

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 09/08/14 for the Period Ending 09/08/14

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): September 8, 2014

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))
-
-

Item 8.01. Other Events.

On September 8, 2014, Opexa Therapeutics, Inc. (the “**Company**”) issued a press release titled “Opexa Therapeutics to Target Rare Disease—Neuromyelitis Optica (NMO) as next Development Program.”

The Company also announced it will host a conference call and webcast with a panel of leading medical authorities to provide an overview of NMO and discuss the Company’s differentiated T-cell treatment approach. The conference call and webcast will be held on September 8, 2014 at 9:30 a.m. EDT. To listen to the conference call, dial in approximately ten minutes before the scheduled 9:30 a.m. EDT time to (253) 237-1170 or toll free at (877) 372-0867. Please reference conference ID 84494085 or the Opexa Therapeutics Business Update. A live webcast of the call can also be accessed via the webcast link on the Investor Relations page of Opexa’s website (www.opexatherapeutics.com).

A copy of the press release issued by the Company on September 8, 2014 is attached hereto as Exhibit 99.1 and incorporated herein by reference. A copy of the Company’s updated Investor Presentation that will be available on the Investor Relations page of the Company’s website (www.opexatherapeutics.com) and may be used with various investor conferences is attached hereto as Exhibit 99.2 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	Press release issued by Opexa Therapeutics, Inc. on September 8, 2014.
99.2	Opexa Therapeutics, Inc. Investor Presentation, September 2014.

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: September 8, 2014

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>
99.1	Press release issued by Opexa Therapeutics, Inc. on September 8, 2014.
99.2	Opexa Therapeutics, Inc. Investor Presentation, September 2014.

Opexa Therapeutics to Target Rare Disease Neuromyelitis Optica (NMO) as next Development Program

THE WOODLANDS, Texas--(BUSINESS WIRE)--September 8, 2014--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biotechnology company developing Tcelna[®] (*imilecleucel-T*), a novel T-cell immunotherapy for the treatment of multiple sclerosis (MS), today disclosed that the Company has commenced development in a second indication, Neuromyelitis optica (NMO). NMO is a rare autoimmune disorder, which is designated as an Orphan disease by the U.S. Food and Drug Administration (FDA). There is currently no cure and there are no FDA approved therapies for this disease.

Opexa initiated preclinical development activities for OPX-212, its drug development candidate for NMO, earlier this year and has achieved several regulatory and early development milestones to date. These include conducting a pre-IND meeting with the FDA and performing in-house manufacturing runs with NMO patient samples. The Company is continuing with preclinical development activities with a goal of filing an IND with the FDA by mid-2015 and then moving into clinical development with a Phase 1/2 proof-of-concept study. The Company believes OPX-212 will qualify for Orphan drug designation and plans also to apply for Fast Track designation for OPX-212.

“We are pleased to announce our development activities in a second indication utilizing our novel T-cell technology platform,” said Neil K. Warma, President and Chief Executive Officer of Opexa. “NMO is a disease with a significant unmet medical need. We believe our approach to the treatment of NMO with OPX-212 is highly differentiated as we are directly targeting the T-cell component of the disease and, therefore, addressing the root cause.”

“We believe part of the value of our Precision Immunotherapy[™] T-cell platform comes from the ability to move relatively quickly and cost effectively into new autoimmune diseases. We do not expect our preclinical development activities related to the NMO program to materially affect the Company’s cash burn through IND submission,” Mr. Warma continued. “We are enthusiastic about moving forward with our NMO development program, while remaining firmly committed to the conduct of our ongoing Phase 2b Abili-T clinical trial with Tcelna in Secondary Progressive MS patients.”

Conference Call and Webcast Details

Opexa will host a virtual panel discussion with Benjamin Greenberg, M.D., Associate Professor of Neurology, University of Texas, Southwestern Medical Center, and Michael Levy, M.D., Ph.D., Assistant Professor of Neurology, The Johns Hopkins University and Staff Neurologist, The Johns Hopkins Hospital, to provide an overview of NMO and discuss Opexa's differentiated T-cell treatment approach today at 9:30 a.m. EDT.

To listen to the conference call, dial in approximately ten minutes before the scheduled 9:30 a.m. EDT time to (253) 237-1170 or toll free at (877) 372-0867. Please reference conference ID 84494085 or the Opexa Therapeutics Business Update.

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).

There will be a brief Question & Answer session following the panel discussion.

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.

About NMO

NMO is a rare autoimmune disorder in which immune system cells and antibodies mistakenly attack and destroy myelin cells in the optic nerves and the spinal cord. The damage to the optic nerves produces swelling and inflammation that cause pain and loss of vision; the damage to the spinal cord causes weakness or paralysis in the legs or arms, loss of sensation, and problems with bladder and bowel function. NMO affects approximately 4,800 people in the U.S., and the estimated worldwide prevalence is 1-2 people per 100,000 population. There is no cure for NMO and there are no FDA-approved therapies.

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), 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 exercises its Option and, if so, whether we receive any development or commercialization milestone payments or royalties from Merck pursuant to the Option; our dependence (if Merck exercises its Option) on the resources and abilities of Merck 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 Securities and Exchange Commission. 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 Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the SEC.

CONTACT:

Opexa Therapeutics, Inc.
Karthik Radhakrishnan, 281-775-0600
Chief Financial Officer
or

Investor Relations:

The Trout Group
Adam Cutler, 646-378-2936
opexa@troutgroup.com



OPEXA THERAPEUTICS



Precision Immunotherapy™

Opexa Therapeutics, Inc.

