**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 12, 2016**

# OPEXA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

| **Texas** | **001-33004** | **76-0333165** |
|---|---|---|
| (State or other jurisdiction ofincorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **2635 Technology Forest Blvd., The Woodlands, Texas** | **77381** |
|---|---|
| (Address of principal executive offices) | (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 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.

| Exhibit No. | Description |
|---|---|
| 99.1 | Opexa Therapeutics, Inc. Investor Presentation, September 2016. |

*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 12, 2016

By: /s/ Neil K. Warma

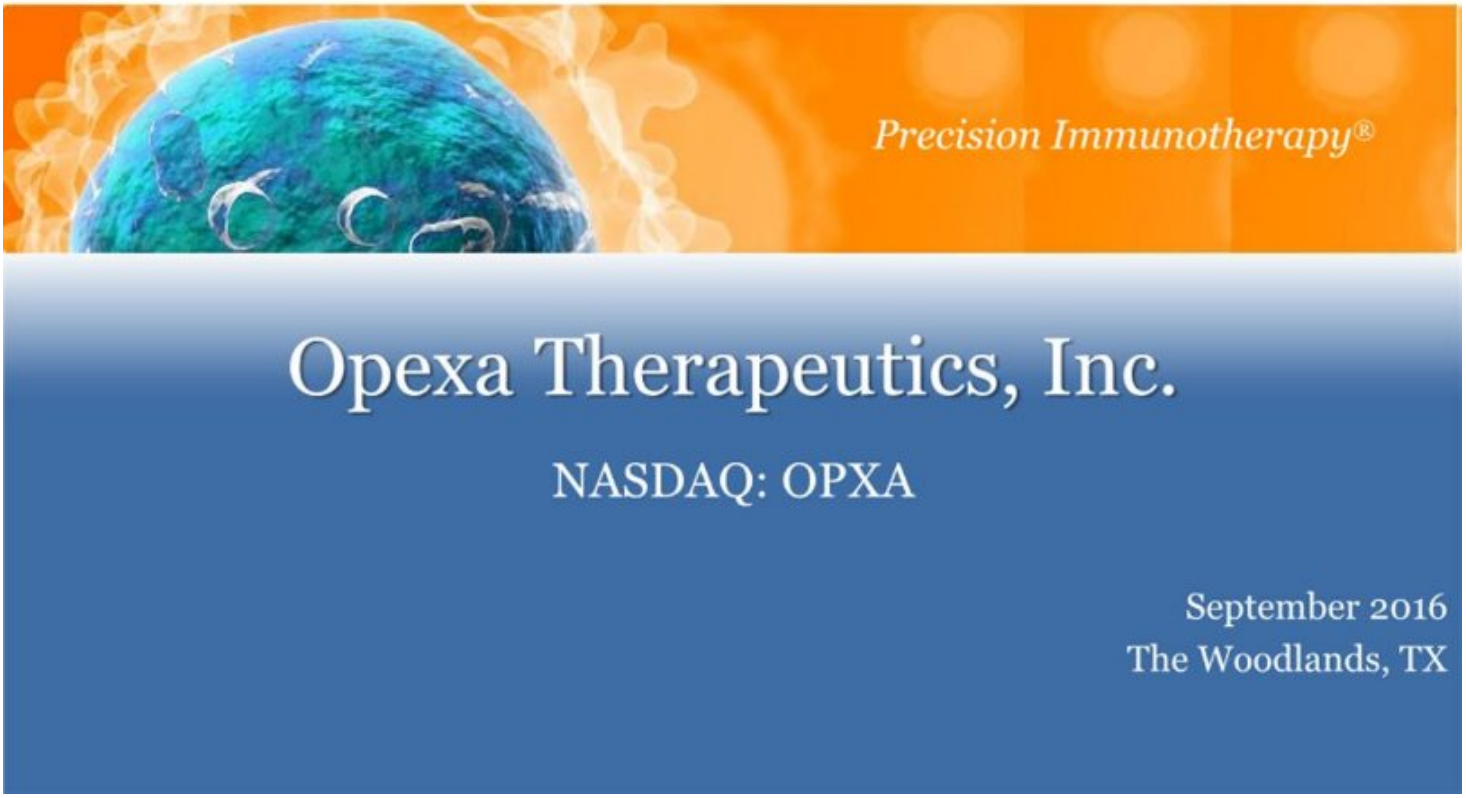
Neil K. Warma
President, Chief Executive Officer and Acting Chief Financial Officer

