
**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 14, 2016

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 1.01. Entry into a Material Definitive Agreement.

On March 14, 2016, Opexa Therapeutics, Inc. (the “**Company**”) entered into an Amendment to Stock Purchase Agreement (the “**Amendment**”) to amend that certain Stock Purchase Agreement (the “**Agreement**”) originally entered into on September 1, 2016 between the Company and certain purchasers party thereto (the “**Purchasers**”). In addition to the first tranche of \$499,999.50 in shares of the Company’s common stock and the Company’s Series N Warrants to purchase shares of the Company’s common stock previously sold to the Purchasers pursuant to the Agreement, the Agreement provides that the Purchasers will purchase and the Company will sell up to an additional \$4.5 million in shares of the Company’s common stock in four additional tranches upon achievement by the Company of certain milestones relating to clinical development of OPX-212, the Company’s autologous T-cell immunotherapy being developed for the treatment of neuromyelitis optica (“**NMO**”). Pursuant to the Amendment, the timeframes for achieving the milestones relating to the four additional tranches were each extended by six months. As amended, the milestones are as follows:

- **Tranche 2:** \$1,000,000 in shares of common stock, at a per share purchase price of 90% of the 10-day volume weighted average price of the common stock for the 10 trading days (the “**10-day VWAP**”) immediately preceding the Tranche 2 milestone, which is the submission to the U.S. Food and Drug Administration (“**FDA**”) of a preclinical study package to support the filing of an Investigational New Drug (“**IND**”) application for OPX-212, so long as such submission occurs on or before August 15, 2016 or any later date agreed to by the Purchasers.
- **Tranche 3:** \$1,500,000 in shares of common stock, at a per share purchase price of 90% of the 10-day VWAP immediately preceding the Tranche 3 milestone, which is the acceptance of such IND by the FDA, so long as such acceptance occurs on or before the later of November 15, 2016 or three months following the Tranche 2 closing, or any later date agreed to by the Purchasers.
- **Tranche 4:** \$1,000,000 in shares of common stock, at a per share purchase price of 90% of the 10-day VWAP immediately preceding the Tranche 4 milestone, which is the enrollment of the first patient in a Phase 1/2 clinical study of OPX-212 in patients with NMO, so long as such enrollment occurs on or before the later of February 28, 2017 or five months following the Tranche 3 closing, or any later date agreed to by the Purchasers.
- **Tranche 5:** \$1,000,000 in shares of common stock, at a per share purchase price of 90% of the 10-day VWAP immediately preceding the Tranche 5 milestone, which is the enrollment of patients representing at least 30% of the minimum targeted enrollment in such Phase 1/2 study, so long as such enrollment occurs on or before the later of June 30, 2017 or four months following the Tranche 4 closing, or any later date agreed to by the Purchasers.

Although the Company has previously indicated that an IND submission to the FDA and/or a Clinical Trial Application submission (“**CTA**”) to Health Canada followed by commencement of a phase 1/2 proof of concept study of OPX-212 in NMO (assuming acceptance of such IND and/or CTA) may occur in the first half of 2016 assuming the availability of sufficient resources, the Company is currently uncertain with respect to both the pace of its ongoing preclinical development and manufacturing activities for OPX-212 in NMO as well as the potential outcome of such activities. OPX-212 in NMO remains an active preclinical program for the Company, and the Company continues to believe that progress in this program is reasonably possible. However, the Company has been confronted with challenges in the development of OPX-212 in NMO, including with respect to the manufacture of OPX-212. For example, it has taken the Company longer than it expected to manufacture certain of the peptides associated with NMO due to their hydrophobic nature. The Company currently does not expect to provide further guidance in the foreseeable future on any timetable with respect to its development of OPX-212 in NMO, but instead to report substantive milestones only when and if they occur.

In connection with the Amendment, the Company also amended and restated the Series N Warrants to purchase shares of the Company's common stock previously issued to the Purchasers to extend by six months the expiration date of the Series N Warrants (i.e., from April 9, 2018 to October 9, 2018).

The foregoing description of the Amendment and the amended and restated Series N Warrants is qualified in its entirety by reference to the Amendment and such amended and restated Series N Warrants, copies of which are Exhibits 10.1 and 4.1, respectively, to this Current Report on Form 8-K and incorporated herein by reference.

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 Form 8-K, 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," "anticipates," "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 Company's resources and 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 the Company's 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 the Company's ability to raise additional capital to continue its development programs, the Company's ability to successfully develop potential products such as Tcelna and OPX-212, the Company's ability to obtain, maintain and protect intellectual property rights (including for Tcelna and 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 the Company's SEC filings, including its Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. All forward-looking statements contained in this Form 8-K speak only as of the date on which they were first made, and the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after such date.

Item 2.02. Results of Operations and Financial Condition.