NASDAQ: OPXA

September 2014
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 this presentation is actually delivered by us in person. 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. You may get these documents for free by visiting EDGAR on the SEC web site at <http://www.sec.gov>.

Opexa Key Investment Highlights

- **Personalized T-cell immunotherapy platform**
 - Autologous cell therapy
 - Potential to address multiple therapeutic areas
 - Strong Patent Estate: 50 patents issued on T-cell platform (domestic and international)
- **Lead Indication: Multiple Sclerosis**
 - Ongoing Phase 2b trial in Secondary Progressive Multiple Sclerosis (SPMS)
 - Potential SPMS market in North America alone could exceed \$7 Billion
 - Fast Track designation from the U. S. FDA for the treatment of SPMS
 - Option Agreement with Merck Serono, a strong potential commercial partner
- **Pipeline (platform) expansion: OPX-212 for Neuromyelitis Optica (NMO)**
 - No FDA approved drugs for the treatment of NMO
 - Identified target antigen: Aquaporin-4
 - NMO is classified as an orphan disease

Opexa Developing Highly Differentiated, Precision Therapies

Programs and indications	Research	Preclinical	Phase 1	Phase 2	Phase 3
Tcelna (imilecleucel-T) *					
Secondary Progressive Multiple Sclerosis (SPMS)	Phase 2b trial ongoing, data expected 2H 2016				
Relapsing Remitting Multiple Sclerosis (RRMS)	Phase 3 not initiated				
OPX-212					
Neuromyelitis Optica (NMO)	IND enabling studies ongoing in 2H 2014				

* Option & License agreement signed with Merck Serono, MS indications only, worldwide, excluding Japan

Recent and Upcoming Expected Milestones

- ✓ 1H 2014: Completed Enrollment in Phase 2b SPMS trial
- ✓ 1H 2014: Initiated Early Development Plan for second indication (NMO)
- 2H 2014: Advance Preclinical Development in NMO
- Mid- 2015: Submit IND for OPX-212 in NMO to FDA
- 2H 2015: Initiation of Clinical Development in NMO (assuming IND accepted)
- 2H 2015: Apply for Orphan Designation and Fast Track for OPX-212 in NMO
- 2H 2016: Top line results for Abili-T Phase 2b SPMS trial
- 2H 2016: Completion and unblinding of Immune Monitoring data



