

OPEXA THERAPEUTICS, INC.

FORM 424B3

(Prospectus filed pursuant to Rule 424(b)(3))

Filed 03/09/15

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

PROSPECTUS SUPPLEMENT NO. 1
To Prospectus dated February 25, 2015



OPEXA THERAPEUTICS, INC.

**Subscription Rights to Purchase up to 28,776,419 Units,
each consisting of one share of common stock and
one Warrant representing the right to purchase one share of common stock**

This Prospectus Supplement No. 1 amends and supplements the prospectus dated February 25, 2015 (the "Prospectus"), which forms a part of our Registration Statement on Form S-1 (Registration No. 333-201731). This Prospectus Supplement is being filed to update and supplement the information included or incorporated by reference in the Prospectus with the information contained in our current report on Form 8-K, filed with the Securities and Exchange Commission on March 9, 2015 (the "Current Report"). Accordingly, we have attached the Current Report to this Prospectus Supplement.

The Prospectus and this Prospectus Supplement relate to our distribution, at no charge, to holders of our common stock and to holders of our outstanding Series L warrants who are entitled to participate in the offering, as of 5:00 p.m., Eastern time, on March 13, 2015 (the "Record Date"), of non-transferable subscription rights (the "Subscription Rights") to purchase up to 28,776,419 Units, at a subscription price per Unit of \$0.70. Each Unit consists of one share of common stock and one Warrant representing the right to purchase one share of common stock. In the Rights Offering, you will receive one Subscription Right for each share of common stock or each share of common stock underlying our Series L warrants held as of the Record Date.

Our common stock is traded on The NASDAQ Capital Market under the symbol "OPXA." On March 6, 2015, the last reported sale price of our common stock was \$0.81 per share. The Subscription Rights are non-transferable and will not be listed for trading on NASDAQ or any other stock exchange or market. We have applied to list the Warrants on NASDAQ following their issuance under the symbol "OPXAW." You are urged to obtain a current price quote for our common stock before exercising your Subscription Rights.

Investing in our securities involves a high degree of risk. See the section entitled "Risk Factors" beginning on page 21 of the Prospectus and in the documents we incorporate by reference into the Prospectus. You should carefully consider these risk factors, as well as the information contained in or incorporated by reference into the Prospectus, before you invest.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this Prospectus Supplement. Any representation to the contrary is a criminal offense.

The date of this Prospectus Supplement is March 9, 2015.

**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 9, 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 1.01. Entry into a Material Definitive Agreement.

On March 9, 2015, Opexa Therapeutics, Inc. (the “**Company**”) entered into a First Amendment of Option and License Agreement (the “**Amendment**”) with Ares Trading S.A., a wholly owned subsidiary of Merck Serono S.A. (“**Merck Serono**”), to amend that certain Option and License Agreement dated February 4, 2013 by and between the parties (the “**Agreement**”). In consideration for the activities described below, Merck Serono will pay the Company the sum of \$3,000,000, payable within 14 days of Merck Serono’s receipt of an invoice from the Company:

(i) The Company will create a detailed Pre-Phase III Plan (including a GANTT chart containing key tasks, decision points, timing, budget and milestones) documenting all of the activities necessary for laboratory facilities both in the U.S. and Europe to reach operational readiness by the end of December 2016 (*e.g.*, review and identification of a preferred contract manufacturing organization in Europe; set-up, identification and qualification of third parties for raw materials; validation of laboratory facilities in the U.S. and Europe; and a hiring plan for key personnel). For Europe, the Pre-Phase III Plan would address the creation of a dedicated lab to support a Phase III trial, and for the U.S., the Pre-Phase III Plan would address the expansion of existing capabilities and infrastructure for a Phase III trial. The Joint Steering Committee (“**JSC**”) established pursuant to the Agreement will be responsible for reviewing, approving and ultimately overseeing the Company’s completion of the Pre-Phase III Plan, which approval may not be unreasonably withheld or delayed. The JSC will meet at least quarterly to advise and make specific recommendations with respect to the Pre-Phase III Plan. In the event the JSC has not approved the Pre-Phase III Plan prior to the end of the Option Period (as defined in the Agreement), the Option Period will be extended for 60 days following approval of the Pre-Phase III Plan by the JSC.

(ii) The Company will provide Merck Serono updates and analysis on a blinded basis, grouped in patient batches according to the Company’s analysis timetable, on the progress of the Company’s immune monitoring program (the “**Program**”) being conducted in conjunction with the Company’s ongoing Abili-T clinical trial, with such updates and analysis to be shared with Merck Serono within 30 days of the Company’s initial assessment of such information. The Company will inform Merck Serono of any existing or future external bioinformatics vendor used by the Company for the Program, and Merck Serono will have the right, at its expense, to review current and future data storage and integrity measures for the on-going Abili-T clinical trial.

