

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 09/11/09 for the Period Ending 09/11/09

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): **September 11, 2009**



Opexa Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Texas

(State or Other Jurisdiction of Incorporation)

001-33004

(Commission File Number)

**2635 N. Crescent Ridge Drive
The Woodlands, Texas**

(Address of Principal Executive Office)

76-0333165

(I.R.S. Employer Identification No.)

77381

(Zip Code)

Registrant's telephone number, including area code: **(281) 272-9331**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions (see General Instruction A.2 below) :

- ☐ 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.

Opexa Therapeutics, Inc. (the “Company”) is furnishing presentation materials, included as Exhibit 99.1 to this report and incorporated herein by reference, which were prepared for the Company’s presentation at Rodman & Renshaw’s 11th Annual Healthcare Conference on Friday, September 11, 2009. The Company is not undertaking to update this presentation. This report should not be deemed an admission as to the materiality of any information contained in the presentation.

The information furnished in this report shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits

(c) Exhibit 99.1

The following exhibit is to be filed as part of this 8-K:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Opexa Therapeutics Investor Presentation for Rodman & Renshaw’s 11th Annual Healthcare Conference.

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 hereunto duly authorized.

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President and Chief Executive Officer

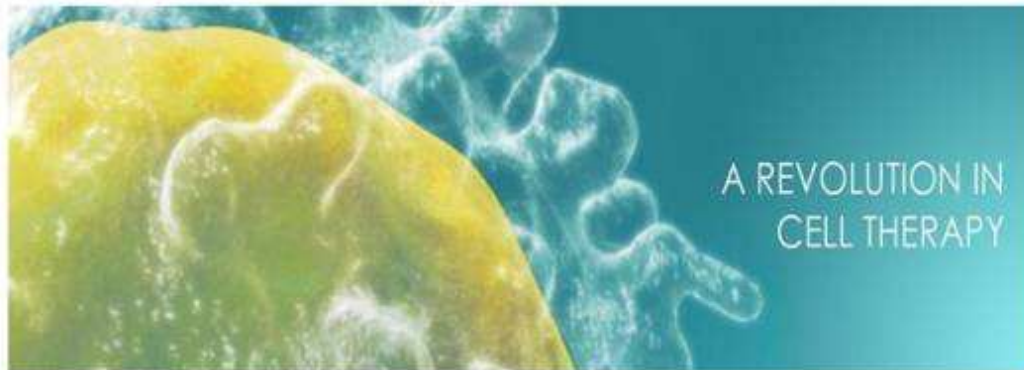
DATE: September 11, 2009

EXHIBIT INDEX

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OPEXA THERAPEUTICS



Corporate Presentation

September 11, 2009

**Neil K. Warma
President & CEO**

(OPXA: NASDAQ)



Forward-Looking Statements

Certain of the information contained herein concerning market size and industry data is based upon or derived from information provided by third-party consultants and other industry sources. We believe that such information is accurate and that the sources from which it has been obtained are reliable. However, we cannot guarantee the accuracy of this information and have not independently verified such information. In addition, included projections and other forward-looking information that can be identified by the use of forward-looking terminology such as "may," "could," "positioning," "potential," "promising," "will," "expect," "believe," "anticipate," "estimate," "plan," or "continue," the negative thereof or other variations thereon or comparable terminology. The projections and information are based on assumptions as to future events that are inherently uncertain and subjective. We make no representation or warranty as to whether we will attain the results projected. The projections of our future performance are based on uncertain assumptions, and our actual results may differ materially and adversely from the results set forth in the projections. You should conduct your own investigation to determine the merits and risks of the proposed investment in our securities.

The projected financial information was not prepared with a view toward complying with published guidelines of the Securities and Exchange Commission or the guidelines established by the American Institute of Certified Public Accountants regarding projections, nor is the projected financial information intended to be presented in a manner consistent with financial statements prepared in accordance with generally accepted accounting principles. Our legal counsel has not compiled, audited or contributed to the creation of the projections or the underlying assumptions in any way. Therefore, none of these parties expresses an opinion or any other form of assurance with respect to such projected financial information.

The information contained is accurate only as of the preparation date(s) and may change after the date(s). We disclaim any responsibility to update the information after the date appearing on the front page and we do not intend to update the information.

You are urged to request any additional information you may consider necessary in making an informed investment decision.