TCELNA[®] (*imilecleucel-T*) **MULTIPLE SCLEROSIS**

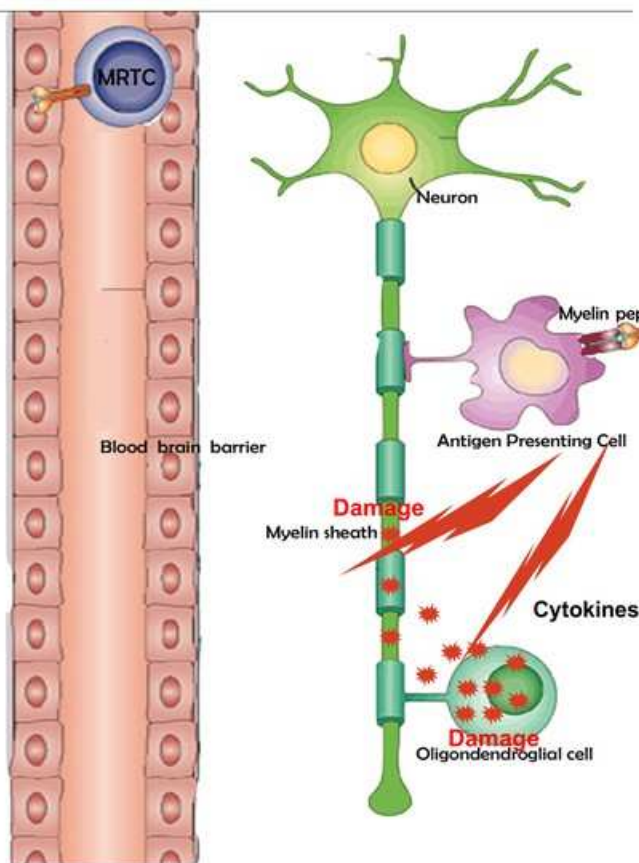
Tcelna®

Lead Program Targeting Secondary Progressive MS patients

Fast Track Designation by FDA

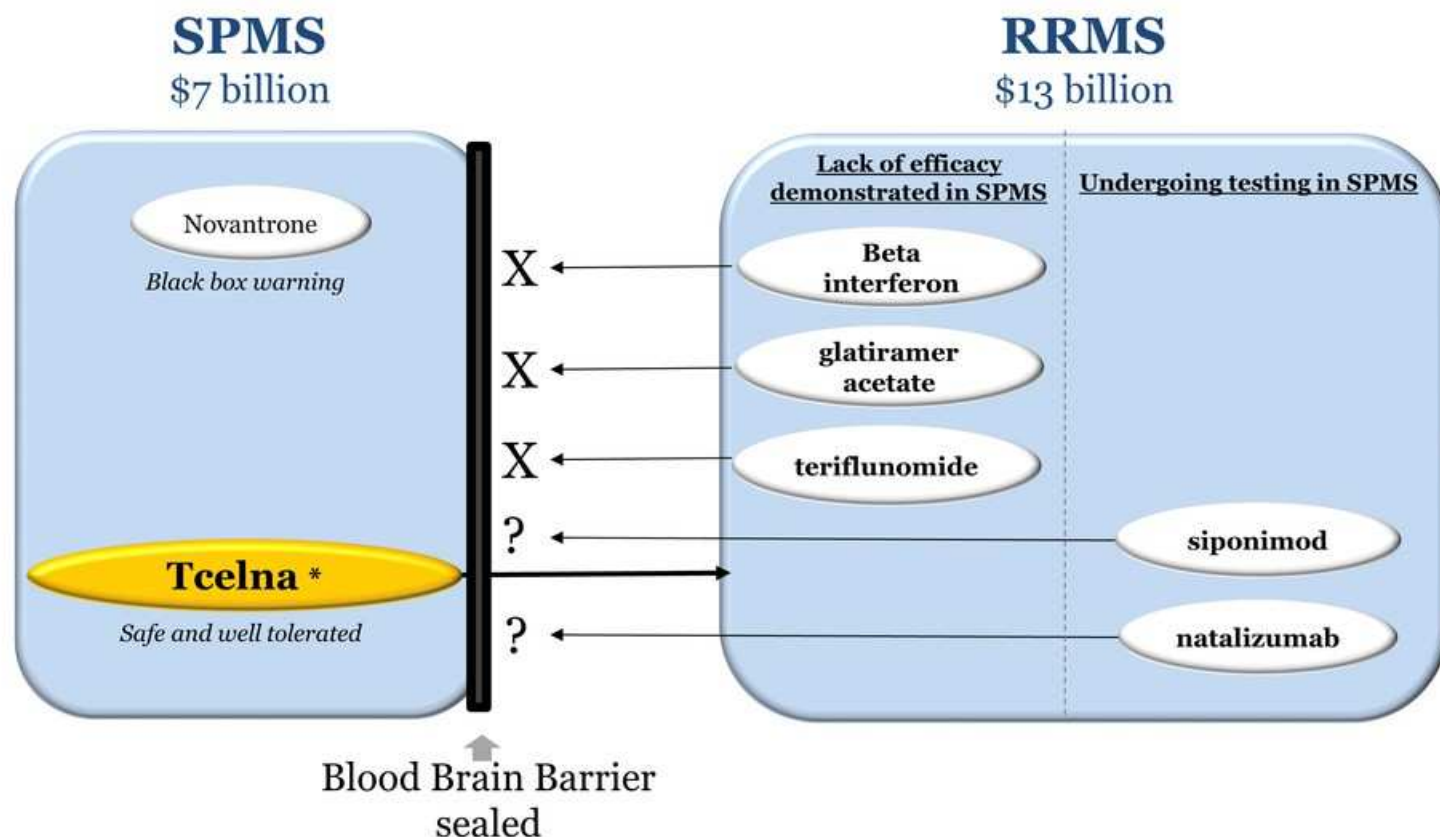
- **Phase 2b clinical trial ongoing**
- **Trial is fully enrolled: 190 patients with SPMS**
- **Top line data expected in 2H 2016**
- **Design**
 - Double-blind, 1:1 randomized, placebo-controlled
 - 35 clinical sites in USA and Canada
 - Two annual courses of personalized therapy
 - Efficacy Endpoints: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

The Root Cause of Multiple Sclerosis: 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) leading to:
 1. Destruction of myelin sheath, the protective coating of nerve fibers
 2. Destruction of oligodendroglial cells, which are responsible for producing myelin
- 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 to specifically target the pathogenic MRTC for elimination or regulation

Differentiation of Tcelna in SPMS



* Subject to successful clinical development and FDA approval

Merck Serono

Agreement signed 2013; strong potential partner

Option and License Agreement for worldwide rights to all Multiple Sclerosis indications, excluding Japan

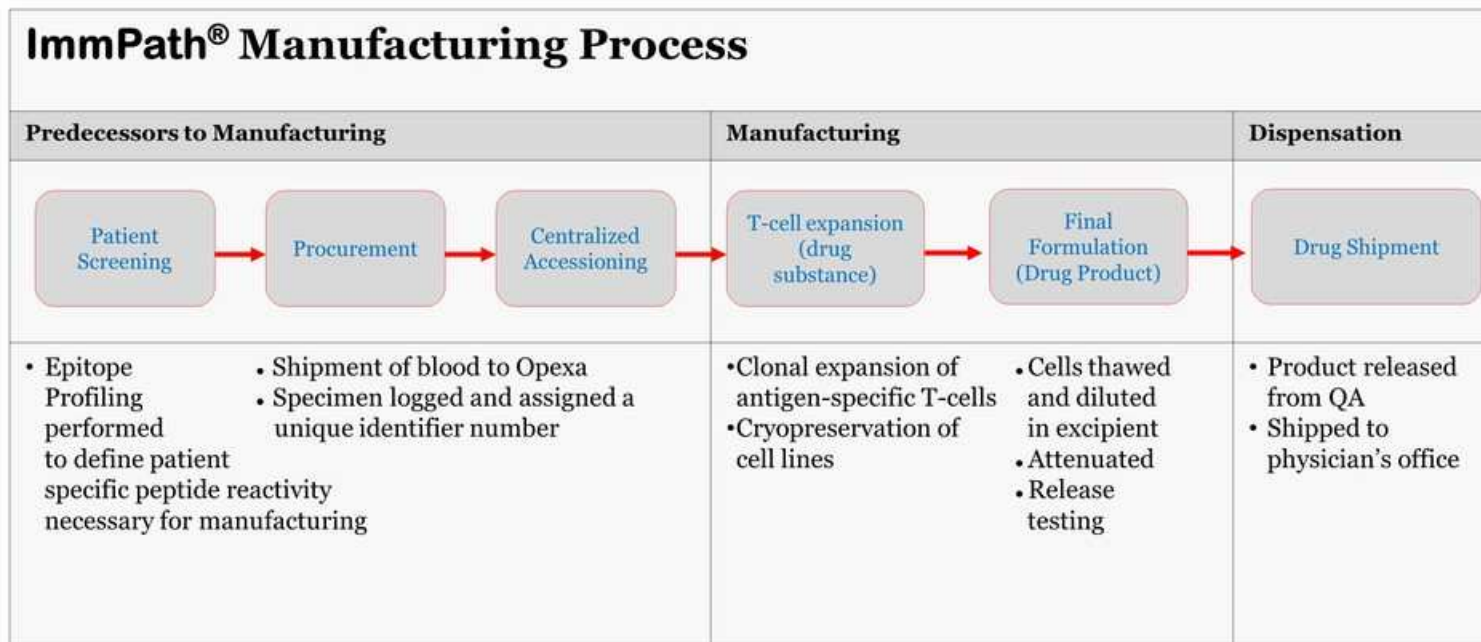
- **If Merck Serono exercises option:**
 - Merck Serono to fund Phase 3, pre-commercial and commercial activities
 - Merck Serono obtains rights to develop Tcelna for all MS indications
 - Worldwide rights excluding Japan
- **Opexa received \$5 million upfront option fee at signing**
- **Opexa has potential to receive additional \$220 million in milestone payments, and**
- **Royalties ranging from 8% to 15% of annual net sales with step-ups occurring if net sales exceed \$500 million, \$1 B & \$2 B**
- **Opexa maintains key rights**
 - Development and commercialization rights to Tcelna in Japan
 - Certain manufacturing rights
 - Co-development funding option in exchange for increased royalties
 - Rights to all other disease indications



