

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 02/23/15 for the Period Ending 02/23/15

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): February 23, 2015

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 23, 2015, Opexa Therapeutics, Inc. (the “Company”) announced its results of operations for the year ended December 31, 2014 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>
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99.1	Press release issued by Opexa Therapeutics, Inc. on February 23, 2015.
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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 23, 2015

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Opexa Therapeutics, Inc. on February 23, 2015.

Opexa Therapeutics Reports Year End 2014 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--February 23, 2015--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biopharmaceutical company developing personalized immunotherapies including multiple sclerosis (MS) and neuromyelitis optica (NMO), today reported financial results for the year ended December 31, 2014 and provided an update on the Company's recent corporate developments.

2014 and early 2015 Operational Highlights:

- Completed enrollment in the Abili-T Phase 2b clinical trial of Tcelna® (imilecleucel-T) in patients with secondary progressive multiple sclerosis (SPMS):
 - 190 individuals have been randomized in the trial, currently being conducted in 35 leading clinical sites across the U.S. and Canada;
- Expanded Opexa's pipeline:
 - Advanced Opexa's proprietary ImmPath® technology into a second autoimmune disease, neuromyelitis optica (NMO);
 - OPX-212, Opexa's NMO therapeutic candidate, is currently in preclinical development; NMO is a rare disease with no approved treatments;
 - Achieved several regulatory and early development milestones for OPX-212, including conducting a pre-IND meeting with the FDA, engaging key thought leaders and patient advocacy groups and performing several in-house manufacturing runs with NMO patient samples;
- Strengthened Opexa's intellectual property portfolio with issuance of the 98th patent (U.S. and international) on the T-cell platform; and
- Added to the Russell Microcap® Index.

"We are pleased with the productive year we had last year, one that was highlighted by completing enrollment in our landmark Abili-T Phase 2b clinical trial of Tcelna in Secondary Progressive MS patients and expanding our pipeline into a second autoimmune disease," said Neil K. Warma, Opexa's President and Chief Executive Officer. "The Abili-T trial in progressive MS is one that we believe could be an important step in advancing a therapy that has the potential to be the treatment of choice in this patient population that currently has access to very limited treatment options. We continue to treat patients in the trial and expect to report top line results in the second half of 2016."

"Additionally, with the initiation of preclinical development activities in our second indication, neuromyelitis optica, we believe we have demonstrated our ability to leverage our T-cell technology platform into other disease areas. We also believe the platform could be leveraged even further to other autoimmune diseases."

Clinical Development Update

Upcoming potential development and regulatory milestones include:

- Mid-2015: Submit IND for OPX-212, which is in development for NMO
- 2H 2015: Initiate a Phase 1/2 clinical trial of OPX-212 in NMO (subject to IND acceptance and financing)
- 2016/2017: Apply for Orphan Drug Designation and Fast Track Designation for OPX-212
- 2H 2016: Report top-line data of the Abili-T Phase 2b trial of Tcelna in SPMS

Financial Results for the Year Ended December 31, 2014

For the year ended December 31, 2014, Opexa reported a net loss of \$15.1 million, or \$0.54 per share, compared to a net loss of \$16.7 million, or \$1.25 per share, for 2013. Research and development expense was \$12.1 million, an increase of 32.0% compared to \$9.2 million in 2013. The increase in expense is primarily due to increases in staff and associated employee compensation expenses, increases in the cost of supplies used both in laboratory and product manufacturing operations and increased clinical investigator costs associated with increased enrollment of patients in the Abili-T clinical study.

General and administrative expense was \$3.83 million, a 4.4% increase compared to \$3.7 million in 2013. The increase in expense is due to a modest increase in stock compensation expense and an increase in the use of professional services, and was partially offset by lower NASDAQ listing fees.

As of December 31, 2014, Opexa had cash and cash equivalents of \$9.9 million compared to \$23.6 million as of December 31, 2013. The Company's monthly burn rate for the year ending December 31, 2014 was approximately \$1.2 million. Based on the current activities, Opexa believes it has sufficient liquidity to support its clinical activities for the Abili-T trial, as well as preclinical development activities for OPX-212 in NMO (with an expected IND submission by mid-2015) and general operations of the Company, into the fourth quarter of 2015.

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

About Opexa

Opexa is a biopharmaceutical company developing personalized immunotherapies with the potential to treat major illnesses, including multiple sclerosis (MS) as well as other autoimmune diseases, such as neuromyelitis optica (NMO). These therapies are based on Opexa's proprietary T-cell technology. 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. Opexa's mission is to lead the field of Precision Immunotherapy[®] by aligning the interests of patients, employees and shareholders.

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

Statements contained in this release, other than statements of historical fact, constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The words "expects," "believes," "may," "intends," "potential" 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 forward-looking statements, including without limitation statements regarding the safety, efficacy and projected development timeline of drug candidates such as Tcelna[®] and OPX-212 constitute forward-looking statements. These forward-looking statements are based upon our current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include without limitation our ability to raise additional capital to continue our development programs, our ability to successfully develop potential products such as Tcelna, our ability to obtain, maintain and protect intellectual property rights (including for Tcelna and future pipeline candidates such as OPX-212), as well as other risks associated with the process of discovering, developing and commercializing drug candidates that are safe and effective for use as human therapeutics. These and other risks are described in detail in our SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2014 and our Quarterly Reports on Form 10-Q. All forward-looking statements contained in this release speak only as of the date on which they were first made by us, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after such date.

OPEXA THERAPEUTICS, INC.

Statement of Operations Data:

	Twelve Months Ended December 31,	
	2014	2013
Revenue:		
Option revenue	\$ 1,271,895	\$ 1,266,611
Research and development	12,118,629	9,181,090
General and administrative	3,833,370	3,670,769
Depreciation and amortization	387,779	335,597
Loss on disposal of fixed assets	-	2,161
Operating loss	(15,067,883)	(11,923,006)
Interest income	15,456	14,985
Other income, net	2,147	37,910
(Loss) on extinguishment of debt	-	(2,518,912)
Interest expense	(1,983)	(2,267,302)
Net loss	\$ (15,052,263)	\$ (16,656,325)
Basic and diluted loss per share	\$ (0.54)	\$ (1.25)
Weighted average shares outstanding	27,821,056	13,332,350

Selected Balance Sheet Data:

	December 31, 2014	December 31, 2013
Cash and cash equivalents	\$ 9,906,373	\$ 23,644,542
Other current assets	758,943	1,122,576
Property and equipment, net	1,098,104	1,295,024
Other long term assets	38,939	177,666
Total assets	11,802,359	26,239,808
Total current liabilities	3,132,424	3,324,493
Deferred revenue	1,230,748	2,338,041
Total stockholders' equity	7,439,187	20,577,274

CONTACT:
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Chief Financial Officer