

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 09/10/13 for the Period Ending 09/10/13

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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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 10, 2013

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

On September 10, 2013, Opexa Therapeutics, Inc. (the “ **Company** ”) will deliver a corporate presentation at the Rodman & Renshaw 15th Annual Global Investment Conference, which will be available via webcast, using slides containing the information attached to this Current Report on Form 8-K as Exhibit 99.1. The presentation includes an overview of the Company’s ongoing clinical development program for Tcelna®, the Company’s lead therapy, in subjects with secondary progressive multiple sclerosis. The attached materials will be made available on the Investor Relations page of the Company’s website at www.opexatherapeutics.com. 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>
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99.1	Opexa Therapeutics, Inc. Corporate Presentation for Rodman & Renshaw 15th Annual Global Investment Conference, held on September 10, 2013.
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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.

Dated: September 10, 2013

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma
Neil K. Warma
President & Chief Executive Officer

Exhibit Index

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OPEXA THERAPEUTICS



Opexa Therapeutics, Inc.

NASDAQ: OPXA

Rodman & Renshaw 15th Annual Global Investment Conference

September 2013
The Woodlands, TX

Forward-Looking Statements

- This investor presentation 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 presentation, other than statements of historical fact, constitute “forward-looking statements.” The words “expects,” “believes,” “anticipates,” “estimates,” “may,” “could,” “intends,” and similar expressions are intended to identify forward-looking statements. 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 the development of our product candidate, Tcelna (imilecleucel-T), 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, but are not limited to, risks associated with: market conditions; our capital position; the rights and preferences provided to the Series A convertible preferred stock and investors in the convertible secured notes we issued in July 2012 (including a secured interest in all of our assets); our ability to compete with larger, better financed pharmaceutical and biotechnology companies; new approaches to the treatment of our targeted diseases; 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); our ability to satisfy various conditions required to access the financing potentially available under the purchase agreements with Lincoln Park Capital Fund, LLC (“Lincoln Park”) or sell shares of our common stock to Lincoln Park or under our at-the-market (ATM) facility; 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 Multiple Sclerosis which, depending upon results, may determine whether Ares Trading SA (“Merck”) elects to exercise its option for an exclusive license to Tcelna for the treatment of multiple sclerosis (the “Option”)); whether Merck exercises the 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 the Option) on the resources and abilities of Merck for the further development of Tcelna; the efficacy of Tcelna for any particular indication; 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; the risk of litigation regarding our intellectual property rights or the rights of third parties; the success of third party development and commercialization efforts with respect to products covered by intellectual property rights that we may license or transfer; our limited manufacturing capabilities; our dependence on third-party manufacturers; our ability to hire and retain skilled personnel; our volatile stock price; and other risks detailed in our filings with the SEC.
- These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update any forward-looking statements to reflect any changes in 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.

Introduction to Opexa

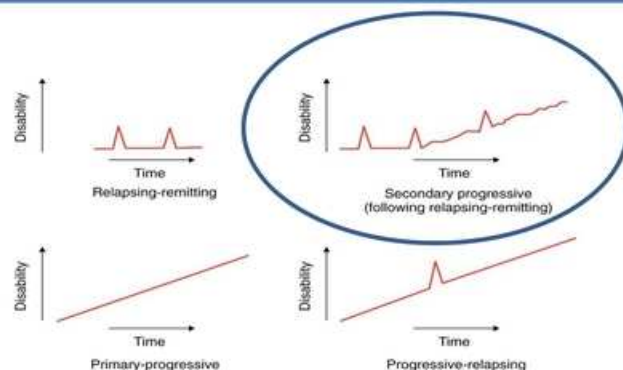
- Antigen specific T-cell immunotherapy platform with potential in multiple autoimmune diseases
- Strong Patent Estate: 50 patents issued on T-cell platform (US and ROW, collectively)
- Precision Immunotherapy potentially optimizes benefit-risk profile
- Lead product, Tcelna[®], under development for Multiple Sclerosis
- Currently conducting a Phase IIb clinical trial in Secondary Progressive MS (SPMS)
- Limited treatment options currently available for SPMS
- Potential SPMS market in North America alone could exceed \$7 Billion
- Fast Track designation from the U. S. Food and Drug Administration (FDA) for the treatment of SPMS
- Option Agreement with Merck Serono, a strong commercial partner

