a loss is probable and can be reasonably estimated.

Relating to loss contingencies the Company accrues the best estimate of a loss within a range. If no estimate in a range is better than any other, the minimum amount is accrued. The Company discloses a reasonably possible loss in excess of the amount accrued, if applicable. For reasonably possible loss contingencies, the Company discloses the nature of the loss contingency and provides a range of the estimate of possible loss or state that an estimate cannot be made.

The other liabilities balance as of March 31, 2015 and December 31, 2014 is made up of payable liabilities primarily related to the acquisition of Mytogen which the Company does not expect to settle within the coming year.

*Grants Receivable* — The Company periodically assesses its grants receivable for collectability on a specific identification basis. If collectability of an account becomes unlikely, the Company records an allowance for that doubtful account. Once the Company has exhausted efforts to collect, management writes off the grants receivable against the allowance it has already created.

**Property and Equipment** — The Company records its property and equipment at historical cost. The Company expenses maintenance and repairs as incurred. Upon disposition of property and equipment, the gross cost and accumulated depreciation are written off and the difference between the proceeds and the net book value is recorded as a gain or loss on sale of assets. In the case of certain assets acquired under capital leases, the assets are recorded net of imputed interest, based upon the net present value of future payments. Assets under capital lease are pledged as collateral for the related lease.

The Company provides for depreciation over the assets' estimated useful lives as follows:

Machinery & equipment 4 years Computer equipment 3 years Office furniture 4 years

Leasehold improvements Lesser of lease life or economic life

**Patents** — The Company follows ASC 350-30, *General Intangibles Other than Goodwill* ("ASC 350-30"), in accounting for its patents. ASC 350-30 provides that costs of internally developing, maintaining, or restoring intangible assets that are not specifically identifiable, that have indeterminate lives, or that are inherent in a continuing business and related to an entity as a whole, shall be recognized as an expense when incurred. The Company has expensed as research and development expense all costs associated with developing its patents.

**Equity Method Investment** — The Company follows ASC 323, *Investments-Equity Method and Joint Ventures*, in accounting for its investment in the joint venture. In the event the Company's share of the joint venture's net losses

reduces the Company's investment to zero, the Company will discontinue applying the equity method and will not provide for additional losses unless the Company has guaranteed obligations of the joint venture or is otherwise committed to provide further financial support for the joint venture. If the joint venture subsequently reports net income, the Company will resume applying the equity method only after its share of that net income equals the share of net losses not recognized during the period the equity method was suspended.

Long-Lived Assets— The Company follows ASC 360-10, *Property, Plant, and Equipment*, which established a "primary asset" approach to determine the cash flow estimation period for a group of assets and liabilities that represents the unit of accounting for a long-lived asset to be held and used. Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less cost to sell. Through March 31, 2015, the Company had not experienced impairment losses on its long-lived assets.

Fair Value Measurements — The Company applies the provisions of ASC 820-10, Fair Value Measurements and Disclosures ("ASC 820-10"). ASC 820-10 defines fair value, and establishes a three-level valuation hierarchy for disclosures of fair value measurement that enhances disclosure requirements for fair value measures. For certain financial instruments, including cash and cash equivalents, grants receivable, prepaid expenses, accounts payable and accrued expenses, the carrying amounts approximate fair value due to their relatively short maturities. The carrying amount of senior secured convertible debentures approximated fair value as the interest rate charged on the debentures was based on the prevailing rate. The three levels of valuation hierarchy are defined as follows:

·Level 1 inputs to the valuation methodology are quoted prices for identical assets or liabilities in active markets.

Level 2 inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.

·Level 3 inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The Company analyzes all financial instruments with features of both liabilities and equity under ASC 480, *Distinguishing Liabilities From Equity*, and ASC 815, *Derivatives and Hedging*. Derivative liabilities are adjusted to reflect fair value at each period end, with any increase or decrease in the fair value being recorded in results of operations as adjustments to fair value of derivatives. The effects of interactions between embedded derivatives are calculated and accounted for in arriving at the overall fair value of the financial instruments. In addition, the fair values of freestanding derivative instruments such as warrant derivatives are valued using the Black-Scholes model.

The Company uses Level 3 inputs for its valuation methodology for the fair value of certain embedded conversion options and other warrant derivative liabilities.

The Company estimated the fair value of the embedded conversion option associated with its 8% convertible debentures using a binomial lattice, which estimated and compared the present value of the principal and interest payments to the as converted value to determine whether the holder of the notes should convert the notes into the Company's common stock or continue to receive principal and interest payments. The Company used this methodology to determine the beneficial conversion features because there were no observable inputs available with respect to the fair value.

The binomial lattice relied on the following Level 3 inputs: (1) expected volatility of the Company's common stock; (2) potential discount for illiquidity of large blocks of the Company's common stock, and (3) discount rate for contractual debt principal and interest payments. The fair value of the embedded beneficial conversion feature was estimated as the difference between the fair value of the notes with and without the conversion feature. The fair value

of the notes without the conversion feature was determined using one Level 3 input, the discount rate for contractual debt interest and principal payments.

The expected volatility of the Company's common stock is estimated from the historical volatility of daily returns in the Company's common stock price. The Company monitors the volatility of its common stock on a quarterly basis to observe trends that may impact the fair value of the notes.

The discount for illiquidity is measured using an average-strike option that calculates the discount as the opportunity cost for not being able to sell a large block of the Company's common stock immediately at prevailing observable market prices. Inputs to the average-strike option model include the expected volatility of the Company's common stock and time to sell a large block of the Company's stock as Level 3 inputs and other observable inputs. The time to sell the stock is estimated considering the historical daily trading volume of our common stock and market maker estimates of the amount of shares that can be offered for sale above the daily trading volume without depressing the price of the Company's common stock.

