

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 11/07/13 for the Period Ending 11/07/13

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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Symbol	OPXA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (date of earliest event reported): November 7, 2013

OPEXA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Texas
(State or other jurisdiction of incorporation)

001-33004
(Commission File Number)

76-0333165
(IRS Employer Identification No.)

2635 Technology Forest Blvd., The Woodlands, Texas
(Address of principal executive offices)

77381
(Zip Code)

Registrant's telephone number, including area code: **(281) 272-9331**
N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition

On November 7, 2013, Opexa Therapeutics, Inc. (the “**Company**”) filed its Quarterly Report on Form 10-Q for the quarter ended September 30, 2013 and announced its results of operations in a press release. A copy of the press release announcing the results is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On the same day, members of the Company’s management will hold a teleconference to discuss the financial results. Interested individuals desiring to participate in the teleconference may dial in approximately ten minutes before the scheduled 5:00 P.M. EST call to (253) 237-1170 or toll free at (877) 372-0867. Please reference conference ID # 94585914 when dialing into the call. A live webcast of the call can also be accessed via the webcast link on the Company’s website (www.opexatherapeutics.com).

Item 7.01 Regulation FD Disclosure.

The slide presentation that will be used in connection with the teleconference disclosed in Item 2.02 above will be posted to the Investor Relations page of the Company’s website at www.opexatherapeutics.com. A copy of the slide presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The Company does not undertake to update this presentation.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Opexa Therapeutics, Inc. on November 7, 2013
99.2	Opexa Therapeutics, Inc. Earnings Update Teleconference Presentation dated November 7, 2013

The information in Items 2.02 and 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities under that Section, nor be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933.

SIGNATURES

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

Dated: November 7, 2013

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

EXHIBIT INDEX

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Opexa Therapeutics Reports Third Quarter 2013 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--November 7, 2013--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biotechnology company developing Tcelna[®], a novel T-cell immunotherapy for the treatment of multiple sclerosis (MS), today reported financial results for the third quarter ended September 30, 2013 and provided an overview of the Company's recent corporate developments.

Recent highlights include:

- **Clinical**

- As of November 6, 2013, enrolled 100 patients in the Phase IIb "Abili-T" clinical study of Tcelna (imilecleucel-T) in patients with Secondary Progressive Multiple Sclerosis (SPMS). The Abili-T clinical trial is a randomized, double-blind, placebo-controlled study designed to enroll 180 patients at approximately 33 leading clinical sites in the U.S. and Canada.
- Furthered the accumulation of comprehensive patient data to support Opexa's Immune Monitoring Program initiative in conjunction with the Abili-T trial, including the potential identification of biomarkers for SPMS and further understanding of the immunopathology of SPMS.

- **Financial**

- Reported cash and cash equivalents of \$20,172,485 as of September 30, 2013.
- Closed an underwritten public offering of 12 million shares of common stock in August 2013 and sold an additional 900,000 shares of common stock in September 2013 through the exercise of an over-allotment option granted to the underwriter of the public offering, with aggregate gross proceeds of \$19.4 million, or net proceeds of approximately \$17.4 million after deducting underwriting discounts and commissions and estimated offering expenses.
- Eliminated debt on Opexa's consolidated balance sheet through the conversion into common stock of the remaining July 2012 convertible secured promissory notes in an aggregate principal amount of \$3.185 million.
- Terminated the remaining \$500,000 deposit control agreement in connection with conversion of the July 2012 convertible secured promissory notes, resulting in the funds being reported as cash and cash equivalents on the consolidated balance sheet instead of as restricted cash.

- **Operational**

- Strengthened the team with the addition of several talented individuals dedicated to furthering the Company's development initiatives, including enhancing the manufacturing and delivery of Tcelna.

"We recently reached a major milestone by enrolling the 100th patient into the Abili-T study," commented Neil K. Warma, Opexa's President and Chief Executive Officer. "With the recent addition of three new clinical trial sites in the U.S., we now have 33 centers across North America participating in the Abili-T study," added Mr. Warma. "We expect to complete enrollment of 180 patients in early 2014 and release the top-line results of the study in the middle of 2016."

