

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 05/12/15 for the Period Ending 05/12/15

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

**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): May 12, 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 2.02. Results of Operations and Financial Condition.

On May 12, 2015, Opexa Therapeutics, Inc. (the “Company”) filed its Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 and announced its results of operations 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.

On the same day, members of the Company’s management will hold a teleconference to discuss the financial results. Interested individuals desiring to participate in the teleconference may dial in approximately ten minutes before the scheduled 4:30 P.M. ET call to (201) 689-8040 or toll free at (877) 407-8133. Please reference conference ID # 13609081 or the Opexa Therapeutics Earnings Call when dialing into the call. A live webcast of the call can also be accessed via the webcast link on the Investor Relations page of the Company’s website (www.opexatherapeutics.com). An archive of the webcast will be available on the Company’s website until August 12, 2015.

Item 7.01. Regulation FD Disclosure.

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) is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is 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 May 12, 2015.
99.2	Opexa Therapeutics, Inc. Investor Presentation, May 2015.

The information in Items 2.02 and 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, 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.

Dated: May 12, 2015

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President and Chief Executive Officer

EXHIBIT INDEX

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99.1	Press release issued by Opexa Therapeutics, Inc. on May 12, 2015.
99.2	Opexa Therapeutics, Inc. Investor Presentation, May 2015.

Opexa Therapeutics Reports First Quarter 2015 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--May 12, 2015-- **Opexa Therapeutics, Inc.** (NASDAQ:OPXA), a biopharmaceutical company developing personalized immunotherapies including multiple sclerosis (MS) and neuromyelitis optica (NMO), today reported financial results for the three months ended March 31, 2015 and provided an update on the Company's recent corporate developments.

Recent highlights include:

Financial Highlights

- In April 2015, Opexa completed a rights offering and raised \$13,804,140 in gross proceeds, before expenses, through subscriptions for 25,098,437 units, including the exercise of over-subscription privileges. Each unit consisted of one share of common stock and a warrant to purchase an additional share of common stock. Net proceeds, after deduction of fees and expenses, are expected to be approximately \$12 million.
- In March 2015, Opexa received a \$3 million payment from Merck Serono (a division of Merck, Darmstadt, Germany).
 - The payment, which was made as part of an amendment to an existing Option and License Agreement between the parties, provides support for the ongoing Phase 2b Abili-T 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.
- Based on the current activities of the Company and projected burn, Opexa believes it has sufficient liquidity into the fourth quarter of 2016. The Company expects this will support the completion and reporting of top line results for the Phase 2b Abili-T study of Tcelna in SPMS patients and the completion of the preclinical activities for OPX-212 in NMO, as well as supporting general operations of the Company.

Clinical Highlights

- As of April 30, 2015, approximately 75% of the patient visits have been completed in the Abili-T study in SPMS patients. The Abili-T clinical trial is a randomized, double-blind, placebo-controlled study being conducted at approximately 35 leading clinical sites in the U.S. and Canada. The trial is fully enrolled with 190 total subjects enrolled.
 - At a recent and regularly scheduled meeting, the independent Data and Safety Monitoring Board (DSMB) overseeing Opexa's Abili-T trial recommended the trial continue as planned based on the committee's review of safety data from the trial. Opexa has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for Tcelna in SPMS.
 - Opexa was invited to present biomarker data on patients with neuromyelitis optica (NMO) at a scientific session and poster presentation at the 67th American Academy of Neurology (AAN) Annual Meeting in April.
 - Opexa continued IND enabling activities for OPX-212 (Opexa's NMO therapeutic candidate), including advancing a bio-activity study and performing process development work. IND submission for OPX-212 is expected in 2015.
-

“We are coming off a productive quarter, which was highlighted with the announcement of a \$3 million payment from Merck Serono to further support the development of Tcelna,” said Neil K. Warma, Opexa’s President and Chief Executive Officer. “We welcome Merck Serono’s continued support as a vote of confidence in our ability to execute on the Abili-T trial. We are pleased that the \$15 million we raised in the first four months of 2015 should enable us to fully fund the balance required for our Phase 2b Abili-T trial of Tcelna in secondary progressive MS patients through the release of top-line data. We expect results from this trial in the second half of 2016.”

“Our second disease program in neuromyelitis optica (NMO) is moving forward as we continue our preclinical and IND enabling studies. We generated some interesting data last quarter and were invited to present these data during the recent American Academy of Neurology annual meeting. Our results showed that despite patients receiving B-cell depleting therapy, there remained an underlying and persistent inflammation due to the presence of activated T-cells. Our belief is that treatment using Opexa’s novel immunotherapy drug development candidate, OPX-212, could dampen both the T-cell and B-cell inflammatory process, thereby attacking the root cause of the disease.”

Financial Results for the Three Months Ended March 31, 2015

Opexa reported total revenues of \$377,543 and \$348,837 for the three months ended March 31, 2015 and 2014, respectively. Included in total revenues is \$307,686 and \$348,837 which was recognized for the three months ended March 31, 2015 and 2014, respectively, related to the \$5 million upfront payment received from Merck Serono in connection with a February 2013 Option and License Agreement. In addition, revenues for the three months ended March 31, 2015 include \$69,767 related to the \$3 million payment from Merck Serono made in connection with the March 2015 amendment to such 2013 Agreement.

Research and development expenses for the three months ended March 31, 2015 were \$2,636,999, a decrease of 6.2% compared to the \$2,811,139 for the three months ended March 31, 2014. The decrease in expenses is primarily due to a decrease in the costs in connection with the ongoing clinical trial of Tcelna in SPMS, a decrease in the procurement and use of supplies for product manufacturing and development, partially offset by increases in employee compensation expense and facility costs.

