

## **OPEXA** THERAPEUTICS

# The Woodlands, Texas (OPXA)

Corporate Presentation
C.E. Unterberg, Towbin Life Sciences Conference

October 31, 2006

### 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," "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.

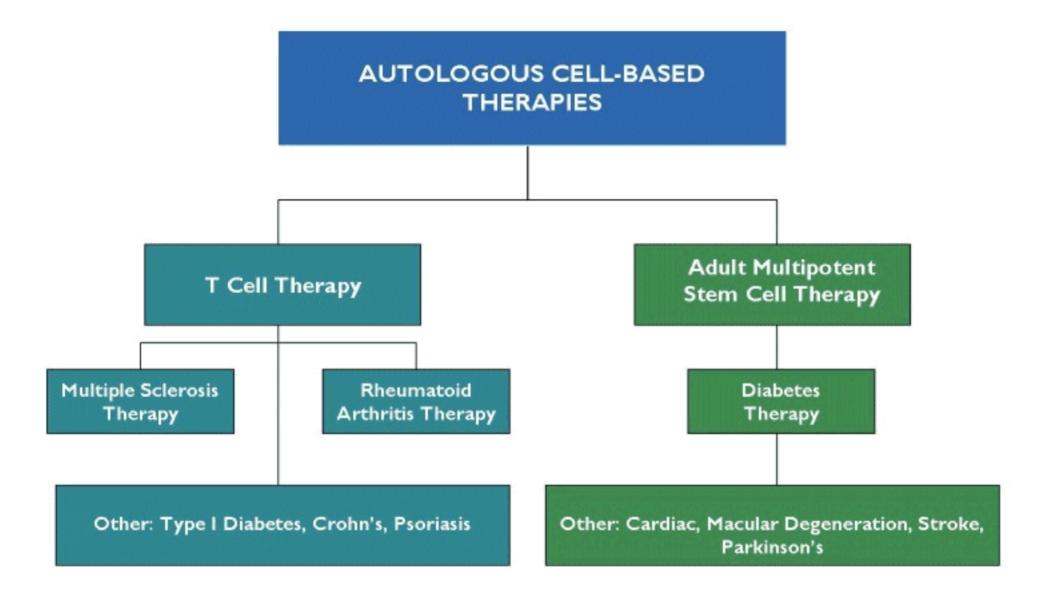
The projected financial information was not prepared with a view toward complying with published guidelines of the Securities and Exchange Commission or the guidelines established by the American Institute of Certified Public Accountants regarding projections, nor is the projected financial information 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.

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## **Technology & Therapeutic Overview**





## **Therapeutic Platforms - Market Potential**

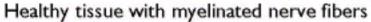
	Target	U.S. Patients	World Wide Drug Market (millions)	Status
T-Cell Platform	Multiple Sclerosis	400,000	\$5,300	Phase IIb
	Rheumatoid Arthritis	2,100,000	\$5,000	Pre-IND
	Type I Diabetes	1,100,000	\$3,000	Research
Stem Cell Platform	Type I Diabetes	1,100,000	\$3,000	Preclinical

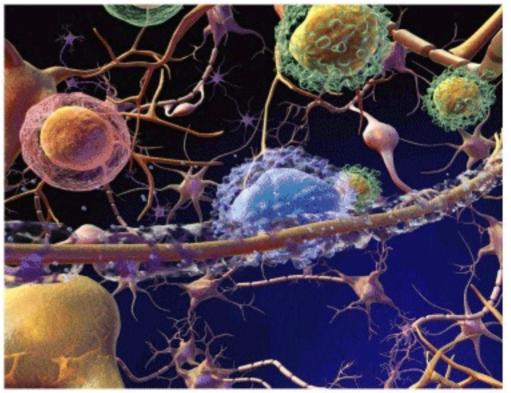


# Myelin Reactive T-Cells in Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, progressive, degenerative disorder that affects nerve fibers in the brain and spinal cord. A fatty substance (called **myelin**) surrounds and insulates nerve fibers and facilitates the conduction of nerve impulse transmissions. Myelin Reactive T-cells infiltrate the healthy tissue of the CNS. A cascade of events lead to demyelination of axons which causes nerve impulse transmissions to diffuse into the tissue.





