

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 02/27/14 for the Period Ending 02/27/14

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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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): February 27, 2014

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 February 27, 2014, Opexa Therapeutics, Inc. (the “**Company**”) announced its results of operations for the year ended December 31, 2013 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.

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 February 27, 2014

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, 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: February 27, 2014

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President and Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Opexa Therapeutics, Inc. on February 27, 2014

Opexa Therapeutics Reports Year End 2013 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--February 27, 2014--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biotechnology company developing a novel T-cell immunotherapy for multiple sclerosis (MS), today reported financial results for the year ended December 31, 2013, and provided an overview of recent corporate developments.

2013 and recent highlights include:

- **Clinical**

- As of February 27, 2014, enrolled over 80% of the total number of patients expected to be enrolled 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 35 leading clinical sites in the U.S. and Canada; and
- Furthered the accumulation of comprehensive patient data to support Opexa’s Immune Monitoring Program which is being conducted in conjunction with the Abili-T trial. The goals of this Program are to identify potential novel biomarkers that could distinguish responders, to strengthen our intellectual property protection, and to broaden our understanding of the mechanism of action of Tcelna and the pathophysiology of SPMS patients.

- **Financial/Operational**

- Reported cash and cash equivalents of \$23,644,542 as of December 31, 2013;
- Closed two underwritten public offerings of an aggregate of 17,638,000 shares of common stock during the second half of 2013 for aggregate gross proceeds of approximately \$27.4 million, or net proceeds of approximately \$24.8 million after deducting underwriting discounts and commissions and offering expenses;
- Eliminated debt on Opexa’s consolidated balance sheet through the conversion into common stock of the July 2012 convertible secured promissory notes in an aggregate principal amount of \$4.1 million, and unencumbered all of our intellectual property and physical assets previously pledged as collateral;
- 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;
- Secured an option and license agreement with Merck Serono which, if exercised by Merck Serono, has the potential to bring in up to \$220 million in milestone payments plus 8-15% royalties;
- Secured the 50th patent for the T-cell immunotherapy platform (U.S. and international jurisdictions, collectively); and
- Laid the foundation to explore potential disease indications beyond MS that could be addressed through use of our T-cell platform.

“2013 was a strong year for Opexa as we executed on several critical strategic goals for the company. We secured a partnering agreement with Merck Serono, a large pharmaceutical company with a deep understanding of Multiple Sclerosis, advanced on the landmark Abili-T study in Secondary Progressive MS patients and ended the year in a strong financial position,” commented Neil K. Warma, President and Chief Executive Officer of Opexa. “In 2014, we look forward to completing enrollment in the Abili-T study, which is expected to occur in the second quarter of this year, and exploring other potential disease areas through the utilization of our Precision Immunotherapy[™] platform.”

“The focus of the Company remains fixed on the execution of the Phase IIb study in Secondary Progressive MS patients. Currently, the treatment options for these patients are very limited, so the importance of bringing a safe and effective therapy to market is heightened. If we are successful with the development of Tcelna in the ongoing SPMS trial and Merck Serono exercises its option, Merck Serono would bear the expense of subsequent clinical development of Tcelna in MS. In addition, we believe Opexa would be solidly positioned with the potential to receive milestone payments in excess of \$200 million as well as royalty payments ranging from 8-15% on product sales in the event Merck Serono is successful in its development efforts.”

“Following our capital raise in August 2013, we were able to activate all the remaining clinical trial sites selected to participate in the Abili-T study. The enthusiasm from the sites and patients has remained strong and we have exceeded 80% of the enrollment target. We are aiming to treat a total of 180 patients in the study and anticipate reaching full enrollment in the second quarter of 2014. We believe presentation of top-line data remains on target for mid-2016,” added Mr. Warma.

“With the MS franchise progressing well, we are evaluating the potential of our T-cell platform, ImmPath[®], in indications beyond MS. We have worked diligently to optimize the manufacturing process and believe that our platform can be leveraged to tailor personalized therapies for patients in other disease areas. Further evaluation will include continued discussions with key opinion leaders, FDA and clinical experts, assessment of the capital requirements and availability of sufficient resources, and a scientific understanding of the disease mechanism.”

“Lastly, we were able to raise a significant amount of capital in 2013,” noted Mr. Warma. As of December 31, 2013, our cash and cash equivalents totaled approximately \$23,644,542. During the first quarter of 2013, we raised net proceeds of approximately \$9.6 million in capital through financing transactions and the \$5 million from an upfront payment from Merck Serono. During the third quarter, we were able to raise net proceeds of approximately \$17.4 million in additional capital through an underwritten public offering of our common stock. During the fourth quarter, we executed on another underwritten public offering of our common stock and raised net proceeds of approximately \$7.3 million of additional capital. Based on our current burn rate, we believe we have sufficient liquidity to support our current clinical activities for the Abili-T trial and general operations to sustain the Company and support such trial into the fourth quarter of 2015.”