Merck Serono Agreement for MS indication

- **February 2013 option and license agreement with Merck Serono**
 - Up to \$220 million in additional payments
 - Option exercise \$25 million for starting Phase III/ or \$15 million if another Phase II
 - \$35 million FDA filing, approval and commercialized in US
 - \$30 million for EU filing, approval and commercialization in at least three countries
 - RRMS development and commercialization of up to \$40 million
 - One time commercial milestones of up to \$85 million
- **Royalties ranging from 8% to 15% of annual net sales with step-ups occurring when 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

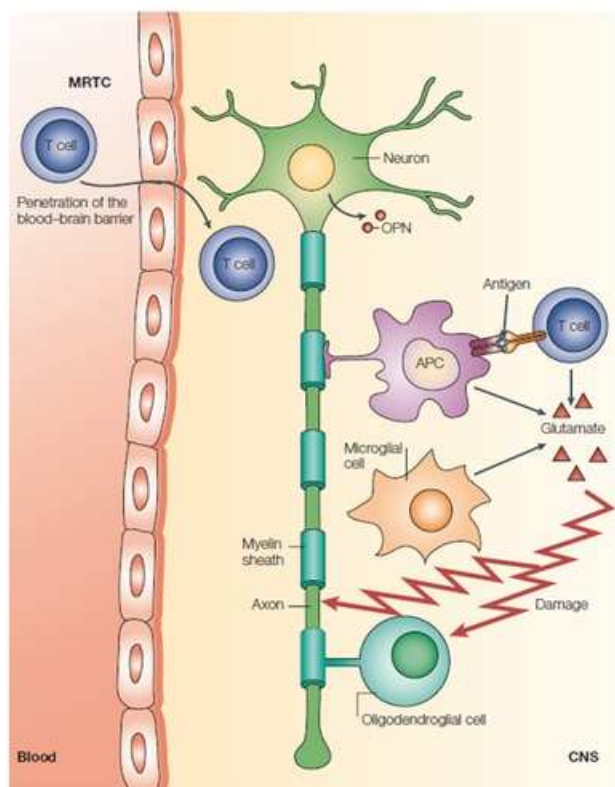
Tcelna in Secondary Progressive Multiple Sclerosis

- Patients initially experience a relapsing-remitting course then transition to SPMS
- SPMS patients experience worsening QOL / disability with or without relapses
- **Over 450,000 patients in North America and 2 million world wide have MS**
- Approximately 30-45% of MS patients can be classified as Secondary Progressive
- Tcelna is being pursued for this SPMS indication
- Potential SPMS market in the North America alone could exceed **\$7 billion** [150,000 SPMS patients at average cost of \$50,000 per year of treatment]
- No SPMS treatment approved by EMA; only one approved by FDA with limited use due to toxicity
- Upon successful clinical development, Tcelna has the potential to be the treatment of choice in SPMS



Tcelna Addressing the Root Cause of Multiple Sclerosis

Preventing Demyelination and Enabling Remyelination



Nature Reviews | Immunology

Adapted by permission from Macmillan Publishers Ltd: NATURE REVIEWS IMMUNOLOGY 3, 483-492 (June 2003), copyright (2003)

- Myelin Reactive T-cells (MRTC) cross the blood brain barrier, enter the brain, bind to antigen presenting cells (APC) causing release of pro-inflammatory cytokines which lead to a two pronged attack through:

- i. Activation of microglial cells leading to destruction of myelin sheath, the protective coating of nerve fibers
- ii. Destruction of oligodendroglial cells which are responsible for producing myelin

