

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 01/07/14 for the Period Ending 01/07/14

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
CIK	0001069308
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): January 7, 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))
-

Item 7.01. Regulation FD Disclosure.

On January 7, 2014, Opexa Therapeutics, Inc. (the “Company”) distributed a letter to its shareholders describing key milestones and strategic goals achieved by the Company in 2013. A copy of the shareholder letter 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

99.1 Shareholder Letter dated January 7, 2014.

The information in Item 7.01 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: January 7, 2014

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Shareholder Letter dated January 7, 2014.



January 7, 2014

To Our Shareholders,

2013 has been an excellent year for Opexa. We reached several key milestones and executed on strategic goals set for the Company. We saw strong enrollment in the landmark Phase IIb **Abili-T** clinical trial evaluating **Tcelna**® (imilecleucel-T) in Secondary Progressive Multiple Sclerosis (SPMS), achieving 70% enrollment in December 2013. We ended the year in a strong financial position with a clean balance sheet. Earlier this year we secured an option and license agreement for Tcelna with Merck Serono, one of the leading multinational companies focused on the treatment of multiple sclerosis (MS). If we are successful with the development of Tcelna and Merck Serono exercises its option, Opexa could be eligible to receive up to \$220 million in milestone payments and, additionally, 8-15% in royalties. Importantly, Merck Serono would also be responsible for absorbing all future costs related to clinical development, including all Phase III trials, as well as pre-commercialization expenses. We feel this agreement provides further validation as to the potential of Tcelna and, if executed, could provide Opexa with a strong development and commercialization partner.

We continued to focus on building and maintaining a strong team of individuals with a broad range of expertise across numerous functions. We are currently a dedicated group of approximately 40 individuals covering a range of activities including manufacturing, quality control and quality assurance, shipping and logistics, clinical and regulatory affairs, research and development, business development, finance, accounting and compliance. Our focus as a group remains locked on working hard to deliver shareholder value and improve the quality of life for individuals with MS.

Should Tcelna prove to be safe and effective in the ongoing Abili-T SPMS clinical trial, Opexa will have differentiated itself significantly from other MS focused companies. Individuals suffering from SPMS have very few treatment options available to them. The estimated potential market for SPMS is over \$7 billion in the United States alone, and we believe Tcelna has the potential to become a treatment of choice in this patient population. A significant milestone in evaluating Tcelna's potential comes in mid-2016, when top-line data from the Abili-T trial are expected.

We have built-up significant knowledge and expertise in the area of immunotherapy and continue the strengthening of our patent estate to protect our assets and technology. In 2013, we secured the 50th patent on our T-cell technology (US and international jurisdictions, collectively), and submitted an additional patent application in 2013 for our proprietary Epitope Screening Assay.

Opexa uses its proprietary manufacturing process, **ImmPath**®, to manufacture all Tcelna product. The process has proven robust over the past year enabling us to manufacture over 350 doses of Tcelna for patients in the Abili-T trial. This T-cell platform technology supports the ongoing and future clinical development manufacturing needs of Tcelna and, importantly, also has the potential to be leveraged for possible therapies against other disease indications.

In summary, we are pleased with the following objectives achieved this past year:

- Achieved enrollment of 70% of patients in the Abili-T clinical trial;
- Achieved initiation and activation of 33 clinical sites in the United States and Canada;
- Implemented what we believe is one of the most comprehensive Immune Monitoring/Biomarker Programs in MS as part of the Abili-T trial;
- Strengthened our financial position and cleaned-up the balance sheet through the elimination of debt;
- Unencumbered all intellectual property and physical assets pledged as collateral;
- Secured an option and license agreement with Merck Serono which, if exercised by Merck Serono, has the potential to bring in \$220 million in milestone payments plus 8-15% royalties;
- Secured the 50th patent (US and international jurisdictions, collectively); and
- Laid the foundation to potentially diversify and expand off the T-cell platform.

We believe 2014 should be another strong year for Opexa. We look forward to reaching full enrollment in the Abili-T trial, which will be a key milestone for the Company and SPMS patients. The ongoing analysis of data generated from the Immune Monitoring program could also yield important developments.

We work closely with the MS Society, sponsoring and supporting important events for the community, including the MS Walk program and the MS 150. Interactions with the MS patient community are rewarding for all members of the Opexa team and remind us of the purpose of our work and, most importantly, what remains to be done.

We are grateful for the support of our shareholders and are committed to working hard to build value in the Company.

Sincerely,
Neil K. Warma
President and Chief Executive Officer

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.

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 letter 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 letter, other than statements of historical fact, constitute "forward-looking statements." The words "expects," "believes," "anticipates," "estimates," "may," "could," "intends," "potential," "possible," "might," "look forward," and similar expressions are intended to identify forward-looking statements. The forward-looking statements in this letter do not constitute guarantees of future performance. Investors are cautioned that statements in this letter 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; 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 Serono") elects to exercise its option for an exclusive license to Tcelna for the treatment of MS (the "Option")); whether Merck Serono exercises its Option and, if so, whether we receive any development or commercialization milestone payments or royalties from Merck Serono pursuant to the Option; our dependence (if Merck Serono exercises its Option) on the resources and abilities of Merck Serono 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, including our Annual Reports on Form 10 K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. 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.