
**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): September 2, 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 7.01. Regulation FD Disclosure.

Opexa Therapeutics, Inc. (the “ **Company** ”) has updated its Investor Presentation that will be available on the Investor Relations page of the Company’s website (www.opexatherapeutics.com) and will be used at investor and other meetings. A copy of the updated Investor Presentation is furnished as Exhibit 99.1 and incorporated herein by reference. The Company does not undertake to update this presentation.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Opexa Therapeutics, Inc. Investor Presentation, September 2015.

The information in Item 7.01 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.

OPEXA THERAPEUTICS, INC.

Dated: September 2, 2015

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Opexa Therapeutics, Inc. Investor Presentation, September 2015.



OPEXA THERAPEUTICS

Precision Immunotherapy®

Opexa Therapeutics, Inc.

NASDAQ: OPXA

September 2015
The Woodlands, TX

Forward-Looking Statements

All statements in this presentation other than those of historical fact, including statements regarding our preclinical and clinical development plans for Tcelna® and OPX-212, our research and other development programs, our ability to undertake certain activities and accomplish certain goals, projected timelines for our research and development activities and possible regulatory approvals, if any, our expectations regarding the relative benefits of our product candidates versus competitive therapies, our expectations regarding the possibility of licensing or collaborating with third parties regarding our product candidates or research, and our expectations regarding the therapeutic and commercial potential of our product candidates, research, technologies and intellectual property, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “potential” and similar expressions, as well as the negative version of these words and similar expressions, are intended to identify forward-looking statements. Our forward-looking statements do not constitute guarantees of future performance, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those anticipated or implied in such statements. Our 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 as a result of various risks and uncertainties which include, without limitation, risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics and risks inherent in the effort to build a business around such drugs. Although we believe our expectations are reasonable, we do not in any way guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any forward-looking statements. Our forward-looking statements in this presentation speak only as of the date of this presentation. We assume no obligation or undertaking to update or revise any statements to reflect any changes in our expectations or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make that further describe risks and uncertainties relevant to us in additional detail in our filings with the Securities and Exchange Commission including our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. You may get these documents for free by visiting EDGAR on the SEC web site at <http://www.sec.gov>.

Opexa Investment Highlights

➤ PIPELINE

- **Tcelna®**: Phase 2b for **secondary progressive multiple sclerosis (SPMS)**, limited competition, \$7BN overall market potential
- OPX-212: Pre-IND for **neuromyelitis optica (NMO)**, no approved therapies, **orphan** indication

➤ TECHNOLOGY

- **Personalized T-cell immunotherapy platform** for autoimmune diseases
- Potential to yield multiple candidates tailored to each patient's disease profile
- **Company owned and scalable cGMP manufacturing facility**
- Strong patent estate (98 domestic and international)

➤ VALIDATION

- Option agreement secured with Merck Serono for Tcelna – strong potential partner
- **FDA Fast Track designation** for Tcelna in SPMS
- Esteemed Scientific Advisory Board

Recent and Upcoming Expected Milestones

Tcelna: Multiple Sclerosis

- ✓ 1H 2014: Completed Enrollment in Phase 2b SPMS trial
- ✓ Q1 2015: Received additional \$3M payment from Merck Serono for Tcelna development
- ✓ Q3 2015: 85% of all patient visits in Abili-T trial have been completed
- 2H 2016: Top line results expected for Abili-T Phase 2b SPMS trial

OPX-212: Neuromyelitis Optica

- ✓ 1H 2014: Initiated Early Development Plan
- ✓ Q3 2015: Secured \$5 million in milestone funding to support OPX-212 NMO development, including Phase I/II proof-of-concept clinical trial
- 2015: Expect to complete preclinical and IND enabling studies and file IND by year-end

Financials

Cash and Cash Equivalents (MM) as of June 30, 2015	~\$18.3
Shares outstanding (MM) as of June 30, 2015	~53.4
Warrants (MM) outstanding as of June 30, 2015	~28.4 ⁽¹⁾
Stock Options (MM) outstanding as of June 30, 2015	~3.3 ⁽²⁾
Debt	None