At March 31, 2015, the Company identified the following assets and liabilities that are required to be presented on the balance sheet at fair value:

	Fair	Fair Value	
	Value	Measurements at	
Description	As of	March 31, 2015	
	March	Using Fair Value	
	31, 2015	Hierarchy	
		Levleevel Level 3	
		1 2 Level 3	
Warrant liabilities	\$ 10,252	10,252	
Total	\$ 10,252	\$-\$ - \$10,252	

The following tables reconcile the change in fair value for measurements categorized within Level 3 of the fair value hierarchy:

	Warrant
	Liabilities
Balance at December 31, 2014	\$ 16,255
Total gains for the period included in earnings	(6,003)
Balance at March 31, 2015	\$ 10,252

Gains and losses included in earnings for the three months ended March 31, 2015 are reported as follows:

Warrant Derivative Liabilities

Total gain included in earnings \$ 6,003

The following table provides quantitative information about measurements categorized within Level 3 of the fair value hierarchy:

Fair Value at March 31, Valuation

Description 2015 Technique Unobservable Input Value Warrant liabilities \$10,252 Black Scholes Model Expected volatility of the Company's common stock 65%

For the three months ended March 31, 2015 and March 31, 2014 the Company recognized gains of \$6,003 and \$287,028, respectively, for the changes in the valuation of derivative liabilities.

The Company did not identify any non-recurring assets and liabilities that were recorded at fair value during the periods presented.

**Revenue Recognition and Deferred Revenue** — The Company's revenues are primarily generated from license and research agreements with collaborators. Licensing revenue is recognized on a straight-line basis over the shorter of the life of the license or the estimated economic life of the patents related to the license.

License fee revenue begins to be recognized in the first full month following the effective date of the license agreement. Deferred revenue represents the portion of the license and other payments received that has not been earned. Costs associated with license revenue are deferred and recognized over the same term as the revenue. Reimbursements of research expense pursuant to grants are recorded in the period during which collection of the reimbursement becomes assured, because the reimbursements are subject to approval.

In some cases, the Company is entitled to receive royalty payments from licensees. In such cases, the Company recognizes the royalties when they are earned and collectability of those royalty payments is reasonably assured.

In connection with its license agreements, the Company recorded \$39,468 and \$39,468 in license fee revenue for the three months ended March 31, 2015 and 2014, respectively, in its consolidated statements of operations, and the remainder of the license fees are included in deferred revenue at March 31, 2015 and December 31, 2014, respectively.

**Research and Development Costs** — Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses consist of (i) employee-related expenses, including salaries, benefits, travel and stock compensation expense; (ii) external research and development expenses incurred under arrangements with third parties, such as contract research organizations, investigational sites and consultants; (iii) the cost of acquiring, developing and manufacturing clinical study materials; (iv) facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and laboratory and other supplies; and (v) costs associated with pre-clinical and clinical activities and regulatory operations.

The Company enters into consulting, research and other agreements with commercial firms, researchers, universities and others for the provision of goods and services. Under such agreements, the Company may pay for services on a monthly, quarterly, project or other basis. Such arrangements are generally cancellable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided to us by the Company's clinical sites and vendors. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company. Reimbursements of research expense pursuant to grants are recorded in the period during which collection of the reimbursement becomes assured, because the reimbursements are subject to approval.

In certain circumstances, the Company is required to make advance payments to vendors for goods or services that will be received in the future for use in research and development activities. In such circumstances, the advance payments are deferred and are expensed when the activity has been performed or when the goods have been received.

Stock Compensation — The Company records stock compensation in accordance with ASC 718, Compensation – Stock Compensation ("ASC 718"). ASC 718 requires companies to measure compensation cost for stock employee compensation at fair value at the measurement date (generally the grant date) and recognize the expense over the employee's requisite service period. The Company recognizes in the statement of operations the grant-date fair value of stock options and other equity-based compensation issued to employees and non-employees.

Income Taxes — Deferred income taxes are provided using the liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carryforwards, and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of the changes in tax laws and rates at the date of enactment.

When tax returns are filed, it is highly certain that some positions taken would be sustained upon examination by the taxing authorities, while others are subject to uncertainty about the merits of the position taken or the amount of the

position that would be ultimately sustained. The benefit of a tax position is recognized in the financial statements in the period during which, based on the weight of available evidence, management believes it is more likely than not that the position will be sustained upon examination, including the resolution of appeals or litigation processes, if any. Tax positions taken are not offset or aggregated with other positions. Tax positions that meet the more-likely-than-not recognition threshold are measured as the largest amount of tax benefit that is more than 50 percent likely of being realized upon settlement with the applicable taxing authority. The portion of the benefits associated with tax positions taken that exceeds the amount measured as described above is reflected as a liability for unrecognized tax benefits in the balance sheets along with any associated interest and penalties that would be payable to the taxing authorities upon examination.

Applicable interest and penalties associated with unrecognized tax benefits are classified as additional income taxes in the statements of operations.

Net Loss Per Share — Basic net loss per share applicable to common stockholders is calculated by dividing net loss applicable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method and the if-converted method. For purposes of the diluted net loss per share calculation, convertible preferred stock, stock options, unvested restricted stock, and warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share was the same for all periods presented. Additionally, dividends associated with the preferred stock, all of which has been extinguished as of March 31, 2015, has been added back in order to calculate the net loss applicable to common stockholders.

At March 31, 2015 and 2014, approximately 2,819,799 and 1,587,115 potentially dilutive shares, respectively, were excluded from the shares used to calculate diluted earnings per share as their inclusion would be anti-dilutive.

Recent Accounting Pronouncements — In April 2015, the Financial Accounting Standards Board (FASB) issued ASU No. 2015-03, Interest – Imputation of Interest (Subtopic 835-30) – Simplifying the Presentation of Debt Issuance Costs. The new standard requires that debt issuance costs be presented in the balance sheet as a direct deduction from the debt liability, consistent with the presentation of a debt discount. The new standard will be effective for the Company on January 1, 2016. The new standard is not likely to have any impact on the Company's financial statements or related disclosures.