“On the financial front, we focused our efforts this quarter on strengthening and cleaning up our balance sheet,” commented Karthik Radhakrishnan, Opexa’s Chief Financial Officer. “Following the receipt of net proceeds of approximately \$17.4 million through our August 2013 public offering and the subsequent exercise of the underwriters’ over-allotment option, we ended the quarter with over \$20 million of cash and cash equivalents. In addition, we eliminated the remaining \$3.185 million principal amount of the July 2012 convertible secured promissory notes through the conversion of principal and accrued interest into shares of our common stock,” added Mr. Radhakrishnan.

“The Company’s cash position is the highest it has been at any previous quarter-end in its recent history, and this positions Opexa to pursue shareholder value by continuing to execute on our clinical mission,” added Mr. Warma. “With the recent infusion of capital along with the conversion of the July 2012 Notes into common stock, our cash position now takes us into the first quarter of 2015.”

Third Quarter Financial Results

Opexa reported revenue of \$348,837 and \$917,774 for the three and nine months ended September 30, 2013, respectively. The revenue is related to the recognized portion of the \$5 million upfront payment received from Merck Serono in conjunction with the Option and License Agreement entered into between Opexa and Merck Serono during February 2013. The unearned revenue is being recognized over the expected term of Merck’s period to exercise its option to license Tcelna for MS. No revenues were recognized during the three and nine months ended September 30, 2012.

Research and development expenses were \$2,494,463 and \$6,338,859 for the three and nine months ended September 30, 2013, respectively, compared with \$1,455,938 and \$4,504,243 for the three and nine months ended September 30, 2012, respectively. The increase was primarily due to costs associated with the initiation of clinical sites and increasing enrollment of patients for the Abili-T clinical study, including increases in manufacturing, the number of employees and registration costs in connection with the Company’s patent portfolio. Expenses were partially offset by costs associated with the training and qualification activities preceding the commencement of the Abili-T clinical trial in the second half of 2012.

General and administrative expenses for the three and nine months ended September 30, 2013 were \$626,668 and \$2,479,708, respectively, compared with \$532,474 and \$1,878,236 for the three and nine months ended September 30, 2012, respectively. The increase was primarily due to a modest increase in employees to support the ongoing clinical trial and increases in legal and stock compensation expenses. The increase for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was partially offset by a decrease in other professional fees.

Depreciation and amortization expense for the three and nine months ended September 30, 2013 was \$90,935 and \$258,144, respectively, compared with \$81,514 and \$225,365 for the three and nine months ended September 30, 2012, respectively. The increase in expense for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 is primarily due to increases in depreciation for laboratory and manufacturing equipment acquired during 2013 and leasehold improvements during 2013 to support increased development activities. The increase in expenses for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 is primarily due to increases in depreciation for laboratory and manufacturing equipment acquired during 2012 and 2013, leasehold improvements during 2013 and software obtained during 2012 to support increased development activities.

Interest expense for the three and nine months ended September 30, 2013 was \$346,239 and \$2,267,293, respectively, compared with \$151,029 and \$152,002 for the three and nine months ended September 30, 2012, respectively. Interest expense for the three months ended September 30, 2013 was primarily related to the amortized debt discount on the remaining July 2012 convertible secured promissory notes for the three months through the conversion date of September 24, 2013 and the amortization of the financing fees over the term of the July 2012 Notes for the three months through the conversion date. Interest expense for the three months ended September 30, 2012 related to the amortized debt discount and interest on the July 2012 Notes and the amortization of the financing fees over the term of the Notes. Interest expense for the nine months ended September 30, 2013 primarily related to the amortized debt discount and interest on both the July 2012 Notes and the January 2013 convertible promissory notes and the amortization of the financing fees over the term of the notes. Interest expense for the nine months ended September 30, 2012 primarily related to the amortized debt discount and interest on the July 2012 Notes.

Interest income for the three and nine months ended September 30, 2013 was \$4,448 and \$9,388, respectively, compared with \$61 and \$256 for the three and nine months ended September 30, 2012, respectively.

Loss on extinguishment of debt related to the September 24, 2013 conversion of the remaining July 2012 convertible secured promissory notes was \$2,518,912 for both the three and nine months ended September 30, 2013. There was no loss on extinguishment of debt recorded for either the three or nine months ended September 30, 2012.

Opexa reported a net loss for the three and nine months ended September 30, 2013 of \$5.72 million, or (\$0.39) per share, and \$12.9 million, or (\$1.29) per share, respectively. For the same three and nine month period ended September 30, 2012, Opexa reported a net loss of \$2.36 million, or (\$0.40) per share, and \$6.9 million, or (\$1.20) per share, respectively.