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Opexa Therapeutics, Inc. Investor Presentation, September 2016. |

Exhibit 99.1

OPEXA THERAPEUTICS




# Opexa Therapeutics, Inc.

NASDAQ: OPXA

September 2016
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 Highlights (Nasdaq: OPXA)

## Opexa: A leading force in personalized therapies for autoimmune diseases

**Advanced, proprietary platform**: Lead asset in Phase 2b development

**Lead indication:** Secondary Progressive Multiple Sclerosis (SPMS)

**Next inflection point**: In 1-2 months with top-line Phase 2b data expected

**Potential Partnership:** Merck Serono, secured option on MS indications

- Possible exercise at completion of Phase 2b

**FDA recognition:** Fast Track designation for SPMS

**IP Estate:** 160+ issued patents

# Opexa's T-Cell Immunotherapy Platform

## Combatting autoimmune disease

- Restoring the function of an individual's faulty immune system
- Modulating the body's immune cells (T-cells) to enable the person to fight the disease itself
- Making individually precise therapies by harnessing cells from every patient treated
- Tailoring each therapy to every individual's disease profile
- Targeting a favorable benefit:risk profile
  - A necessity for marketing approval and reimbursement
- Targeting manageable costs and margins
  - A necessity for commercial success
  - Manufacturing done in-house, enables focus on COGS and process

# Near Term Possible Value Generation: 1-2 months

## The Abili-T trial

- Phase 2b top-line data in SPMS expected in early Q4 2016
- 180 patient trial, 35 centers in U.S. and Canada
- **Final patient visit has now been completed**
- End points: 1) Brain atrophy and 2) disease progression
- FDA *Fast Track* designation in SPMS

# Significant Market Potential: Secondary Progressive MS


- 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)
  - Black Box warning, drug not suitable for chronic use due to severe side effects

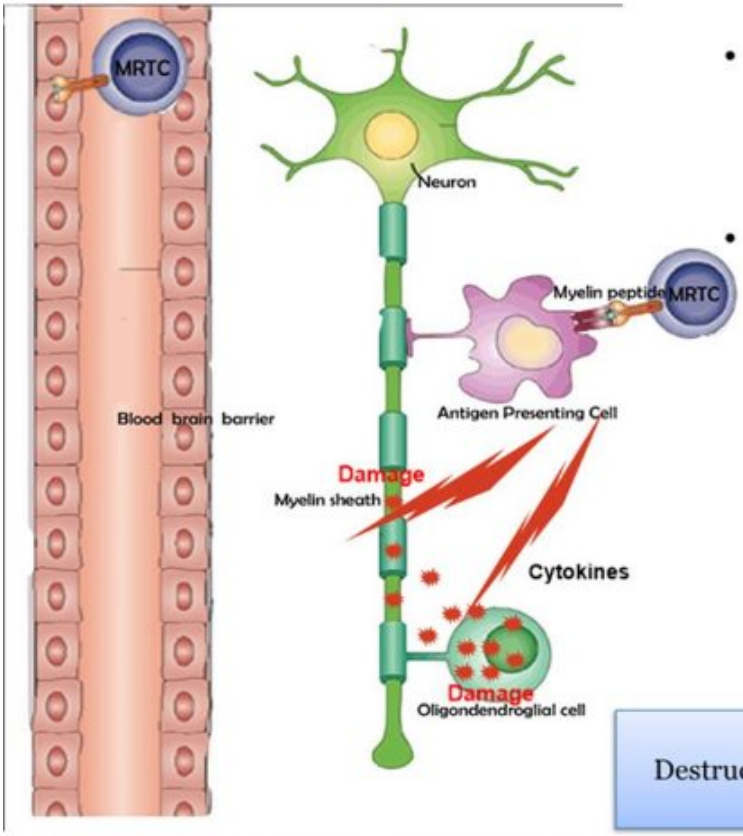
# Additional Near Term Possible Value Generation

