

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 02/11/13 for the Period Ending 02/11/13

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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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): February 11, 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 February 11, 2013, Opexa Therapeutics, Inc. (the “ **Company** ”) will deliver a corporate presentation at the 15th Annual BIO CEO & Investor 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 Abili-T clinical study for Tcelna™, the Company’s lead therapy, in subjects with secondary progressive multiple sclerosis, as well as an overview of the Company’s recent Option and License Agreement with Merck Serono for Tcelna in 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 15th Annual BIO CEO & Investor Conference, held on February 11, 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: February 11, 2013

OPEXA THERAPEUTICS, INC.

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

Exhibit Index

Exhibit No.

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OPEXA THERAPEUTICS



A REVOLUTION IN
CELL THERAPY

Opexa Therapeutics, Inc.

Precision Medicine

February 2013

*Neil Warma
President & CEO*



Forward-Looking Statements

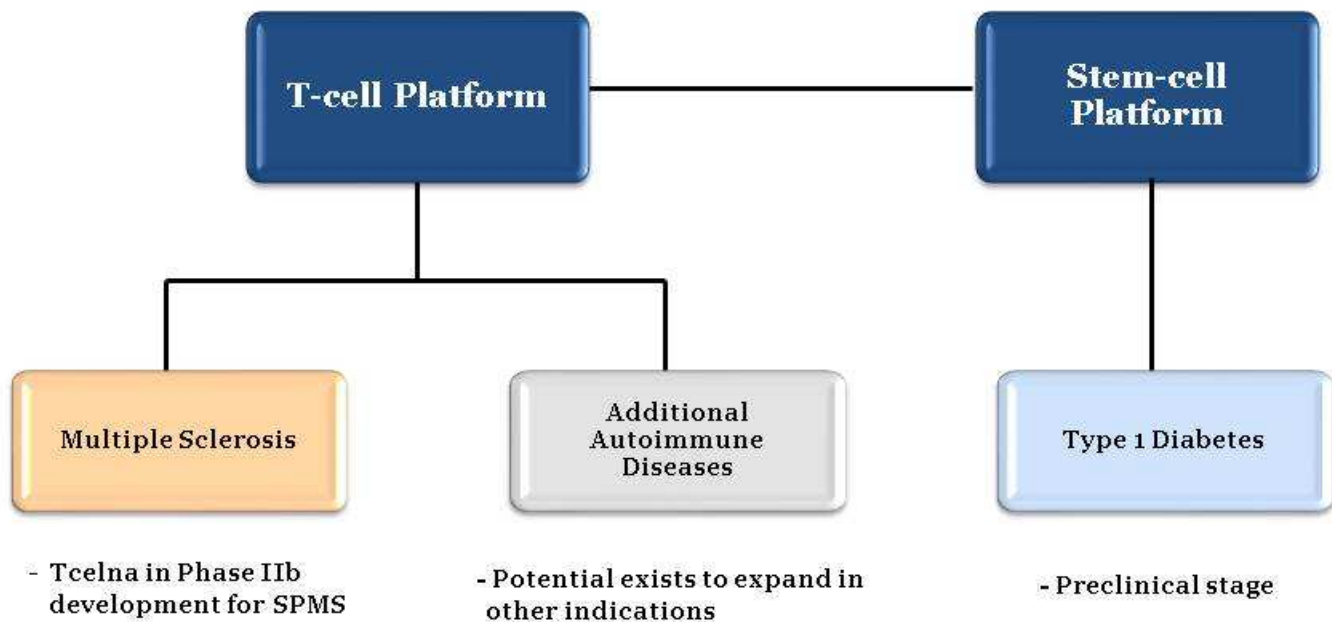
This presentation contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words “expects,” “believes,” “may,” “could,” “potential” and similar expressions are intended to identify forward-looking statements. These forward-looking statements do not constitute guarantees of future performance. Investors are cautioned that statements in this presentation which are not strictly historical statements, including, without limitation, statements regarding development of the Company’s technologies, including its 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, including, without limitation, risks associated with: our ability to finance our ongoing Phase IIb trial for Tcelna in secondary progressive multiple sclerosis (MS), as well as any other development programs; the efficacy and safety profile of Tcelna, including for any particular indication such as relapsing remitting MS or secondary progressive MS; the success of our development efforts, including the Phase IIb trial for Tcelna in secondary progressive MS which, depending upon results, may determine whether Merck Serono elects to exercise its option pursuant to an option and development agreement dated February 5, 2013 to acquire control of Tcelna in MS; whether Merck Serono exercises such option and, if so, whether we receive any development or commercialization milestone payments or royalties from Merck Serono pursuant to such option and development agreement; our dependence, if Merck Serono exercises its option, on Merck Serono for the further development of Tcelna; whether we are able to establish, obtain financing for and otherwise initiate and/or continue development programs beyond Tcelna in MS; our compliance with all Food and Drug Administration regulations; our ability to obtain, maintain and protect intellectual property rights (including for Tcelna); 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 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 reports filed with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2011 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.