Result → Destruction of the myelin sheath with barriers to prevent remyelination

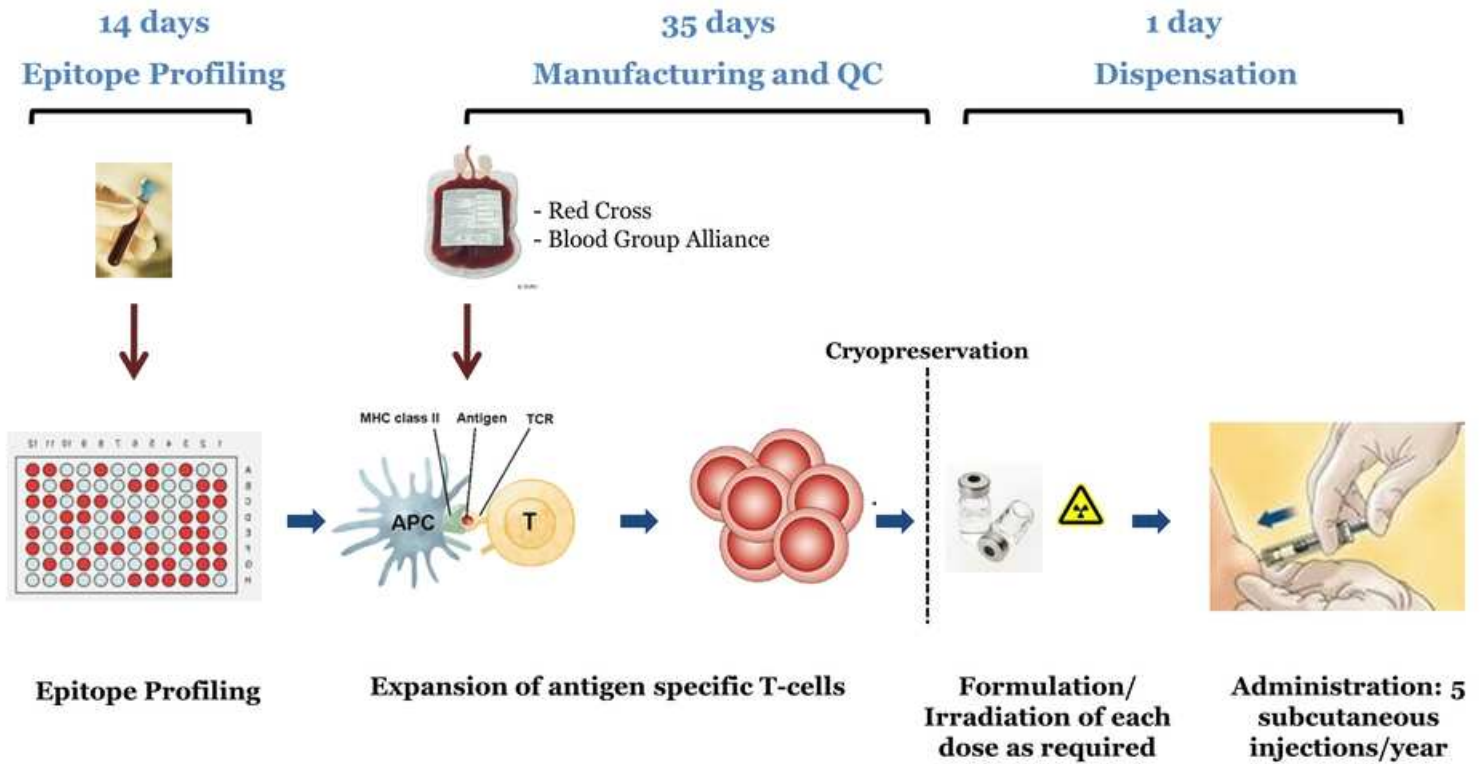
- T cells play a vital role in our immune system. Only a very small proportion develop into MRTCs. Most competing therapies **non-specifically** suppress all T-cells (including beneficial T cells) and/or focus on preventing their entry into the central nervous system, which may lead to serious side effects.