Cash and cash equivalents were \$20,172,485 as of September 30, 2013, compared to \$592,004 as of December 31, 2012. Inclusive of the \$5 million upfront payment received from Merck Serono in conjunction with the License and Option Agreement, the Company's financing activities generated approximately \$27 million in net proceeds for the nine months ended September 30, 2013.

For additional information please see Opexa's Quarterly Report on Form 10-Q filed today with the SEC.

Conference Call and Webcast Details

Opexa will conduct a conference call and webcast to provide a corporate update and discuss the financial results at 5:00 p.m. Eastern Time today. To participate in the conference call, dial in approximately ten minutes before the scheduled 5:00 p.m. time to (253) 237-1170 or toll free at (877) 372-0867. Please reference conference ID 94585914 or the Opexa Therapeutics Earnings Call.

A live webcast of the call can also be accessed via the webcast link on the Investor Relations page of Opexa's website (www.opexatherapeutics.com).

About Opexa

Opexa's mission is to lead the field of Precision Immunotherapy™ by aligning the interests of patients, employees and shareholders. The Company's leading therapy candidate, Tcelna®, is a personalized T-cell immunotherapy that is in a Phase IIb clinical development program (the Abili-T trial) for the treatment of Secondary Progressive MS. Tcelna is derived from T-cells isolated from the patient's peripheral blood, expanded ex vivo, and reintroduced into the patients via subcutaneous injections. This process triggers a potent immune response against specific subsets of autoreactive T-cells known to attack myelin.

About Multiple Sclerosis (MS)

Multiple Sclerosis is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that approximately two million people have MS worldwide.

While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common. The Secondary Progressive form of MS represents about a third of the MS patient population.

About Tcelna

Tcelna® is a potential personalized therapy that is under development to be specifically tailored to each patient's disease profile. Tcelna is manufactured using ImmPath™, Opexa's proprietary method for the production of a patient-specific T-cell immunotherapy, which encompasses the collection of blood from the MS patient, isolation of peripheral blood mononuclear cells, generation of an autologous pool of myelin-reactive T-cells (MRTCs) raised against selected peptides from myelin basic protein (MBP), myelin oligodendrocyte glycoprotein (MOG) and proteolipid protein (PLP), and the return of these expanded, irradiated T-cells back to the patient. These attenuated T-cells are reintroduced into the patient via subcutaneous injection to trigger a therapeutic immune system response.

Opexa is currently conducting a Phase IIb study of Tcelna. Named “Abili-T,” the trial is a randomized, double-blind, placebo-controlled clinical study in patients who demonstrate evidence of disease progression with or without associated relapses. The trial is expected to enroll 180 patients at approximately 33 leading clinical sites in the U.S. and Canada with each patient receiving two annual courses of Tcelna treatment consisting of five subcutaneous injections per year. The trial’s primary efficacy outcome is the percentage of brain volume change (atrophy) at 24 months. Study investigators will also measure several important secondary outcomes commonly associated with MS, including disease progression as measured by the Expanded Disability Status Scale (EDSS), annualized relapse rate and changes in disability as measured by EDSS and the MS Functional Composite.

For more information visit the Opexa Therapeutics website at www.opexatherapeutics.com.

Cautionary Statement Relating to Forward-Looking Information for the Purpose of "Safe Harbor" Provisions of the Private Securities Litigation Reform Act of 1995