The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the Amendment, a copy of which is attached hereto as Exhibit 10.1 and incorporated herein by reference. A copy of the press release issued by the Company in connection with the Amendment 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>
10.1	First Amendment of Option and License Agreement by and between Opexa Therapeutics, Inc. and Ares Trading S.A. dated March 9, 2015.
99.1	Press Release issued by Opexa Therapeutics, Inc. on March 9, 2015.

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 9, 2015

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>
10.1	First Amendment of Option and License Agreement by and between Opexa Therapeutics, Inc. and Ares Trading S.A. dated March 9, 2015.
99.1	Press Release issued by Opexa Therapeutics, Inc. on March 9, 2015.

First Amendment of Option and License Agreement

THIS FIRST AMENDMENT OF OPTION AND LICENSE AGREEMENT (the “ **Amendment** ”) is dated as of March 9, 2015 (the “ **Amendment Effective Date** ”) by and between Opexa Therapeutics, Inc., a corporation organized under the laws of Texas having a place of business at 2635 Technology Forest Boulevard, The Woodlands, TX 77381 (“ **Opexa** ”), and Ares Trading S.A., a corporation organized under the laws of Switzerland having a place of business at Zone Industrielle de l’Ourietaz, 1170 Aubonne, Switzerland (“ **Merck** ”). Opexa and Merck may be referred to herein as a “ **Party** ” or, collectively, as “ **Parties** .”

RECITALS:

WHEREAS, Opexa and Merck entered into an Option and License Agreement dated February 4, 2013 (“ **Option Agreement** ”) pursuant to which Opexa granted certain exclusive rights to Merck to develop and commercialize Opexa’s personalized T-cell immunotherapy (Tcelna®) in multiple sclerosis.

WHEREAS, the Parties wish to amend the Option Agreement as provided in this Amendment;

NOW, THEREFORE, it is mutually understood and agreed by and between the Parties as follows:

Article 1 AMENDMENT OF THE OPTION AGREEMENT

1.1 Effective upon the Amendment Effective Date, the Option Agreement is amended as provided in this Article 1. Except as expressly modified in this Article 1, all provisions of the Option Agreement shall remain in full force and effect.

1.2 Any capitalized term not otherwise defined herein shall have the same meaning as defined in the Option Agreement.

1.3 Article 2 of the Option Agreement is amended by adding the following new Sections immediately following Section 2.3 thereof:

2.4 Creation of Pre-Phase III Plan. Commencing on March 15, 2015, Opexa will create a detailed plan, including a GANTT chart containing key tasks, decision points, timing, budget and milestones, documenting all of the activities necessary for laboratory facilities both in the U.S. and Europe to reach operational readiness by the end of December 2016 (such plan, the “ **Pre-Phase III Plan** ”). The Pre-Phase III Plan will include, among other items, (i) review and identification of a preferred contract manufacturing organization in Europe, (ii) set-up, identification and qualification of third parties for raw materials, (iii) validation of laboratory facilities in the U.S. and Europe; and (iv) a hiring plan for the key personnel to complete the Pre-Phase III Plan. For Europe, the Pre-Phase III Plan will address the creation of a dedicated lab to support a Phase III trial. For the US, the Pre-Phase III Plan will address the expansion of existing capabilities and infrastructure to handle a Phase III trial.

2.5 Approval of Pre-Phase III Plan. Opexa will present its proposed Pre-Phase III Plan to the JSC and the JSC shall review the proposed Pre-Phase III Plan. The Pre-Phase III Plan shall be subject to the approval of the JSC, which approval shall not be unreasonably withheld or delayed.

2.6 Pre-Phase III Plan and Extension of Option Period. Notwithstanding anything to the contrary in Section 2.1, in the event that the JSC has not approved the Pre-Phase III Plan prior to end of the Option Period, the Option Period shall be extended, and Merck may exercise the Option, until sixty (60) days following the approval of the Pre-Phase III Plan by the JSC.

2.7 R&D Funding Payment. As consideration in advance of Opexa's creation and performance of the Pre-Phase III Plan as well as Opexa's performance of Section 2.8, Merck will pay to Opexa the sum of U.S. Three Million Dollars (\$3,000,000) (the "**R&D Funding Payment**"), which sum shall be payable within fourteen (14) days of Merck's receipt of an invoice from Opexa for the R&D Funding Payment. For clarity, Opexa may submit such invoice on or after March 9, 2015.

2.8 Immune Monitoring Data. Opexa will provide to Merck updates and analysis on a blinded basis, grouped in patient batches according to Opexa's analysis timetable, on the progress of Opexa's immune monitoring program (the "**Program**") being conducted in conjunction with the Abili-T Trial, with such updates and analysis to be shared by Opexa with Merck within thirty (30) days of Opexa's initial assessment of such information. Opexa will inform Merck of any existing or future external bioinformatics vendor used by Opexa for the Program, and Merck will have the right, at its expense, to review current and future data storage and integrity measures for the Abili-T Trial.

