

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 08/14/13 for the Period Ending 08/14/13

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
Fiscal Year	12/31

**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): August 14, 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 August 14, 2013, Opexa Therapeutics, Inc. (the “**Company**”) filed its Quarterly Report on Form 10-Q for the quarter ended June 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 8:00 A.M. ET call to (253) 237-1170 or toll free at (877) 372-0867. Please reference conference ID # 31008302 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 August 14, 2013
99.2	Opexa Therapeutics, Inc. Earnings Update Teleconference Presentation dated August 14, 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: August 14, 2013

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

EXHIBIT INDEX

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99.1	Press Release issued by Opexa Therapeutics, Inc. on August 14, 2013
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Opexa Therapeutics Reports Second Quarter 2013 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--August 14, 2013--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biotechnology company developing Tcelna[®], a novel T-cell therapy for multiple sclerosis (MS), today reported financial results for the quarter ended June 30, 2013 and provided an overview of recent corporate developments.

Recent highlights include:

- **Clinical**

- Enrolled 68 patients as of August 8, 2013 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 and will enroll 180 patients through approximately 30 leading clinical sites in the U.S. and Canada;
- Furthered the accumulation of comprehensive subject 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; and
- Presented baseline data from Opexa's Immune Monitoring Program in a poster session at the 2013 Annual Meeting of the Consortium of Multiple Sclerosis Centers (CMSC) and the Fifth Cooperative Meeting with the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS).

- **Financial**

- Closed an underwritten public offering of 12 million shares of common stock for gross proceeds of \$18 million in August 2013, or net proceeds of approximately \$16.2 million after underwriting discounts and commissions and estimated offering expenses.

- **Operational**

- Strengthened our team to advance Precision Immunotherapy[™] in SPMS by hiring several talented individuals to further our development initiatives as well as enhance the manufacture and delivery of Tcelna to our patients enrolled in the Abili-T study.

"We are coming off a productive quarter with demonstrated progress in the Abili-T clinical trial and the announcement of our recent public offering of \$18 million in shares of our common stock," commented Neil K. Warma, Opexa's President and Chief Executive Officer. "We are pleased with the positive response from the investment community and the proceeds raised from this offering will allow us to focus on patient enrollment and trial execution. Top-line data from the trial is expected in the first half of 2016."

“The physician and patient community responded well earlier in the year to the announcement of the option and license agreement we executed with Merck Serono in February 2013. Following our receipt of the \$5 million upfront option fee from Merck Serono, we were able to redouble our efforts to focus on increasing patient enrollment and executing on the Abili-T clinical trial. We believe that the potential introduction of Tcelna as a safe and effective therapy for individuals afflicted with SPMS may address a significant unmet medical need that exists in the SPMS community.”

“We have implemented a comprehensive biomarker program as part of the Abili-T study and were invited by the ACTRIMS committee to present baseline data related to this immune monitoring program at their annual conference in June. Throughout the course of the trial, this study is expected to yield some very important data on the mechanism of action of Tcelna as well as the SPMS indication. In addition, to support the expected increase in trial activities, we added several key individuals to the Opexa team throughout the quarter further strengthening our expertise in the area of precision immunotherapy,” added Mr. Warma.

“As of June 30, 2013, our cash and cash equivalents totaled \$5,028,280, excluding \$500,000 held in a controlled account,” stated Karthik Radhakrishnan, Opexa’s Chief Financial Officer. “Our monthly burn rate for the six months ending June 2013 was approximately \$855,000 and is projected to increase to approximately \$1.2 million for the remaining six months of the year given the expected increase in patient enrollment in the trial. With the closing of the \$18 million offering, we believe our cash runway should extend into the second half of 2014.”

Second Quarter Financial Results

Opexa reported revenue of \$348,837 and \$568,937 for the three and six months ended June 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 February 2013 Option and License Agreement between Opexa and Merck Serono. The unearned revenue will be recognized over the expected term of Merck’s period to exercise its option to license Tcelna for multiple sclerosis. No revenues were recognized during the three and six months ended June 30, 2012.