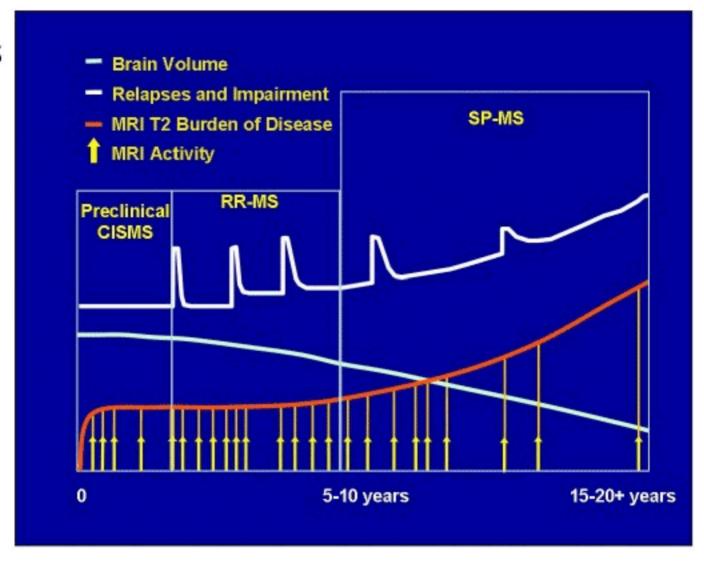


Demyelinated nerve fibers



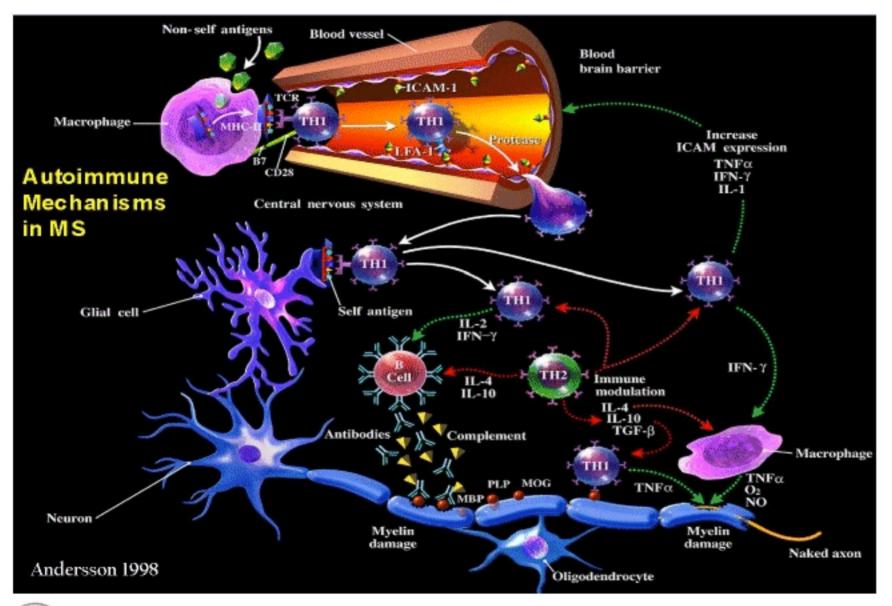
### Four Types of Multiple Sclerosis

- Chronic disease of the CNS
- Pre-MS = Clinically Isolated Syndrome
- Relapsing Remitting MS
- Secondary Progressive MS
- Primary Progressive MS
- Environment, genetic predisposition, antigenic mimicry, infections as contributing factors