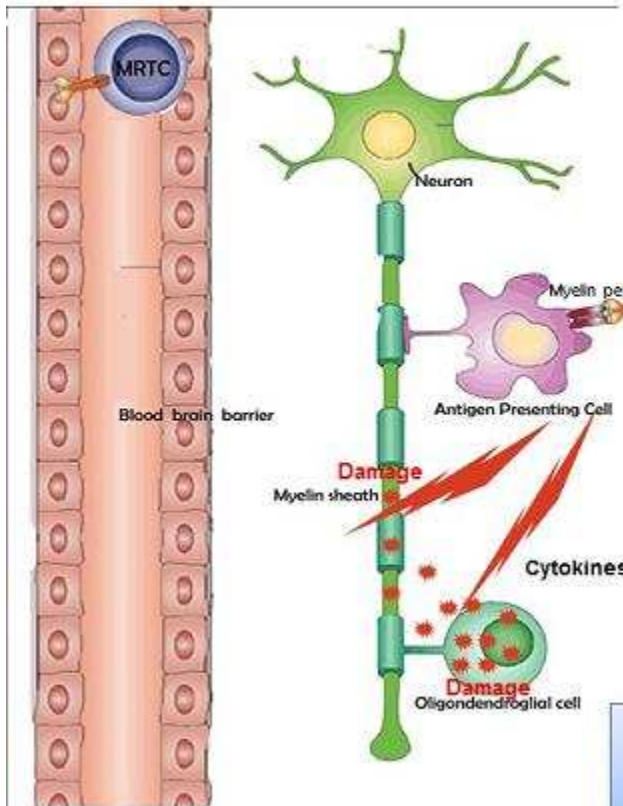
(1) Weighted average exercise price = \$.80 as of June 30, 2015

(2) Weighted average exercise price = \$2.28 as of June 30, 2015



OPEXA'S NOVEL APPROACH; PRIMING THE IMMUNE SYSTEM

Root cause of MS: Activated T-cells degrade myelin and damage myelin producing cells

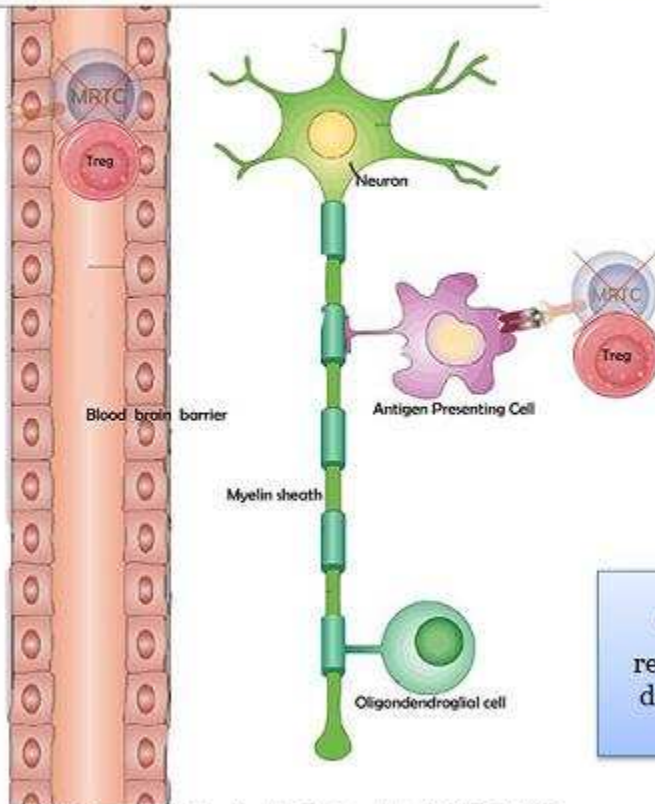


- In MS patients, the faulty immune system is not able to prevent the attack of a small sub-population of myelin reactive T-cells (MRTC)
- MRTCs cross the blood brain barrier, enter the brain, and bind to antigen presenting cells (APC), causing a release of pro-inflammatory cytokines which lead to a two pronged attack through:
 1. Destruction of myelin sheath, the protective coating of nerve fibers
 2. Destruction of oligodendroglial cells, which are responsible for producing myelin