#### 3. INVESTMENT IN JOINT VENTURE

On December 1, 2008, the Company and CHA Bio & Diostech Co., Ltd. ("CHA"), formed an international joint venture. The new company, Stem Cell & Regenerative Medicine International, Inc. ("SCRMI"), will work towards developing human blood cells and other clinical therapies based on the Company's hemangioblast program. Under the terms of the agreement, the Company purchased upfront a 33% interest in the joint venture, and has received another 7% interest upon fulfilling certain obligations under the agreement over a period of 3 years. The Company's contribution includes (a) the uninterrupted use of a portion of its leased facility at the Company's expense, (b) the uninterrupted use of certain equipment in the leased facility, and (c) the release of certain of the Company's research and science personnel to be employed by the joint venture. In return, for a 60% interest, CHA has agreed to contribute \$150,000 cash and to fund all operational costs in order to conduct the hemangioblast program. Effective May 1, 2010, the Company was no longer obligated to provide laboratory space to SCRMI. As of March 31, 2015, the Company holds a 40% interest in the joint venture and CHA owns a 60% interest. The two partners to the joint venture are in negotiations on further funding of the joint venture, but there can be no assurances that an agreement will be reached. Any financial statement impact at this time is unclear should an agreement not be reached.

The Company has agreed to collaborate with the joint venture in securing grants to further research and development of its technology. Additionally, SCRMI has paid the Company a fee of \$500,000 for an exclusive, worldwide license to the hemangioblast program. The Company recorded \$7,353 and \$7,353 in license fee revenue for the three months ended March 31, 2015 and 2014, respectively, in its accompanying consolidated statements of operations, and the balance of unamortized license fee of \$314,951 and \$322,304 is included in deferred revenue in the accompanying consolidated balance sheets at March 31, 2015 and December 31, 2014, respectively.

On July 15, 2011, the Company and CHA entered into a binding term sheet, with the expectation of entering into a future definitive agreement, in which the joint venture was realigned around both product development rights and research responsibilities. Under the terms of the binding term sheet, SCRMI exclusively licensed the rights to the hemangioblast program to the Company for United States and Canada and expanded the jurisdictional scope of the license to CHA to include Japan (in addition to South Korea, which was already exclusively licensed to CHA). As part

of the agreement, the scientists at SCRMI involved in the hemangioblast program were transferred to the Company, and SCRMI discontinued its research activity and became solely a licensing entity. The Company fulfilled its obligation to meet a minimal research spending requirement of \$6.75 million by July 31, 2014 in order to maintain its exclusive license, up to the point of filing an investigational new drug for a therapeutic product. Intellectual property rights created by the Company in the course of its research are subject to a non-exclusive license to CHA for Japan and South Korea, and to SCRMI to be sub-licensable under certain circumstances for countries other than the United States, Canada, Japan and South Korea. Pursuant to the agreement, the Company paid \$820,000 to SCRMI which is recorded as "losses attributable to equity method investments." By filing the investigational new animal drug application on September 12, 2013 with the Federal Drug Administration, the Company has met the commitment required to maintain its exclusive license.

## 4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at March 31, 2015 and December 31, 2014:

	Monah 21	December
	March 31,	31,
	2015	2014
Machinery & equipment	\$1,206,666	\$1,186,232
Computer equipment	104,857	104,857
Office furniture	54,226	54,226
Leasehold improvements	620,252	620,252
	1,986,001	1,965,567
Accumulated depreciation	(1,197,748)	(1,132,604)
Property and equipment, net	\$788,253	\$832,963

Depreciation expense for the three months ended March 31, 2015 and 2014 amounted to \$65,144 and \$30,960, respectively.

#### 5. ACCRUED SETTLEMENT

The accrued settlement is comprised of the following at March 31, 2015 and December 31, 2014:

	March 31,	December	
		31,	
	2015	2014	
SEC Civil Action	\$672,098	\$1,356,202	
SEC Section 16 Investigation	375,000	375,000	
Total	\$1.047.098	\$1,731,202	

Securities and Exchange Commission - Civil Action

In May 2012, the Company was named as a defendant in a civil action brought by the Securities and Exchange Commission (the "SEC") related to transactions involving the sale and issuance of the Company's securities. The

Securities and Exchange Commission alleges that Company violated Section 5(a) and 5(c) of the Securities Act of 1933 (the "Securities Act") because certain sales of shares to outside organizations, completed in late 2008 and early 2009 under the Company's former management, resulted in \$3.5 million in proceeds to the Company, were neither registered under the Securities Act nor subject to an exemption from registration under Section 3(a)(10) of the Securities Act, as amended. In addition, the Company is alleged to have violated Section 13(a) of the Exchange Act of 1934 because the Company did not disclose the sale and issuance of the shares to the SEC on a timely basis.

In December 2013, the Company settled the civil action. Under the terms of the settlement accepted by the SEC, the Company consented to entry of judgment under which it neither admits nor denies liability and agreed to the disgorgement of \$3.5 million in proceeds from the transactions in question. In addition, the Company will pay approximately \$587,000 in pre-judgment interest. The total amount due, approximately \$4.1 million, will be paid over six equal quarterly installments. In addition, the settlement permanently restrains and enjoins the Company from violations of Sections 5(a) and 5(c) of the Securities Act, Section 13(a) of the Exchange Act and Rule 13a-11 under the Exchange Act.

#### Securities and Exchange Commission – Section 16 Investigation

In April 2013, it was determined that Gary Rabin, the Company's former Chief Executive Officer, failed to report 27 transactions in a timely manner on Form 4 under Section 16 of the Exchange Act in which Mr. Rabin sold shares of the Company's common stock that took place between February 7, 2011 and January 10, 2013. The SEC then investigated the unreported transactions involving sales of shares of the Company's common stock. In September 2014, the Company settled the SEC action arising from the SEC's investigation. Under the terms of the settlement accepted by the SEC, the Company consented to the entry of order under which it neither admits nor denies liability and has agreed to pay a civil penalty of \$375,000, which has been previously accrued for, by July 2015. In addition, the settlement requires the Company to engage an independent Section 16 compliance consultant, provide Section 16(a) training to each Section 16(a) reporting person, and provide a certification of compliance that each of the preceding requirements were completed. The settlement also requires the Company to cease and desist from committing or causing any violations and any future violations of Section 17(a)(2) of the Securities Act, Sections 13(a) and 14(a) of the Exchange Act, and Rules 12b-20, 13a-1, and 14a-9 thereunder. The terms of this settlement require the Company to allocate financial and management resources to complying with the settlement's terms, which may have adverse effect on our business. Also, if the SEC deems the Company to not have complied with any portion of the settlement, it may issue additional fines or sanctions against us which may limit our ability to issue securities or otherwise conduct our business as currently conducted.