General and administrative expenses for the three months ended March 31, 2015 were \$1,006,130, a decrease of 8.8% compared to the \$1,102,880 for the three months ended March 31, 2014. The decrease in expense is due to decreases in employee compensation and stock compensation expenses partially offset by increases in business development expenses.

Depreciation and amortization expenses for the three months ended March 31, 2015 were \$96,982 compared with \$95,586 for the three months ended March 31, 2014. The increase in expense is due to increases in depreciation for laboratory, manufacturing and computer equipment acquired during 2014 and 2015.

Opexa reported a net loss for the three months ended March 31, 2015 of \$3,350,880, or \$.12 loss per share (basic and diluted), compared with a net loss of \$3,655,574, or \$.13 loss per share (basic and diluted), for the three months ended March 31, 2014. The decreased net loss is primarily related to the decrease in research and development expenses and the decrease in general and administrative expenses, and was partially offset by the gain on exchange rate and by higher revenues for the quarter ending March 31, 2015.

Cash and cash equivalents were \$9,572,880 as of March 31, 2015, compared to \$9,906,373 as of December 31, 2014. The Company's monthly burn rate for the three months ending March 31, 2015 was approximately \$1.1 million.

For additional information please see Opexa's Annual Report on Form 10-Q filed today with the SEC.

Conference Call and Webcast Details

Opexa will conduct a conference call and webcast to provide a corporate update and discuss the financial results at 4:30 P.M. ET today. To participate in 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. Please reference conference ID 13609081 or the Opexa Therapeutics Earnings Call.

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 August 12, 2015.

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 IIb 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.

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 release, 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," "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 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 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 in such forward-looking statements as a result of various risks and uncertainties, which include without limitation our ability to raise additional capital to continue our development programs, our ability to successfully develop potential products such as Tcelna, our ability to obtain, maintain and protect intellectual property rights (including for Tcelna and future pipeline candidates such as 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 our SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2014 and our Quarterly Reports on Form 10-Q. All forward-looking statements contained in this release speak only as of the date on which they were first made by us, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after such date.

OPEXA THERAPEUTICS, INC.**Statement of Operations Data:**

	Three Months Ended March 31,	
	2015	2014
Revenue:		
Option revenue	\$ 377,453	\$ 348,837
Research and development	2,636,999	2,811,139
General and administrative	1,006,130	1,102,880
Depreciation and amortization	96,982	95,586
Operating loss	(3,362,658)	(3,660,768)
Interest income	1,478	5,194
Other income, net	10,300	-
Net loss	<u>\$ (3,350,880)</u>	<u>\$ (3,655,574)</u>
Basic and diluted loss per share	\$ (0.12)	\$ (0.13)
Weighted average shares outstanding	28,234,751	27,584,615

Selected Balance Sheet Data:

	March 31, 2015	December 31, 2014
Cash and cash equivalents	\$ 9,572,880	\$ 9,906,373
Other current assets	683,452	758,943
Property and equipment, net	1,007,532	1,098,104
Other long term assets	29,204	38,939
Total assets	11,293,068	11,802,359
Total current liabilities	5,330,355	3,132,424
Deferred revenue	2,178,877	1,230,748
Total stockholders' equity	3,783,836	7,439,187

CONTACT:

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



OPEXA THERAPEUTICS



Opexa Therapeutics, Inc.

NASDAQ: OPXA

May 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
- 2H 2016: Top line results expected for Abili-T Phase 2b SPMS trial

OPX-212: Neuromyelitis Optica

- ✓ 1H 2014: Initiated Early Development Plan
- 2015: Complete preclinical and IND enabling studies, expected to file IND by year-end
- 2016/17: Apply for Orphan Designation and Fast Track

Financials

Cash and Cash Equivalents (MM) as of March 31, 2015	~\$9.6
Rights Offering Net Proceeds (MM) (completed April 2015)	~\$12
Shares outstanding (MM) as of May 1, 2015	~53.4
Warrants (MM) outstanding as of March 31, 2015	~3.0 ⁽¹⁾⁽²⁾
Stock Options (MM) outstanding as of March 31, 2015	~3.4 ⁽³⁾
Debt	None

(1) Weighted average exercise price = \$4.08 as of March 31, 2015. Excludes 25,098,437 warrants issued as part of the rights offering completed in April 2015

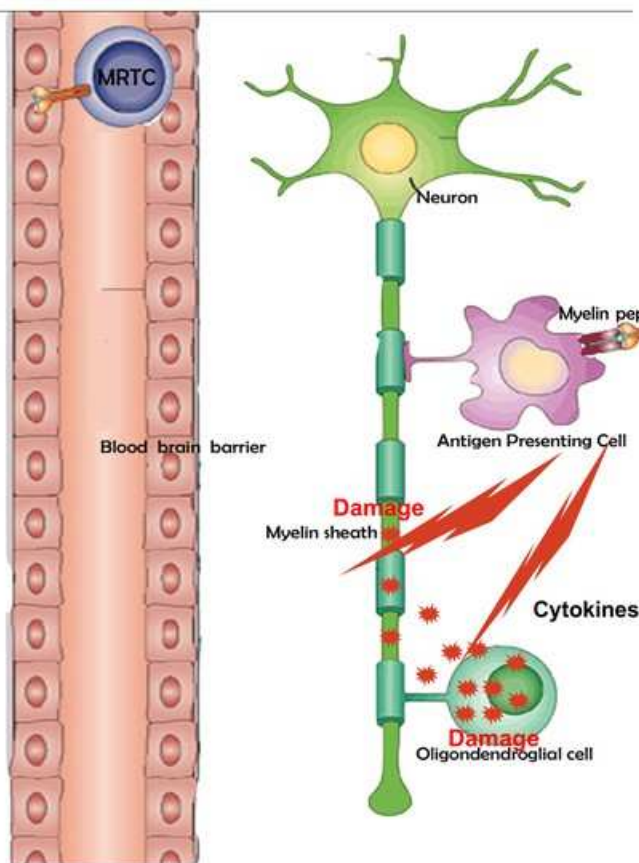
(2) As part of the rights offering an additional 25,098,437 warrants were issued (exercise price = \$0.50 through 06/30/16 and \$1.50 from 07/01/16 through end of 3 year expiration)