Result

Destruction of the myelin sheath and myelin producing cells, thereby preventing remyelination

Tcelna could address the root cause of MS by preventing demyelination and enabling remyelination



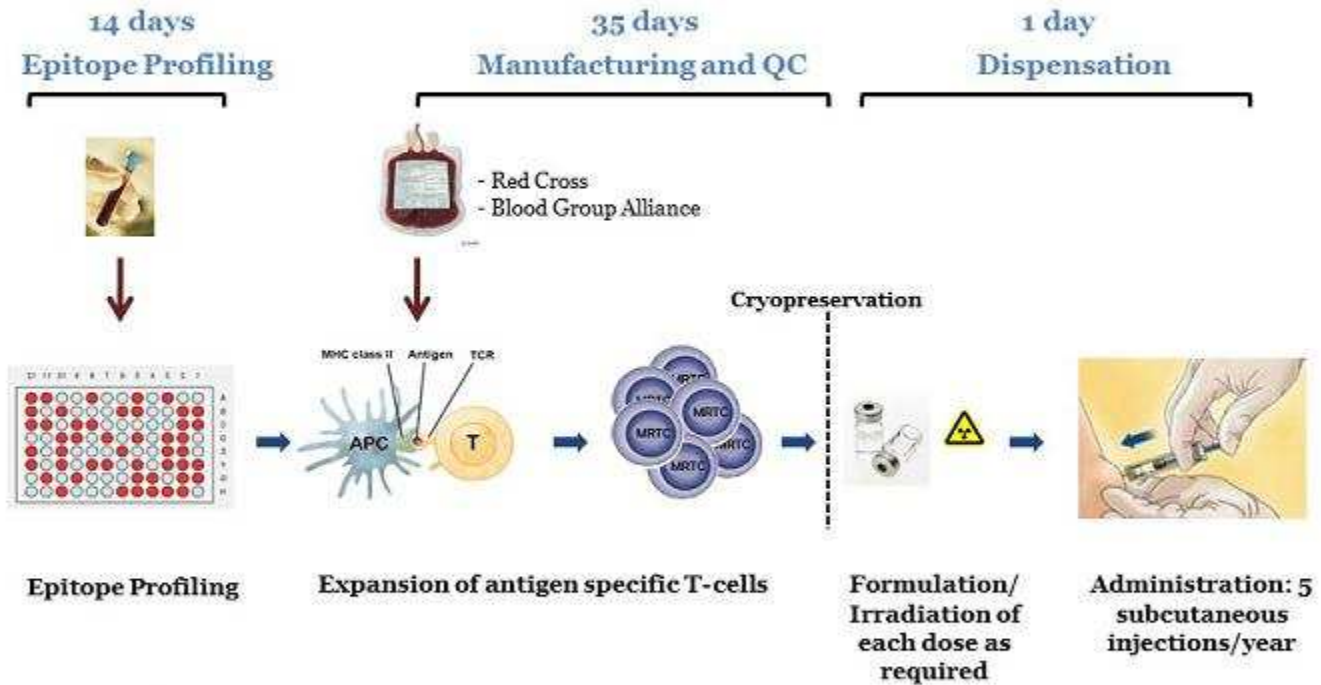
- Therapeutic dose of Tcelna (attenuated T-cell clones) is injected subcutaneously
- This triggers an immune response specifically targeting circulating MRTC
- Immune cells, including Tregs, have been primed, or sensitized, we believe, to specifically target the pathogenic MRTC for elimination or regulation
- Elimination of harmful MRTC may lead to:
 1. Stabilization of disease by preventing further destruction of myelin
 2. Improvement in condition by allowing oligodendroglial cells to remyelinate axons (neuroprotection)

Opexa's Strategy

Tcelna programs the immune system to **specifically** recognize MRTC as pathogenic, thereby inhibiting further destruction of the myelin sheath and potentially enabling remyelination

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ImmPath[®] manufacturing platform