Opexa's Strategy

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

Single Cycle Manufacturing Process:

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



Tcelna Development Program

Broad Spectrum of MS patients treated

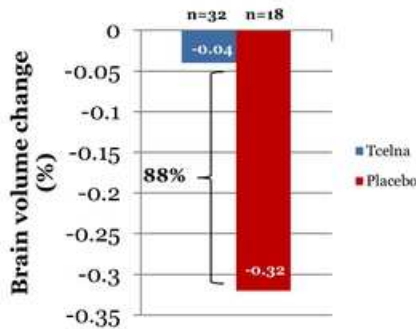
Phase	Completion Dates	Population	Total N	Treatment Duration (months)	Tcelna	Placebo
Baylor	1998	RRMS, PPMS, SPMS (26)	114	Up to 24 months	114	
Phase I dose escalation	2006	RRMS (5) SPMS (6)	16	12	16	-
Phase I/II Open label retreatment	2007	RRMS (9) SPMS (4)	13	12	13	-
Phase IIb TERMS	2008	RRMS, CIS	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	1 st Half 2016*	SPMS	180*	24*	90*	90*

* Expected upon completion of ongoing SPMS Abili-T trial

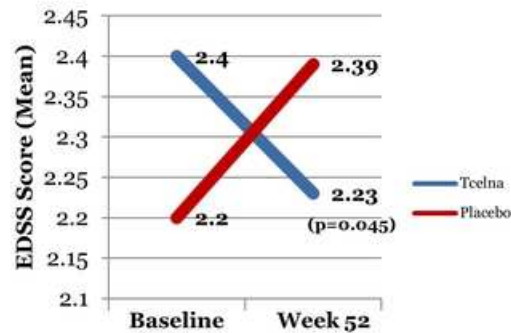
TERMS Study - Prospective Analysis in More Active or Progressive Patients

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

Percent Brain Volume Change at Week 52

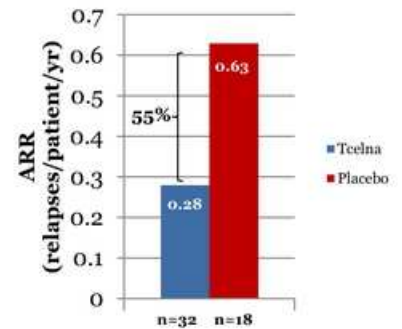


Change in Disability (EDSS) at Week 52



Statistically Significant Improvement in Disability (p=0.045)