Tovaxin[®]

A safe and effective cell therapy treatment in clinical
development for MS



From Breakthrough Technology to Significant Market Opportunity

- **Opexa is a leading cell therapy company**
 - **Patient's own cells act as "drug" – result is powerful efficacy and reduced side effects**
- **Opexa is advancing the reality of personalized medicine**
 - **Proprietary Epitope Technology maps disease progression, allows tailored therapies**
- **Opexa is currently in advanced clinical trials for its T-cell therapy in Multiple Sclerosis**
- **Built around T-cell platform with the ability to potentially generate multiple drug opportunities**



Progress since November 2008 (last R&R presentation)

We are 10 months into our recovery plan from clinical study design flaws,
hedge fund sell offs and a challenging capital markets environment

Value added milestones:

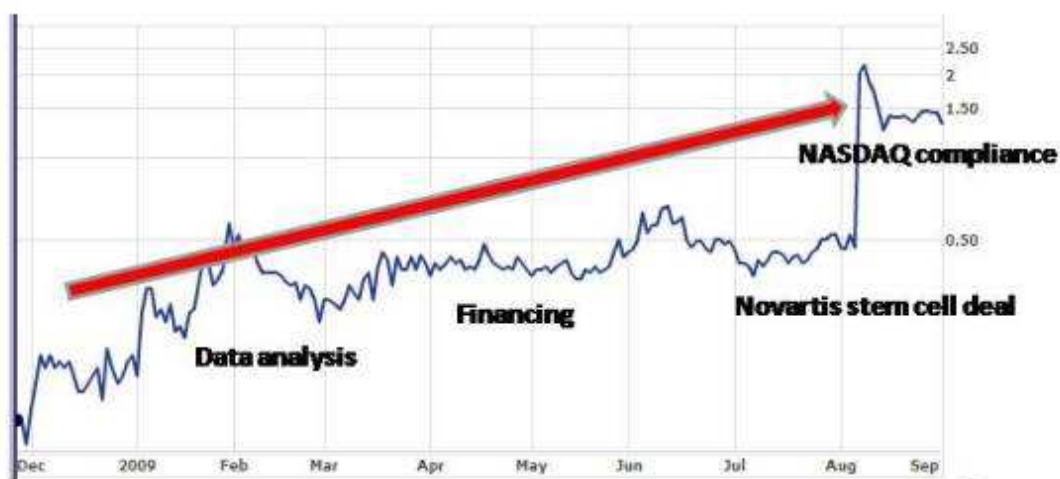
- ✓ **Further Data Analysis:** Tovaxin is emerging as a safe and effective treatment for MS and one of the most promising therapies in development for MS
- ✓ **Financing:** Closed a private offering of convertible notes which demonstrated strong support by existing investors, directors and officers
- ✓ **Deal flow:** Monetized an asset that had generated little perceived value for the company by securing a \$50+ million deal with Novartis for stem cell technology
- ✓ **Compliance:** OPXA regained compliance with NASDAQ Capital Markets, elimination of going concern reference

Well on our way with the recovery

Significant increase in share price over 10 months

End November 2008
<\$0.25

End August 2009
\$1.46



OPXA (NASDAQ)



Recovery Plan Shifts to Growth Strategy

Company priorities for next 6-12 months

- ❖ Focus on partnership for Tovaxin in MS

- ❖ Advance the planning and preparation for the second confirmatory Phase IIb clinical study with Tovaxin



50% of MS patients are non-compliant after 2 years

Reason for non-compliance

Safety

- Side effects have plagued MS patients for years
 - Fatigue, flu-like symptoms
 - Serious infections

Administration

- Cumbersome treatment
 - Daily, 3X/wk injections, monthly infusions

Tovaxin

- No serious adverse events to date
- Mild to moderate injection site reactions
- 5 subcutaneous injections/year

MS Patient Population



Worldwide market:

- 2.5 million patients WW
- 450-500,000 in U.S.
- Currently: ~\$9B
- At 2015: \$15 B*

(* Goldman Sachs 3/01/09)



Tovaxin Positioning at Market

- **1st line treatment for first Relapsing Remitting MS, high risk CIS, and possibly Secondary Progressive MS patients**
- **Tovaxin has potential to generate significant revenue through:**
 - Capturing non-compliant market (currently 50% of MS patients)
 - Capturing newly diagnosed patients
 - Capturing existing market from currently marketed drugs (dissatisfied patients)
- **Tovaxin could be used in combination with other MS therapies such as the Type I interferons and natalizumab**
 - In clinical practice, combination therapy may be used.
- **Submission of a BLA for RRMS is expected in 2015 with a launch in 2016**
- **Strong patent estate for Tovaxin – exclusivity well beyond launch.**
 - One of the key patents issued in 2006 will continue in effect until at least 2027