Annual course of treatment consists of 5 doses manufactured from a single procurement of blood product

Clinical evidence for Tcelna MoA

T-cell technology demonstrated a significant reduction in reactive T-cells (52 week study results of MS)

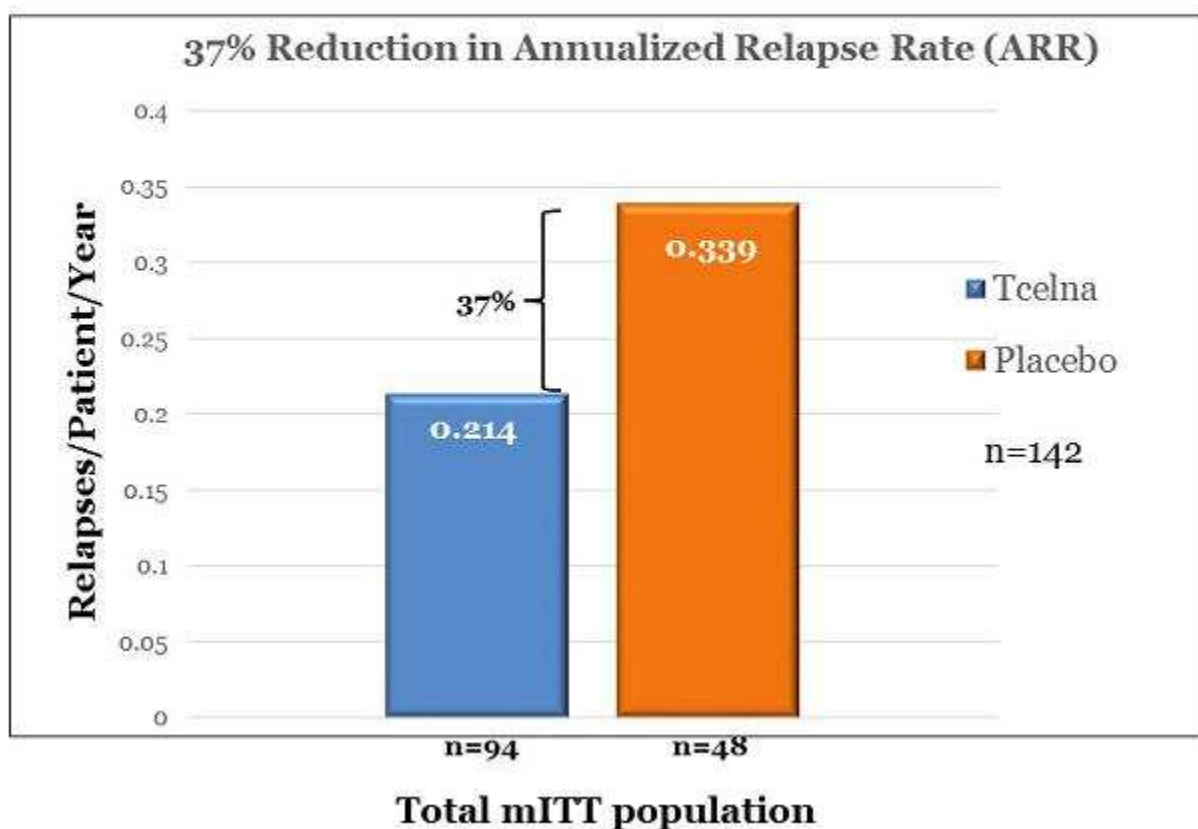


MRTC: Myelin Reactive T-cells

Phase 2b RRMS prior clinical trial

Tcelna showed 37% improvement over placebo (mITT)

(secondary endpoint measurement, primary MRI endpoint measure not met)



IMMPATH®: OPEXA'S PROPRIETARY T-CELL IMMUNOTHERAPY PLATFORM

Leveraging ImmPath® platform in new indications

ImmPath®: Personalized, Precision Immunotherapy Platform

Potential New Targets:

Certain diseases with known antigen profile

- Grave's Disease
- Idiopathic thrombocytopenic purpura
- Myasthenia Gravis
- Pemphigus vulgaris/foliaceus
- Primary Biliary Cirrhosis
- Type 1 Diabetes
- Hashimoto's thyroiditis
- Vitiligo

Certain diseases with unknown antigen profile

- RA
- Celiac
- Psoriasis
- Uveitis
- IBD
- Sjögren's

Preclinical

**Neuromyelitis
optica**

Phase 2b

**Secondary Progressive
Multiple Sclerosis**

Expansion of Pipeline Increases Partnering Opportunities

**Multiple Sclerosis
Japan**



- Quick access to market
- Leverage U.S. trial success

**Autoimmune
diseases with
known antigens**



- Development stage programs
 - i.e. OPX-212 for NMO
- Orphan disease benefits

**Autoimmune
diseases with
unknown antigens**



- Discovery stage programs
- Possible expansion to large markets (e.g. RA, Psoriasis)



TCELNA[®] FOR MULTIPLE SCLEROSIS

Tcelna in Secondary Progressive MS

450,000 Individuals in North America diagnosed with MS;
30-45 % potentially have an SPMS diagnosis



- Secondary Progressive MS market potential in North America could exceed **\$7 billion** (for all therapies)
- Roughly 150,000 SPMS patients in North America
- Only one drug approved for SPMS in U.S. (none in EU or Asia)
 - Drug not suitable for chronic use due to severe side effects

Tcelna being developed to be a potential therapy of choice in SPMS

Tcelna®

Lead Program Targeting Secondary Progressive MS patients

Fast Track Designation by FDA

- **Phase 2b is fully enrolled: 190 patients with SPMS**
- **Top line data expected in 2H 2016**
- **Design**
 - Double-blind, 1:1 randomized, placebo-controlled
 - 35 clinical sites in USA and Canada
 - Two annual courses of personalized therapy
 - Efficacy Endpoints: Primary-Whole Brain Atrophy, Secondary-Disease Progression
- **Immune Monitoring being conducted in parallel**
 - Comprehensive biomarker analysis

Merck Serono Agreement

Agreement signed 2013; strong potential partner

- Option and License Agreement for worldwide rights to all Multiple Sclerosis indications, excluding Japan
- If Merck Serono exercises option:
 - Merck Serono to fund Phase 3, pre-commercial and commercial activities
 - Opexa has potential to receive up to an additional \$220 million in option exercise and milestone payments
 - Opexa has potential to receive royalties ranging from 8% to 15% of annual net sales, with step-ups occurring if net sales exceed \$500 million, \$1 B & \$2 B
- Merck Serono increased their commitment to Opexa's MS program this year
 - In anticipation of the Phase IIb trial results expected in 2H 2016, Merck Serono gave Opexa \$3 million of support in March 2015 to begin planning for Phase III studies

LEVERAGING THE T-CELL PLATFORM: OPX-212 FOR NEUROMYELITIS OPTICA (NMO)

NMO: A rare disease of the Central Nervous System



Image reprinted with permission from MultiSys, Inc.

- Neuromyelitis optica (NMO) is a rare or orphan autoimmune disease
- Immune system cells and antibodies mistakenly attack and destroy myelin cells in the optic nerves and the spinal cord
- Individuals with NMO develop optic neuritis, which causes pain in the eye and vision loss, and transverse myelitis, which causes weakness, numbness, and sometimes paralysis of the arms and legs
- There are no FDA-approved therapies for NMO
- Affects any age varying from 3 to 90 years, the average age of onset ~41 years

An orphan disease with no FDA-approved therapy

Key Milestones Achieved to Date in OPX-212 Development Program

Funding support

- Recently secured \$5 million private funding for OPX-212 to advance further NMO development, including Phase I/II clinical study

KOL support

- Engaged key thought leaders to validate scientific hypothesis and discuss clinical trial design
 - Benjamin Greenberg, M.D., University of Texas, Southwestern Medical Center
 - Michael Levy, M.D., Ph.D., The Johns Hopkins Hospital