#### 6. CONVERTIBLE PROMISSORY NOTES

CAMOFI Senior Secured Convertible Debentures

On January 11, 2013, the Company entered into a settlement agreement and mutual release ("the Settlement Agreement") with CAMOFI Master LDC ("CAMOFI") and CAMHZN Master LDC ("CAMHZN" and together with CAMOFI, the "CAMOFI Parties"), relating to the lawsuit between the CAMOFI Parties, as plaintiffs, and the Company, as defendant, in the Supreme Court of New York. Pursuant to the Settlement Agreement the Company issued Debentures in the principal amount of \$4,732,781 and \$1,267,219 to CAMOFI and CAMHZN, respectively (together the "Debentures").

The Company received conversion notices during the three months ended March 31, 2014 for \$2,400,000. The Company issued 433,736 shares of its common stock for these conversion notices.

The Debentures had contained an embedded beneficial conversion feature as the Debentures are convertible at a price per share of common stock equal to 80% of VWAP of the ten consecutive trading days prior to the conversion date. The embedded beneficial conversion feature was modeled using a binomial lattice model, and had a calculated value at March 31, 2014 of \$287,000. The Company recorded a gain of \$376,000 for the change in the fair value of the embedded conversion option liability for the three months ended March 31, 2014.

The Company recorded a debt discount of \$725,000, which was to be amortized over the life of the Debentures using the effective interest rate of 22.9%. For the three months ended March 31, 2014, the Company amortized \$154,648 of the debt discount and recorded it as interest expense. The unamortized discount at March 31, 2014 was \$108,229. The Company recorded interest expense of \$51,440 for the three months ended March 31, 2014 based on the contractual interest rate. The unamortized discount balance of \$108,229 was written off to interest expense with the retirement of the remaining outstanding Debentures.

On May 2, 2014, the Company paid to the CAMOFI Parties an aggregate amount of approximately \$1,616,000 calculated in accordance with the payment acceleration provisions of the Debentures and satisfying the Company's obligations under the Debentures. The payment represented the remaining \$1,200,000 in principal amount due and an additional amount of approximately \$416,000, which represented penalties, interest and legal cost reimbursement to the CAMOFI Parties. With the payment, the Company satisfied in full its obligations under the Debentures and the terms of the Settlement Agreement and Mutual Release dated as of December 31, 2012 pursuant to which the Debentures were issued in January 2013. The Company received correspondence from the CAMOFI Parties stating that the CAMOFI Parties believe the aggregate amount due to be different than the amount the Company paid. The Company believes that their interpretation of the Debentures is accurate and complete and its liability under the

Debentures remains at zero as of March 31, 2015.

#### 7. WARRANT SUMMARY

#### Warrant Activity

A summary of warrant activity for the three months ended March 31, 2015 is presented below:

			Weighted	
		Weighted	Average	Aggregate
		Average	Remaining	Intrinsic
	Number of	Exercise	Contractual	Value
	Warrants	Price \$	Life (in years)	(000)\$
Outstanding, December 31, 2014	45,906	40.46	1.45	_
Granted	_	_		
Exercised	_	_		
Forfeited/Canceled	_	_		
Outstanding, March 31, 2015	45,906	40.46	1.21	_
Exercisable, March 31, 2015	45,906	40.46	1.21	_

The aggregate intrinsic value in the table above is before applicable income taxes and is calculated based on the difference between the exercise price of the warrants and the quoted price of the Company's common stock as of the reporting date.

#### 8. STOCKHOLDERS' DEFICIT TRANSACTIONS

On September 19, 2012 the Company entered into a purchase agreement with Lincoln Park Capital, LLC ("Lincoln Park"). Pursuant to the purchase agreement, the Company had the right to sell to Lincoln Park up to \$35,000,000 in shares of its common stock. On June 18, 2014, the Company completed the last sale of common stock to Lincoln Park under this agreement.

On June 27, 2014, the Company entered into a similar purchase agreement, the "2014 Purchase Agreement," with Lincoln Park pursuant to which the Company has the right to sell to Lincoln Park up to \$30,000,000 in shares of its common stock, subject to certain limitations set forth in the purchase agreement.

During the three months ended March 31, 2015, Lincoln Park purchased 972,699 shares of common stock pursuant to the 2014 Purchase Agreement for cash proceeds of \$6,120,702.

During the three months ended March 31, 2015, the Company issued various board members 7,500 shares of common stock valued at \$46,200 as compensation for board services.

On August 28, 2014, the Company completed a 100-to-1 reverse stock split of its common stock. Unless otherwise noted, all references in these financial statements to number of shares, price per share and weighted average number of shares outstanding of common stock have been adjusted to reflect the reverse stock split on a retroactive basis. The split was also applied to any outstanding equity-based awards.

At the annual meeting of the Company's stockholders held in November 2014, the Company's stockholders approved a Certificate of Amendment to the Company's Certificate of Incorporation. The Certificate of Amendment provided for an increase in the number of authorized shares of the Company's common stock, par value \$0.001 per share, from 37,500,000 to 60,000,000. The Certificate of Amendment became effective upon its filing with the Secretary of State of the State of Delaware on November 12, 2014.