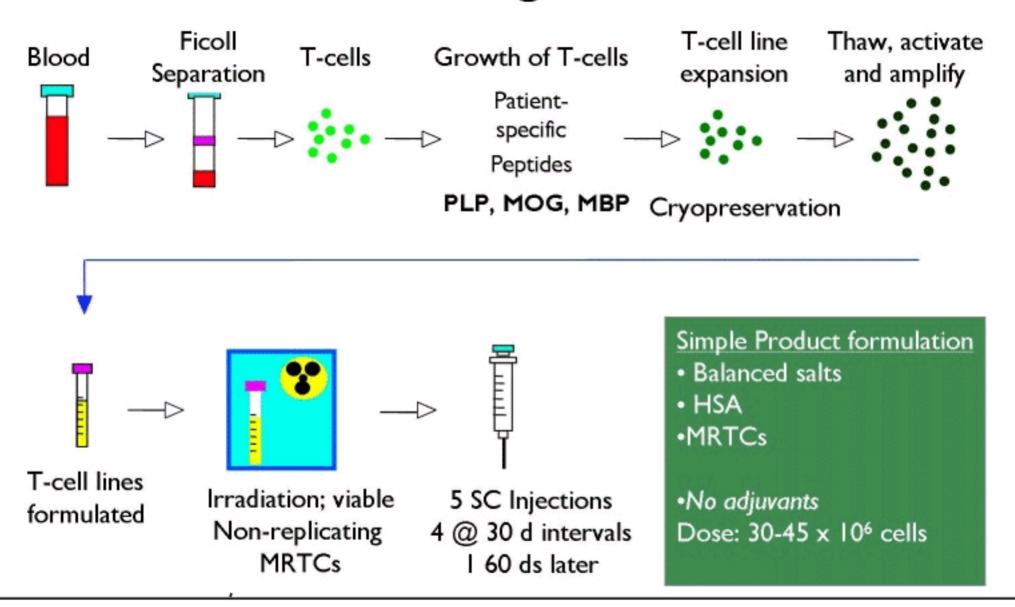


### T-Cell Therapy





### **Tovaxin Manufacturing Process**





# **Chronology of Clinical Studies**

Therapy version	Investigator	T-Cell Targets	Patients	Results
I	Zhang: Baylor, Houston	MBP:  2 peptides	114	40% relapse reduction No safety issues
2	Sheba Medical Center: Israel	MBP/MOG; 4 peptides	20	55% relapse reduction No safety issues
3	Tovaxin Phase I/II - Loftus: Houston	MBP/MOG/PLP; 6 peptides	15	93% relapse reduction No safety issues
4	Tovaxin Phase IIb Fox: Multi-site	MBP/MOG/PLP; Variable patient- specific	150	Study Progress Sites 30 Patients Screened >70 First Randomization Q4 06



#### Phase I/II Studies

#### (Annualized Relapse Rate Reduction)

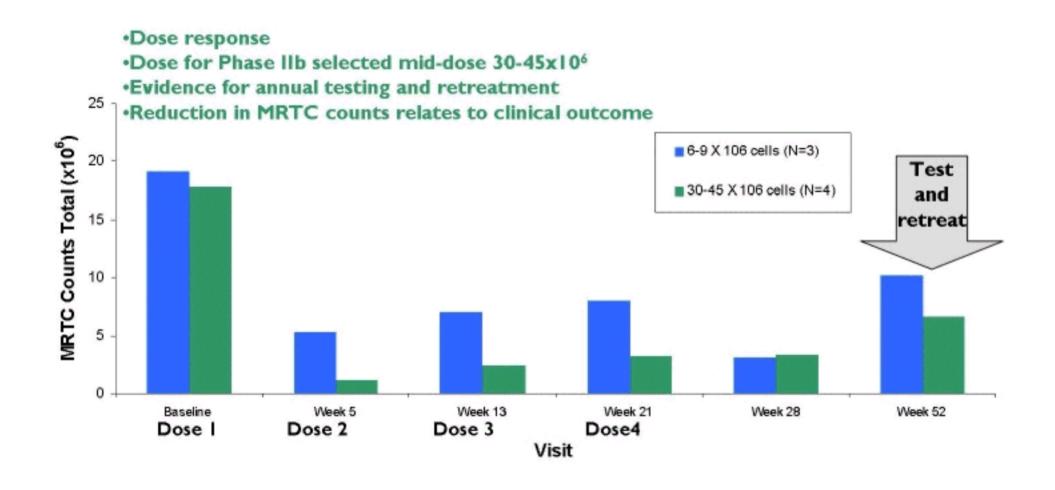
Patient Group	Time Period	Annualized Relapse Rate <sup>c</sup>	% Reduction
Dose escalation	Pre-vaccine <sup>a</sup>	1.39	
(N=7)	Post vaccineb	0.14	94
Extension study	Pre-vaccine <sup>a</sup>	1.42	
(N=8)	Post vaccine <sup>b</sup>	0.12	91
RRMS	Pre-vaccine <sup>a</sup>	1.62	
(N=II)	Post vaccineb	0.18	90
SPMS	Pre-vaccine <sup>a</sup>	0.92	
(N=4)	Post vaccineb	0.00	100