## Potential Partner

- Merck Serono signed option and license agreement in 2013
- Following evaluation of Phase 2 data, they could exercise their option, which would trigger:
  - Milestone payment to Opexa (up to $25 million to proceed to Phase 3)
  - Merck to pay for all future costs
  - Total additional milestones up to $195 M
  - Total future royalties, from 8-15% of sales
- In return, Merck to gain rights to all MS indications, world-wide, excluding Japan
- Merck Serono: stellar partner, significant experience in MS, worldwide presence and expertise

# 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:
  - Destruction of myelin sheath, the protective coating of nerve fibers
  - Destruction of oligodendroglial cells, which are responsible for producing myelin

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

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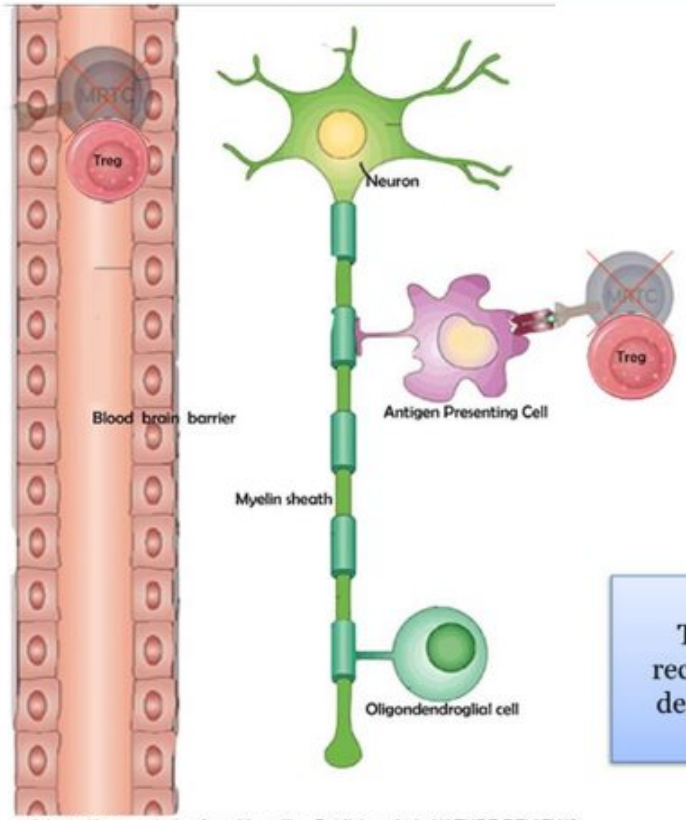
# Tcelna Could Address the Root Cause of MS by Preventing Demyelination and Enabling Remyelination

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- 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)