IMMPATH®: **PROPRIETARY DRUG DEVELOPMENT PLATFORM**

Proprietary Platform

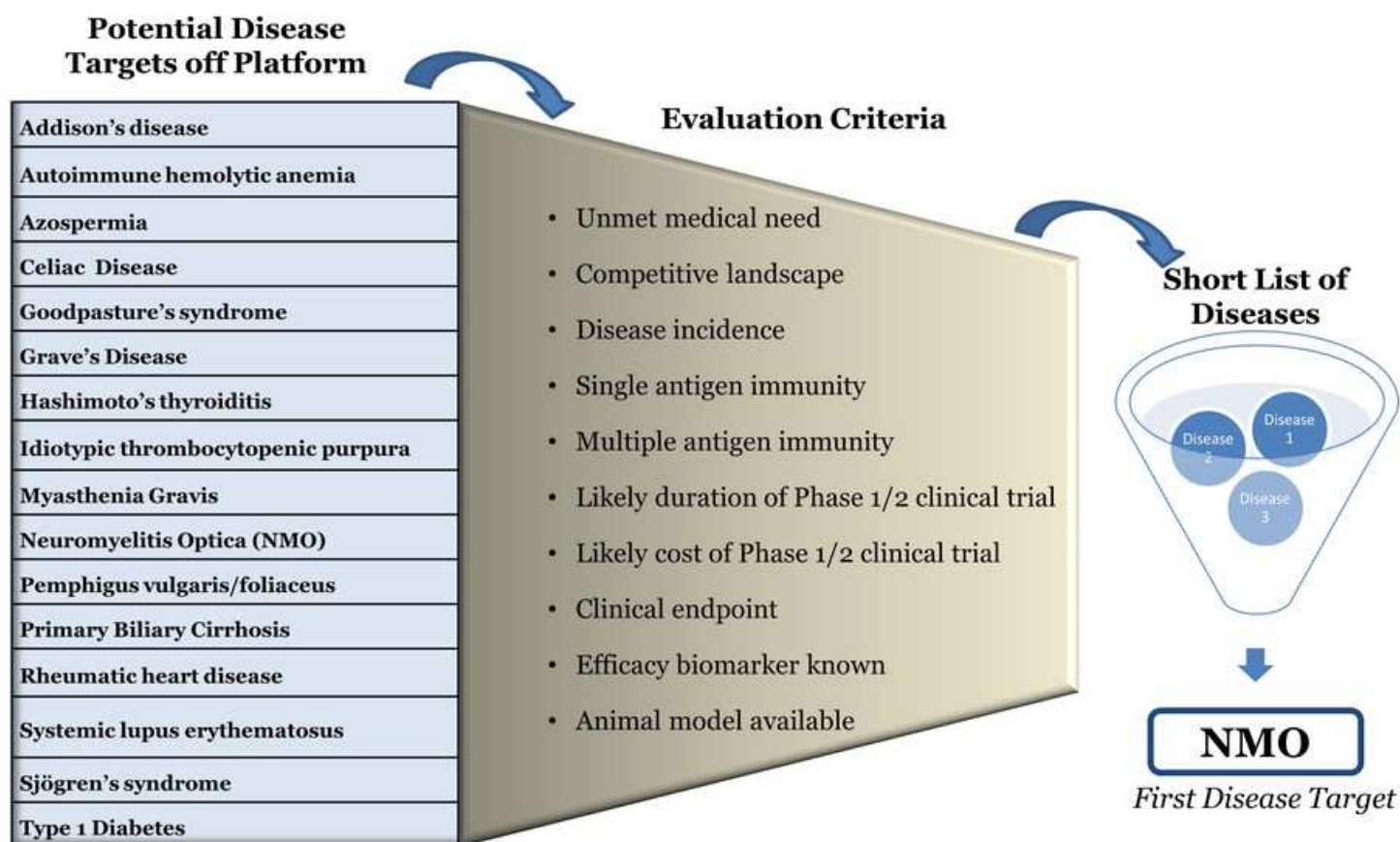
Leverage existing platform to generate new drug candidates