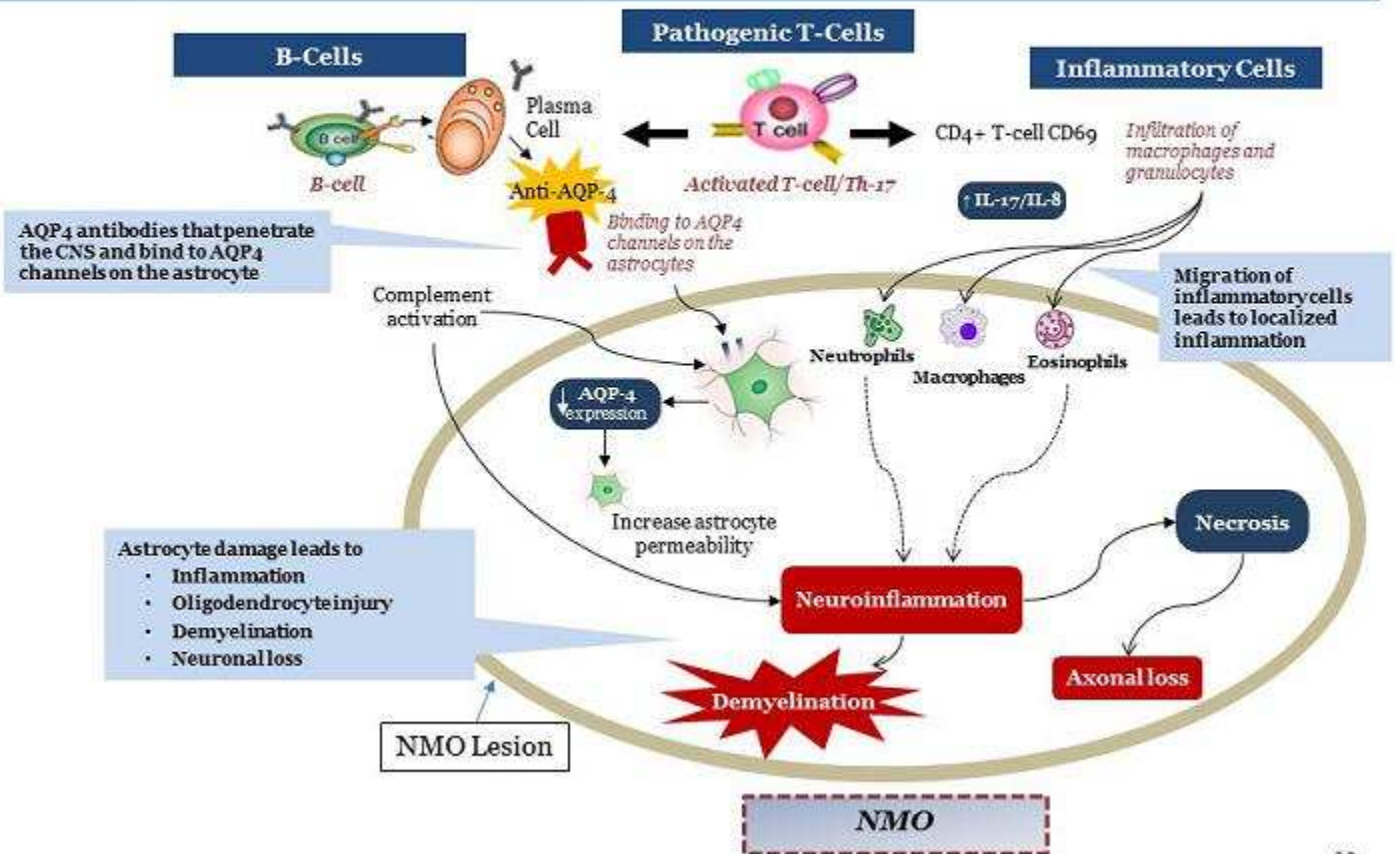
FDA feedback

- Conducted Pre-IND meeting to discuss pre-clinical and clinical program to support OPX-212 development in NMO