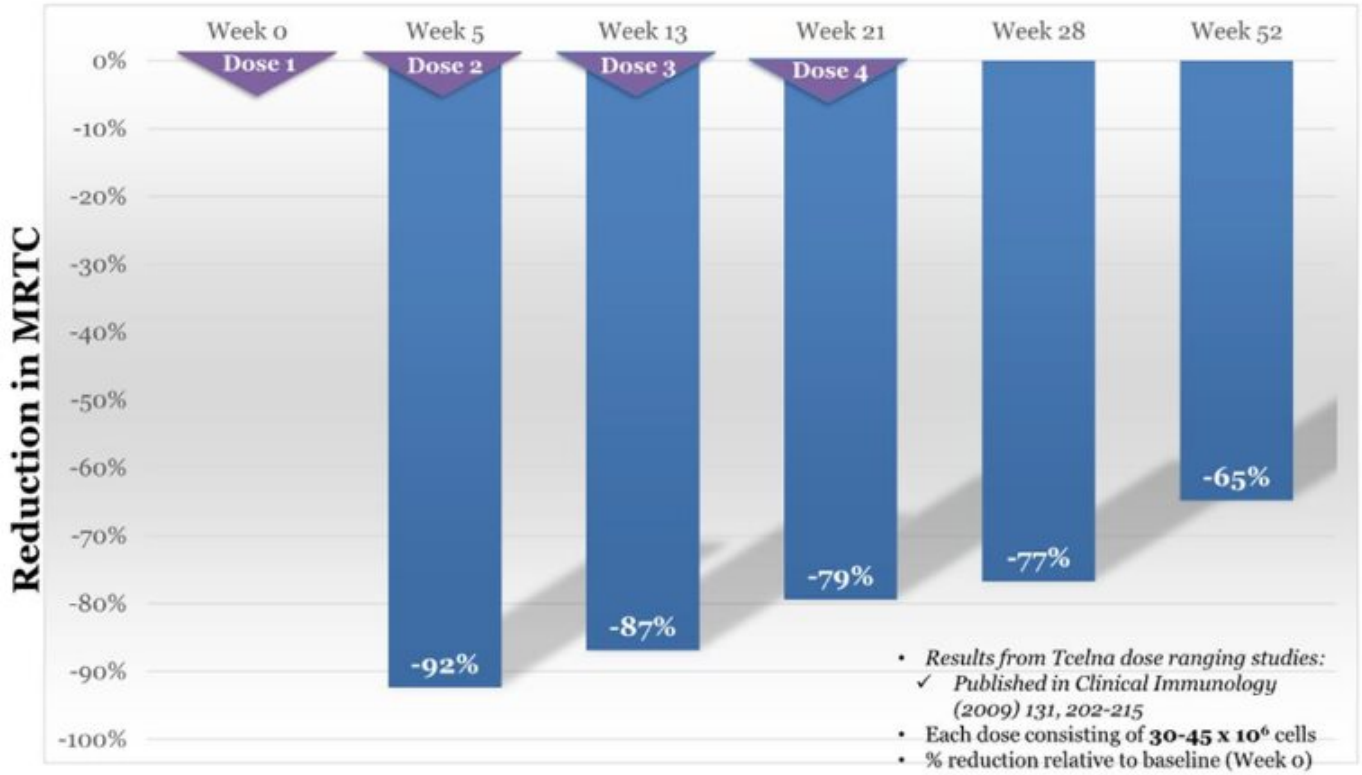
**Opexa's Strategy**

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

# TCELNA® FOR MULTIPLE SCLEROSIS

# Clinical Evidence for Tcelna MoA

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

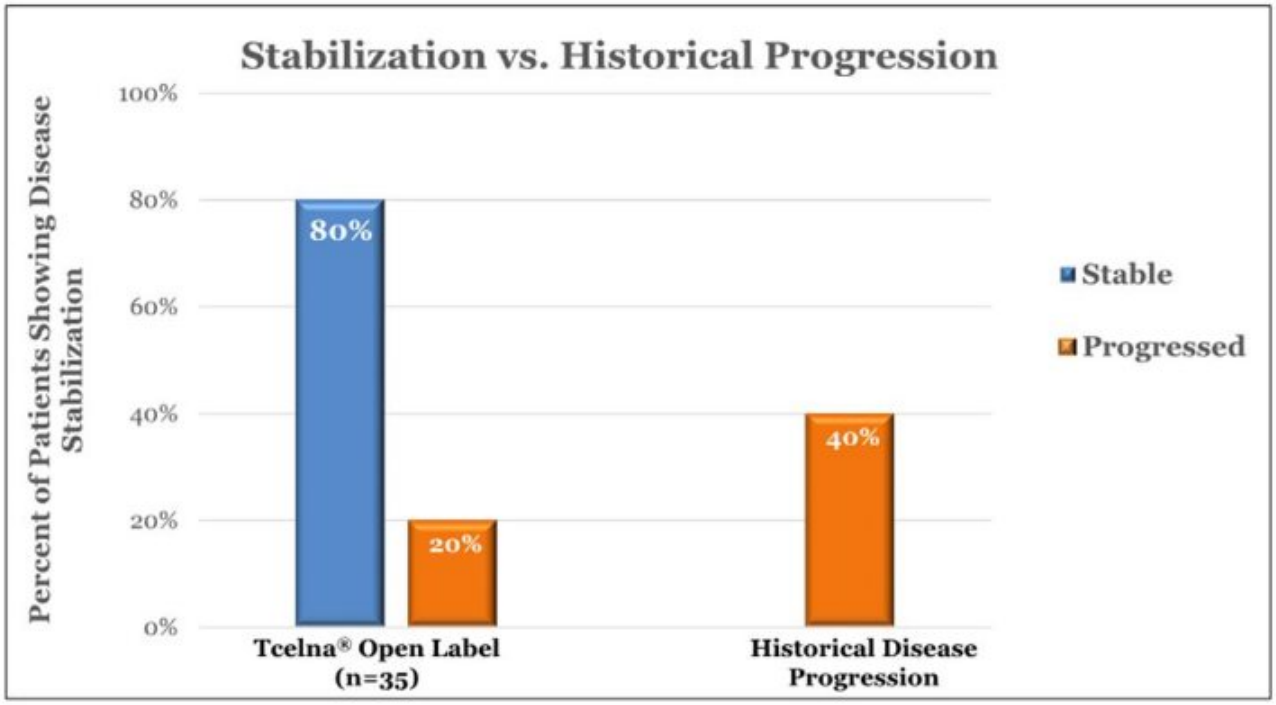



*MRTC: Myelin Reactive T-cells*

