



Opexa Therapeutics, Inc.
(NasdaqCM:OPXA)

July 15, 2014
Target Price: \$6.00
Recent Price: \$1.64

Market Data

Fiscal Year	December 31
Industry	Biotechnology
Market Cap	\$52.9M
Price/Earnings (ttm)	N/A
Price/Book (mrq)	3.1x
Price/Sales (ttm)	37.9x
Institutional Ownership	10.4%
Insider Ownership	5.7%
Shares Outstanding	27.5M
Float	24.6M
Avg. Daily Vol. (3 mos.)	228,824

As of July 15, 2014

Income Snapshot

	TTM
Revenue	\$1.4M
EBITDA	(\$11.0M)
Net Loss	(\$16.1M)

Balance Sheet Snapshot

	MRQ
Cash	\$19.7M
Debt	\$0.0M

Company Overview

Opexa Therapeutics, Inc. (NASDAQ: OPXA) is a publicly-traded biotechnology company dedicated to the development of patient-specific immunotherapies for the treatment of autoimmune diseases. Its lead product candidate, Tcelna® (imilecleucel-T), has the potential to address the significant unmet medical needs of the large multiple sclerosis population. Tcelna is an autologous T-cell immunotherapy being developed for the treatment of multiple sclerosis (MS) and is specifically tailored to each patient’s immune response profile to myelin. Tcelna targets the root cause of MS as it is designed to reduce the number and/or functional activity of specific subsets of myelin-reactive T-cells (MRTC) known to attack myelin. To date, five clinical trials have been completed with Tcelna in over 300 subjects with Relapsing Remitting and Secondary Progressive MS. The Company is unique in developing a personalized T-cell vaccine based on this approach and has demonstrated encouraging efficacy and safety data across all MS populations. Opexa has the potential to leverage its proprietary platform technology to treat other autoimmune diseases.

Valuation

Based on an NPV calculation, we come up with a fair value of \$6.00 per share. Our model assumes a very conservative penetration rate of 10.8% by 2024 for North America and 4.5% for the rest of the world outside of Japan. We are also assuming that Merck Serono will exercise its option agreement and have applied royalty step ups at \$500M, \$1B, and \$2B in annual sales. We apply a 15% discount rate and a 35% probability of commercialization of the Company’s therapy.

Investment Highlights

- Secondary-progressive multiple sclerosis (SPMS) clinical trials represent a high-reward, high-risk value proposition for investors.
- Lead Program: Tcelna demonstrates impressive clinical trial results that provide the basis for trials in SPMS.
- Phase 2b clinical trial for SPMS is fully enrolled; top-line results expected in mid-2016.
- Mechanism of action (MoA) reduces harmful MRTCs; this MoA could stabilize MS and possibly enable remyelination.
- Tcelna is prepared using an efficient single-cycle manufacturing process.
- Fast Track designation granted by FDA for Tcelna in SPMS.
- Option agreement with Merck Serono worth up to \$220 million in additional payments.
- Limited approved treatment options available for SPMS; current treatments have limitations.

Investment Highlights

Secondary-progressive multiple sclerosis (SPMS) clinical trials represent a high-reward, high-risk value proposition for investors. We believe that OPXA's SPMS phase 2b clinical trial represents a high-reward, high-risk value proposition for investors. SPMS represents an estimated \$7 billion market with only one approved therapy, which is associated with serious safety issues. If OPXA's remaining clinical trials show superior efficacy and safety compared to existing treatments, the Company will have the potential for a blockbuster drug. However, there is significant risk to investors given the larger cost and length of clinical trials, meaning that the therapy would not be eligible to reach the market until 2020 at the earliest. The characteristics of the clinical trial can benefit OPXA over the long-term, as we believe that fewer companies overall will want to enter clinical trials in SPMS, giving OPXA less competition over the long-term and ultimately allowing them to capture more of the SPMS market.

Lead Program: Tcelna demonstrates impressive clinical trial results that provide the basis for trials in SPMS. In late 2008 Opexa completed a Tovaxin for Early Relapsing Multiple Sclerosis (TERMS) Phase 2b clinical study designed for patients with Relapsing Remitting Multiple Sclerosis (RRMS), or clinically isolated syndrome (CIS). This trial was a multi-center, placebo-controlled study in 150 patients conducted in 33 cities across the U.S.