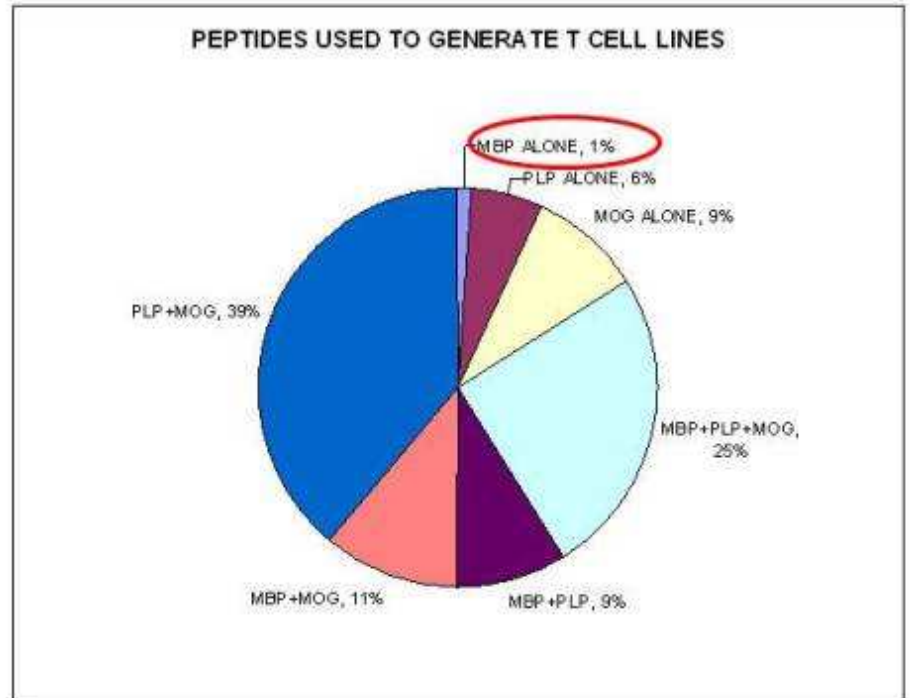
Tovaxin Description

- **Product:**
 - An autologous immune modulating cell therapy treatment
- **Produced by:**
 - Isolating Myelin Reactive T-Cells (MRTC) from patient's blood and expanding the cells *ex-vivo* to a therapeutic dose and reintroducing into the patients via five subcutaneous injections
 - MRTC reactivity to all three key myelin proteins (MOG, MPB, PLP) is determined to maximize effect
- **Potent Immune response:**
 - Reintroduction of attenuated T-cells elicits targeted immune response against most highly reactive pathogenic MRTCs
- Over 300 patients have been treated with Tovaxin, including 150 patients in the TERMS IIb clinical study (completed late 2008)
- Not one Serious Adverse Event associated with Tovaxin treatment to date



Selected Peptides for Manufacturing - utilized all three key proteins -

- Each individual patient's disease profile is mapped using Opexa's proprietary technology
- 109 peptides are screened in the assessment of an individual's epitope
- Peptides demonstrating the highest level of reactivity, signaling the most pathogenic, are selected for manufacturing
- Each Tovaxin preparation is personalized to each patient's specific peptide reactivity
- Opexa has shown that peptide reactivity occurs across all three proteins
- 85% of all Tovaxin preparations included peptides from at least 2 of the 3 proteins

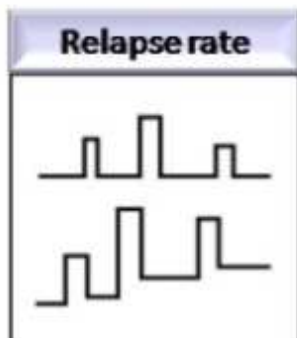


Tovaxin: Promising Efficacy

In clinical target population $ARR \geq 1$



- Over 73% showed stabilization or improvement in disability
- 16.5% demonstrated sustained improvement in disability



- $ARR = 0.20$
- 42% reduction vs. placebo
- One of lowest relapse rates of any marketed drug