(3) Weighted average exercise price = \$2.26 as of March 31, 2015



HOW DOES TCELNA WORK?

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

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 any 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 **received additional \$3** million payment in March 2015 as part of an amendment
- 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**

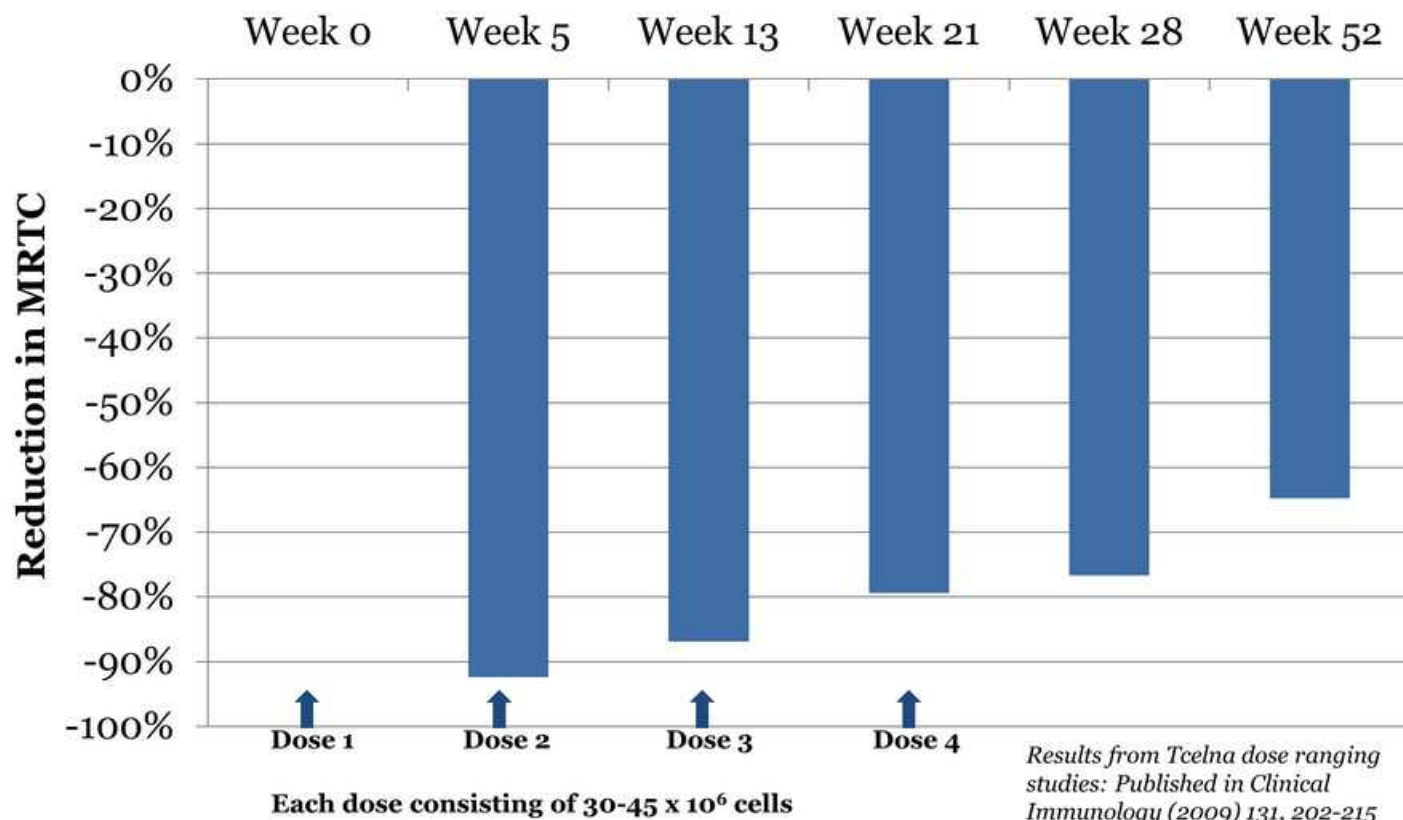