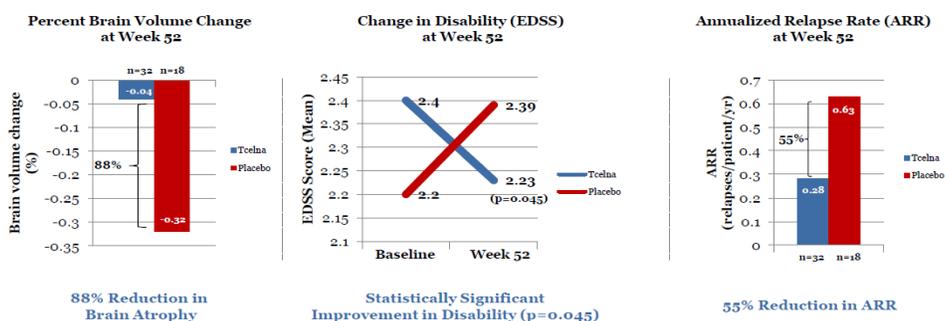
Out of this population of 150 patients, 50 patients (32 treated with Tcelna, 18 placebo) were classified as having a more progressed form of the disease. This subgroup had many positive results, including:

- An 88% reduction in brain atrophy
- A statistically significant improvement in disability (as measured by Expanded Disability Status Scale (EDSS))
- A 55% reduction in the annualized relapse rate (ARR)



TERMS Study - Prospective Analysis in More Active or Progressive Patients

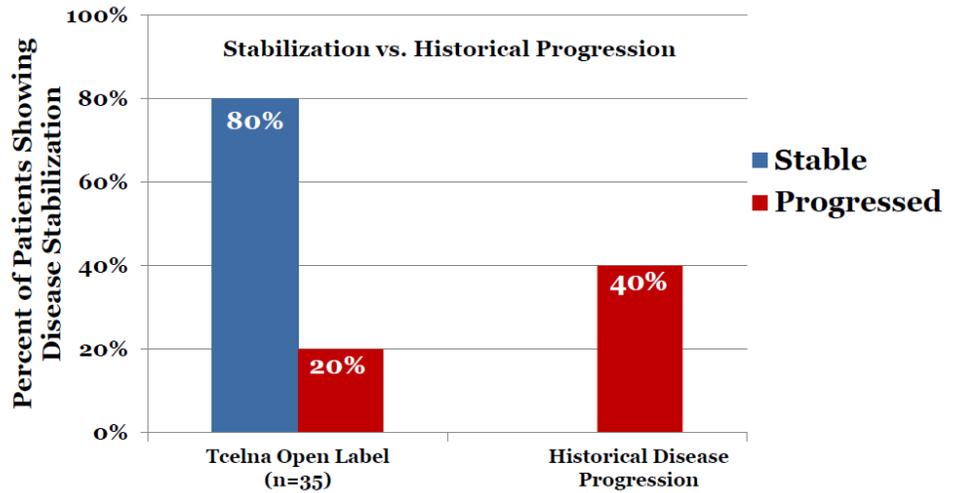
Sub-population of patients (n=50) with more progressed/active disease profile (baseline ARR >1)



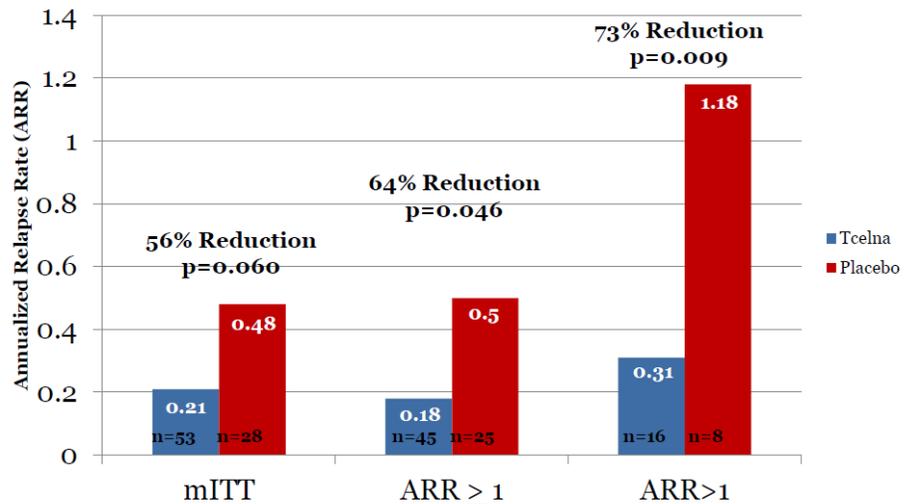
These Data Support Phase IIb Program in SPMS