Patient support

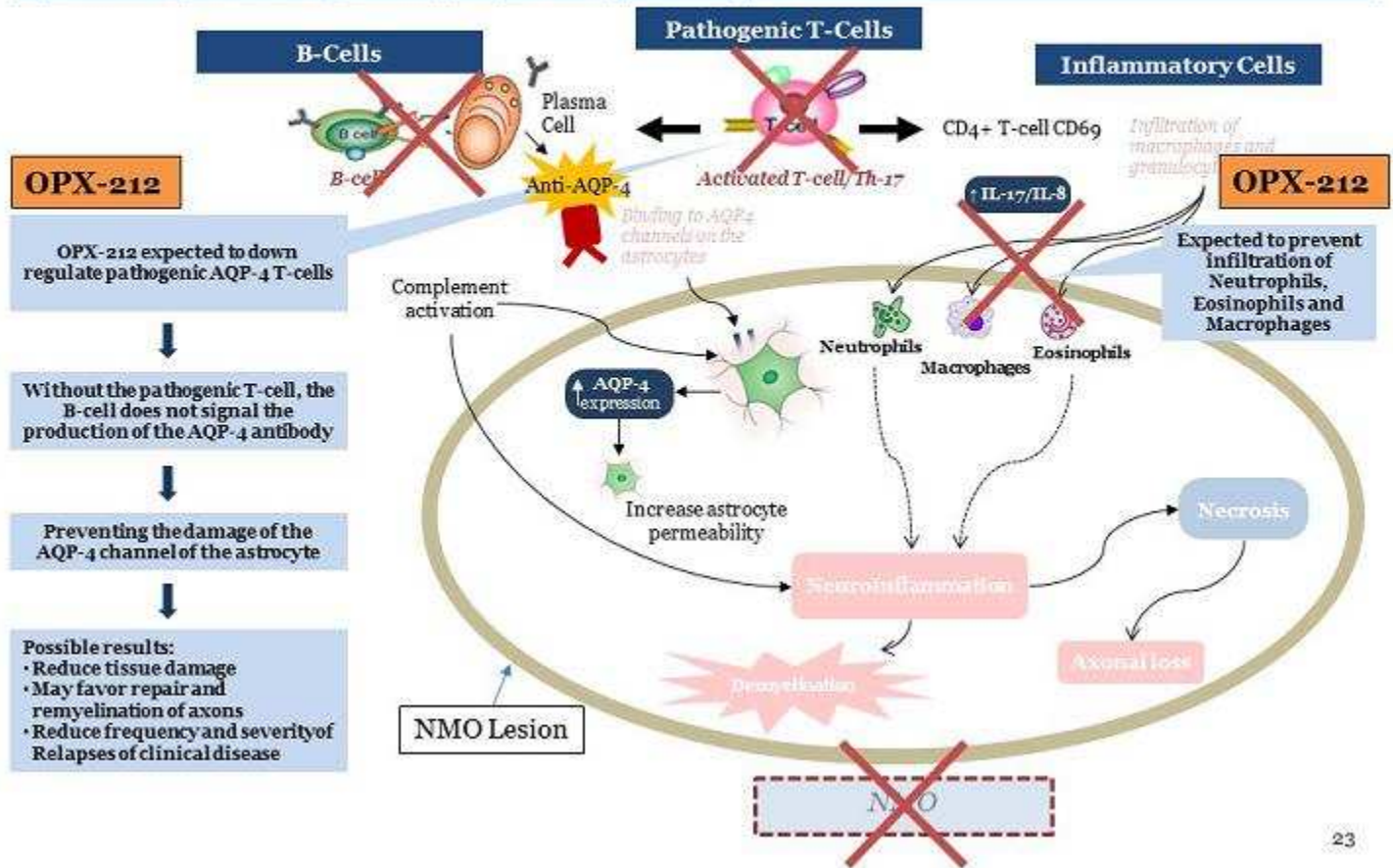
- Collected NMO patient blood samples to conduct pre-IND activities, process development and research into mechanism of action

NMO disease pathogenesis



Potential intervention points for T-cell therapy

T-cell therapy believed to inhibit AQP-4 autoantibody, pro-inflammatory cytokines and prevent infiltration of macrophages and granulocytes