# SPMS Patient Data: Previous Studies

## Tcelna stabilizes disease in SPMS Patients at 2 years

### 80% of patients showed no further disease progression by EDSS at 2 years



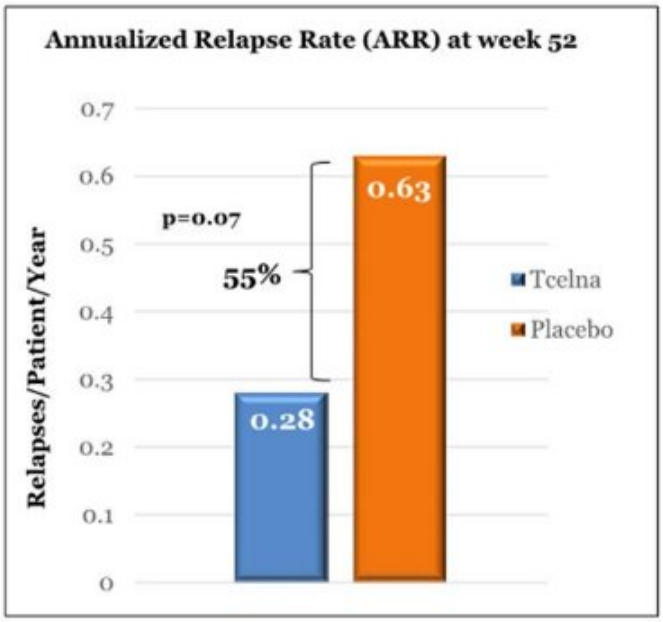

*A small percentage of patients in pooled analysis showed an improvement (i.e. decrease in progression)