<sup>&</sup>lt;sup>a</sup> Based on 24 months prior to first vaccination; <sup>b</sup> Based on 6 and 12 months after first vaccination;



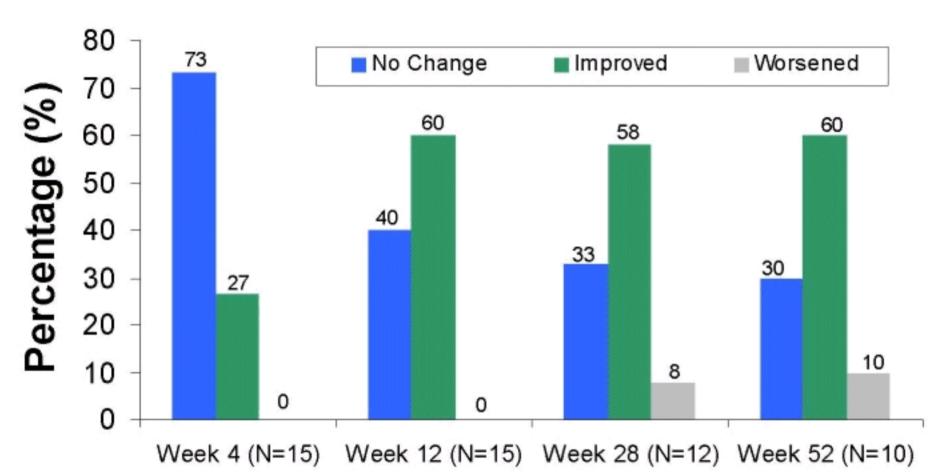
<sup>&</sup>lt;sup>c</sup> Primary endpoint for Phase III

## Average MRTC Total Counts Over Time By Assigned Dose Group





## Change in EDSS – RRMS Subjects



Changes in EDSS Scores by Time Period

Data consolidated from both Phase I/II Studies



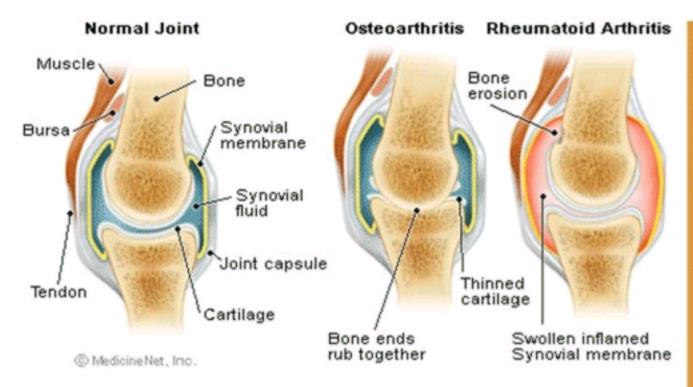
### **Advantages of Tovaxin**

Therapy**	Effectiveness*	Safety	Admin
TOVAXIN	93%	Injection site Rx (25%) Minimal systemic Rx	4-5x/yr (SC)
Avonex	43%	Flu symptoms (49%) Headache (58%)	Weekly (IM)
Betaseron	38%	Flu symptoms (60%) Headache (57%)	Every other day (SC)
Copaxone	75%	Inj. site R× (66%) Infection (50%)	Daily (SC)
Rebif	51%	Flu symptoms (56%) Headache (65%)	3×/wk (SC)
Tysabri	67%****	Infusion R×ns (22%) Infections (18%) Headache (35%) Deaths	l×/mo (IV)