Research and development expenses were \$2,223,030 and \$3,844,396 for the three and six months ended June 30, 2013, respectively, compared with \$1,558,208 and \$3,048,305 for the three and six months ended June 30, 2012, respectively. The increase for the three and six months ended June 30, 2013 compared to the three and six months ended June 30, 2012 was primarily due to an increase in the procurement and use of supplies for product manufacturing and development, the initiation of clinical sites and increasing enrollment of patients for the ongoing clinical trial of Tcelna in SPMS and an increase in the number of employees to support the ongoing clinical trial, and was partially offset by costs associated with the training and qualification activities preceding the commencement of the clinical trial in the second half of 2012.

General and administrative expenses for the three and six months ended June 30, 2013 were \$750,605 and \$1,853,040, respectively, compared with \$529,566 and \$1,345,762 for the three and six months ended June 30, 2012, respectively. The increase for the three and six months ended June 30, 2013 compared to the three and six months ended June 30, 2012 was primarily due to an increase in business development activities and a modest increase in employees to support the ongoing clinical trial, and was partially offset by a decrease in professional fees.

Depreciation and amortization expense for the three and six months ended June 30, 2013 was \$88,898 and \$167,209, respectively, compared with \$76,496 and \$143,851 for the three and six months ended June 30, 2012, respectively. The increase in expense is primarily due to increases in depreciation for laboratory and manufacturing equipment acquired during 2012 and 2013 to support increased development activities.

Interest expense for the three and six months ended June 30, 2013 was \$285,800 and \$1,921,054 respectively, compared with \$486 and \$973 for the three and six months ended June 30, 2012, respectively. The increase in interest expense for the three months ended June 30, 2013 was primarily related to the amortized debt discount and interest on the July 2012 convertible secured promissory notes and the amortization of the financing fees over the term of the notes. The increase in interest expense for the six months ended June 30, 2013 was primarily related to the amortized debt discount and interest on both the July 2012 convertible secured promissory 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 three and six months ended June 30, 2012 related solely to the financing of insurance premiums.

Interest income for the three and six months ended June 30, 2013 was \$3,066 and \$4,940, respectively, compared with \$59 and \$195 for the three and six months ended June 30, 2012, respectively.

Opexa reported a net loss for the three and six months ended June 30, 2013 of \$3.0 million, or \$0.37 per share, and \$7.17 million, or \$0.94 per share, respectively. For the same three and six month period ended June 30, 2012, Opexa reported a net loss of \$2.16 million, or \$0.38, and \$4.54 million, or \$0.79, respectively.

Cash and cash equivalents were \$5,028,280 as of June 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, our financing activities generated approximately \$9.5 million in gross proceeds for the six months ended June 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 8:00 a.m. Eastern Time today. To participate in the conference call, dial in approximately ten minutes before the scheduled 8:00 a.m. time to (253) 237-1170 or toll free at (877) 372-0867. Please reference conference ID #31008302 while dialing into the call.

A live webcast of the call can also be accessed via the webcast link on our website (www.opexatherapeutics.com) or by going to the following URL:

<http://investor.shareholder.com/media/eventdetail.cfm?eventid=133472&CompanyID=OPXA&e=1&mediaKey=52AF10A2390CE08BC8D2847172A3B20C>

There will be a brief Question & Answer session following management commentary. Shareholders and interested parties are highly encouraged to submit questions in advance by e-mail addressed to kradhakrishnan@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 Multiple Sclerosis. 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.

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

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 30 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.

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," "may," "could," "intends," and similar expressions are intended to identify forward-looking statements. The forward-looking statements in this release do not constitute guarantees of future performance. Investors are cautioned that statements in this report which are not strictly historical statements, including, without limitation, statements regarding the 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; the rights and preferences provided to the Series A convertible preferred stock and investors in the convertible secured notes we issued in July 2012 (including a secured interest in all of our assets); 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 Operations Data (unaudited):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Option Revenue	\$ 348,837	\$ -	\$ 568,937	\$ -
Research and development	2,223,030	1,558,208	3,844,396	3,048,305
General and administrative	750,605	529,566	1,853,040	1,345,762
Depreciation and amortization	88,898	76,496	167,209	143,851
Operating loss	\$ (2,713,696)	(2,164,270)	(5,295,708)	(4,537,918)
Interest income	3,066	59	4,940	195
Other income, net	-	-	37,910	-
Interest expense	(285,800)	(486)	(1,921,054)	(973)
Net loss	\$ (2,996,430)	\$ (2,164,697)	\$ (7,173,912)	\$ (4,538,696)
Basic and diluted loss per share	\$ (0.37)	\$ (0.38)	\$ (0.94)	\$ (0.79)
Weighted average shares outstanding	7,991,559	5,762,028	7,617,409	5,762,028