**Historical control: ESIMS Study, published Hommes Lancet 2004

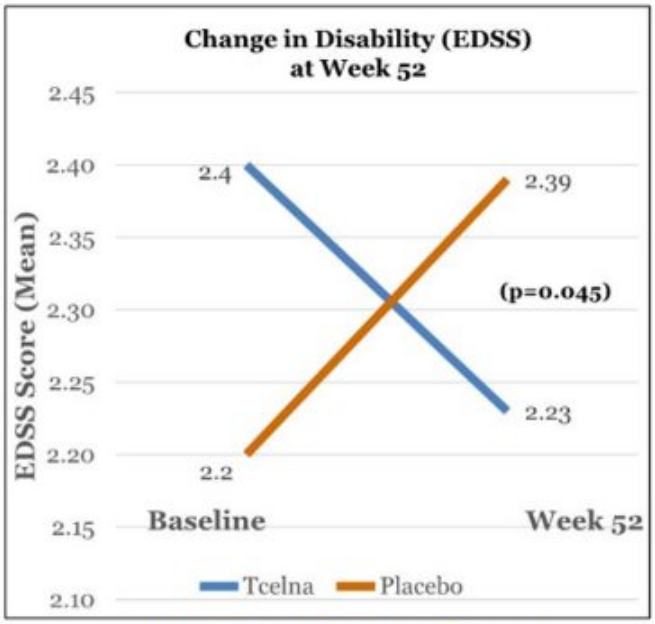
# Results of Phase 2b TERMS study in RRMS

## Reversal of disability in prospective analysis in more active patients

### Sub-population of patients (n=50) with more progressed/active disease profile (baseline ARR >1)




55% Reduction in ARR




Statistically Significant Improvement in Disability (p=0.045)

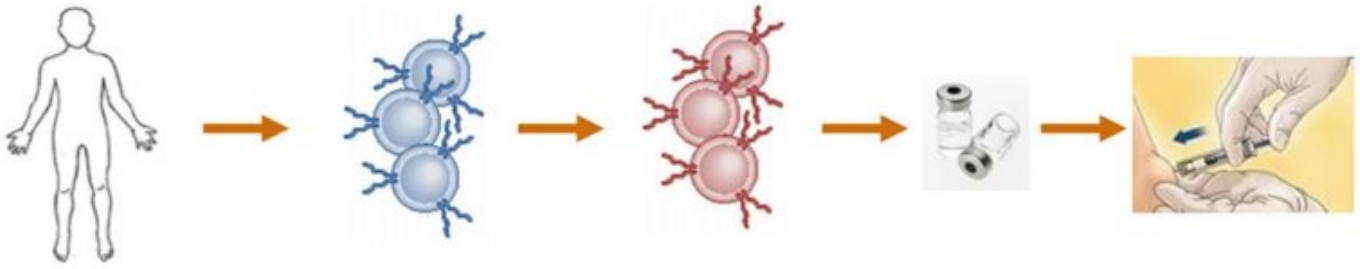
# IMMPATH®: OPEXA'S PROPRIETARY T-CELL IMMUNOTHERAPY PLATFORM

# ImmPath®: Harnessing the Power of the Patient's Own Immune System to Restore Tolerance

**Procurement**

**Manufacturing and QC**
35 Days

**Dispensation**
1 Day



**Antigen-sourced seed material (Blood collection)**

**Expansion of T-cells**

**Attenuation**

**Formulation & cryopreservation**

**Administration 5 SC doses/year**

- **Annual course of treatment generated from a single manufacturing run**
- **Therapy is personalized annually and is tailored to evolving epitope profile**

# 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 MultiView, 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 Operational Milestones Achieved For NMO Program

## FDA feedback

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

## Preclinical animal study

- Results show statistically significant dose dependent reduction of AQP4 reactive T-cells in murine model
- Supportive of MOA