The trial results for RRMS and CIS provide the support for a phase 2b trial in SPMS. We note that this trial was a 12-month trial, versus the current clinical trial which is a 24-month trial. We believe that the longer trial has the potential to show additional significant data, both related to the possibility of improved efficacy, and conversely, the potential to uncover safety related issues.

Digging deeper into the data, both from the TERMS study and other clinical trials/studies shows some interesting data points that provide further evidence of the potential efficacy of OPXA’s drug. Previous studies have indicated that over a 2-year period, 80% of subjects treated with Tcelna show no further disease progression, as opposed to the historical control group, of which only 60% showed no further disease progression:



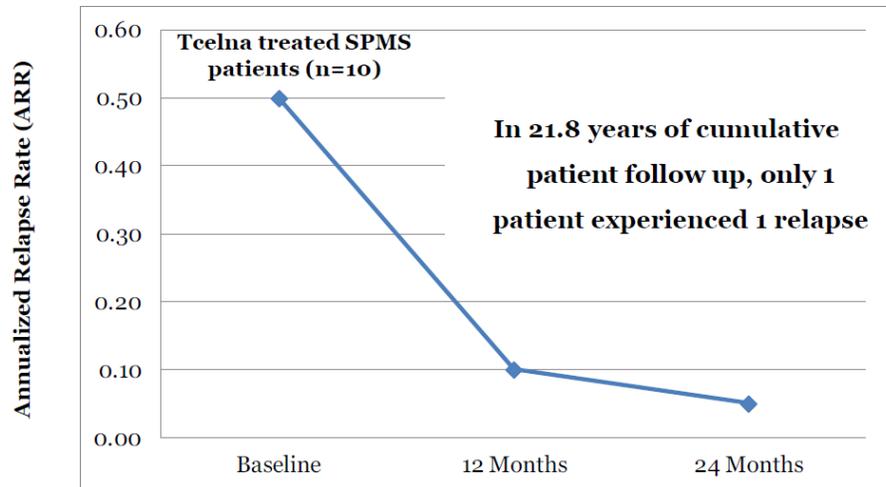
Taking into account only the TERMS clinical trial subjects that did not have previous disease modifying treatment showed a greater reduction in the ARR:



Annualized relapse rate in DMT naïve populations. ARR in placebo subjects without previous disease modifying treatment (DMT) experience reflects relapse rates commonly seen in other placebo controlled trials in MS. In this subpopulation, treatment with Tcelna resulted in a 56–73% reduction in ARR compared with placebo.

This subgroup analysis indicates a larger reduction in ARR among patients that did not have previous RRMS/CIS treatments. It stands to reason that patients who previously received treatment would show a lower reduction in ARR, as their disease had already shown some improvement, and the overall efficacy of Tcelna during the trial could be understated. While the sample size for the 73% reduction group is small, the p-value is very strong (p=0.009).

In SPMS patients treated with Tcelna, only one patient has experienced a relapse in 21 cumulative patient years. We note the small sample size (n=10) of this population, but the data is still promising for the Company's large clinical trial for Tcelna:



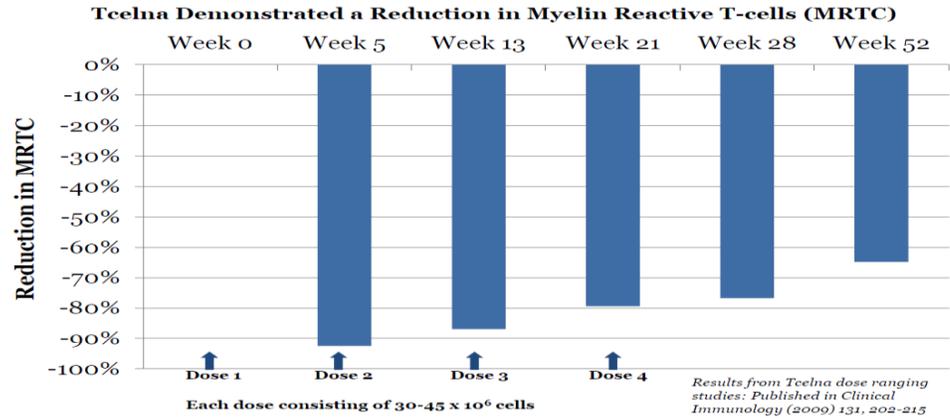
One relapse observed in 21 years of cumulative patient follow up