Selected Balance Sheet Data (unaudited):

	June 30, 2013	December 31, 2012
Cash and cash equivalents	\$ 5,028,280	\$ 592,004
Other current assets	1,694,010	1,077,546
Fixed assets, net	1,229,333	1,265,041
Restricted cash	500,000	1,000,000
Deferred financing costs, net	112,515	211,479
Other long-term assets	96,064	-
Total assets	8,660,202	4,146,070
Total current liabilities	3,760,934	885,975
Notes payable, net	521,942	376,763
Deferred revenue	3,035,715	-
Total stockholders' equity	1,341,611	2,883,332

CONTACT:

Company

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or

Investor Relations

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OPEXA THERAPEUTICS



Opexa Therapeutics, Inc.
Second Quarter 2013 Earnings Update Call
14 August 2013
NASDAQ: OPXA



Forward-Looking Statements

This earnings presentation 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," "may," "could," "intends," and similar expressions are intended to identify forward-looking statements. The forward-looking statements in this presentation do not constitute guarantees of future performance. Investors are cautioned that statements in this presentation which are not strictly historical statements, including, without limitation, statements regarding the 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; the rights and preferences provided to the Series A convertible preferred stock and investors in the convertible secured notes we issued in July 2012 (including a secured interest in all of our assets); 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.

Investment Thesis

- T-cell platform company
- 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



Pipeline and Potential Areas of Investigation

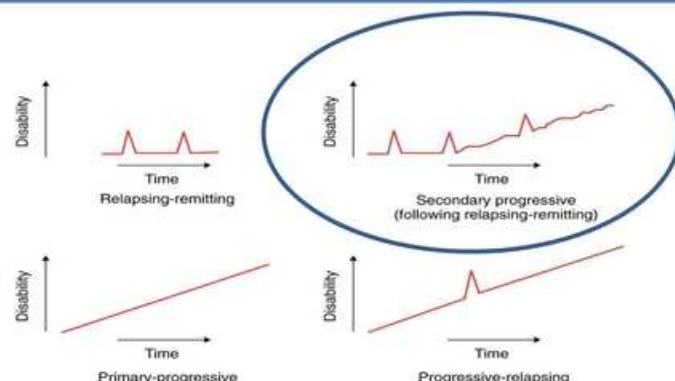
Stage of Development

Indication	Evaluation	Preclinical	Phase I	Phase II	Phase III	Commercial
T-CELL PLATFORM						
Multiple Sclerosis (Tcelna)*						
<i>Secondary Progressive MS*</i>		<i>Phase IIb ongoing</i>				
<i>Relapsing Remitting MS*</i>		<i>Phase III not yet initiated</i>				
STEM CELL PLATFORM						
Type 1 Diabetes						

* Rights granted to Merck Serono under option and license agreement (Feb. 5, 2013)

Tcelna® in Secondary Progressive Multiple Sclerosis

- Patients initially experience a relapsing-remitting course then transition to SPMS
- SPMS patients experience worsening QOL / disability with or without relapses
- Over 450,000 patients in North America and over 2 million worldwide have MS
- Approximately 30-45% of MS patients can be classified as Secondary Progressive
- Tcelna is being pursued for this SPMS indication
- Potential SPMS market in the U.S. alone could exceed \$7 billion [150,000 SPMS patients at average cost of \$50,000 per year of treatment]
- No SPMS treatment approved by EMA; only one approved by FDA with limited use due to toxicity
- Upon successful clinical development, Tcelna has the potential to be the treatment of choice in SPMS



