

# OPEXA THERAPEUTICS, INC.

## **FORM 8-K** (Current report filing)

Filed 03/29/13 for the Period Ending 03/28/13

|             |                                                         |
|-------------|---------------------------------------------------------|
| Address     | 2635 TECHNOLOGY FOREST BLVD.<br>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                                                   |

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

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

**Date of Report (date of earliest event reported): March 28, 2013**

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**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)

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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 March 28, 2013, Opexa Therapeutics, Inc. filed its Annual Report on Form 10-K for the fiscal year ended December 31, 2012 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.

**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 March 28, 2013. |
|------|---------------------------------------------------------------------|

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.

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## 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: March 28, 2013

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

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## **EXHIBIT INDEX**

| <b><u>Exhibit No.</u></b> | <b><u>Description</u></b>                                          |
|---------------------------|--------------------------------------------------------------------|
| 99.1                      | Press Release issued by Opexa Therapeutics, Inc. on March 28, 2013 |

## Opexa Therapeutics Reports Year End 2012 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--March 28, 2013--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biotechnology company developing a novel T-cell therapy for multiple sclerosis (MS), today reported financial results for the year ended December 31, 2012 and provided an overview of recent corporate developments.

2012 and recent highlights include:

- **Clinical**

- Commenced a Phase IIb clinical study of Tcelna™ (imilecleucel-T) in patients with Secondary Progressive Multiple Sclerosis (SPMS). The randomized, double-blind, placebo controlled study is titled the “Abili-T” trial and will enroll 180 patients through approximately 30 leading clinical sites in the U.S. and Canada;
- Gained approval from Health Canada to expand the Abili-T clinical trial to include several renowned sites in Canada; and
- Initiated a comprehensive Immune Monitoring Program to capture valuable information from the Abili-T trial, including the potential identification of biomarkers for SPMS and further understanding of the immunopathology of SPMS.

- **Financial/Operational**

- Closed a private offering of convertible secured notes and warrants to purchase common stock for gross proceeds of approximately \$4.1 million in July 2012;
- Entered into two stock purchase agreements with Lincoln Park Capital Fund LLC in November 2012 in which Opexa may sell up to an aggregate of \$16.5 million of shares of common stock to Lincoln Park subject to certain limitations and conditions over a 30-month period;
- Executed a key strategic option and license agreement with Merck Serono in February 2013 for the development and commercialization of Tcelna in patients with MS. If Merck Serono exercises the licensing option, Merck would be solely responsible for funding development, regulatory and commercialization activities for Tcelna in MS. Potential milestone payments to Opexa if Tcelna is successfully commercialized could total \$225 million. Additionally, Opexa is eligible to receive tiered royalties on commercial sales at rates ranging from 8% to 15% of annual net sales;
- Raised \$3.25 million of gross proceeds through a registered offering of common stock and warrants in February 2013; and
- Strengthened our expertise in cell therapy through the hiring of several cell therapy experts in the areas of manufacturing, quality assurance, quality control and R&D.

“2012 was a transformative year for Opexa as we commenced the Abili-T clinical trial for Tcelna in patients with SPMS,” commented Neil K. Warma, President and Chief Executive Officer of Opexa. “The enthusiastic response from physicians and patients alike to the Abili-T study has resulted in us being able to sign on some of the leading institutions and physician practices across the U.S. to enroll patients. We expect to further enhance our enrollment with recently activated sites who serve large MS populations. Overall, the Abili-T clinical study is expected to enroll 180 patients at approximately 30 clinical sites and top-line data is expected during the first half of 2016.”

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“Our active strategic development discussions which progressed well in 2012 culminated with the signing of an option and license agreement with Merck Serono in February 2013,” added Mr. Warma. “We are very pleased to have entered into an option and license agreement with Merck Serono given their long-term strategic commitment to, and existing franchise position in, the field of multiple sclerosis.”

“The team at Opexa performed exceptionally well in 2012, hitting their key target which was to get back into the clinic with the initiation of a well designed MS clinical trial. Modifications and improvements to ImmPath™, Tcelna’s manufacturing process, and to the clinical trial protocol were submitted to the FDA in 2012. This enabled a smooth and uninterrupted transition into the Abili-T trial. We had increased staff levels throughout the first half of 2012 in anticipation of the trial’s start and now have a very experienced group of people well qualified to manage the clinical development of a personalized immune therapy,” continued Mr. Warma.