Opexa Highlights

- **Opexa is one of the leading cellular therapy companies**
 - Focused on developing **Tcelna™**, a T-cell immunotherapy for Multiple Sclerosis (MS)
- **Currently conducting a Phase IIb clinical trial in Secondary Progressive MS (SPMS)**
 - Fast Track designation granted by FDA
- **February 5, 2013 announcement of option and license agreement with Merck Serono for Tcelna in MS**
 - Up to \$225 million in payments + royalties
- **Opexa platform capable of generating multiple disease treatment opportunities**
 - Pharma agreement is supportive of platform's potential
- **Publicly traded on NASDAQ Capital Markets (NASDAQ : OPXA)**

Personalized Medicine: Autologous Cell Therapy

T-cell platform: Every dose is personalized, tailored to each patient's disease profile





Pipeline and Potential Areas of Investigation

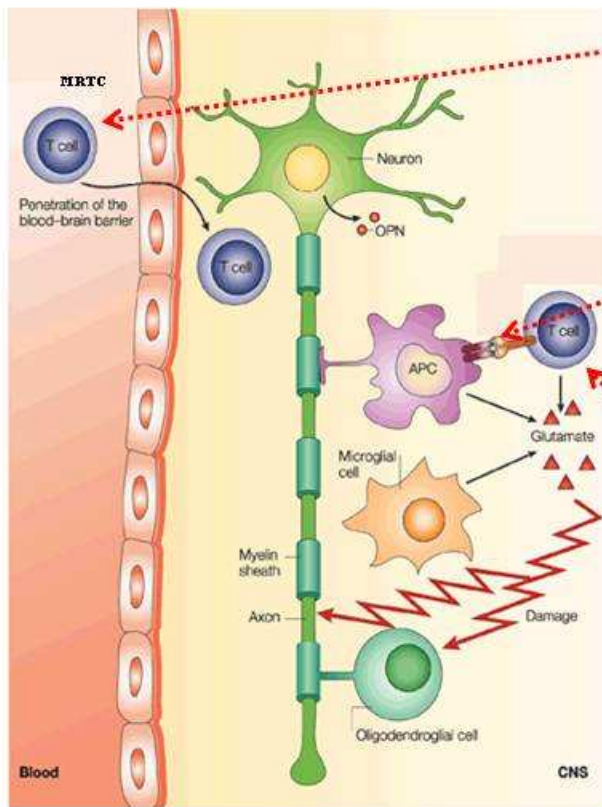
Stage of Development

Indication	Evaluation	Preclinical	Phase I	Phase II	Phase III	Commercial
T-CELL PLATFORM						
Multiple Sclerosis (Tcelna)*						
<i>Secondary Progressive MS*</i>		<i>Phase IIb ongoing</i>				
<i>Relapsing Remitting MS*</i>		<i>Phase III not yet initiated</i>				
STEM CELL PLATFORM						
Type 1 Diabetes						