## 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

## Patient support

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

# KEY FINANCIAL DATA

# Financials

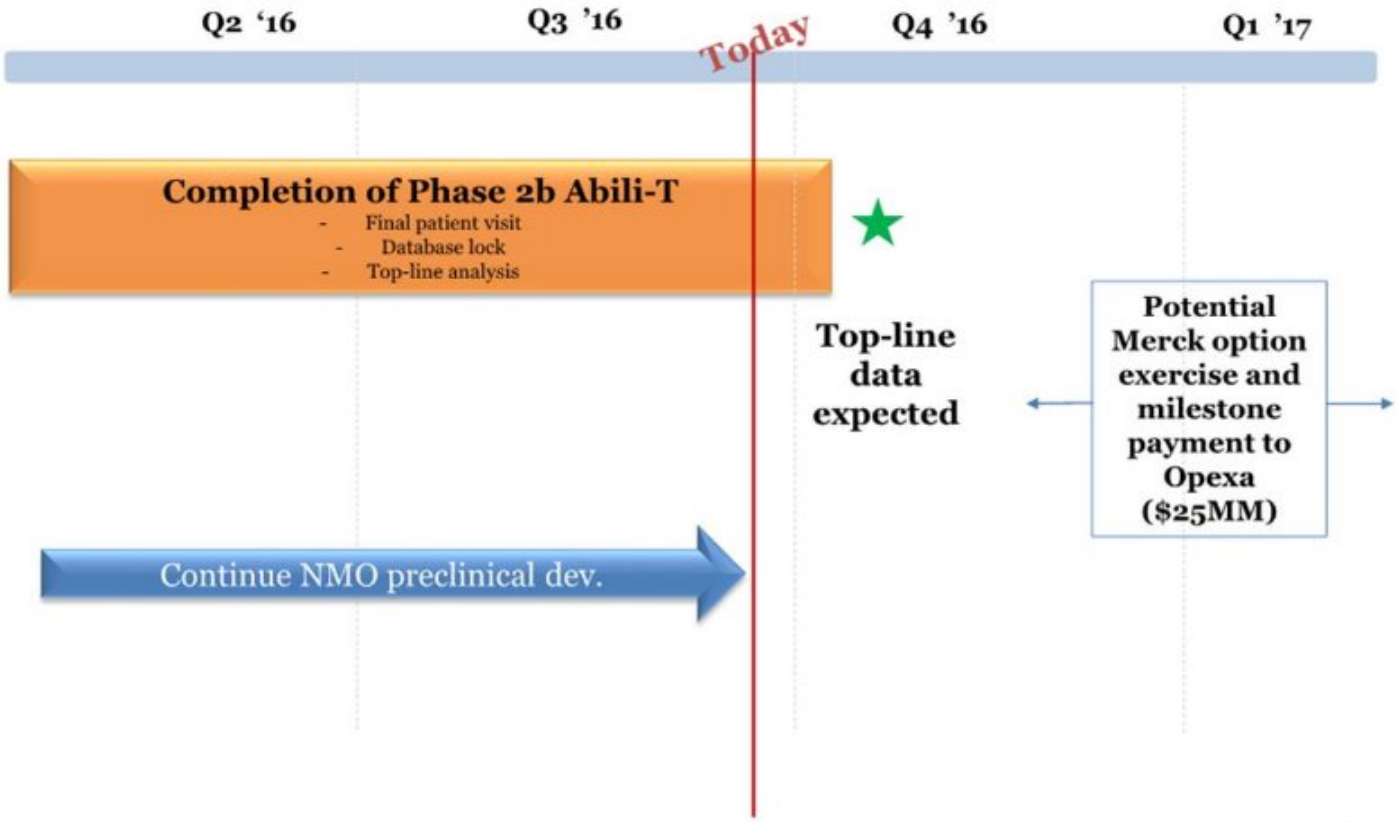
| | |
|---|---|
| Cash and Cash Equivalents (MM) as of June 30, 2016 | ~$7.8 |
| Shares outstanding (MM) | ~7.0 |
| Shares issuable for Warrants (MM) outstanding as of June 30, 2016 | ~3.6(1) |
| Shares issuable for Stock Options (MM) outstanding as of June 30, 2016 | ~0.6(2) |
| Debt | None |

(1) Weighted average exercise price =$5.19 as of June 30, 2016

(2) Weighted average exercise price =$10.91 as of June 30, 2016

# SUMMARY AND OVERVIEW

# Expected Milestones



# Opexa Therapeutics:
## A Leader in Developing T-Cell Immunotherapies

### PIPELINE

- Tcelna®: Phase 2b for **secondary progressive multiple sclerosis** (SPMS), limited competition, $7BN overall market potential
  - Top line results expected for Abili-T Phase 2b SPMS trial in early Q4 2016
- 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
- **Scalable cGMP manufacturing facility**
- Strong patent estate (160 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