On March 15, 2016, the Company announced its results of operations for the year ended December 31, 2015 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.

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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
4.1	Amended and Restated Series N Warrants issued on March 14, 2016 (incorporated by reference to Exhibit 4.13 to the Company's Annual Report on Form 10-K filed on March 15, 2016).
10.1	Amendment to Stock Purchase Agreement, dated March 14, 2016, by and between Opexa Therapeutics, Inc. and the purchasers party thereto (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on March 15, 2016).
99.1	Press release issued by Opexa Therapeutics, Inc. on March 15, 2016.

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.

OPEXA THERAPEUTICS, INC.

Dated: March 15, 2016

By: /s/ Neil K. Warma

Neil K. Warma

President, Chief Executive Officer and
Acting Chief Financial Officer

EXHIBIT INDEX

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**Opexa Therapeutics Reports 2015 Year End Financial Results and Provides Corporate Update
Conference Call Scheduled Today at 4:30 PM ET**

THE WOODLANDS, Texas (March 15, 2016) - Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biopharmaceutical company developing personalized immunotherapies for autoimmune disorders, including Tcelna[®] for multiple sclerosis (MS) and OPX-212 for neuromyelitis optica (NMO), today reported financial results for the year ended December 31, 2015, and provided an update on the Company's recent corporate developments.

"The primary focus of the Company for 2015 was our ongoing Phase 2b Abili-T clinical trial of Tcelna in secondary progressive MS. The Abili-T trial advanced during 2015 and the release of top-line results is currently expected to occur early in the fourth quarter of this year," stated Neil K. Warma, President and Chief Executive Officer of Opexa. "There is a high unmet medical need for secondary progressive MS patients as there are no approved treatments for these individuals. Furthermore, if we are successful in the development of Tcelna, we believe the market potential could be significant."

"The Abili-T study currently being conducted in patients with secondary progressive MS is an important study for the MS community and we are all eagerly awaiting the results from the trial expected later this year," said Clyde Markowitz, MD, Director of the Multiple Sclerosis Center at the University of Pennsylvania and Associate Professor of Neurology at the Hospital and one of the Principle Investigators in the Abili-T trial. "There is an urgent need for safe and effective therapies for individuals with progressive MS and Tcelna could be the therapy that provides hope to these patients."

"Opexa continues to engage in preclinical development of OPX-212 for the treatment of NMO," said Donald Healey, Ph.D., Chief Scientific Officer of Opexa. "Although we have been confronted with certain scientific hurdles, primarily in the manufacturing of the individual peptides, we continue to believe in OPX-212 as a novel potential therapy for this rare disease for which there are currently no approved treatments."

Business Highlights

Clinical and Preclinical Efforts

- In February 2016, the Company announced the completion of dosing in the Phase 2b Abili-T study. The final dose was administered to the last patient in the last week of February, and 97% of all patient visits have been completed. Top-line results are expected early in the fourth quarter of 2016.
- In February 2016, a regularly scheduled meeting of the independent Data Safety Monitoring Board (DSMB) took place. The DSMB recommendation was to continue the Abili-T study as per protocol. The DSMB also stated that because dosing has been completed and no concerns over safety had been noted, no further DSMB meetings would be required for the Abili-T study.
- In April 2015, the Company was invited to present at the Annual Meeting of the American Academy of Neurology (AAN).
- In November 2015, the Company announced the successful completion of a preclinical animal study for OPX-212, its therapy candidate for NMO. The results showed a dose dependent and statistically significant reduction in pathogenic (AQP4) T-cells in a mouse model.
- OPX-212 in NMO remains an active preclinical program for Opexa. However, the Company has been confronted with challenges in the development of OPX-212, including with respect to the manufacture of OPX-212. For example, it has taken the Company longer than it expected to manufacture certain of the peptides associated with NMO due to their hydrophobic nature. While the Company believes that progress in the development of OPX-212 is possible, Opexa is currently uncertain as to the pace and potential outcome of development activities and the Company does not expect to provide guidance in the foreseeable future on any timetable with respect to its development of OPX-212 in NMO, but instead to report substantive milestones only when and if they occur.

Corporate Activities

- In March 2016, the Company announced a restructuring initiative driven by reduced operational demands associated with the Phase 2b Abili-T clinical trial of Tcelna in SPMS following administration of the final dose to the last patient, which occurred in the last week of February 2016. The restructuring is intended to allow the Company to focus resources on the completion of the Abili-T clinical trial and extends the Company's current cash into the first quarter of 2017, providing the Company with additional runway beyond the expected release of top-line data early in the fourth quarter of 2016.
 - In September 2015, Opexa announced it had secured an agreement with a private investor for up to \$5 million in funding for the Company's NMO development program, with all such funding after an initial \$500,000 tranche which occurred in September 2015 to be dependent upon timely achievement of certain pre-specified development milestones. This agreement was amended in March 2016 to extend the timeframes for achieving the milestones by six months.
 - In April 2015, Opexa raised \$13.8 million in gross proceeds in a rights offering.
 - In March 2015, the Company announced that it had received an additional \$3 million payment from Merck Serono to support the Abili-T study as well as preparation and planning for potential future Phase 3 studies. Merck Serono has an Option and License Agreement with Opexa and, subject to the results of the Abili-T study, may exercise the option to advance with further development of Tcelna in MS.
 - In 2015, Opexa continued work on its intellectual property estate and obtained the issuance of additional patents. Opexa's patent estate now consists of over 160 issued patents (domestic and international) for its novel personalized immunotherapy technology.
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Financial Results for the Year Ended December 31, 2015