* Rights granted to Merck Serono under option and license agreement (Feb. 5, 2013)



MRTCs' Role in Multiple Sclerosis

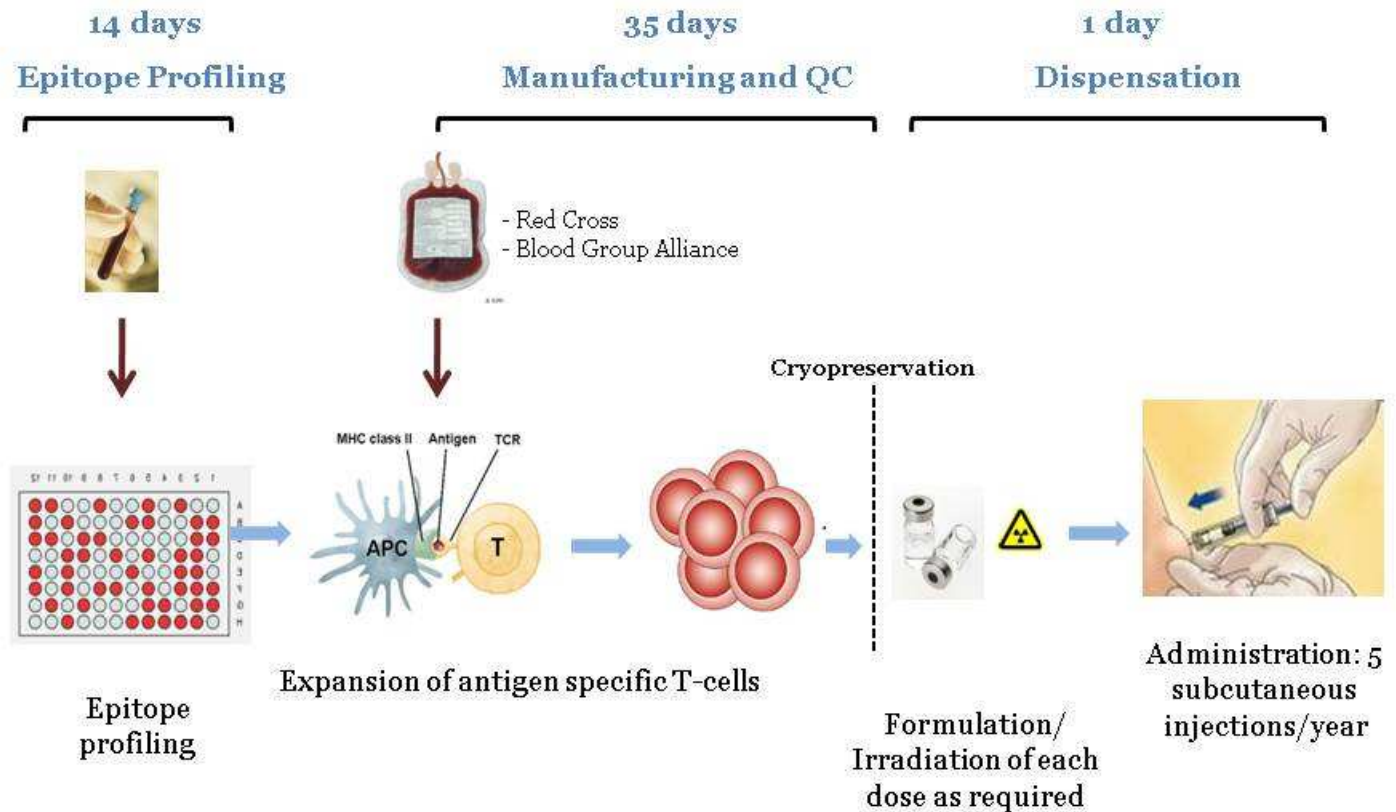


Nature Reviews | Immunology

- In MS patients, the faulty immune system is not able to prevent the attack of a small sub-population of myelin reactive T-cells (MRTCs)
- Opexa's strategy is to inject a large therapeutic bolus of attenuated MRTCs back into the patient
- **Important to Opexa's Strategy:** Identify which *specific* antigens within each *individual* patient may be targeted by the immune response
- Tcelna consists of attenuated antigen-specific Myelin Reactive T-cells (MRTCs)
- The bolus subcutaneous injection of Tcelna, it is believed, primes or educates the body's immune system to recognize similar MRTCs as "foreign" and destroy or downregulate them
- Tcelna therapy is selective, targeting pathogenic T-cells only, not other immune cells



Tcelna™ Manufacturing





Safety and Tolerability Overview

- **To date, Tcelna has demonstrated superior safety to MS drugs marketed and in development**
- **Tcelna is very well tolerated with favorable safety profile**
- **No Serious Adverse Events (SAE) associated with treatment in previous Phase IIb Relapsing Remitting MS (RRMS) clinical trial in 150 patients (100 on active therapy)**
- **Most common side effect – mild and transient injection site reactions**



Tcelna Clinical and Regulatory Overview

- Five Phase I and Phase II clinical trials have been conducted to date with Tcelna in both RRMS and SPMS patients
