

# OPEXA THERAPEUTICS, INC.

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

Filed 03/20/14 for the Period Ending 03/19/14

|             |                                                         |
|-------------|---------------------------------------------------------|
| 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                                                   |

---

**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): March 19, 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 5.03. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On March 19, 2014, the Board of Directors (the “ **Board** ”) of Opexa Therapeutics, Inc. (the “ **Company** ”) appointed Timothy Barabe and Hans-Peter Hartung, M.D. as directors, each with a term of office expiring at the 2014 annual meeting of shareholders. Mr. Barabe will also serve as a member of the Board’s Audit Committee and Compensation Committee.

In connection with their appointment to the Board, Mr. Barabe and Dr. Hartung participate in the Company’s compensation package for non-employee outside directors and received the following (reflecting approximately 80% of the standard annual compensation package for directors due to their mid-year commencement of service):

- (i) an option to purchase 12,900 shares of the Company’s common stock having a Black-Scholes determined value of \$24,000 on the date of grant, with 50% vesting upon grant and the balance vesting on December 31, 2014, and with an exercise price equal to the fair market value of the common stock on the grant date;
- (ii) an option to purchase 4,300 shares of the Company’s common stock having a Black-Scholes determined value of \$8,000 on the date of grant, with 50% vesting upon grant and the balance vesting on February 28, 2015, and with an exercise price equal to the fair market value of the common stock on the grant date; and
- (iii) \$12,000 in cash, payable in equal installments on each of June 30, 2014, September 30, 2014 and December 31, 2014, which, at the individual election of each director, may instead be paid in the form of either (x) an option to purchase shares of the Company’s common stock with a Black-Scholes determined value of \$12,000 on the date of grant, with vesting and other terms to be the same as the first option component noted above except that vesting will take place in equal installments on each of June 30, 2014, September 30, 2014 and December 31, 2014 or (y) restricted shares of the Company’s common stock with a fair market value equal to \$12,000, with vesting in equal installments on each of June 30, 2014, September 30, 2014 and December 31, 2014.

Dr. Hartung has been, and continues to be, a member of the Company’s Scientific Advisory Board. However, there have been no transactions in the past two years to which the Company or any of its subsidiaries was or is to be a party and in which Mr. Barabe or Dr. Hartung had, or will have, a direct or indirect material interest.

Additional information about Mr. Barabe and Dr. Hartung can be found in the press release issued by the Company, a copy of which is attached hereto as Exhibit 99.1 and 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 20, 2014. |

## 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 20, 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 March 20, 2014 |

## Opexa Therapeutics Appoints Prof. Hans-Peter Hartung and Timothy Barabe to the Board of Directors

THE WOODLANDS, Texas--(BUSINESS WIRE)--March 20, 2014--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biotechnology company developing Tcelna<sup>®</sup>, a novel T-cell immunotherapy for the treatment of multiple sclerosis (MS), today announced the addition of two highly experienced individuals to join the Company's Board of Directors. Hans-Peter Hartung, MD, PhD, FRCP, a world leading clinician and expert in the treatment of Multiple Sclerosis and other neurological diseases, and Timothy Barabe, a proven CFO with global operational and financial expertise, have each been appointed to the Company's Board of Directors, effective March 19<sup>th</sup>.

"We are thrilled to be adding such esteemed individuals to complement our existing Board," commented Neil K. Warma, Opexa's President and CEO. "Hans Peter has been a critical member of our Scientific Advisory Board for several years and has been instrumental to the design of the Phase IIb trial we are currently running in Secondary Progressive MS. He is a recognized worldwide leader in the field of clinical immunology with a strong standing in the MS and neurology fields. Complementing the addition of Hans Peter, Tim brings a wealth of expertise in operations and finance, including in international settings. Tim served in senior executive roles in Novartis, including as CFO of its Sandoz Generics business unit, and CFO of Affymetrix and Human Genome Sciences, combining knowledge from both the pharmaceutical and biotech industries."

"I am honored to join Opexa's Board and work closely with an outstanding management team," commented Professor Hartung. "I believe that Opexa's novel personalized T-cell immunotherapy platform has tremendous potential in MS and possibly in other immune mediated diseases. I look forward to contributing to the Company."

Mr. Barabe remarked, "I am thrilled to be joining such an innovative and forward-looking company. I am impressed by the potential of Tcelna and I believe my operational and financial experience can be useful to the Company's future."

Professor Hartung holds the Chair of Neurology at Heinrich-Heine University, Düsseldorf, and is chairman of the Department of Neurology. He was educated at the medical schools of the Universities of Düsseldorf, Glasgow, Oxford, Harvard and Johns Hopkins, and at the Institute of Neurology, Queen Square, London. Professor Hartung is a member of various international and national societies, serving on executive boards for ECTRIMS, the European Neurological Society, the International Society for Neuroimmunology, the International Federation of Multiple Sclerosis Societies and the World Health Organization Advisory Board on Multiple Sclerosis, as well as on the editorial board of various international journals. He has written extensively on neurology, neuroimmunology, peripheral nerve disease and MS.

Mr. Barabe retired in 2013 as EVP and CFO of Affymetrix, Inc. Previously, he was SVP and CFO of Human Genome Sciences, Inc. and CFO of Regent Medical Limited, a U.K.-based, privately owned, surgical supply company. Mr. Barabe was also with Novartis AG for more than 20 years where he served in a succession of senior executive positions in finance and general management, most recently as the CFO of Sandoz GmbH, the generic pharmaceutical subsidiary of Novartis. Mr. Barabe serves on the board of ArQule, a Boston-based, NASDAQ-listed biotech company. Mr. Barabe received his undergraduate degree from the University of Massachusetts (Amherst) and his MBA from the University of Chicago.

---

## 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<sup>®</sup>, 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 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<sup>®</sup> is a potential personalized therapy that is under development to be specifically tailored to each patient's disease profile. Tcelna is manufactured using ImmPath<sup>®</sup>, 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.

For more information visit the Opexa Therapeutics website at [www.opexatherapeutics.com](http://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 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. Statements contained in this earnings release, other than statements of historical fact, constitute "forward-looking statements." The words "expects," "believes," "potential," "possibly," "estimates," "may," "could" and "intends," as well as 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 plans and objectives 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); 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.

### CONTACT:

#### **Company Contact:**

Karthik Radhakrishnan  
Opexa Therapeutics, Inc.  
Chief Financial Officer  
281-775-0600

or

#### **Investor Relations:**

The Trout Group  
Adam Cutler  
646-378-2936

[opexa@troutgroup.com](mailto:opexa@troutgroup.com)