RESULTS AND EXPLANATION OF RRMS & SPMS CLINICAL TRIALS

Mechanism of Action

Reduction in Myelin Reactive T-Cells

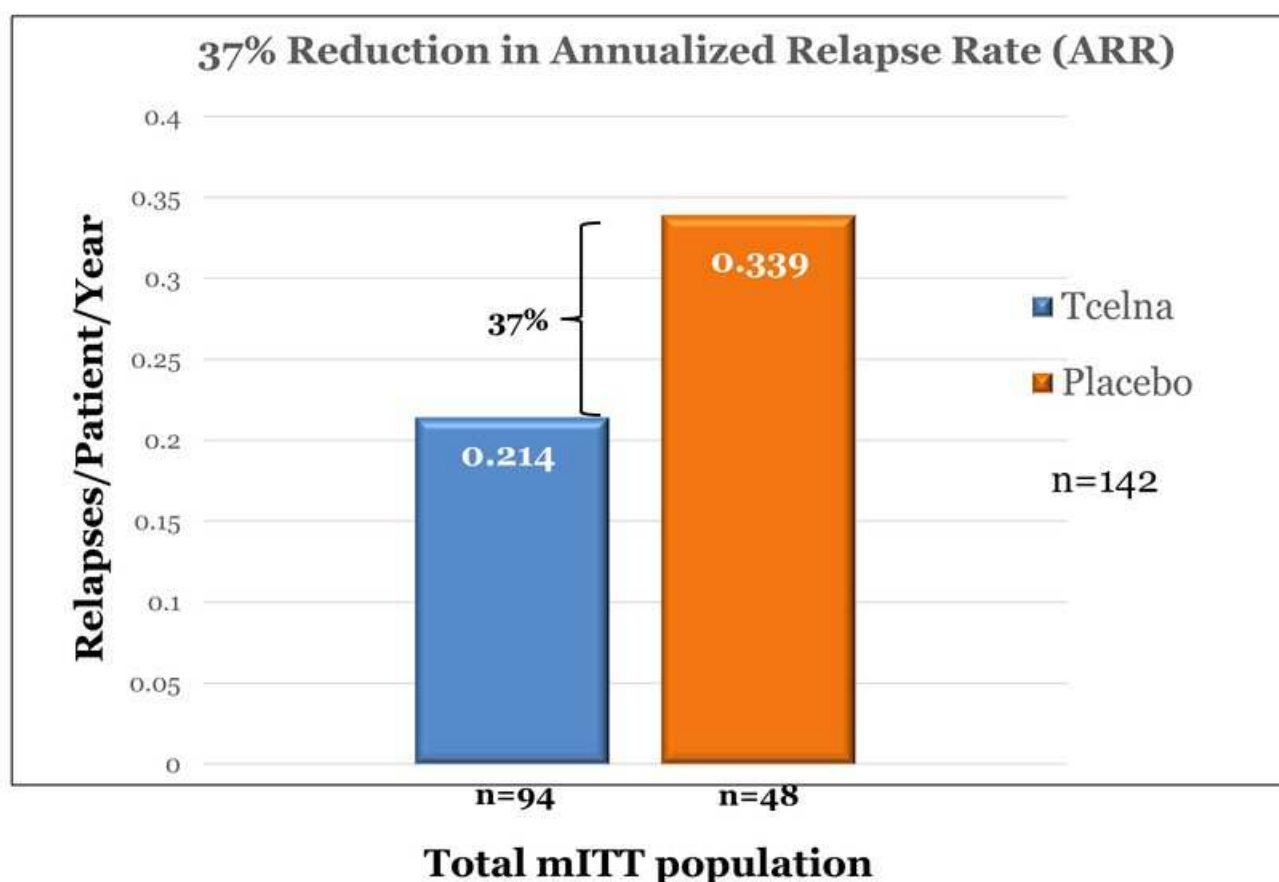
Tcelna Demonstrated a Reduction in Myelin Reactive T-cells (MRTC)



Phase 2b RRMS prior clinical trial

Tcelna showed 37% improvement over placebo (mITT)

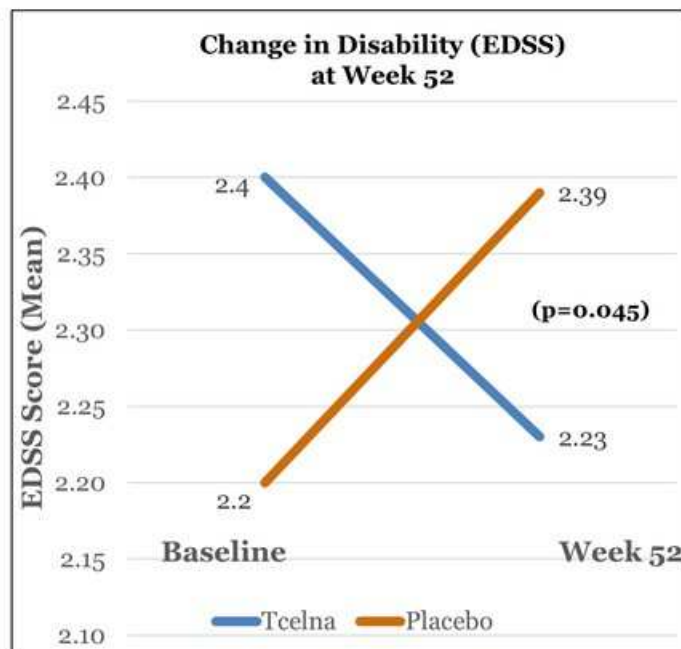
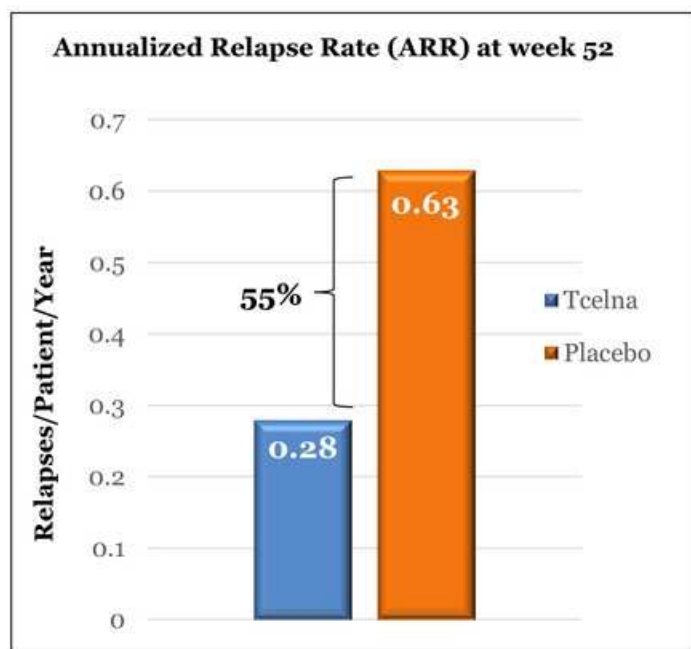
(secondary endpoint measurement, primary MRI endpoint measure not met)