This earnings release contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements contained in this release, other than statements of historical fact, constitute "forward-looking statements." The words "expects," "believes," "anticipates," "estimates," "enables," "may," "could," "intends," "positions," and similar expressions are intended to identify forward-looking statements. Forward-looking statements do not constitute guarantees of future performance. Investors are cautioned that statements which are not strictly historical statements, including, without limitation, statements regarding current or future financial payments, returns, royalties, performance and position, management's strategy, plans and objectives for future operations, plans and objectives for product development, plans and objectives for present and future clinical trials and results of such trials, plans and objectives for regulatory approval, litigation, intellectual property, product development, manufacturing plans and performance, and management's initiatives and strategies, and the financing and development of the Company's product candidate, Tcelna (imilecleucel-T), constitute forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated. These risks and uncertainties include, but are not limited to, risks associated with: market conditions; our capital position; our ability to compete with larger, better financed pharmaceutical and biotechnology companies; new approaches to the treatment of our targeted diseases; our expectation of incurring continued losses; our uncertainty of developing a marketable product; our ability to raise additional capital to continue our development programs (including to undertake and complete any ongoing or further clinical studies for Tcelna), including in this regard our ability to satisfy various conditions required to access the financing potentially available under the purchase agreements with Lincoln Park Capital Fund, LLC ("Lincoln Park") (such as the minimum closing price for our common stock and the requirement for an ongoing trading market for our stock); our ability to raise additional capital through the sale of shares of our common stock under the purchase agreements with Lincoln Park or under our at-the-market (ATM) facility; our ability to maintain compliance with NASDAQ listing standards; the success of our clinical trials (including the Phase IIb trial for Tcelna in secondary progressive MS which, depending upon results, may determine whether Ares Trading SA ("Merck") elects to exercise its option for an exclusive license to Tcelna for the treatment of MS (the "Option")); whether Merck exercises its Option and, if so, whether we receive any development or commercialization milestone payments or royalties from Merck pursuant to the Option; our dependence (if Merck exercises its Option) on the resources and abilities of Merck for the further development of Tcelna; the efficacy of Tcelna for any particular indication, such as for relapsing remitting MS or secondary progressive MS; our ability to develop and commercialize products; our ability to obtain required regulatory approvals; our compliance with all Food and Drug Administration regulations; our ability to obtain, maintain and protect intellectual property rights (including for Tcelna); the risk of litigation regarding our intellectual property rights or the rights of third parties; the success of third party development and commercialization efforts with respect to products covered by intellectual property rights that we may license or transfer; our limited manufacturing capabilities; our dependence on third-party manufacturers; our ability to hire and retain skilled personnel; our volatile stock price; and other risks detailed in our filings with the SEC. These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update any forward-looking statements to reflect any changes in expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the SEC.

OPEXA THERAPEUTICS, INC.
(a development stage company)

Statements of Expenses Data (unaudited):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Option Revenue	\$ 348,837	\$ -	\$ 917,774	\$ -
Research and development	\$ 2,494,463	\$ 1,455,938	\$ 6,338,859	\$ 4,504,243
General and administrative	626,668	532,474	2,479,708	1,878,236
Depreciation and amortization	90,935	81,514	258,144	225,365
Loss on disposal of assets	-	-	-	-
Operating loss	(2,863,229)	(2,069,926)	(8,158,937)	(6,607,844)
Interest income	4,448	61	9,388	256
Other income, net	-	-	37,910	-
Loss on extinguishment of debt	(2,518,912)	-	(2,518,912)	-
Loss on derivative instruments	-	(136,889)	-	(136,889)
Interest expense	(346,239)	(151,029)	(2,267,293)	(152,002)
Net loss	<u>\$ (5,723,932)</u>	<u>\$ (2,357,783)</u>	<u>\$ (12,897,844)</u>	<u>\$ (6,896,479)</u>
Basic and diluted loss per share	\$ (0.39)	\$ (0.40)	\$ (1.29)	\$ (1.20)
Weighted average shares outstanding	14,721,474	5,762,028	10,011,453	5,762,028

Selected Balance Sheet Data:

	September 30, 2013 (unaudited)	December 31, 2012
Cash and cash equivalents	\$ 20,172,485	\$ 592,004
Other current assets	1,304,146	1,077,546
Fixed assets, net	1,226,511	1,265,041
Restricted cash	-	1,000,000
Deferred financing costs, net	-	211,479
Other long term assets	85,047	-
Total assets	22,788,189	4,146,070
Total current liabilities	3,365,965	885,975
Notes payable, net	-	376,763
Deferred revenue	2,686,878	-
Total stockholders' equity	16,735,346	2,883,332

CONTACT:
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Karthik Radhakrishnan
Chief Financial Officer
281-775-0600

or
Investor Relations:
The Trout Group
Adam Cutler
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OPEXA THERAPEUTICS



Precision Immunotherapy™

Opexa Therapeutics, Inc.