Phase 2b clinical trial for SPMS is fully enrolled; top-line results expected in mid-2016. On May 13, 2014, Opexa achieved a milestone with the enrollment of 180 patients in its Abili-T Phase 2b trial. The trial is taking place in 35 of the leading clinical sites in the U.S., and can be viewed at the following link: <http://www.opexatherapeutics.com/clinical-trials/abili-t-clinical-study-for-secondary-progressive-multiple-sclerosis-overview/default.aspx>

Opexa is expecting top-line results in mid-2016, corresponding with the end of its 24-month trial. The primary endpoint is whole-brain atrophy, and secondary endpoints include sustained progression measured by EDSS, time to sustained progression, T2 lesions progressing to hypointense lesions, change in EDSS, ARR, change in MSFC assessment of disability, and change in symbol digit modality test.

Mechanism of action (MoA) reduces harmful MRTCs; this MoA could stabilize MS and possibly enable remyelination. As exhibited in the following chart, Opexa's MoA has shown the ability to reduce MRTCs:

Mechanism of Action Reduction in Myelin Reactive T-Cells



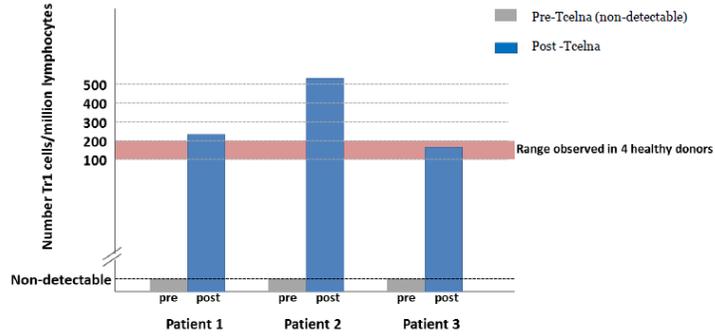
We believe that over a 2-year period, additional doses and additional treatment time could lead to further reduction in MRTCs. If the Company’s hypothesis is correct, this MoA could cause a compounding effect over time that makes the therapy more effective, as additional doses are administered and over the general passage of time. Dosing in year one will occur slightly earlier than previous dosing schedules (at week 0, week 4, week 8, week 12, and week 24), and this will follow a similar dosing schedule in year two (at week 52, week 56, week 60, week 64, and week 76).

Tcelna’s MoA can reduce the destruction of myelin through the reduction of harmful MRTCs that destroy the myelin in the central nervous system, which is the underlying cause of Multiple Sclerosis. Over time, the reduction in MRTCs could improve patient outcomes and condition by allowing oligodendroglia cells to remyelinate axons in the central nervous system, leading to improvements in areas such as percent of brain volume change, EDSS scores, and the annualized relapse rate.

In addition to the attenuated, patient specific MRTCs, using Tcelna’s therapy has the potential to induce up-regulation of regulatory cells (Foxp3+ and Tr1 cells) that reduce the inflammation and provide possible neuroprotection against MS, should the cells gain entry in to the central nervous system. Opexa has documented observations of the increase in Tr1 cells from non-detectable to detectable levels in their patients. These Tr1 cells have demonstrated increases to levels similar to those of healthy donor samples, with no statistical differences.