Phase 2b RRMS Prior 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)

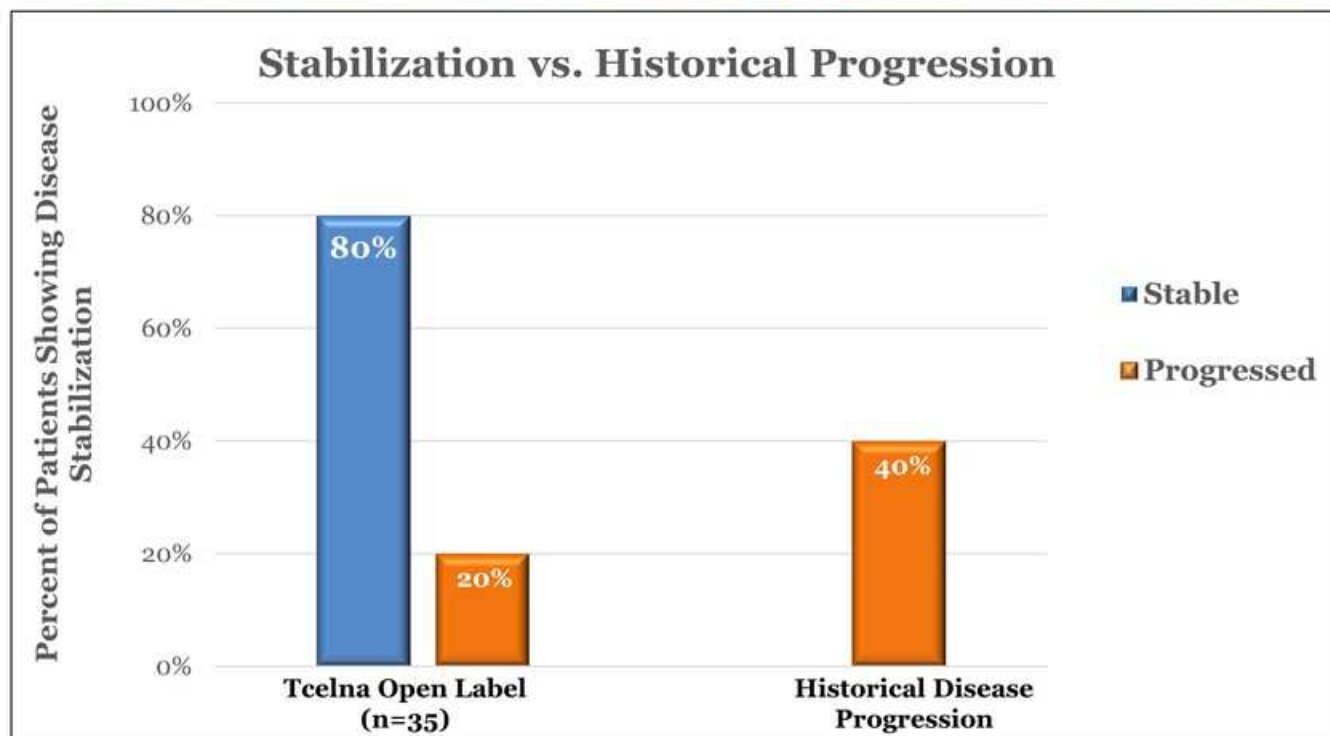


Statistically Significant Improvement in Disability (p=0.045)

Phase I/II SPMS Prior 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)