OPX-212: NEUROMYELITIS OPTICA (NMO)

Comprehensive Process to Determine Optimal Additional Indications for Opexa



Neuromyelitis Optica (NMO) Market Opportunity

Epidemiological Trend

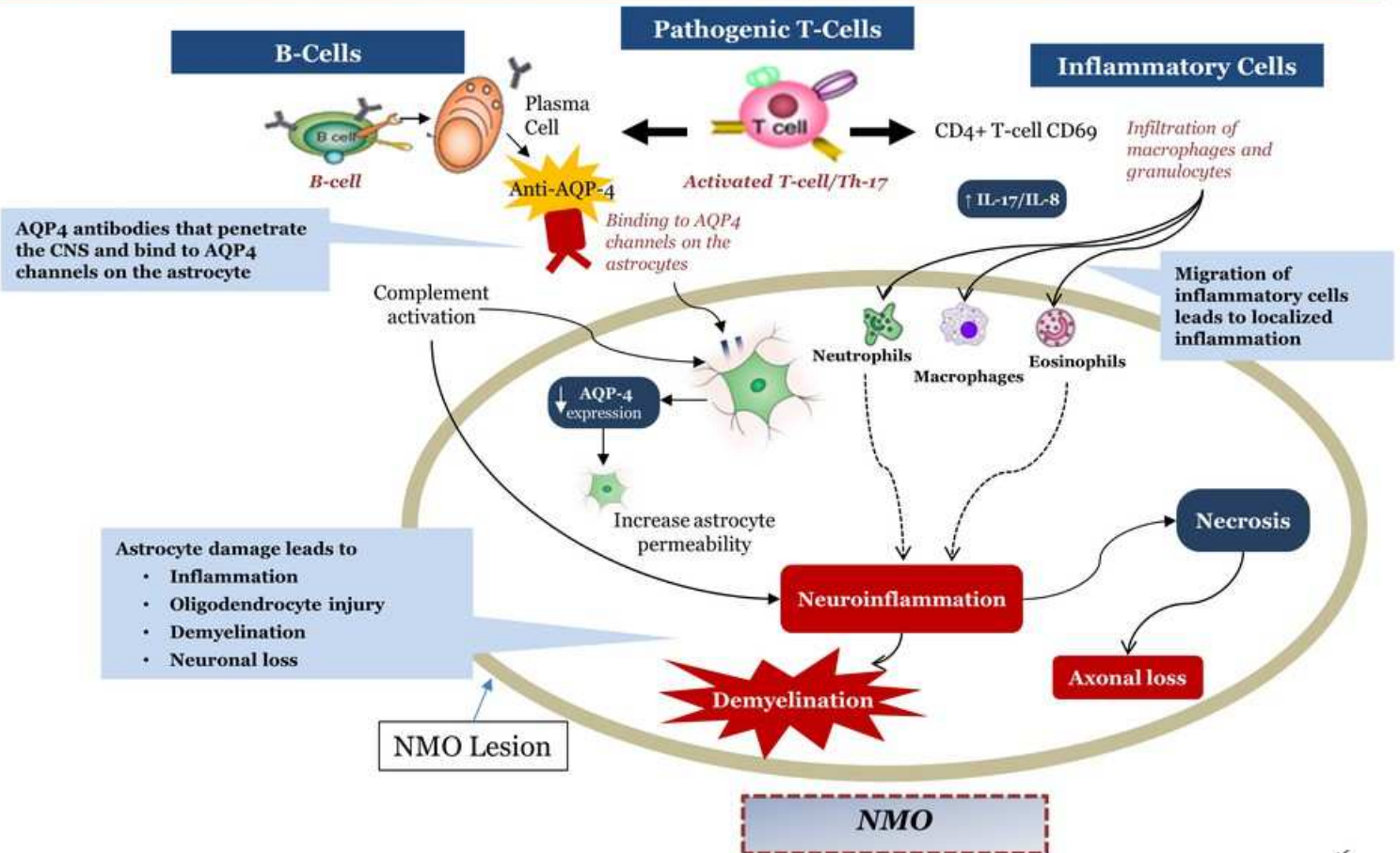
- NMO is a rare inflammatory demyelinating disease of the CNS.
- Affects any age varying from 3 to 90 years, the average age of onset ~41 years
- Prevalence: Worldwide: estimated 1-2 people per 100,000 population
- U.S.: 4,800, EU: 5,800, Japan: 3,500 and China: 37,700

Opportunity for OPX-212

- No FDA-approved therapy
- Limited treatment options and significant unmet medical needs:
 - Steroids and plasmapheresis for acute attacks
 - Immunosuppressants for prevention of relapses
 - Off-label use of drugs: Corticosteroids (methylprednisolone) and immunosuppressant (rituximab, mycophenolate mofetil, azathioprine)
- Rituximab generally considered primary off-label NMO treatment
- NMO has significant unmet needs:
 - Clear disease understanding and better diagnostics for early detection of NMO
 - Limited efficacy of approved therapies
 - Safety concerns with current therapies that cause immune suppression and carry black box warning
 - Need for a targeted therapy without causing immune suppression and steroid sparing that relieves the clinical signs and symptoms, prevents progression of disease, reverses the disease process and is well tolerated