- Possible neuroprotection
- Reduction in atrophy
- Reduction in progression to black holes



Competitive Advantage of Tovaxin vs. Marketed Drugs

Therapy	Efficacy (ARR)	Safety	Admin	Revenues (2008) ⁺
TOVAXIN*	.20	No SAEs to date Injection site Rx	5x/yr (SC)	N/A
Avonex**	.67	Flu symptoms (49%) Headache (58%)	Weekly (IM)	\$2.20B
Betaseron**	.90	Flu symptoms (60%) Headache (57%)	Every other day (SC)	\$1.66B
Copaxone**	.86	Inj. site Rx (66%) Infection (50%)	Daily (SC)	\$2.26B
Rebif**	.86	Flu symptoms (56%) Headache (65%)	3x/wk (SC)	\$1.96B
Tysabri**	.22	Infusion Rxns (22%) Infections (18%) Headache (35%) Deaths (PML)	1x/mo (IV)	\$0.81B

** Source: package inserts

* Datamonitor report; Company reports

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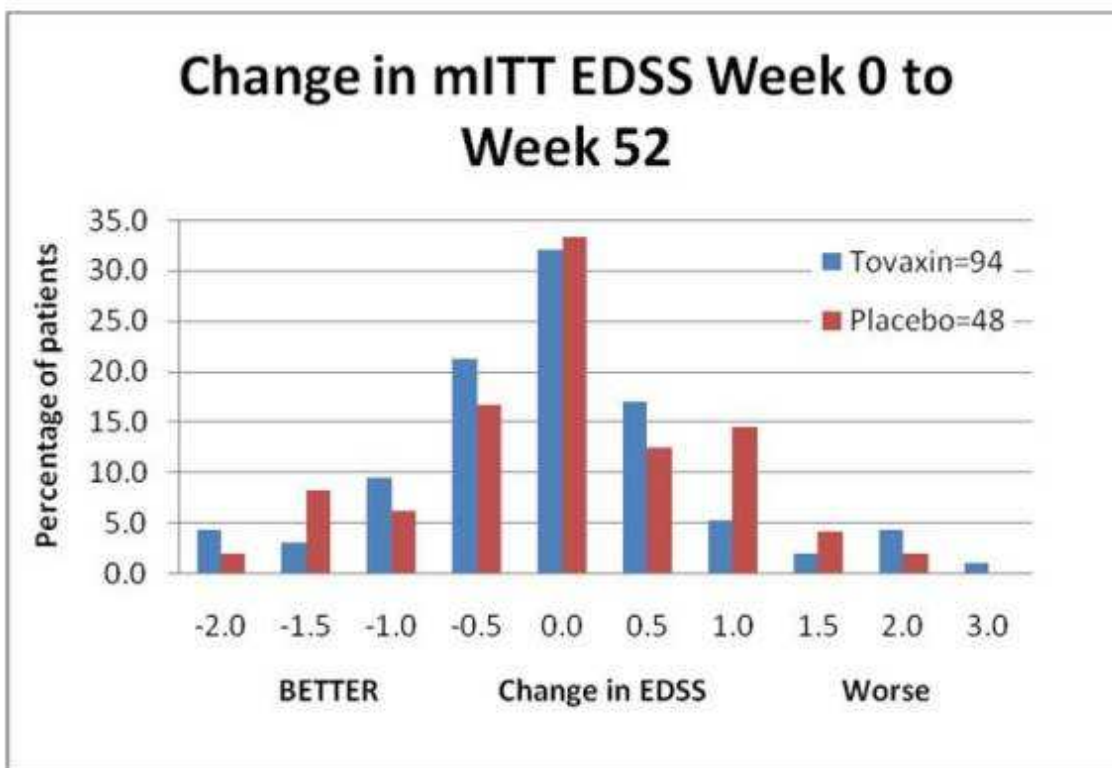
Analysis of ARR_{≥1} patient population

-- over 16% of population showed improved EDSS --

Endpoint measured	0-52 weeks	
	Tovaxin	Tovaxin
	ARR _{≥1}	ARR _{≥1}
Group Annualized Relapse Rate	0.282	0.204
% Relapse Free	71.9%	83.4%
EDSS Change: mean	-0.141	-0.0882
EDSS: % no Change or better	71.9%	72.9
EDSS: % Improved by 0.5 or better	40.6%	37.6
EDSS: % Improved by 1.0 or better	21.8%	16.5
Atrophy: Mean	-0.04258	-0.1365
Atrophy: % None or Improved	50.0%	56.5
Proportion of Black Holes: Mean	0.08188	0.1230
Subjects % with No Black Holes	81.2%	72.9
Number of Subjects	n=32	n=85