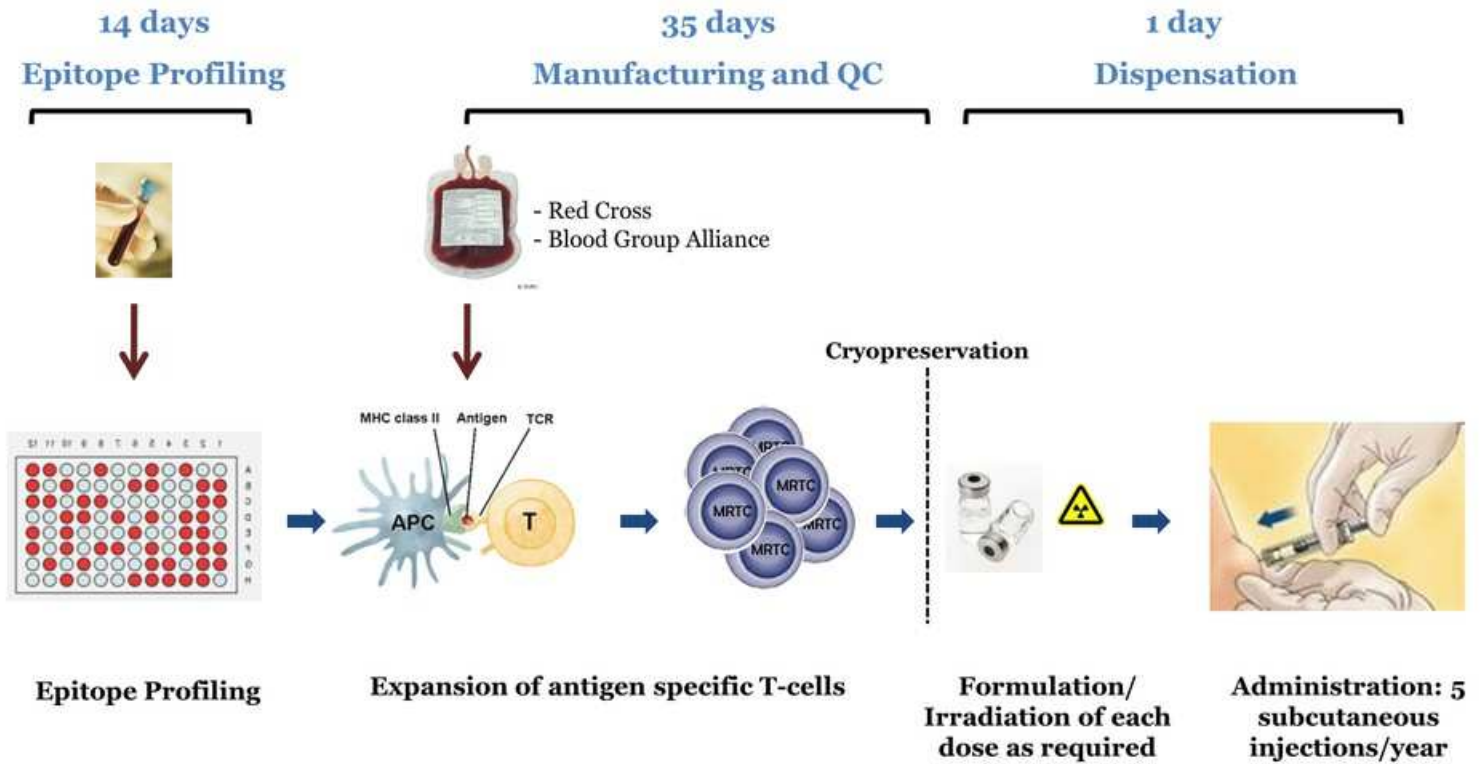
**Historical control: ESIMS Study, published *Hommes Lancet* 2004



IMMPATH®: **PROPRIETARY DRUG DEVELOPMENT PLATFORM**

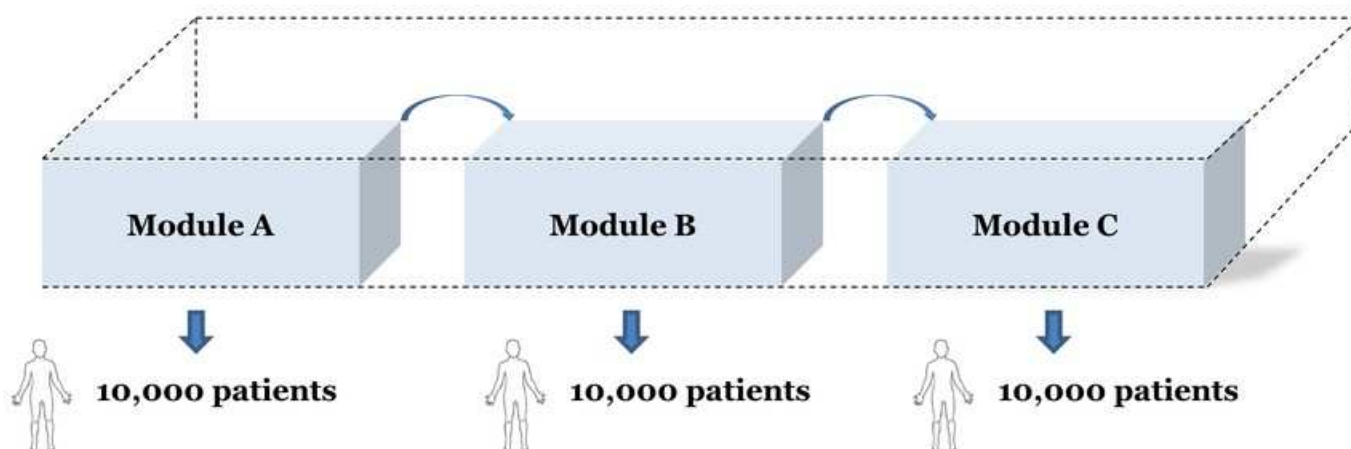
Single Cycle Manufacturing Process:

Annual course of treatment (5 doses) from one blood draw



Expected Commercialization Model

“Build-Out” not a “Scale-up” process

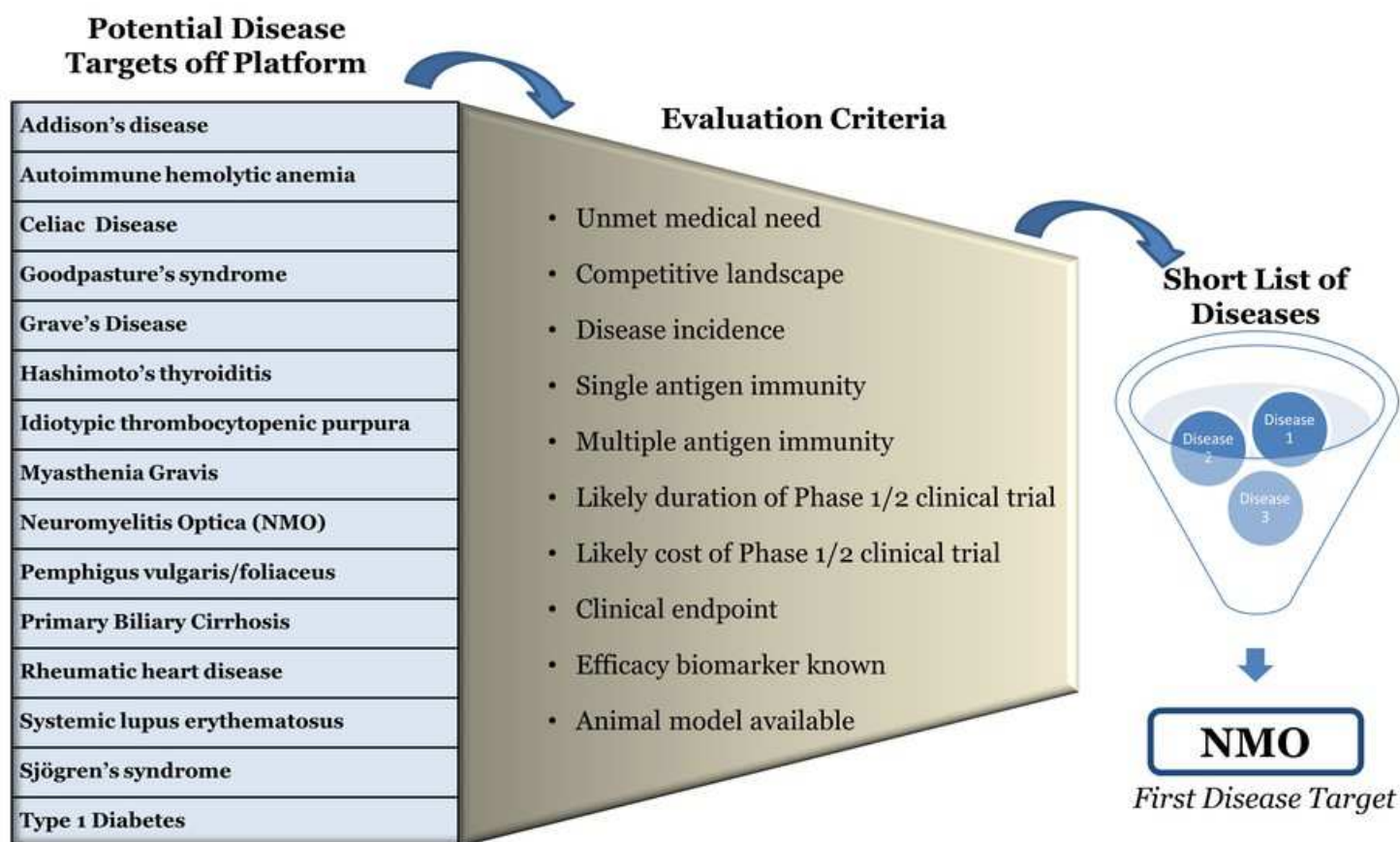


- Opexa fully owns and operates its cGMP Facility
- Modular design, allows for cost effective commercial scale out
- Focus on reduced Cost of Goods (COGS) should result in attractive margins



OPX-212: NEUROMYELITIS OPTICA (NMO)

Comprehensive Process to Determine Optimal Additional Indications for Opexa



NMO: A rare disease of the Central Nervous System



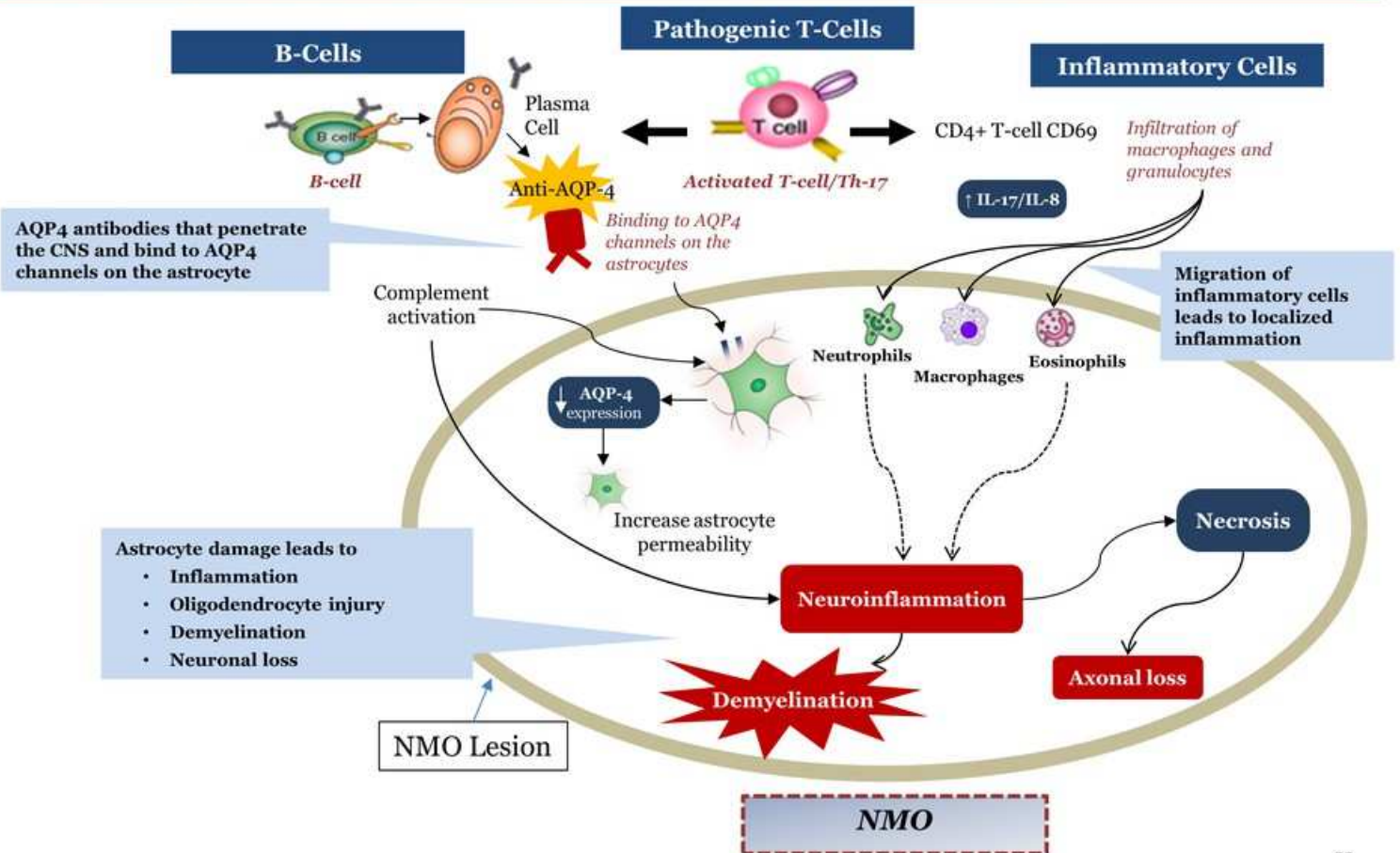
Image reprinted with permission from MultiView, Inc.