Merck Serono Agreement for MS indication

- **February 2013 option and license agreement with Merck Serono**
 - Up to \$220 million in additional payments
 - Option exercise \$25 million for starting Phase III/ or \$15 million if another Phase II
 - \$35 million FDA filing, approval and commercialized in US
 - \$30 million for EU filing, approval and commercialization in at least three countries
 - RRMS development and commercialization of up to \$40 million
 - One time commercial milestones of up to \$85 million
- **Royalties ranging from 8 % to 15% of annual net sales with step-ups occurring when net sales exceed \$500 million, \$1 B & \$2 B**
- **Opexa maintains key rights:**
 - Development and commercialization rights to Tcelna in Japan
 - Certain manufacturing rights
 - Co-development funding option in exchange for increased royalties
 - Rights to all other disease indications



Financials (unaudited)

Income Statement	Q2 2013	Q2 2012
Option Revenue	\$348,837	-
Research & Development	\$2,223,030	\$1,558,208
General & Administrative	\$750,605	\$529,566
Earnings Per Share	\$ (0.37)	\$ (0.38)
Balance Sheet Details	June 30, 2013	Dec 31, 2012
Cash and Cash Equivalents	\$5,028,280 ⁽¹⁾	\$592,004
Convertible Debt ⁽²⁾	\$3,185,000	
Shares Outstanding as of 06/30 ⁽³⁾	7,991,559	5,762,028
Warrants	3,069,113	Weighted average X=\$4.12
Stock Options	1,089,500	Weighted average X=\$4.46

(1) Excludes (i) \$500,000 of restricted cash subject to a deposit control agreement and (ii) net proceeds of approximately \$16.2 million received upon closing of August 2013 underwritten public offering.

(2) Principal outstanding on convertible secured promissory notes.

(3) Excludes 12,000,000 shares issued 8-13-13 upon closing of underwritten public offering.



Tcelna Development Program

Broad Spectrum of MS patients treated

Phase	Completion Dates	Population	Total N	Treatment Duration (months)	Tcelna	Placebo
Baylor	1998	RRMS, PPMS, SPMS (26)	114	Up to 24 months	114	
Phase I dose escalation	2006	RRMS (5) SPMS (6)	16	12	16	-
Phase I/II Open label retreatment	2007	RRMS (9) SPMS (4)	13	12	13	-
Phase IIb TERMS	2008	RRMS, CIS	150	12	100	50
Phase IIb extension OLTERMS	2008	RRMS, CIS	38	At least one dose post TERMS	15 from placebo arm	
Phase IIb Abili-T	1 st Half 2016*	SPMS	180*	24*	90*	90*

* Expected upon completion of ongoing SPMS Abili-T trial

Abili-T: Landmark trial in SPMS

- **Abili-T Phase IIb clinical trial in SPMS is ongoing**
 - Double-blind, 1:1 randomized, placebo-controlled
 - Inclusion criteria: Secondary Progressive MS with EDSS of 3 to 6
 - 68 patients randomized as of August 8, 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 30 sites in USA and Canada
- **Key Efficacy Endpoints:**
 - Primary endpoint: Whole Brain Atrophy
 - Secondary endpoint: Disability metrics including EDSS, ARR, etc.
 - Exploratory endpoints: Quality of Life
- **2 annual courses of personalized therapy**

Goals and Milestones

- Present Immune Monitoring base line data at ACTRIMS Conference (2013)
- Activate Canadian sites and initiate enrollment in Canada (2013)
- Activate and Initiate all Abili-T clinical sites in U.S. (2013)
- Advance and complete enrollment in Phase IIb ABILI-T study in SPMS (2013-14)
- Evaluate and present interim immune monitoring data (2013-15)
- Evaluate potential of T-cell platform in additional autoimmune diseases (2013-14)

Investment Highlights

- Lead product, **Tcelna**[®], a T-cell immunotherapy for Multiple Sclerosis (MS)
- Currently conducting a Phase 2b clinical trial in Secondary Progressive MS (SPMS)
- Limited treatment options currently available for SPMS
- Potential SPMS market in North America alone could exceed \$7 Billion
- Tcelna positioned as potential first-to-market personalized T-cell immunotherapy
- Option and license agreement secured with Merck Serono for Tcelna in MS indications only, worldwide excluding Japan
- Opexa's in-house cGMP manufacturing enables close control of process and COGS
- In previous MS clinical studies, Tcelna has demonstrated good safety and potential indications of clinical efficacy
- FDA has granted Opexa Fast Track Designation for Tcelna in SPMS