Year Ended December 31, 2013 Financial Results

During the year ended December 31, 2013, Opexa reported revenue of \$1,266,611 related to the \$5 million upfront payment from Merck in connection with the Option and License Agreement. No commercial revenues were recorded for the year ended December 31, 2012.

Research and development expenses were \$9,181,090 for the year ended December 31, 2013, compared to \$6,318,476 for the year ended December 31, 2012. The increase in expenses was primarily due to increases in staff to conduct increased development activities, the procurement and use of supplies used in both our laboratory and product manufacturing operations, the engagement of consultants and the costs of patient participation in our Phase IIb clinical study, facilities costs, legal costs and stock compensation expense, and was partially offset by a decrease in 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 were \$3,670,769 for the year ended December 31, 2013, as compared to \$2,508,541 for the year ended December 31, 2012. The increase in expenses was primarily due to a modest increase in employees to support the ongoing clinical trial, an increase in consultants and other costs to support business development and investor relations activities, and increases in NASDAQ listing fees, legal costs and stock compensation expense.

Interest expense was \$2,267,302 for the year ended December 31, 2013, compared to \$350,300 for the year ended December 31, 2012. The increase in interest expense 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 financing fees over the terms of the notes.

Loss on extinguishment of debt was \$2,518,912 for the year ended December 31, 2013. The loss on extinguishment of debt was related to the conversion of the remaining July 2012 convertible secured promissory notes on September 24, 2013, at the amended conversion price. There was no loss on extinguishment of debt for the year ended December 31, 2012.

Net loss for the year ended December 31, 2013, was \$16,656,325, or \$1.25 per share (basic and diluted), compared with a net loss of \$8,930,833, or \$1.54 per share (basic and diluted), for the year ended December 31, 2012. The increase in net loss is primarily due to increases in research and development, general and administrative, depreciation and interest expenses and loss on extinguishment of debt.

Cash and cash equivalents were \$23,644,542 as of December 31, 2013, compared to \$592,004 as of December 31, 2012. The monthly burn rate for the twelve months ending December 2013 was approximately \$1 million. Our financing activities generated approximately \$28.3 million in net proceeds for the year ended December 31, 2013.

For additional information, please see Opexa's Annual Report on Form 10-K filed today with the SEC.

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 a patient's peripheral blood, expanded ex vivo, and reintroduced into the patient 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)

MS 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 35 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 earnings release, other than statements of historical fact, constitute "forward-looking statements." The words "expects," "believes," "hopes," "anticipates," "estimates," "may," "could," "intends," "exploring," "evaluating," "progressing," "proceeding," and similar expressions are intended to identify forward-looking statements. These 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, performance and position as well as plans and objectives for future operations, for product development (including for Tcelna (imilecleucel T) and the related Immune Monitoring Program) and for potential expansion of the T-cell platform into other disease indications, 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, without limitation, risks associated with the following: 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 such as Multiple Sclerosis (MS); 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 or clinical studies related to our T-cell platform), 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 (such as the minimum closing price for our common stock, the registration of the underlying shares of common stock under the Securities Act of 1933, as amended, and the requirement for an ongoing trading market for our stock); 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), a wholly owned subsidiary of Merck Serono S.A., elects to exercise its option (Option) to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna program for the treatment of MS); 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 and future pipeline candidates); 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 suppliers and manufacturers; our ability to hire and retain skilled personnel; our volatile stock price; and other risks detailed in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update or revise any forward-looking statements contained herein to reflect any changes in its 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 the reports we file with the SEC.

OPEXA THERAPEUTICS, INC.
(a development stage company)

Statements of Expenses Data:

	Twelve Months Ended December 31,	
	2013	2012
Revenue:		
Option revenue	\$ 1,266,611	\$ -
Research and development	9,181,090	6,318,476
General and administrative	3,670,769	2,508,541
Depreciation and amortization	335,597	303,677
Loss on disposal of fixed assets	2,161	3,097
Operating loss	(11,923,006)	(9,133,791)
Interest income	14,985	280
Other income and expense, net	37,910	-
Loss on extinguishment of debt	(2,518,912)	-
Gain on derivative instruments	-	552,978
Interest expense	(2,267,302)	(350,300)
Net loss	<u>\$ (16,656,325)</u>	<u>\$ (8,930,833)</u>
Basic and diluted loss per share	\$ (1.25)	\$ (1.54)
Weighted average shares outstanding	13,332,350	5,785,372

Selected Balance Sheet Data:

	2013	2012
Cash and cash equivalents	\$ 23,644,542	\$ 592,004
Other current assets	1,122,576	1,077,546
Fixed assets, net	1,295,024	1,265,041
Restricted cash	-	1,000,000
Deferred financing costs, net	-	211,479
Other long term assets	177,666	-
Total assets	26,239,808	4,146,070
Total current liabilities	3,324,493	885,975
Total long term liabilities	2,338,041	376,763
Total stockholders' equity	20,577,274	2,883,332

CONTACT:

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or

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