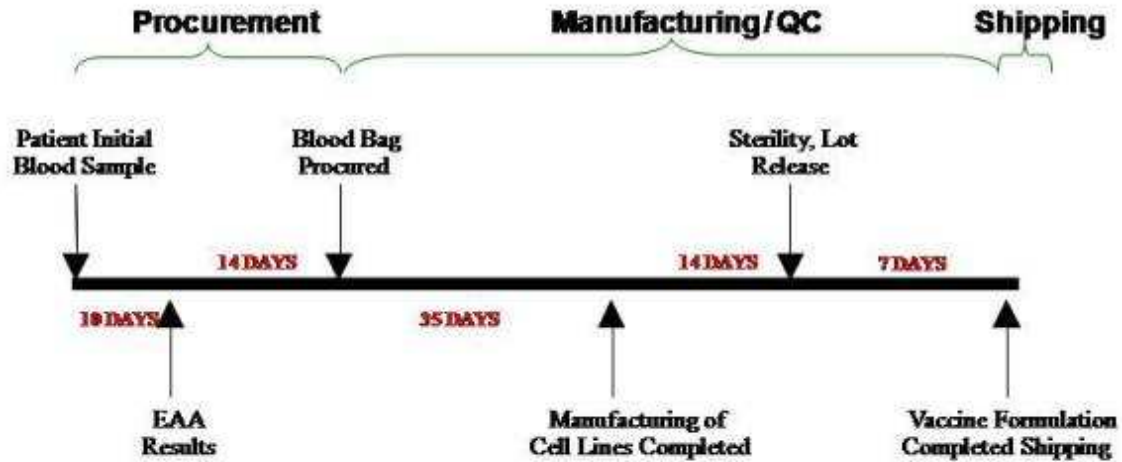
*Negative numbers represent improvement (i.e. the greater negative number, the greater the improvement)

Tovaxin: total population





Tovaxin Streamlined Manufacturing



- Attractive margins based on reduced COGS
 - Cell line generation: 97% success rate
 - Vaccine generation: 99% success rate
- Average time required to produce the patient-tailored vaccine: 35 days



External Validation Supports Inherent Value

Opexa's drug in development for multiple sclerosis,
Tovaxin®, has been positively received:

"I have seen remarkable effect from this intervention, with only one recorded relapse in 18 months...", physician treating Tovaxin patients in TERMS trial

"Tovaxin freed me from wheelchair/walker dependency.... my body emphatically demonstrated Tovaxin works and it works superbly!" patient on Tovaxin

"Tovaxin, to my family, has been a shining star or ray of hope!"..... "I have done quite well on it", patient on Tovaxin

"...the drug Tovaxin seems to be a miracle." sister of patient on Tovaxin

"Tovaxin treatment alone worked where all other treatments faltered." patient on Tovaxin



Clinical Development Plan

- Next step -

- **Confirmatory Phase IIb trial**
- **200 patients with active RRMS, powered based on TERMS data**
- **Placebo-controlled, 1:1 randomization**
- **30 U.S. sites (most already confirmed from TERMS trial)**
- **1 year study - 6 months treatment and 6 months follow-up**
- **Primary Endpoint**
 - Relapse Rate
- **Secondary Endpoints**
 - EDSS
 - New T1 hypointense lesions
 - Whole brain atrophy
 - Mean total T1 volume

Tovaxin Clinical Development

- Completed the 150 patient landmark ***Tovaxin for Early Relapsing Multiple Sclerosis*** (TERMS) Phase IIb clinical study in late 2008
- Data from this clinical study show compelling evidence that Relapsing Remitting MS (RRMS) patients treated with Tovaxin saw overall clinical, MRI, and immunological benefits over the placebo group
- Second confirmatory IIb clinical study in preparation