#### 9. STOCK-BASED COMPENSATION

A summary of stock plans as of March 31, 2015 is presented below:

#### Stock Plans

			Options/Shares	
	Options/Shares	Options	Available	Total
Stock Plan	Issued	Outstanding	For Grant	Authorized
2005 Stock Incentive Plan	2,756,356	2,132,893	3,217,495	5,818,388
2014 Stock Option and Incentive Plan	173,000	138,000	77,000	250,000
	2.929.356	2.270.893	3.294.495	6.068.388

#### Stock Option Activity

A summary of option activity for the three months ended March 31, 2015 is presented below:

			Weighted	
		Weighted	Average	
		Average	Remaining	Aggregate
	Number of	Exercise	Contractual	Intrinsic
	Options	Price	Life (in years)	Value
Outstanding, December 31, 2014	2,245,381	\$ 12.03	8.12	\$ 12,110
Granted	63,000	6.31		
Exercised	_	_		
Forfeited/canceled	(37,488)	21.27		
Outstanding, March 31, 2015	2,270,893	\$ 11.72	7.94	\$ 13,408
Vested and expected to vest at March 31, 2015	2,140,783	\$ 11.97	7.85	\$ 13,028
Exercisable, March 31, 2015	1,270,049	\$ 14.94	6.84	\$ 10,483

The aggregate intrinsic value in the table above is before applicable income taxes and is calculated based on the difference between the exercise price of the options and the quoted price of the Company's common stock as of the reporting date.

The assumptions used in calculating the fair value of options granted using the Black-Scholes option pricing model for options granted during the three months ended, are as follows:

	March 31,	March 31,
	2015	2014
Risk-free interest rate	1.59 - 1.92%	1.72 - 2.09%
Expected life of the options	5.00 - 6.25 years	5.00 - 6.25 years
Expected volatility	112 - 129%	112 - 148%
Expected dividend yield	0%	0%

The weighted average grant-date fair value for the options granted during the three months ended March 31, 2015 and 2014 was \$5.50 and \$8.00, respectively.

The unrecognized compensation expense related to the unvested options as of March 31, 2015, was \$7,080,676 which will be recognized over the weighted average vesting period of 2.30 years.

## Restricted Stock Unit Activity

A summary of the restricted stock unit activity for the three months ended March 31, 2015:

	Number of Shares Underlying Restricted Units	Weighted Average Grant-Date Fair Value per Share	Weighted Average Remaining Recognition Period (in years)
Outstanding, December 31, 2014	493,000	\$ 7.28	2.60
Granted	10,000	6.62	
Outstanding, March 31, 2015	503,000	\$ 7.19	2.42

Unearned stock-based compensation expense of outstanding restricted units \$2,933,395

Stock compensation expense to employees and non-employees for the three months ended March 31, 2015 and 2014 are as follows:

March 31, March 31, 2015 2014

R&D \$554,720 \$85,185

G&A 964,434 261,410

\$1,519,154 \$346,595

## 10. SUBSEQUENT EVENTS

## Lincoln Park

On various dates from April 1, 2015 through May 7, 2015, Lincoln Park purchased 280,892 shares of common stock for cash proceeds to the Company of \$1,904,816. As of May 7, 2015, the Company has \$10,593,933 available through the Lincoln Park financing arrangement.

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

#### Note Regarding Forward-Looking Statements

Certain statements in this quarterly report on Form 10-Q that are not historical in fact constitute "forward-looking statements." Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," and similar expressions are intended to identify forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors based on the Company's estimates and expectations concerning future events that may cause the actual results of the Company to be materially different from historical results or from any results expressed or implied by such forward-looking statements. These risks and uncertainties, as well as the Company's critical accounting policies, are discussed in more detail under "Management's Discussion and Analysis—Critical Accounting Policies" and in periodic filings with the Securities and Exchange Commission. You should review carefully the factors identified in Part I, Item 1A under the heading "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and below under Part II, Item IA, "Risk Factors." We disclaim any intent to update or announce revisions to any forward-looking statements to reflect actual events or developments, except as required by law. Except as otherwise indicated herein, all dates referred to in this report represent periods or dates fixed with reference to our fiscal year ended December 31. The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

You should read the following discussion of our financial condition and results of operations together with the audited financial statements and the notes to the audited financial statements included in this annual report. This discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results may differ materially from those anticipated in these forward-looking statements.

#### **Overview**

We are a clinical stage biotechnology company focused on the development and commercialization of Regenerative Ophthalmology<sup>TM</sup> therapeutics. Our most advanced products are in clinical trials for the treatment of Stargardt's macular degeneration, dry age-related macular degeneration, and myopic macular degeneration. We are also developing several pre-clinical terminally differentiated-cell therapies for the treatment of other ocular disorders. Additionally, we have a number of pre-clinical stage assets in disease areas outside the field of ophthalmology, including autoimmune, inflammatory and wound healing-related disorders. Our intellectual property portfolio includes pluripotent human embryonic stem cell, or hESC; induced pluripotent stem cell, or iPSC, platforms; and other cell therapy technologies. We have no therapeutic products currently available for sale and do not expect to have any therapeutic products commercially available for sale for a period of years, if at all. These factors indicate that our ability to continue research and development activities is dependent upon the ability of management to obtain

additional financing as required.

We pursue a number of approaches to generating transplantable tissues both in-house and through collaborations with other researchers who have particular interests in, and skills related to, cellular differentiation. Our research in this area includes projects focusing on the development of many different cell types that may be used to treat a range of diseases within ophthalmology and other therapeutic areas. Control of cellular differentiation and the culture and growth of stem and differentiated cells are important areas of research and development for us. Based on the success to date of our Phase 1 clinical trials and what we see as favorable market dynamics of the ophthalmology sector, we have shifted our strategic priorities to focus primarily on the development, and ultimate commercialization of ophthalmology therapies. The largest indication involving macular degeneration is "age-related macular degeneration", or AMD. AMD is the leading cause of blindness and visual impairment in adults over fifty years of age. The Company is also pursuing a treatment for Stargardt's Maculuar Degeneration, or SMD, an inherited juvenile onset form of macular degeneration. The Company plans to initiate the Phase 2 clinical trial for dry AMD in the second quarter of this year.