NMO Investment Thesis

- Any therapy that could achieve tolerization of the AQP-4 reactive T-cells may offer a cure for NMO
- OPX-212 has the potential to address the root cause of NMO
- OPX-212 leverages Opexa's T-cell platform to B-cell mediated orphan diseases
- Opexa currently retains world wide rights to OPX-212
- Higher prevalence of NMO in Asia could complement Opexa's MS rights in Japan
- IND filing expected by 12/31/15

Experienced Management Team and Board of Directors

Neil Warma, President & CEO, Director

- › 19+ years international healthcare experience with large Pharma and emerging biotechnology companies
- › Former Senior Management, Novartis Pharmaceuticals, Basel, Switzerland
- › Former CEO, Viron Therapeutics, Inc.
- › Co-founder and President of MedExact Inc., a company subsequently acquired

Karthik Radhakrishnan, Chief Financial Officer

- › 10+ years of health care capital markets experience
- › Formerly, Vice President at ING Investment Management
- › MBA, MS in Engineering, CFA charter holder

Don Healey, Ph.D., Chief Scientific Officer

- › 25+ years of experience in cellular immunology and immune regulation
- › Former Director of Immunology, Argos Therapeutics

Donna Rill, Chief Development Officer

- › 30 years in cell and gene therapy research and clinical application
- › Designed and validated cGMP Cell & Gene Therapy Laboratories, Vector Production facilities, and Translational Research Labs

Jason Kralic, Ph.D., VP, Business Development

- › Former Head of Business Development for the Neurosciences Therapy Area Unit at GlaxoSmithKline
- › Ph.D. in Pharmacology from University of N. Carolina at Chapel Hill School of Medicine

Board of Directors

Timothy Barabe

Board member of Arqule, Inc.; Former CFO of Affymetrix, Human Genome Sciences, Inc., Regent Medical UK and Sandoz GmbH

Dr. Hans-Peter Hartung

Chair of Neurology at Heinrich-Heine University, Germany; Executive Board member of ECTRIMS

Gail J. Maderis

Former CEO, BayBio, Former CEO of Five Prime Therapeutics, Founder of Genzyme Molecular Oncology

Michael S. Richman

CEO, Amplimmune

Scott B. Seaman

Executive Director, Alkek Foundation

Neil K. Warma

President & CEO, Opexa

SPMS Scientific Advisory Board

- **Dawn McGuire, M.D., FAAN (Chair)**
 - Advisory Council of the Gill Heart Institute
 - Former Vice President of Clinical Research at Elan Pharmaceuticals
- **Hans-Peter Hartung, M.D**
 - Chair of Neurology at Heinrich-Heine University, Düsseldorf
 - Executive Board member ofECTRIMS, World Health Organization Advisory Board on MS
- **Mark S. Freedman, M.D.**
 - Director of the Multiple Sclerosis Research Unit at Ottawa Hospital
 - Multiple Sclerosis Society of Canada, National MS Society (USA)
 - ACTRIMS committee member
- **Clyde Markowitz, M.D.**
 - Director of MS Center at the University of Pennsylvania
- **Doug Arnold, M.D.**
 - James McGill Professor Neurology and Neurosurgery at the Montreal Neurological Institute
- **Edward Fox, M.D., Ph.D.**
 - Director of Multiple Sclerosis Clinic of Central Texas
 - Advisory Committee, Lone Star Chapter of the National Multiple Sclerosis Society

Opexa Investment Thesis

TECHNOLOGY

- Proprietary Platform: potential to yield multiple drug candidates
- Differentiated, personalized approach
- Strong patent estate (98 domestic and international)

PIPELINE

- **Tcelna**: Secondary Progressive MS, limited competition, \$7BN potential market
- **OPX-212**: Recently launched development program in NMO, no approved therapies, orphan indication
- Precision Immunotherapy potentially optimizes benefit-risk profile

VALIDATION

- Option agreement secured with Merck Serono – strong potential partner
- FDA Fast track designation for Tcelna in SPMS
- Esteemed Scientific Advisory Board