\*Relapse rate reduction on drug vs. patient history; \*\*Novantrone not shown; \*\*\* Versus placebo: SOURCE: 15<sup>th</sup> Meeting of European Neurological Society, June 2005



#### Rheumatoid Arthritis – T Cell Platform

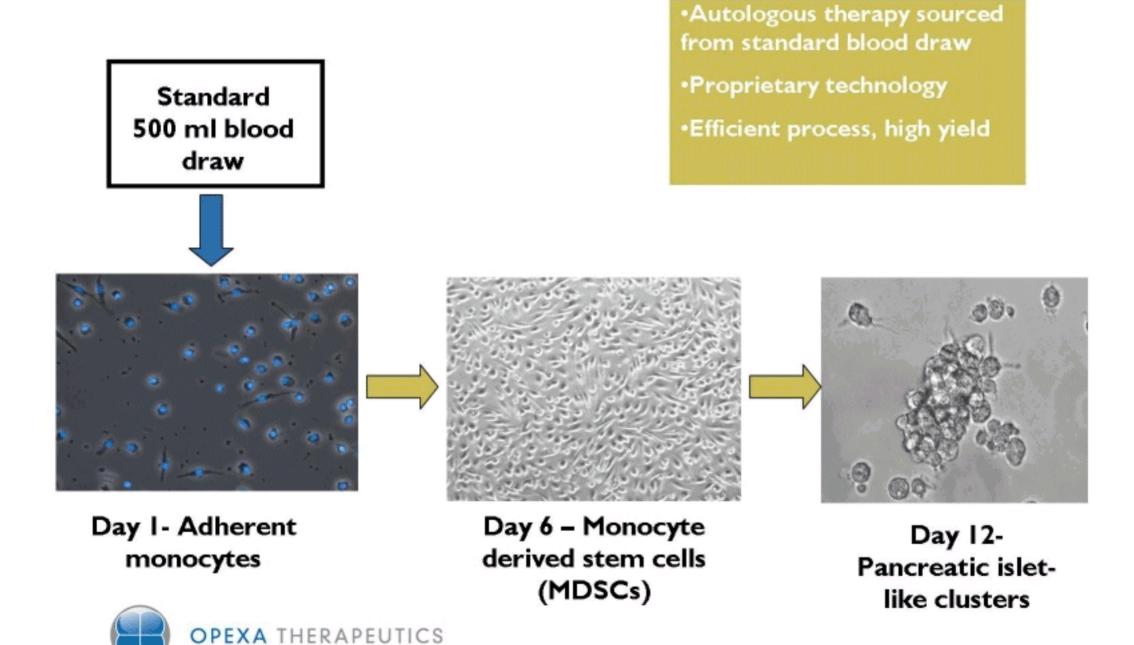


Normal and Arthritic Joints

- •Large Market >\$5Billion
- Unmet Clinical Need
- •T-Cell Therapy similar to Tovaxin:
  - Pathogenic T-cell
  - •Isolate T-cells from synovial fluid
  - Attenuated T-cells injected SC into patients
  - Minimal side effects expected