# Comparison of Three months Ended March 31, 2015 and 2014

	Three Months Ended				
	March 31,				
	2015	2014	\$ Change	%	
	2013	2014	φ Change	Change	
Revenue	\$39,468	\$39,468	\$-	0	%
Cost of revenue	15,609	15,609	_	0	%
Gross profit	23,859	23,859	_	0	%
Research and development expenses:					
-R&D expenses, excluding non-cash stock compensation	2,822,853	2,422,659	400,194	16.5	%
- R&D stock compensation	554,720	85,185	469,535	551.2	%
Total Research and Development	3,377,573	2,507,844	869,729	34.7	%
General and administrative expenses:					
-G&A expenses, excluding non-cash stock compensation	2,723,426	3,051,153	(327,727)	(10.7)	)%
-G&A stock compensation	964,434	261,410	703,024	268.9	%
Total General and Administrative	3,687,860	3,312,563	375,297	11.3	%
Litigation settlement contingency	_	1,901,538	(1,901,538)	(100	)%
Non-operating income (expense)	6,003	(991,688)	(992,291)	100.1	%
Net loss	\$(7,035,571)	\$(8,689,774)	\$1,654,203	(19.0	)%

# Revenue

Revenue relates to license fees and royalties collected that are being amortized over the period of the license granted. Revenue was unchanged at \$39,468 for the three months ended March 31, 2015 and 2014. The deferred revenue balance of \$1,710,231, as of March 31, 2015, is being amortized and recorded to revenue over approximately 11 years. We currently have no therapeutic products available for sale and do not expect to have any commercially available for sale for a period of years, if at all.

# Research and Development Expenses

Our research and development, or "R&D", expenses consist mainly of payroll and payroll related expenses for our scientific, manufacturing, clinical and regulatory staff, services attained in connection with our ongoing clinical trials and pre-clinical programs, our R&D and manufacturing facilities, and research supplies and materials. Our primary focus is on the development of novel therapies based on terminally differentiated cells. R&D expenses represent both pre-clinical and clinical development costs and costs associated with support activities such as manufacturing, quality control and regulatory processes. The cost of our research and development personnel is the most significant category of R&D expense; however, we also incur expenses with third parties, including license agreements, sponsored

research programs and consulting expenses.

R&D expenditures, excluding non-cash stock compensation expense, increased from \$2,422,659 for the three months ended March 31, 2014 to \$2,822,853 for the same period in 2015, for an increase of \$400,194 or 16.5%. The increase in R&D expenditures was primarily due to an increase in employee costs of approximately \$202,000, an increase in expenses related to travel and conferences of approximately \$163,000, an increase in costs related to our scientific advisory board of approximately \$83,000, and an increase in consulting expenses of approximately \$38,000. These increases were partially offset by decreases in pre-clinical program expenditures of approximately \$79,000 and lab supplies of approximately \$40,000. These shifts in expenditures were driven primarily by our shift in focus from pre-clinical programs to our planned expansion of our clinical capabilities as we continue to prepare for the commencement of our Phase 2 clinical trial in AMD and Pivotal clinical trial in SMD.

R&D expenses related to non-cash stock compensation increased from \$85,185 for the three months ended March 31, 2014 to \$554,720 for the same period in 2015, for an increase of \$469,535, or 551.2%. This increase is due to Q3 grants to the Chief Science Officer and Chief Medical Officer in the third quarter of 2014 which each accounted for approximately \$150,000 of the increase. Additionally, company-wide grants were made to non-executives during the third quarter of 2014 which resulted in higher stock compensation expense for the three months ended March 31, 2015 as compared to the same period in 2014.

We expect that R&D expenses will increase from period to period, for the foreseeable future. This planned increase will be driven primarily by our expansion of our clinical operations capabilities as we initiate and scale our Phase 2 clinical trial for AMD and Pivotal clinical trial for SMD. Spending will continue to increase throughout 2015 as our trials are initiated and patients are being enrolled in the trials. We currently work with four clinical sites in the US and two in the UK. We plan to expand the number of sites in both the US and in Europe. In addition, we are expanding the network of consultants and service providers we contract and we also plan to expand our internal workforce. These expansions and the increased spend that will result from these expanded capabilities is consistent with our previously stated plans to transition to become a product development company. Our spending is impacted by the timing of enrollment and treatment of clinical trial patients along with interim results of our many pre-clinical programs. The amount and timing of these fluctuations can be difficult to predict due to the uncertainty inherent in the timing and extent of progress in our research programs, initiation of new clinical trials and rate of progression of existing clinical trials. In addition, the results from our basic research and pre-clinical trials, as well as the results of trials of similar therapeutics under development by others, will influence the number, size and duration of future trials. As our research efforts mature, we will continue to review the direction of our research based on an assessment of the value of possible commercial applications emerging from these efforts. Based on this continuing review, we expect to establish discrete research programs and evaluate the cost and potential for cash inflows from commercializing products, partnering with others in the biotechnology or pharmaceutical industry, or licensing the technologies associated with these programs to third parties.

We believe that it is not possible at this stage to provide a meaningful estimate of the total cost to complete our ongoing projects and bring any proposed products to market. The use of human embryonic stem cells as a therapy is an emerging area of medicine, and it is not known what clinical trials will be required by the U.S. Food and Drug Administration, or FDA, in order to gain marketing approval. Costs to complete could vary substantially depending upon the projects selected for development, the number of clinical trials required and the number of patients needed for each study. It is possible that the completion of these studies could be delayed for a variety of reasons, including difficulties in enrolling patients, delays in manufacturing, incomplete or inconsistent data from the pre-clinical or clinical trials, and difficulties evaluating the trial results. Any delay in completion of a trial would increase the cost of that trial, which would harm our results of operations. Due to these uncertainties, we cannot reasonably estimate the size, nature or timing of the costs to complete, or the amount or timing of the net cash inflows from, our current activities. Until we obtain further relevant pre-clinical and clinical data, we will not be able to estimate our future expenses related to these programs or when, if ever, and to what extent we will receive cash inflows from resulting products.