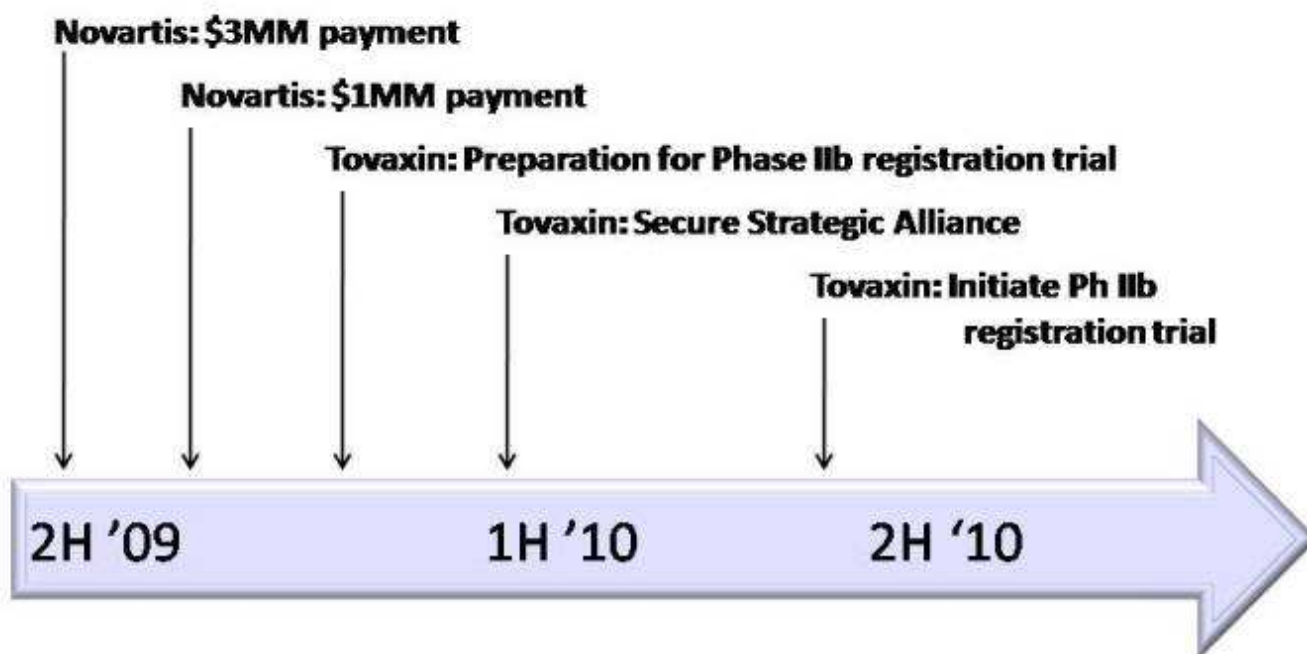
- Timing of second IIb study dependent on securing the necessary capital
 - Partnering discussions progressing



Opexa's Stem Cell Agreement with Novartis

- **Bringing value to an early stage asset**
 - Significant increase in share price on day of announcement
- **Completed a deal with Novartis whereby Novartis acquired Opexa's stem cell technology**
 - Early stage program, demonstrating ability to convert adult peripheral blood mononuclear cells into pancreatic-like cells (monocyte derived islets)
- **Overall deal potentially worth \$50M**
- **Important to Opexa was the upfront and immediate payments totaling \$4 million**
- **Opexa to receive possible clinical and sales milestones + royalties, and manufacturing rights**
- **Allows Opexa to maintain clear focus on Tovaxin (Tovaxin/T-cell technology was not included as part of the Novartis agreement)**
- **\$4 million to contribute to preparation and planning of Tovaxin clinical development**

Opexa's 12 Month Growth Strategy



Stock Information

- Stock Exchange NASDAQ
- Stock Symbol OPXA
- Basic Shares Outstanding 12.3 million
- Current Market Capitalization ~\$50-60 million
- 52 week range \$0.09-\$5.66

Summary

- **Opexa planned recovery has gone well, achieving key milestones in a challenging economic climate**
- **Focus is on progressing Tovaxin through clinical development**
- **Partnership discussions are ongoing**
- **Tovaxin is well positioned in MS - a critical market with significant unmet need and market potential**
- **Tovaxin competitive advantage**
 - Setting new benchmarks in safety
 - Lowest ARR of most marketed drugs, improvement in disability and possible neuroprotection
 - Personalized therapy targeting specific root cause of MS
 - Patient compliant: 5 sc injections/year – addresses patient compliance concerns
 - Streamlined process; leverages standardized distribution and logistic channels, strong margins projected at launch