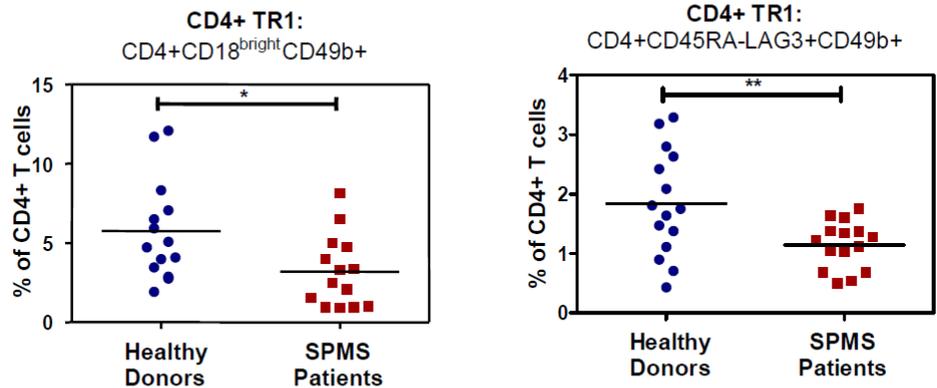
Observations

- Increase in Tr1 cells from non-detectable to detectable levels in Tcelna treated patients (n=3)
- Increase in Tr1 cells to a level similar to those observed in healthy controls (n=4)
- p=0.971 (i.e. no statistical difference between healthy donor and post-treatment TR1 dose levels)



While the sample size here is small, the data is very encouraging. SPMS patients have shown a reduced frequency of IL-10 secreting TR1 cells, and improving the amount of TR1 cells up to the level of a healthy patient could help stabilize SPMS.

SPMS subjects have a reduced frequency of IL-10 secreting TR1 cells

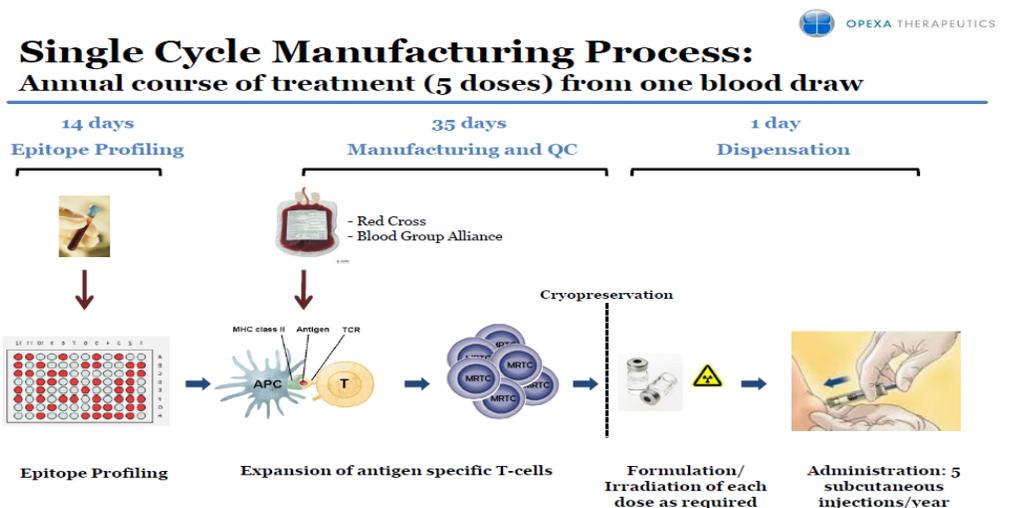


* (p=0.02)

** (p=0.01)

ACTRIMS 2013 Poster: Profiling of Secondary Progressive MS by Multicolor Flow Cytometry
 Lauren W Collison, Ph.D; Chris L Ayers, Ph.D., Jordan L Harrell, MBE; Don Healey, Ph.D.

Tcelna is prepared using an efficient single-cycle manufacturing process. As the following chart shows, a single, annual dose of Tcelna can be prepared in 50 days:



From a single dose of blood, Opexa performs epitope profiling by screening for MRTCs and maps/analyzes 109 peptides from all three key myelin proteins (MBP, MOG, PLP). This step takes 14 days. The Company then uses its proprietary ImmPath™ process to generate a patient specific therapy. The manufacturing is done according to GMP/GTP standards. Manufacturing and quality control take approximately 35 days. Giving the dose to the patient takes about one day. This process produces five doses, which are given to the patient during the year. At the end of the year, Opexa performs the patient's epitope profiling again, makes any needed adjustments based on the patient's new profile, and manufactures a new dose for the patient.

The Company performs manufacturing in its GMP-certified facility. Over 850 Tcelna doses have been made at this facility, ensuring that the process is reproducible and consistent. We also believe that this experience bodes well for potential commercialization, as Opexa is gaining valuable experience with regards to quality manufacturing that can ultimately help control the cost of goods sold and lead to a high gross margin therapy.