*November 7, 2013
Q3 2013 Earnings Call*



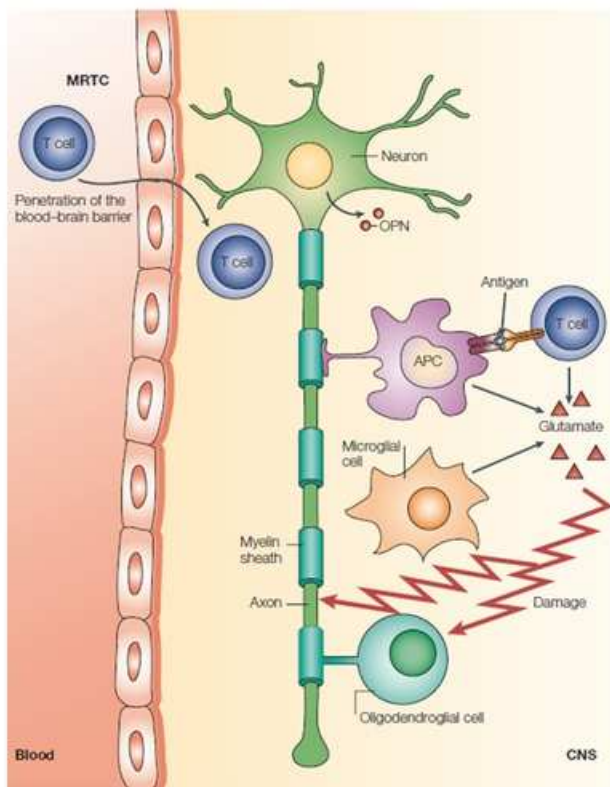
Forward-Looking Statements

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Tcelna Addressing the Root Cause of Multiple Sclerosis

Preventing Demyelination and Enabling Remyelination



Nature Reviews | Immunology

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- Myelin Reactive T-cells (MRTC) cross the blood brain barrier, enter the brain, bind to antigen presenting cells (APC) causing release of pro-inflammatory cytokines which lead to a two pronged attack through:

- i. Activation of microglial cells leading to destruction of myelin sheath, the protective coating of nerve fibers
- ii. Destruction of oligodendroglial cells which are responsible for producing myelin

Result → Destruction of the myelin sheath with barriers to prevent remyelination

- T cells play a vital role in our immune system. Only a very small proportion develop into MRTCs. Most competing therapies **non-specifically** suppress all T-cells (including beneficial T cells) and/or focus on preventing their entry into the central nervous system, which may lead to serious side effects.

Opexa's Strategy

Tcelna programs the immune system to **specifically** recognize MRTCs as pathogenic thereby inhibiting further destruction of the myelin sheath and potentially enabling remyelination



Abili-T : Landmark trial in SPMS

- **Abili-T Phase IIb clinical trial in SPMS is ongoing**
 - Double-blind, 1:1 randomized, placebo-controlled
 - Two annual courses of personalized therapy
 - Inclusion criteria: Secondary Progressive MS with EDSS of 3 to 6
 - 100 patients enrolled as of November 6, 2013
 - Immune Monitoring program conducted on a blinded basis
- **Fast Track designation granted by FDA for Tcelna in SPMS**
- **180 Patients expected to be enrolled**
 - SPMS population
 - Approximately 33 sites in USA and Canada
- **Primary Endpoint**
 - Whole-brain atrophy
- **Secondary Endpoints**
 - Sustained progression measured by EDSS
 - Time to sustained progression
 - Change in EDSS, etc.



Balance Sheet Highlights

	Sept 2013	Dec 2012
Assets		
Cash & Cash Equivalents	\$20,172,485	\$592,004
Property Plant & Equipment	\$1,226,511	\$1,265,041
Deferred Financing Costs net	\$-	\$211,479
Liabilities & Shareholders' Equity		
Accounts Payable	\$914,317	\$412,096
Shareholders' equity	\$16,735,346	\$2,883,332



Income Statement

	Sept 2013	Sept 2012
Revenues	\$348,837	-
R&D Expense	\$2,494,463	\$1,455,938
General & Administrative	\$626,668	\$532,474
Interest Expense	\$346,239	\$151,029
Loss on Extinguishment of debt	\$2,518,912	\$-
Net Loss	\$5,723,932	\$2,357,783
Basic and diluted Loss per share	\$0.39	\$0.40



Investment Thesis

- T-cell platform company with Fast Track designation in SPMS
- Strong Intellectual property with 50 issued patents
- Esteemed Scientific Advisory Board
- Precision Immunotherapy potentially optimizes benefit-risk profile
- Targeting an unmet medical need in a potentially substantial market
- Option Agreement with Merck Serono, a strong commercial partner
- Replacement value of company is multiples of present market cap
- Attractive potential risk-reward profile for long term/value investors
- Goal-oriented management team focused on value creation