# General and Administrative Expenses

General and administrative, or "G&A", expenses consist mainly of payroll and payroll related expenses, legal costs relating to corporate matters, and fees for consultants, service providers and other administrative costs. G&A expenditures, excluding non-cash stock compensation expense, decreased from \$3,051,153 for the three months ended March 31, 2014 to \$2,723,426 for the same period in 2015, for a decrease of \$327,727 or 10.7%.

The decrease in G&A expenditures was primarily due to a reduction in legal costs of approximately \$508,000, a decrease in severance costs related our prior CEO of approximately \$335,000, and a decrease in recruiting fees of approximately \$91,000. Legal costs incurred in the three months ended March 31, 2014 included the costs associated with the resolution of several legacy matters. These decreases were partially offset by increases in payroll and other compensation costs of approximately \$381,000, in consulting and other professional fees of approximately \$189,000, and in insurance of approximately \$31,000. Payroll costs were higher due to the hiring of a new Chief Executive Officer and a Chief Commercial Officer during the second half of 2014. The increase in consulting and other professional fees was primarily attributable to the Company becoming listed on the NASDAQ exchange as well as an increase in IT spending period over period.

G&A expenses related to non-cash stock compensation increased from \$261,410 for the three months ended March 31, 2014 to \$964,434 for the same period in 2015, for an increase of \$703,024, or 268.9%. This increase is due to grants to the Chief Executive Officer, Chief Financial Officer, and Chairman of the Board of Directors in the third quarter of 2014 which accounted for approximately \$634,000 of the increase. Additionally, company-wide grants were made to non-executives during the third quarter of 2014 which resulted in higher stock compensation expense for the three months ended March 31, 2015 as compared to the same period in 2014.

# <u>Litigation Settlement Contingency</u>

In connection with the unsettled warrant obligation as of March 31, 2014, and the need for a loss contingency accrual relating to the associated litigation, the Company determined that a loss was probable and the amount of loss was reasonably estimable, based on the facts and circumstances surrounding the litigation during the last quarter of 2013. The loss contingency amount for the first quarter of 2014 represents the change from the last quarter of 2013 to the estimated number of shares to settle multiplied by the stock price at the end of the quarter plus an additional amount for potential interest charges. In June 2014, the legal matter giving rise to this obligation was settled, thereby eliminating the loss contingency accrual through the date of this report.

# Other Income (Expense)

	2015	2014	\$ Change	% Change
Interest income	\$-	\$54,890	\$(54,890)	(100) %
Interest expense	_	(296,972)	296,972	(100) %
Other loss	_	(50,726)	50,726	(100) %
Adjustments to fair value of unsettled warrant obligation	_	(985,908)	985,908	(100) %
Adjustments to fair value of derivatives	6,003	287,028	(281,025)	(97.9) %
Total non-operating expense	\$6,003	\$(991,688)	\$997,691	(100.6)%

Interest expense for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 decreased from \$296,972 to \$0. The decrease is due to the discontinuation of interest expense on our previously outstanding debt obligations to CAMOFI Master LDC and CAMHZN Master LDC, or together the "CAMOFI Parties."

The change in other loss during the three months ended March 31, 2015, compared to that of the same period in 2014, relates primarily to an accrued loss contingency that was deemed no longer likely to be settled during 2014.

The unsettled warrant obligation, adjustments to which generated \$985,908 in expense for the three months ended March 31, 2014, was settled on June 4, 2014 and therefore there was no activity related to this item in the current quarter.

Adjustments to the fair value of derivatives resulted in a gain of \$6,003 for the three months ended March 31, 2015 compared to a gain of \$287,028 for the three months ended March 31, 2014. The change of \$281,025 is primarily due to the retirement in 2014 of the derivatives associated with the debt issued to the CAMOFI Parties and therefore less derivative instruments are being re-valued for the three months ended March 31, 2015 as compared to the same period in 2014.

#### Liquidity and Capital Resources

#### Cash Flows

The following table sets forth a summary of our cash flows for the periods indicated below:

	Three Months Ended March 31,		
	2015	2014	
Net cash used in operating activities	\$(6,992,040)	\$(5,353,622)	
Net cash used in investing activities	(20,434)	(91,402)	
Net cash provided by financing activities	6,120,702	7,706,756	
Net increase (decrease) in cash and cash equivalents	(891,772)	2,261,732	
Cash and cash equivalents at the end of the period	\$3,532,602	\$4,005,217	

# **Operating Activities**

Our net cash used in operating activities during the three months ended March 31, 2015 and 2014 was \$6,992,040 and \$5,353,622, respectively. Net cash used in operating activities increased in the three months ended March 31, 2015 period compared to the same period in 2014 period despite generating a smaller net loss. The net loss decrease of approximately \$1.6 million was offset primarily by an increase in stock compensation of \$1.2 million. Other drivers include a decrease in the change in operating assets and liabilities of approximately \$1.5 million and an add-back to cash in the 2014 period of approximately \$2.0 million for non-cash financing costs. The non-cash financing costs was primarily related to the change in the non-cash warrant holder litigation expense.

#### Cash Used in Investing Activities

Cash used in investing activities during the three months ended March 31, 2015 and 2014 was \$20,434 and \$91,402, respectively. Our cash used in investing activities during both periods was attributed to the purchase of fixed assets.

#### Cash Flows from Financing Activities

On June 27, 2014, we entered into the 2014 Purchase Agreement with Lincoln Park pursuant to which we have the right to sell to Lincoln Park up to \$30,000,000 in shares of its common stock, subject to certain limitations set forth in the 2014 Purchase Agreement.

Upon the satisfaction of the conditions set forth in the 2014 Purchase Agreement, we obtained the right over a 36-month period to sell up to \$30,000,000 worth of shares of our common stock to Lincoln Park based upon the terms set forth in the 2014 Purchase Agreement. Pursuant to the 2014 Purchase Agreement, the purchase price of such common stock will be based on the prevailing market price of our common stock immediately preceding the time of sales, with our controlling the timing and amount of any future sales, if any, of common stock to Lincoln Park. There are no upper limits to the price Lincoln Park may pay to purchase our common stock. Lincoln Park shall not have the right or the obligation to purchase any shares of common stock on any business day that the closing price of our common stock is below a floor price of \$1.00, as adjusted under the 2014 Purchase Agreement due to the 100-to-1 reverse split of our common stock effected in August 2014.