- Over 300 subjects have been enrolled in these trials with over 140 being treated with Tcelna
- Encouraging signs of clinical efficacy observed in both MS patient populations treated with Tcelna
- Dose range studies have been conducted confirming dose and treatment regimen
 - 30-45 million cells per dose, 5 subcutaneous injections (doses) administered/year
- RRMS - Opexa received FDA endorsement to initiate Phase III pivotal studies but deferred in favor of SPMS trial
- SPMS – Opexa received Fast Track designation from FDA



Tcelna Efficacy Data Overview

RRMS
Phase IIb
clinical
trial
(completed)

- **Phase IIb trial in RRMS: U.S. trial in 150 patients**
 - Strong clinical signal : 37% reduction in Annualized Relapse Rate (ARR) vs. placebo
 - ARR = 0.21 vs. 0.34 (on par with existing marketed drugs)
 - 77% relapse free in Tcelna group
- **Sub population of more active patients from Phase IIb trial (patients with ARR ≥ 1 at baseline, n=50)**
 - Statistically significant improvement in disability (p=0.05)
 - 56% reduction in ARR vs. placebo
 - 88% improvement in whole brain atrophy with Tcelna

SPMS
Phase I/II
clinical
trials
(completed)

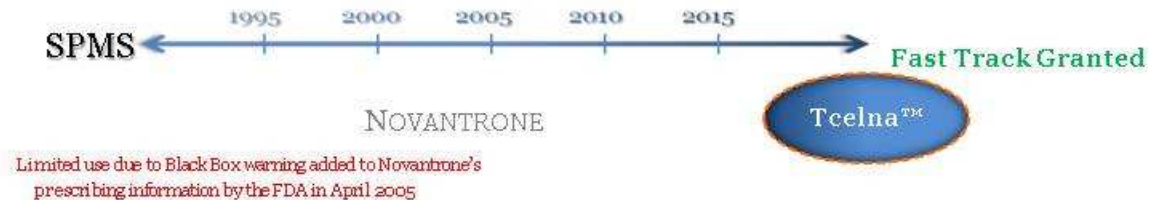
- **SPMS Phase I/II Clinical trials**
 - Disease stabilization in 80% of patients at two years
 - Significant reduction in relapse rates
 - Stabilization of key quality of life indicators (physical and psychological condition) after 2 years of treatment



Opexa's Focus: Filling the Void in SPMS Treatment

Over 1 million people affected by SPMS worldwide...