1.4 Section 3.1 of the Option Agreement is amended by adding the following sentence immediately following the last sentence thereof:

In addition to the foregoing responsibilities, the JSC shall also have responsibility for approving, and overseeing the completion by Opexa, of the Pre-Phase III Plan. The JSC will meet at least quarterly beginning in the second (2nd) quarter of 2015 to advise and make specific recommendations with respect to the Pre-Phase III Plan, although the foregoing responsibility of the JSC shall not modify decision-making under Section 3.4 hereof.

**Article 2
ELECTRONIC EXECUTION**

2.1 This Amendment may be executed by the Parties by electronic means, by exchanging signed PDF copies that are scanned and emailed, and shall come into effect immediately upon execution by the last Party.

Article 3
RELATIONSHIP OF THE AMENDMENT WITH THE OPTION AGREEMENT

- 3.1** The terms and conditions of this Amendment shall constitute a part of the Option Agreement as amended hereby, and shall be construed in accordance with the terms and conditions of the Option Agreement as amended.
- 3.2** Except as expressly modified by this Amendment, the Option Agreement shall continue in full force and effect.
- 3.3** If there is a conflict between the Option Agreement and this Amendment, this Amendment shall prevail.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed and delivered by their respective duly authorized officers as of the Effective Date.

Opexa Therapeutics, Inc.

Ares Trading S.A.

By: /s/ Neil K. Warma
Name: Neil K. Warma
Title: CEO

By: /s/ Cedric Hyde
Name: Cedric Hyde
Title: Authorized Representative

By: /s/ Karthik Radhakrishnan
Name: Karthik Radhakrishnan
Title: CFO

By: /s/ James Singleton
Name: James Singleton
Title: Authorized Representative

Opexa Amends Agreement with Merck Serono and Receives Additional \$3 Million Payment to Support Ongoing Development of Tcelna[®] for Multiple Sclerosis

THE WOODLANDS, Texas--(BUSINESS WIRE)--March 9, 2015-- **Opexa Therapeutics, Inc.** (NASDAQ:OPXA), a company developing personalized immunotherapies for autoimmune disorders, including multiple sclerosis (MS) and neuromyelitis optica (NMO), today announced that it has amended its option and license agreement with Merck Serono (a division of Merck, Darmstadt, Germany) and will receive a \$3 million payment. The payment provides support for the ongoing Phase 2b clinical study of Tcelna[®] (*imilecleucel-T*), Opexa's personalized immunotherapy in development for patients with Secondary Progressive MS (SPMS), as well as the preparation and planning of potential Phase 3 studies.

"Tremendous progress has been achieved in the treatment of multiple sclerosis over the past two decades but there remains a high unmet medical need for certain areas of the disease," said Belén Garijo, Member of the Executive Board of Merck and CEO Healthcare. "Building on our strong heritage in multiple sclerosis, we will continue to focus our innovation efforts on areas where we can make a difference, such as secondary progressive multiple sclerosis where there are currently very limited therapeutic options. The additional support to Opexa to further develop Tcelna (imilecleucel-T) is another sign of our long-standing and continuing commitment to improving the lives of people living with multiple sclerosis."

Opexa and Merck Serono entered into the original option and license agreement for the development and commercialization of Tcelna in MS in February of 2013, at which time Opexa received a \$5 million upfront payment. Pursuant to the original agreement, Merck Serono has an option to acquire an exclusive, worldwide (excluding Japan) license of Opexa's Tcelna program for the treatment of MS. The option may be exercised by Merck Serono prior to or upon completion of Opexa's ongoing Phase 2b Abili-T trial of Tcelna in patients with SPMS. Top-line data from the Abili-T trial is expected in the second half of 2016. Tcelna has received Fast Track Designation from the U.S. Food and Drug Administration for SPMS.

"We are pleased with this show of support by Merck Serono towards Opexa's novel and personalized immunotherapy," commented Neil K. Warma, Opexa's President and Chief Executive Officer. "Our relationship with Merck Serono over the last two years has been productive and we are pleased to strengthen this relationship and expand our development efforts with them in the critical work we are doing in the field of multiple sclerosis. We continue to focus on the careful execution of our ongoing Abili-T trial in SPMS patients and look forward to our continued collaboration with Merck Serono."

Further details of the transaction are included in a Form 8-K filed by Opexa with the U.S. Securities and Exchange Commission.

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 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 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 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 OPX-212), 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 MS and NMO; 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, to complete preclinical development activities and potentially file an IND for OPX-212, and potentially to conduct a Phase 1/2 proof-of-concept study for OPX-212 in NMO); 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"), 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); the success of our development programs (including the preclinical development activities with respect to OPX-212); 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 FDA regulations; our ability to obtain, maintain and protect intellectual property rights (including for Tcelna and future pipeline candidates such as OPX-212); the risk of litigation regarding our intellectual property rights or the rights of third parties; 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 SEC. 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 our 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 SEC filings, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.

CONTACT:

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nwarma@opexatherapeutics.com