Fast Track designation granted by FDA for Tcelna in SPMS. Given the need to find a viable, safe therapy for SPMS, the FDA has granted Tcelna a fast track designation. Currently, mitoxantrone is the only U.S. FDA approved therapy for SPMS and although it has demonstrated positive efficacy it is also associated with serious side effects, including nausea/vomiting, alopecia (hair loss), amenorrhea (absence of menstrual periods), urinary tract infections, upper respiratory tract infections, leukopenia (low white blood cell count), cardiotoxicity, myelosuppression (decrease in bone marrow activity), and in rare cases, leukemia. This is driving the need for a treatment that is both effective against SPMS and has an acceptable side effect profile. In both the TERMS study for RRMS and CIS (150 patients) and the phase 1/2 patients (36 patients) that have been treated for SPMS, the Tcelna therapy was shown to be well tolerated with a favorable safety profile. The most common adverse event was a mild to moderate injection site reaction. Safety is very important as serious side effects diminish the overall benefit of a therapy and could argue against its use.

The FDA has also recognized that in addition to the relative safety Tcelna provides for SPMS patients, there is a need for a timely solution. It is estimated that 50% of patients who live with Relapse Remitting Multiple Sclerosis (most common form) will convert to SPMS within 10 years of diagnosis. Therefore given the lack of viable alternatives for SPMS, the fast track designation may help lower hurdles for the Company to pass clinical trials.

Option agreement with Merck Serono worth up to \$220 million in additional payments. Opexa has entered into an option agreement with Merck Serono, one of the largest pharmaceutical companies in the world, which generated 11.1 billion euros in revenue in 2013. Should Merck Serono exercise its option, it would be responsible for funding the further development of Tcelna through phase 3 and commercialization to market. This would be a significant cost which Opexa would not have to bear. Additionally, if successful, Opexa could receive up to \$220 million

in milestone payments, payable as follows (Opexa has already received a \$5 million option fee from Merck Serono):

- Option exercise worth \$25 million for starting phase 3, or \$15 million for another phase 2 trial
- \$35 million for FDA filing, approval, and commercialization in U.S.
- \$30 million for EU filing, approval, and commercialization in at least three countries
- Relapsing Remitting MS development and commercialization of up to \$40 million
- One-time commercial milestones of up to \$85 million

Opexa will also receive 8%-15% royalties, with step-ups when annual sales are greater than \$500 million, \$1 billion, and \$2 billion. With this agreement, Opexa still retains development and commercialization rights for Japan. OPXA also retains a co-development funding option which could result in the Company receiving increased royalties from Merck Serono and complete rights to all other possible disease indications. If the option agreement is executed and Opexa makes it through its projected commercialization timeline, this agreement could potentially fund all of the development of the Tcelna therapy. Also, through the royalty agreement, Opexa could take advantage of Merck Serono's superior commercialization expertise, ultimately saving expenses on what could be an expensive sales and marketing plan.

Merck Serono currently markets Novantrone® (mitoxantrone), the only FDA approved drug for SPMS (Novantrone is not approved for SPMS anywhere outside the U.S.). Merck Serono is one of the foremost experts in the SPMS space, and we believe that the options agreement they have entered into with Opexa indicates the potential they see in Tcelna.

Personalized T-cell immunotherapy platform with the potential to address multiple therapeutic areas. Opexa has also announced that its T-cell immunotherapy platform has the potential to treat additional autoimmune diseases. OPXA has been evaluating various autoimmune diseases and have had discussions with thought leaders and clinicians on how T-cell immunotherapy could be used to treat disease indications. While nothing concrete has yet been announced, Opexa currently retains all rights to other possible disease indications. The announcement of a second disease indication could add further value to OPXA's stock.