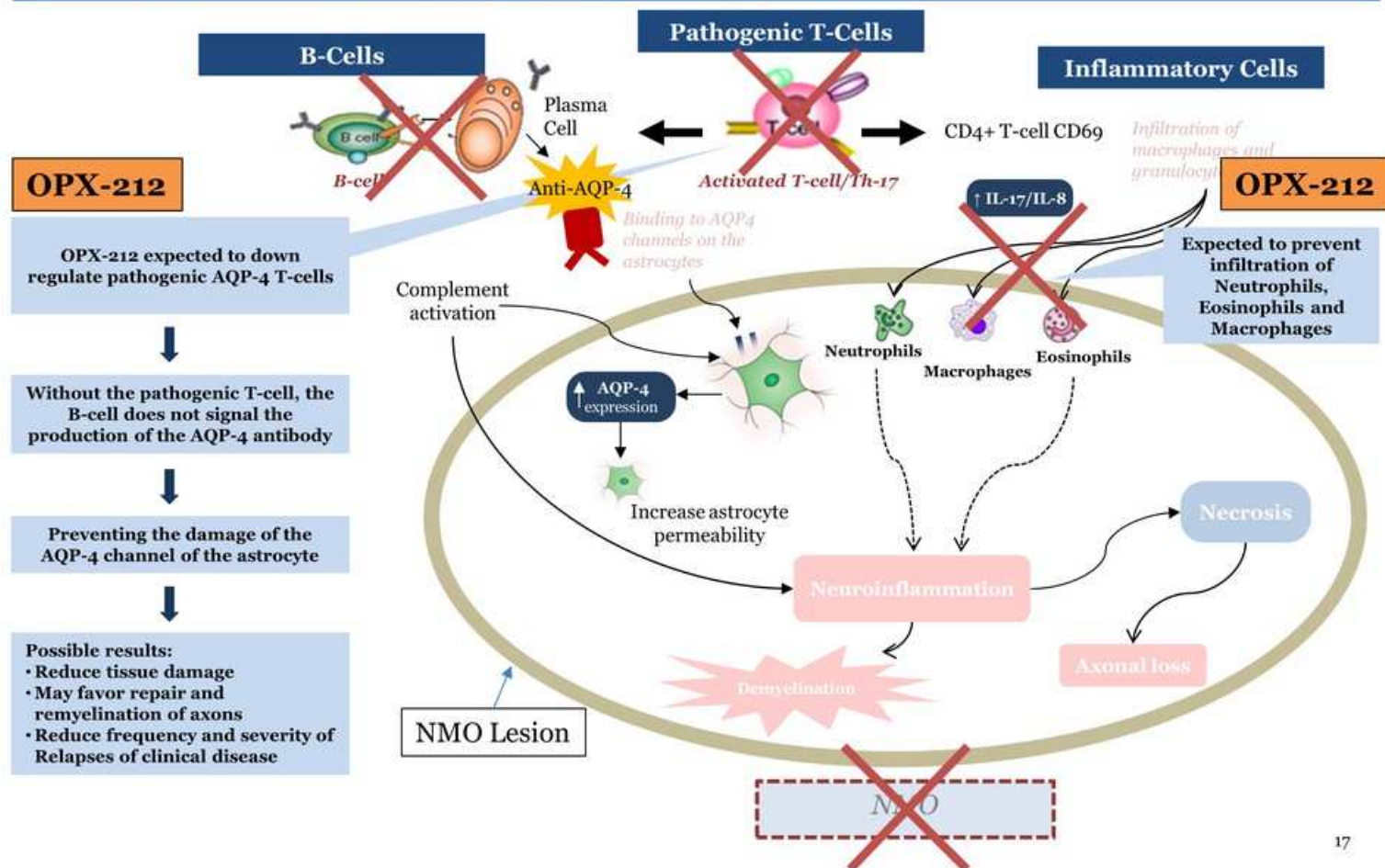
Disease Pathogenesis

An astrocytopathic disease of the CNS characterized by optic neuritis, transverse myelitis; it is a B-cell-dependent disease associated with anti-aquaporin-4 antibodies



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 Development Program

OPX-212 Early Development Plan was initiated in Q1 2014

Completed Activities		
✓	Q1/2 2014	Regulatory/Clinical - Pre-IND meeting conducted with FDA - Engaged Thought Leaders - Engaged Patient Advocacy Groups
✓	Q1/2 2014	R&D, Process Development, Manufacturing - Scientific justification of Mechanism of Action - Detection of EPA response in multiple NMO patient samples - Successful preclinical manufacturing runs
Planned Development Activities		
	2014	Preclinical Development
	Mid-2015	IND submission (subject to successful preclinical development)
	2H 2015	Clinical Development (subject to FDA review and acceptance of IND)