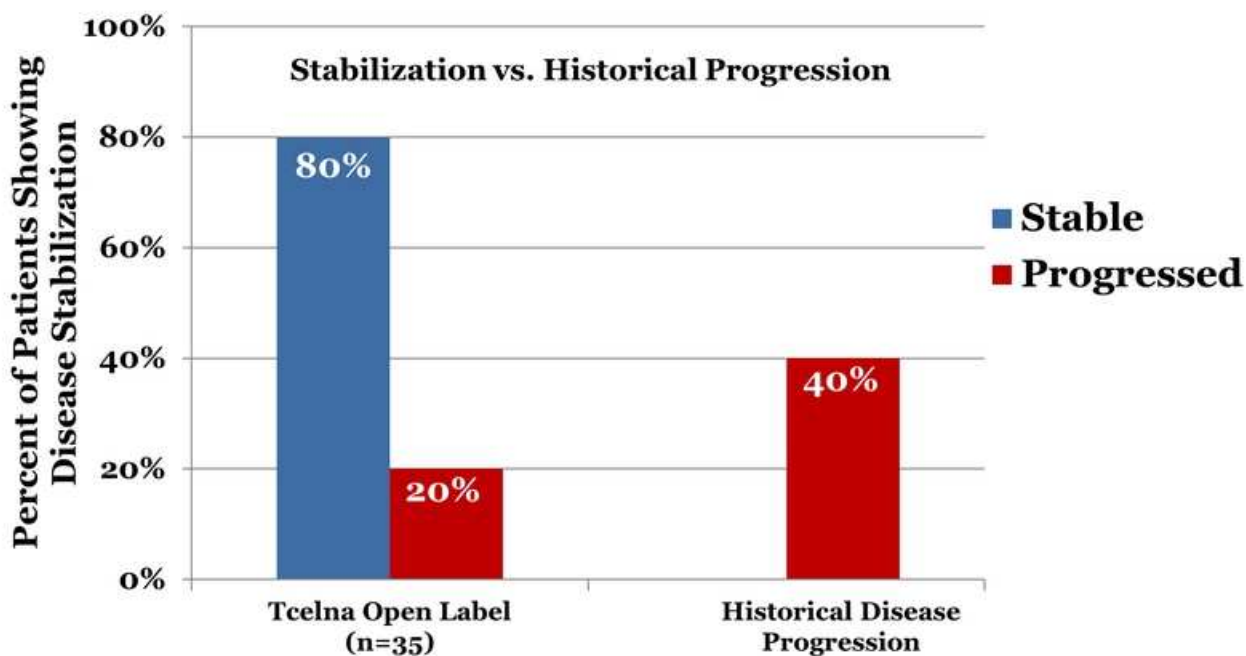
Annualized Relapse Rate (ARR) at Week 52



These Data Support Phase IIb Program in SPMS

Tcelna Stabilizes Disease in SPMS at 2 Years

80% of subjects treated with Tcelna 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

Abili-T : Landmark trial in SPMS

- **Abili-T Phase IIb clinical trial in SPMS is ongoing**
 - Double-blind, 1:1 randomized, placebo-controlled
 - Inclusion criteria: Secondary Progressive MS with EDSS of 3 to 6
 - 68 patients enrolled as of August 8, 2013
 - Immune Monitoring program conducted on a blinded basis
- **Fast Track designation granted by FDA for Tcelna in SPMS**
- **180 Patients expected to be enrolled**
 - SPMS population
 - 30 sites in USA and Canada
- **2 annual courses of personalized therapy**
- **Top line Data in 1st Half of 2016**

Efficacy Assessments

- **Primary Endpoint**
 - Whole-brain atrophy
- **Secondary Endpoints**
 - Sustained progression measured by EDSS
 - Time to sustained progression
 - T2 lesions progressing to hypointense lesions (black holes)
 - Change in EDSS
 - Annualized Relapse Rate (ARR)
 - Change in MSFC Assessment of disability
 - Change in Symbol Digit Modality Test (SDMT)
- **Exploratory Endpoints**
 - Quality of life assessment by MSQLI
 - Gd-enhancing lesion volume with increasing MTR
 - Gd-enhancing lesion volume with decreasing MTR
 - Change in MTR in normal-appearing white matter
 - Changes in T-regulatory cell repertoire and function



Immune Monitoring Program



Immuno vigilance

Whole blood analysis:
Absolute frequency of T-cells, B-cells, Dendritic cells and Monocytes

- Goal is to show no systemic impact on immune response, i.e. Tcelna is a Precision Immunotherapy
- Tcelna differentiates by not depleting a broad spectrum of T-cells

Phenotypical Analysis (CD4 and CD8)

Pro-inflammatory Anti-inflammatory

TH1	Treg
TH17	Tr1
	TH2
IL-2	IL-4
IL-6	IL-5
IL-12	IL-10
IL-17E, IL-17F	
IL-23	IL-27
TNF α	TGF β
IFN γ	BDNF

Plausible indicators of Tcelna efficacy

- Reduction in Th1/TH17
- Increase in Treg/Tr1 cells
- Reduction in proinflammatory cytokines (IL-12, IL-23, IFN γ , TNF α)
- Increase in anti-inflammatory cytokines (IL-10, IL-27)
- Loss of proinflammatory monocyte markers (CD16/HLA-DR, CCR5)
- Gain in anti-inflammatory monocyte markers (PDL-1, HLA-G, ICOS)