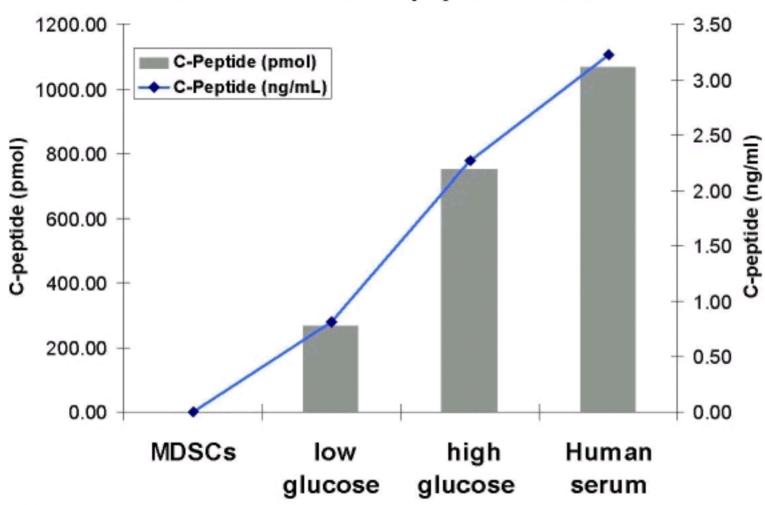


## Stem Cell Therapy



### Pancreatic Islet Cells – C-Peptide Levels

#### Measurement of C-peptide levels





## **Current Stem Cell Technologies**

Points to	Peripheral blood		Umbilical		
Consider	monocytes	Bone marrow	cord	Embryonic	Cadaveric
Availability	Easily obtained	Obtainable	Limited	Restricted	Limited
		Bone marrow		252	Requires 2
		aspiration		250 embryos per	donors per
Collection	Blood Draw	Invasive	Only at birth	cell line	transplant
	High Yield with		Low yields	High yields,	
	short culturing	High Yield with longer	and requires	unable to control	
Therapeutic	time, can be	culture time, can be	additional	growth - tumor	
dose yield	cryopreserved	cryopreserved	procedures	issues	Difficult
		• • • • • • • • • • • • • • • • • • • •		Brief	
				(unable to	
Ease of				control	
expansion	Brief	Long	Long	differentiation)	Poor
		Allogenic or	Allogenic or		
Type of use	Autologous	Autologous	Autologous	Allogenic	Allogenic



### **Management Team**

#### David McWilliams, CEO, Director

- 30 years of experience with private and public biotechnology companies
- President and CEO of Encysive Pharmaceuticals (ENCY) for 10 years raising \$250 million in public financing and corporate partnerships
- Licensed, developed, and received FDA approval for an anticoagulant (Argatroban which was launched by GlaxoSmithKline in 2004)

#### Jim Williams PhD, COO

- 10 years heading up regulatory affairs at OSIRIS, PowderJect, Wyeth, Aventis
- 4 years FDA, CBER, OVRR
- 20 years basic and applied research for NIH, NIAID, US Navy, FDA, US Public Health Service
- I 30 publications in the areas of infectious diseases, vaccinology, oncology and 4 books

#### Lynne Hohlfeld, CFO

- Over 20 years of financial management experience, certified public accountant
- Held positions of COO, CFO and controller in private and public life science companies –Bacterial Barcodes, Spectral Genomics, LifeCell (LIFC)

#### **Donna Rill, VP Operations**

 30 years of extensive clinical and research cGMP laboratory experience with cell therapy at St. Jude's Hospital, Baylor College of Medicine and Opexa Pharmaceuticals



### Financial Summary

**Financing Proceeds** 

-April 2006 Financing	\$23M
	<b>4-0</b>

Cash as of June 30, 2006 \$20M

Headcount 34

Cash Survival Q3 2007

6.7M shares

Outstanding Common Stock

- -I-for-10 Reverse split June 2006
- -Nasdaq Global Market Listing September



#### **Opexa Near Term Milestones**

#### 2H 2006

- Tovaxin Phase I/II study complete
- Phase IIb First patient Randomized
- Stem Cell Diabetes Preclinical Study
- Publication of RA paper with China clinical data
- FDA Pre-IND meeting for RA T cell program
- FDA Pre-Pre-IND meeting for diabetes

#### IH 2007

- Tovaxin Phase IIb fully enrolled
- IND filed for RA
- IND filed for diabetes

#### 2H 2007

- Tovaxin Phase IIb Descriptive analysis
- Initiate Phase I for Diabetes