Cash flows provided by financing activities during the three months ended March 31, 2015 and 2014 was \$6,120,702 and \$7,706,756, respectively. During the three months ended March 31, 2015, we received \$6,120,702 from the issuance of 972,699 shares to Lincoln Park as part of the 2014 Purchase Agreement.

We plan to fund our operations for the foreseeable future from the following sources:

·As of March 31, 2015, we have \$3,532,602 in cash.

As of March 31, 2015, \$12,498,749 is available to us through the Lincoln Park financing arrangement. On various dates from April 1, 2015 through May 7, 2015, Lincoln Park purchased 280,892 shares of common stock for cash proceeds to the Company of \$1,904,816. As of May 7, 2015, the Company has \$10,593,933 available to us through the Lincoln Park financing arrangement.

We have no expectation of generating any meaningful revenues from our product candidates for a substantial period of time and must rely on raising funds in capital transactions to finance our research and development programs. Our future cash requirements will depend on many factors, including the pace and scope of our research and development programs, the costs involved in filing, prosecuting and enforcing patents, and other costs associated with commercializing our potential products.

We believe that our current cash balance, and the \$12,498,749 available to us under the Lincoln Park financing arrangement as of March 31, 2015, will be sufficient to fund our operations into early 2016. This belief is based on the assumption that our stock price does not realize any significant or prolonged decreases. Our ability to fund our operations through the Lincoln Park arrangement is highly dependent on our stock price. A significant decline in our share price could force us to curtail our operations in part, or entirely. We are continually in discussions with potential investors and collaborators to explore alternative sources of funding which may or may not result in immediate and substantial dilution to our stockholders, so that we may either extend our current cash runway beyond early 2016 or accelerate the rate of investment in our many clinical and pre-clinical programs.

We cannot assure you that public or private financing or grants will be available on acceptable terms, if at all. Several factors will affect our ability to raise additional funding, including, but not limited to, the volatility of our common stock and the broader public equity market, especially public equities issued by other pre-commercial biotechnology companies, and our ability to raise capital through non-dilutive transactions such as out-licenses. If we are unable to raise additional funds, we will be forced to either scale back our business efforts or curtail our business activities entirely. As of March 31, 2015, the Company has an accumulated deficit of \$356.2 million, recurring losses from operations, and negative working capital which raise substantial doubt about the ability of the Company to continue as a going concern.

# **Off-Balance Sheet Arrangements**

We do not maintain any off-balance sheet arrangements, transactions, obligations or other relationships with unconsolidated entities that would be expected to have a material current or future effect upon our financial condition or results of operations.

# ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a significant portion of our investments are in short-term debt securities issued by the U.S. government and institutional money market funds. The primary objective of our investment activities is to preserve principal. Due to the nature of our marketable securities, we believe that we are not exposed to any material market risk. We do not have any derivative financial instruments or foreign currency instruments. If interest rates had varied by 10% in the quarter ended March 31, 2015, it would not have had a material effect on our results of operations or cash flows for that period.

#### ITEM 4. CONTROLS AND PROCEDURES

#### **Disclosure Controls and Procedures**

Our principal executive and financial officer after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in the Exchange Act Rule 13a- 15(e) or Rule 15d-15(e)), with the participation of our management has concluded that as of the end of the period covered by this Quarterly Report on Form 10-Q our disclosure controls and procedures were effective and were designed to ensure that information we are required to disclose in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to management including our principal executive and financial officer as appropriate to allow timely decisions regarding required disclosure and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms. It should be noted that any system of controls is designed to provide reasonable but not absolute assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances. Our principal executive and financial officer has concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at a level that provides such reasonable assurances.

We carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2015. Based upon that evaluation, the Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

# **Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended March 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

# PART II. OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, as of March 31, 2015, we were not party to any legal or arbitration proceedings that may have, or have had in the recent past, significant effects on our financial position or profitability. No governmental proceedings are pending or, to our knowledge, contemplated against us. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

# ITEM 1A. RISK FACTORS

Investment in our securities involves a high degree of risk. Our Annual Report on Form 10-K for the year ended December 31, 2014, which was filed with the SEC on March 16, 2015, as amended, contains in Part I, Item 1A numerous risk factors relating to, among other things, our business and operations, our intellectual property, clinical trials, regulatory matters, our dependence on third parties, our industry and our common stock.

During the three months ended March 31, 2015, there were no material changes to the risk factors that were disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2014.

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

On March 31, 2015, we issued various board members 7,500 shares of common stock valued at \$46,200 as compensation for board services.

We relied on the exemption from registration provided by Section 4(a)(2) of the Securities Act, with respect to each of the issuances of unregistered securities set forth above.

# **ITEM 6. EXHIBITS**

# **Exhibit Description**

- 31.1 Section 302 Certification of Principal Executive Officer.\*
- 31.2 Section 302 Certification of Principal Financial Officer.\*
- 32.1 Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.\*
- 32.2 Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350.\*
- 101.SCH XBRL Schema Document\*
- 101.CALXBRL Calculation Linkbase Document\*
- 101.DEF XBRL Definition Linkbase Document\*
- 101.LABXBRL Label Linkbase Document\*
- 101.PRE XBRL Presentation Linkbase Document\*

<sup>\*</sup> Filed herewith

# **SIGNATURE**

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

# OCATA THERAPEUTICS, INC.

By: /s/ Paul K. Wotton Paul K. Wotton

President and Chief Executive Officer

Dated: May 7, 2015 (Principal Executive Officer)

# OCATA THERAPEUTICS, INC.

By: /s/ Edward Myles Edward Myles

Chief Operating Officer and Chief Financial Officer

Dated: May 7, 2015 (Principal Financial Officer and Principal Accounting Officer)