Financials

Cash and Cash Equivalents (MM) as of June 30, 2013	\$5.0 ⁽¹⁾
Estimated Net Proceeds (MM) from August 2013 common stock offering	\$17
Convertible Debt (MM) ⁽²⁾	\$3.2
Shares outstanding (MM) as of September 4, 2013	~20.8
Warrants (MM) ⁽³⁾	~3.1
Stock Options (MM) ⁽⁴⁾	~1.1

(1) Excludes \$500,000 of restricted cash subject to a deposit control agreement

(2) Principal outstanding on convertible secured promissory notes

(3) Weighted average exercise price = \$4.12 as of June 30, 2013

(4) Weighted average exercise price = \$4.46 as of June 30, 2013

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

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

Board of Directors

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

David E. Jorden

Interim CEO, Nanospectra Biosciences

Neil K. Warma

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
 - President ECTRIMS, 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

- T-cell platform company with Fast Track designation in SPMS
- Strong Intellectual property with 50 issued patents
- Esteemed Scientific Advisory Board
- Precision Immunotherapy potentially optimizes benefit-risk profile
- Targeting an unmet medical need in a potentially substantial market
- Option Agreement with Merck Serono, a strong commercial partner
- Replacement value of company is multiples of present market cap
- Attractive potential risk-reward profile for long term/value investors
- Goal-oriented management team focused on value creation



APPENDIX

Tcelna Manufacturing: Personalization followed by Expansion Step

The Epitope Profiling Assay (EPA)

- Screen peripheral blood for Myelin-Reactive T-cells (MRTCs), and mapping of immunodominant epitopes to MBP, MOG and PLP
 - 109 overlapping peptides encompassing MBP, MOG and PLP
 - Interferon gamma response to individual peptide pools defines positive response in 7 day assay

ImmPath™ Process

- Procure unit of blood from which up to six T-cell lines reactive with immunodominant myelin peptides are generated and pooled as a patient-specific Tcelna product
 - Manufacturing performed under GMP/GTPs in functionally closed system
 - Process generates a year of Tcelna doses from a single unit of blood

Tcelna Manufacturing: Precision Medicine

Proprietary Assay Enables Annual Personalized Treatments

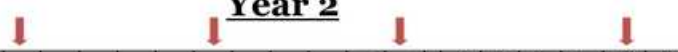
Year 1

Conduct analysis of 109 peptides from all three key myelin proteins (MBP, MOG, PLP)



Patient XX	Peptide 1	Peptide 2	Peptide 3	Peptide 4	Peptide 5	Peptide 6	Peptide 7	Peptide 8	Peptide 9	Peptide 10	Peptide 11	Peptide 104	Peptide 105	Peptide 106	Peptide 107	Peptide 108	Peptide 109
MBP																	
MOG																	
PLP																	

Year 2



Patient XX	Peptide 1	Peptide 2	Peptide 3	Peptide 4	Peptide 5	Peptide 6	Peptide 7	Peptide 8	Peptide 9	Peptide 10	Peptide 11	Peptide 104	Peptide 105	Peptide 106	Peptide 107	Peptide 108	Peptide 109
MBP																	
MOG																	
PLP																	

- Re-assess epitope profile annually to identify epitope shift
- Develop newly personalized formulation annually based on evolved epitope profile

Year 3



Patient XX	Peptide 1	Peptide 2	Peptide 3	Peptide 4	Peptide 5	Peptide 6	Peptide 7	Peptide 8	Peptide 9	Peptide 10	Peptide 11	Peptide 104	Peptide 105	Peptide 106	Peptide 107	Peptide 108	Peptide 109
MBP																	
MOG																	
PLP																	