Expect minimal impact on cash burn to IND submission



CLINICAL DATA

Tcelna Development Program

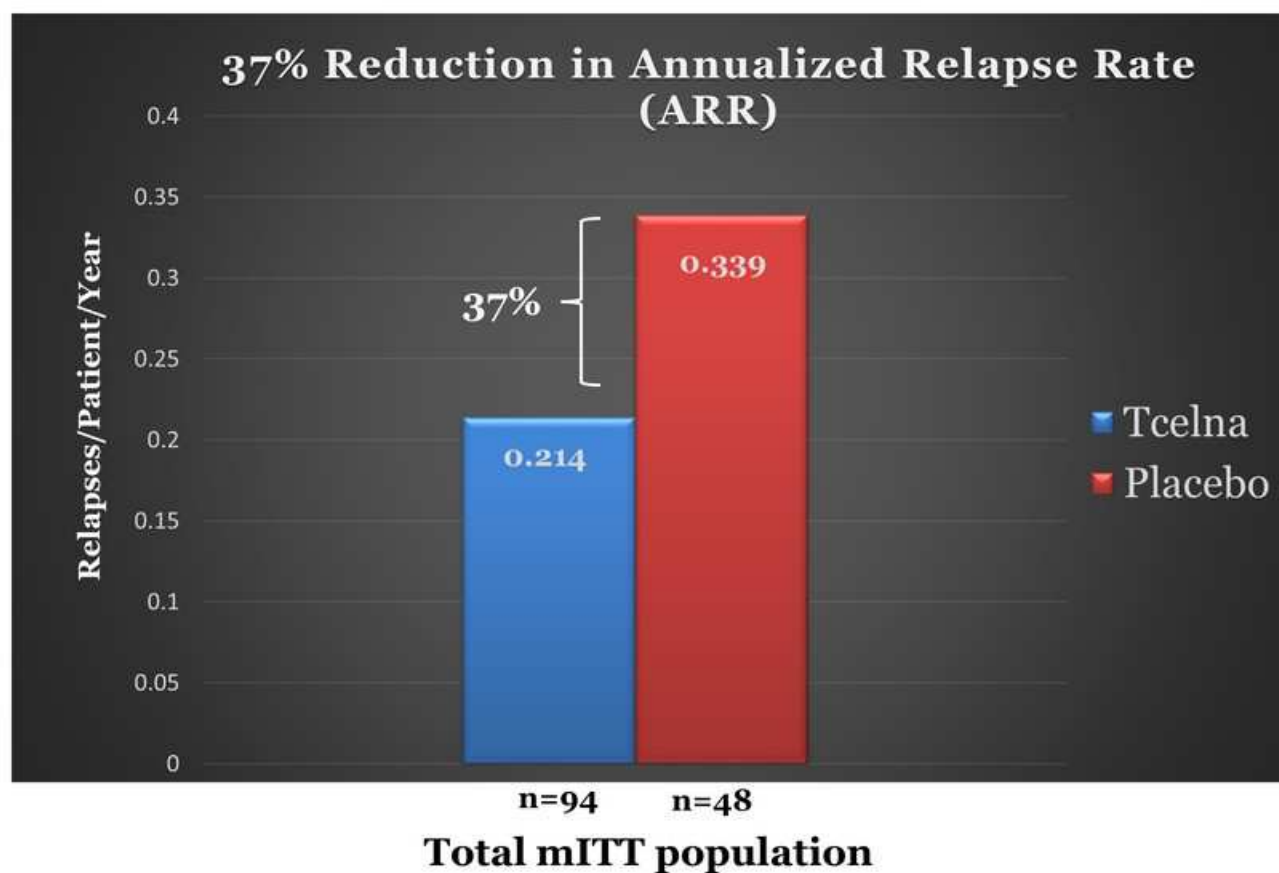
Broad Spectrum of Multiple Sclerosis patients enrolled in clinical trials

Phase	Completion Dates	Population	Total N	Treatment Duration (months)	Tcelna	Placebo
Baylor	1998	RRMS, PPMS, SPMS (26)	114	Up to 24 months	114	
Phase I dose escalation	2006	RRMS (5) SPMS (6)	16	12	16	-
Phase I/II Open label retreatment	2007	RRMS (9) SPMS (4)	13	12	13	-
Phase IIb TERMS	2008	RRMS, CIS	150	12	100	50
Phase IIb extension OLTERMS	2008	RRMS, CIS	38	At least one dose post TERMS	15 from placebo arm	
Phase IIb Abili-T	2H 2016*	SPMS	190*	24*	95*	95*

* Expected upon completion of ongoing SPMS Abili-T trial

Phase 2b RRMS clinical trial

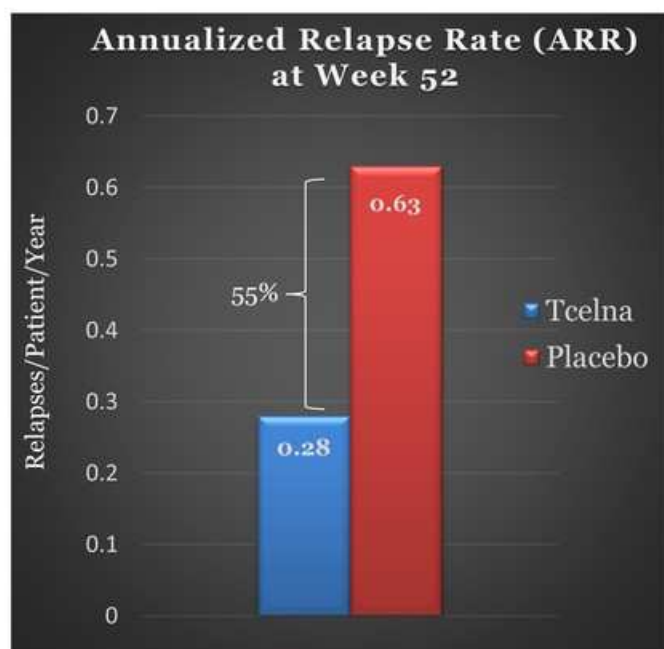
Tcelna showed 37% improvement over placebo (mITT)