...only ONE FDA approved product for SPMS



- There are no effective therapies for SPMS
- Teelna offers the opportunity to capture an unmet medical need with exclusivity
- \$5 billion market opportunity



Abili-T™ : Landmark trial in SPMS

- **Abili-T Phase IIb clinical trial in SPMS is ongoing**
 - Double-blind, 1:1 randomized, placebo-controlled
- **Enthusiasm among MS community (patients and sites) is high**
- **Approval by Health Canada enables expansion into Canada**
- **180 Patients**
 - SPMS population
 - 30 sites in USA and Canada
- **Key Efficacy Endpoints:**
 - Whole-brain atrophy
 - Sustained progression measured by EDSS
- **2 annual courses of personalized therapy**
- **2 years of assessment**



Opexa's Immune Monitoring Program

Overview

- Opexa is undertaking a comprehensive Immune Monitoring Program to capture valuable information from the **Abili-T** trial in SPMS patients
- The Immune Monitoring Program will harvest multiple samples from 180 SPMS patients over two years and will be analyzed in real time
- The longitudinal assessment of both placebo and active patient samples will provide valuable first time information for a key underserved patient population

Purpose

- Identify potential biomarkers for SPMS
- Investigate the impact of Tcelna treatment on systemic immunity
- Further define the Mechanism of Action of Tcelna
- Further elucidate the Immunopathology of SPMS



Opexa secures option and license agreement with Merck Serono for MS indication

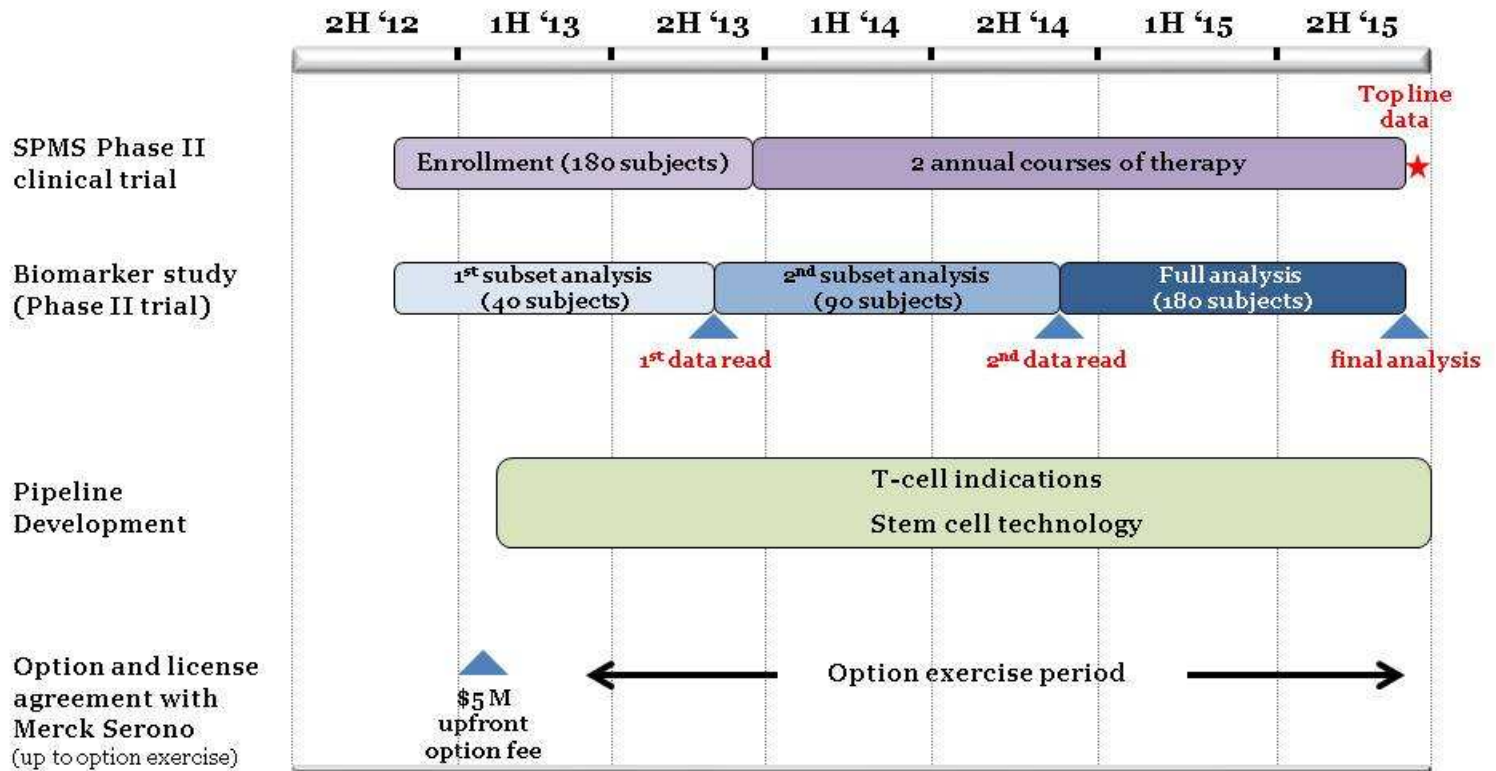
- **Option and License agreement jointly announced February 5, 2013**
- **Total potential payments to Opexa up to \$225 million**
 - \$5 million upfront option grant fee
 - \$25 million, or \$15 million, option exercise fee
 - Up to \$195 in development and commercial milestone payments
 - Royalties: Tiered, based on net sales, from upper single digit – mid teens
- **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