- 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

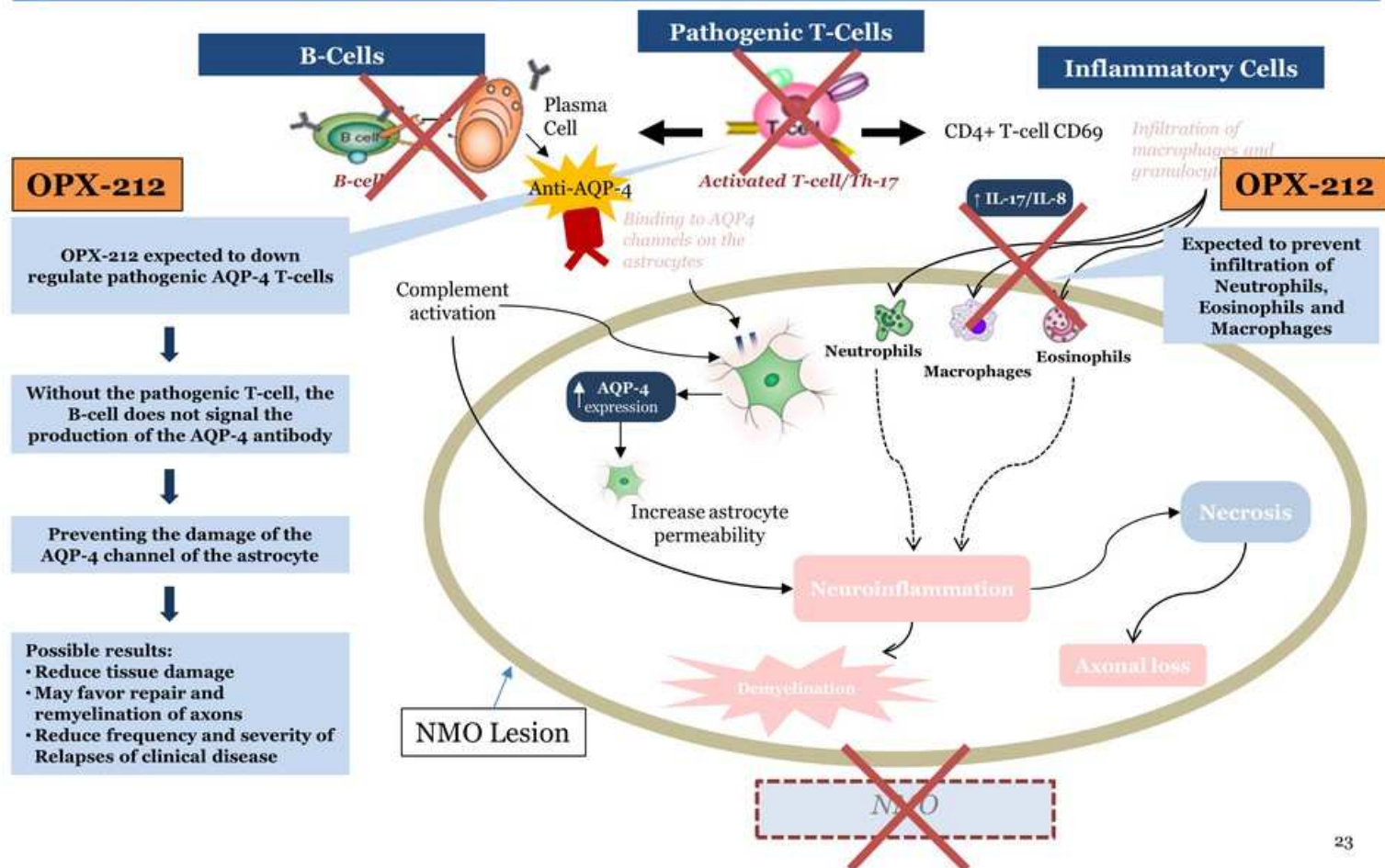
Disease Pathogenesis

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 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

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