“As of December 31, 2012, our cash and cash equivalents totaled approximately \$592,000,” noted Mr. Warma. “Our monthly burn rate for the twelve months ending December 2012 was approximately \$830,000. During the first quarter of 2013, we raised approximately \$9.5 million in additional capital through financing transactions and the \$5 million upfront payment from Merck Serono. We will need to raise additional capital to fund our current business plan and support our clinical trial operations. Based on our current burn rate, we believe we have sufficient liquidity to support our current clinical trial activities into the fourth quarter of 2013.”

### **Year Ended December 31, 2012 Financial Results**

Opexa reported no commercial revenues in the year ended December 31, 2012 or in the comparable prior-year period.

Research and development expenses were \$6,318,476 for the year ended December 31, 2012, compared to \$3,340,038 for the year ended December 31, 2011. 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, the costs of subject participation in our Phase IIb clinical study, facilities costs and stock compensation expense, and was partially offset by a decrease in legal costs.

General and administrative expenses were \$2,508,541 for the year ended December 31, 2012, as compared to \$2,406,269 for the year ended December 31, 2011. The increase in expense is due to increases in legal expense, capital financing activities, stock compensation expense and facilities costs, and was partially offset by a reduction in professional service fees.

Depreciation and amortization expenses were \$303,677 for the year ended December 31, 2012, as compared to \$210,252 for the year ended December 31, 2011. The increase in expense is due to an increase in depreciation for facility build-out costs incurred during the first half of 2011, an increase in depreciation for laboratory and manufacturing equipment acquired during 2011 and 2012 to support increased development activities and an increase in depreciation for information technology equipment to replace and upgrade obsolete equipment.

Interest expense was \$350,300 for the year ended December 31, 2012, compared to \$3,135 for the year ended December 31, 2011. The increase in interest expense was primarily related to the non-cash amortized debt discount and interest on the July 25, 2012 convertible notes and the amortization of the financing fees over the life of the notes. Interest expense for the year ended December 31, 2011 related solely to the financing costs on insurance policies and the loan payable on an equipment line.

Opexa reported a net loss for the year ended December 31, 2012 of \$8,930,833, or \$1.54 per share (basic and diluted), compared with a net loss of \$5,968,448, or \$1.06 per share (basic and diluted), for the year ended December 31, 2011. The increase in net loss is primarily due to increases in research and development, general and administrative, depreciation and interest expenses.

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Cash and cash equivalents were \$592,004 as of December 31, 2012 compared to \$7,109,215 as of December 31, 2011. Our financing activities generated approximately \$4.0 million in net proceeds for the year ended December 31, 2012.

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

### **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.

### **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 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.

### **About Opexa**

Opexa is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases such as MS. The Company's leading therapy candidate, Tcelna™, is a personalized cellular immunotherapy that is in Phase IIb clinical development for MS. Tcelna is derived from T-cells isolated from 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](http://www.opexatherapeutics.com).

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

This press 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. 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 press release 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 (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 regain and 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 Merck elects to exercise its 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 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 Securities and Exchange Commission.

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**OPEXA THERAPEUTICS, INC.**  
**(a development stage company)**

**Statements of Expenses Data:**

|                                     | <b>Twelve Months Ended<br/>December 31,</b> |                |
|-------------------------------------|---------------------------------------------|----------------|
|                                     | <b>2012</b>                                 | <b>2011</b>    |
| Research and development            | \$ 6,318,476                                | \$ 3,340,038   |
| General and administrative          | 2,508,541                                   | 2,406,269      |
| Depreciation and amortization       | 303,677                                     | 210,252        |
| Loss on disposal of assets          | 3,097                                       | 9,686          |
| Operating loss                      | (9,133,791)                                 | (5,966,245)    |
| Interest income                     | 280                                         | 932            |
| Gain on derivative instruments      | 552,978                                     | -              |
| Interest expense                    | (350,300)                                   | (3,135)        |
| Net loss                            | \$ (8,930,833)                              | \$ (5,968,448) |
| Basic and diluted loss per share    | \$ (1.54)                                   | \$ (1.06)      |
| Weighted average shares outstanding | 5,785,372                                   | 5,633,124      |

**Selected Balance Sheet Data:**

|                               | <b>2012</b> | <b>2011</b>  |
|-------------------------------|-------------|--------------|
| Cash and cash equivalents     | \$ 592,004  | \$ 7,109,215 |
| Other current assets          | 1,077,546   | 124,773      |
| Fixed assets, net             | 1,265,041   | 1,029,236    |
| Restricted cash               | 1,000,000   | -            |
| Deferred financing costs, net | 211,479     | -            |
| Total assets                  | 4,146,070   | 8,263,224    |
| Total current liabilities     | 885,975     | 1,067,860    |
| Total long term liabilities   | 376,763     | -            |
| Total stockholders' equity    | 2,883,332   | 7,195,364    |

**CONTACT:**

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