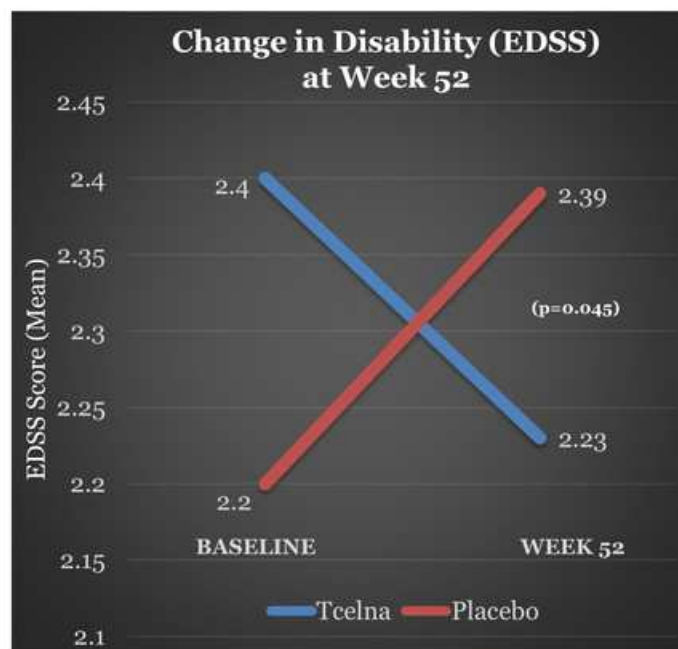
Phase 2b RRMS Clinical Trial

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

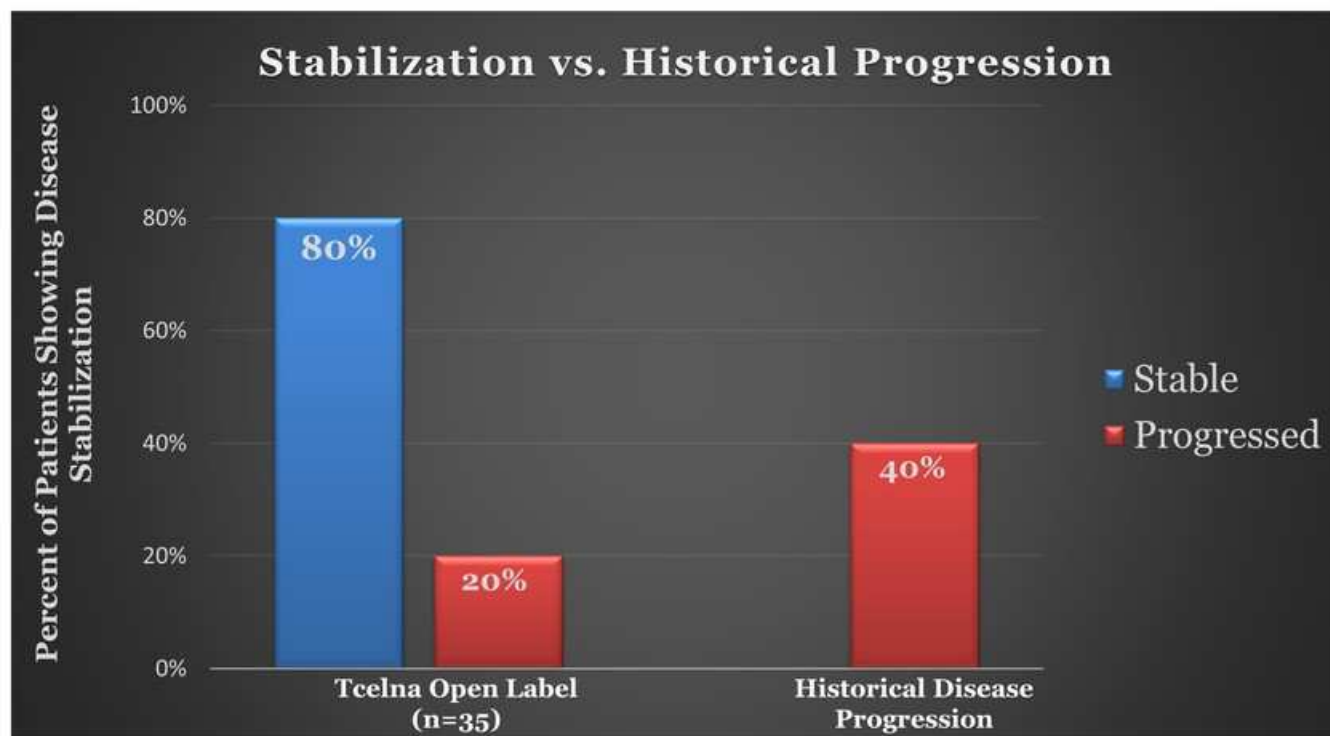


Statistically Significant Improvement in Disability (p=0.045)

Phase I/II SPMS Clinical Trials

Tcelna Stabilizes Disease in SPMS 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

Financials

Cash and Cash Equivalents (MM) as of June 30, 2014	\$16.2
Shares outstanding (MM) as of June 30, 2014	~27.7
Warrants (MM) (1)	~3.1
Stock Options (MM) (2)	~2.5
Debt	None

(1) Weighted average exercise price = \$4.12 as of June 30, 2014

(2) Weighted average exercise price = \$2.96 as of June 30, 2014

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

Kenny Frazier, VP of Clinical Dev. and Regulatory Affairs

- › 25+ years of extensive clinical and regulatory experience
- › Formerly, Head of Clinical Operations, Lexicon Pharmaceuticals and Tanox, Inc.

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

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

Investment Thesis

TECHNOLOGY

- Proprietary Platform: potential to yield multiple drug candidates
- Differentiated, personalized approach
- Strong patent estate (over 50 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