- **Cash position:** Cash and cash equivalents were \$12,583,764 as of December 31, 2015, compared to \$9,906,373 as of December 31, 2014.
 - **R & D Expense:** Research and development expenses were \$10,039,496 for the year ended December 31, 2015, compared to \$12,118,629 for the year ended December 31, 2014. The decrease in expenses was primarily due to decreases in the need for supplies used both in research and clinical trial product manufacturing operations and decreased clinical investigator costs associated with a decreasing number of patients in the Abili-T clinical study following completion of participation.
 - **G & A Expense:** General and administrative expenses were \$4,258,147 for the year ended December 31, 2015, compared to \$3,833,370 for the year ended December 31, 2014. The increase in expenses is due to an increase in staff compensation expenses, higher professional service fees and higher insurance premiums. These increases were partially offset by lower stock option expenses.
 - **Net loss:** Net loss reported for the year ended December 31, 2015 was \$12,019,278, or \$2.05 per share (basic and diluted), compared with a net loss of \$15,052,263, or \$4.33 per share (basic and diluted), for the year ended December 31, 2014. The decreased net loss for the year is primarily related to the increase in revenue due to the March 2015 amendment to the Company's Option and License Agreement with Merck Serono and a decrease in research and development expenses, which was partially offset by the increase in general and administrative expenses.
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Financial Guidance

- Based on the current activities of the Company and projected burn, Opexa believes it has sufficient liquidity to support its current clinical activities for the Abili-T trial of Tcelna in SPMS, to continue planned preclinical development activities for OPX-212 in NMO, and for general operations to sustain the Company and support such activities into the first quarter of 2017. Opexa expects top-line data for the Abili-T trial to be available early in the fourth quarter of 2016, and thus believes it has sufficient resources to complete such trial.

Conference Call and Webcast Details

To listen to the conference call, dial in approximately ten minutes before the scheduled 4:30 P.M. ET time to 201-689-8040 or toll free at 877-407-8133 . The conference ID number is 13632961 .

A live webcast of the call can also be accessed [here](#) or via the webcast link on the Investor Relations page of Opexa's website (www.opexatherapeutics.com). An archive of the webcast will be available on the Company's website until June 15, 2016.

There will be a brief Question & Answer session following management commentary.

About Opexa

Opexa is a biopharmaceutical company developing a personalized immunotherapy 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 2b clinical development program (the Abili-T trial) for the treatment of secondary progressive MS. Tcelna consists of myelin-reactive T-cells, which are expanded ex vivo from the patient's peripheral blood and reintroduced into the patient in an attenuated form via subcutaneous injections. This process triggers a potent immune response against specific subsets of autoreactive T-cells known to attack myelin for each individual patient.

For more information, visit the Opexa Therapeutics website at www.opexatherapeutics.com or follow company news on Twitter via [@OpexaCEO](#).

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OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Twelve Months Ended December 31,	
	2015	2014
Revenue:		
Option revenue	\$ 2,556,329	\$ 1,271,895
Expenses:		
Research and development	10,039,496	12,118,629
General and administrative	4,258,147	3,833,370
Loss on disposition of assets	1,167	-
Depreciation and amortization	351,403	387,779
Operating loss	(12,093,884)	(15,067,883)
Interest income, net	5,911	13,473
Other income, net	68,695	2,147
Net loss	<u>\$ (12,019,278)</u>	<u>\$ (15,052,263)</u>
Basic and diluted loss per share	\$ (2.05)	\$ (4.33)
Weighted average shares outstanding - Basic and diluted	5,854,438	3,477,628
Selected Balance Sheet Data:		
	December 31, 2015	December 31, 2014
Cash and cash equivalents	\$ 12,583,764	\$ 9,906,373
Other current assets	995,067	758,943
Fixed assets, net	837,867	1,098,104
Other long term assets	-	38,939
Total assets	14,416,698	11,802,359
Total current liabilities	4,801,436	3,132,424
Total long-term liabilities	-	1,230,748
Total stockholders' equity	9,615,262	7,439,187
Total liabilities and stockholders' equity	\$ 14,416,698	\$ 11,802,359

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