Value for Opexa

- **If option is exercised, potential payments to Opexa up to \$225 million over next several years and beyond plus tiered royalties based on net sales**
- **Alliance with one of the leading global Pharma companies with commitment, franchise and expertise in MS**
- **Path to commercialization of Tcelna potentially streamlined**
 - **Merck Serono to fully fund clinical, regulatory and commercial development (subject to Opexa's co-development rights)**
- **Endorsement and support for Opexa's platform**
 - **Potential to expand pipeline to other autoimmune diseases**
- **Valuable rights retained by Opexa**



Expected Development Timeline



Milestones and Goals

- ✓ Obtained FDA Fast Track approval for Teelna™ in SPMS (Q4'11)
- ✓ Initiated “Abili-T” 180 patient Phase IIb SPMS clinical trial in U.S. (Q3'12)
- ✓ Closed option and license agreement with Merck Serono, global leader in MS (Q1'13)
- ✓ Secured \$3.25 million in private offering (Q1'13)
- ☐ Evaluate T-cell platform to possibly advance in other development opportunities
- ☐ Secure additional resources to fund Phase IIb SPMS trial
- ☐ Evaluate potential of stem cell platform



Financial Highlights

- Basic Shares Outstanding **~7.9 M**
- Fully Diluted **~14.8 M**
- Market Capitalization **~\$20 M**
- 52 week range **\$1.07-\$5.19**
- Monthly Burn **\$885,000**
- Cash Position **\$2.2 M** (at 9/30/12 per Q3 Earnings Release)
- \$5 M** (upfront option fee 2/5/13 option agreement)
- \$3.25 M** (gross proceeds from private placement (2/7/13))

Opexa Highlights

- **Developing one of most promising therapies for Multiple Sclerosis**
 - Personalized, patient specific, with encouraging clinical efficacy and superior safety profile
- **Secured option agreement for Tcelna in MS with leading global Pharma company (potential payments up to \$225 M + royalties)**
- **Key rights retained by Opexa could generate future value**
- **Endorsement highlights potential of Opexa's platform in other disease areas**
- **Ownership of manufacturing platform enables tight control of costs and quality assurance**



OPEXA THERAPEUTICS



A REVOLUTION IN
CELL THERAPY

Opexa: Developing Novel Treatments for Cell Therapy