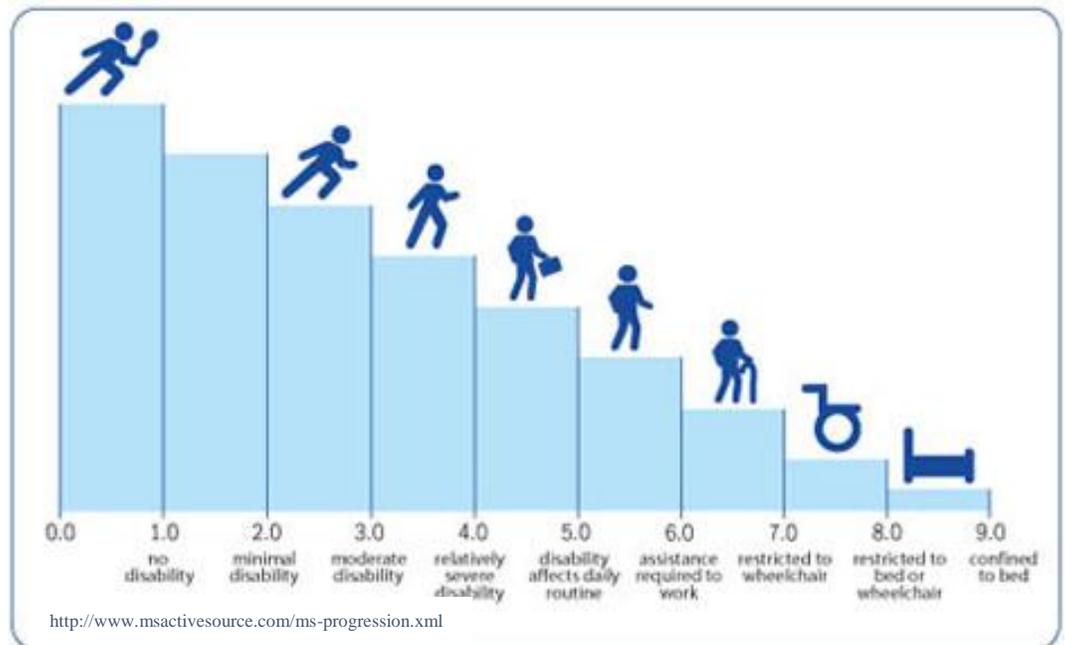
Strong patent portfolio of 50 issued patents both domestic and internationally. Opexa has protected its technology with 50 surrounding patents that have been issued for domestic and international use. We believe that these patents will provide strong protection for the Company's IP domestically, internationally, and in different potential therapeutic indications.

Market

\$7 billion North American market for SPMS. Multiple Sclerosis (MS) is a chronic disease of the central nervous system. The disease attacks areas in the brain, optic nerves, and spinal cord that severely affect basic human functions. MS is currently

the most common neurological disorder in adults, affecting approximately 2.5 million individuals worldwide. In the U.S. there are 450,000 people with MS and about 200 more diagnosed every week.

Doctors are able to determine if the disease is progressing by using a scale called the Expanded Disability Status Scale (EDSS). EDSS is a way of measuring physical disability. When measured, people with RRMS tend to have a score of four or less. People with SPMS usually have a score of six or higher, meaning that some form of assistance is needed to walk. People with RRMS who reach a level of 4 to 5.5 (indicated by the inability to walk more than 500 meters without resting) usually develop SPMS within a fairly short time period. The following chart from www.msactivesource.com gives a good overview of the quality of life of people depending based on their EDSS.



Market reports estimate that of the 2.5 million patients with MS, about 85% have RRMS with 50% converting to SPMS within 10 years of their diagnosis. The transition to SPMS is very common for patients, as the disease shifts from an after-effect of the nerve damage done earlier in the disease. In North America there are currently 150,000 patients affected by SPMS, giving an estimated market size of \$7 billion.

Limited approved treatment options available for SPMS; current treatments have limitations. Novantrone (mitoxantrone), a chemotherapeutic agent, is the only medication that has been approved by the FDA specifically for SPMS.

Marketed by Merck Serono, Novantrone is the chemotherapeutic agent that most physicians will likely recommend. Novantrone was approved for use in MS in 2000. After a review of all the available evidence, the original report of the Therapeutics and Technology Assessment Subcommittee (TTA) in 2003 concluded that Novantrone probably reduced clinical attack rates, MRI activity, and disease progression. The therapy proved to show effectiveness but it also was known to cause

adverse side effects. Some of the more common side effects include shortness of breath, cardiotoxicity, nausea/vomiting, alopecia (hair loss), irregular heartbeat, urinary tract infections, upper respiratory tract infections, leukopenia (low white blood cell count), cardiotoxicity, myelosuppression (decrease in bone marrow activity), and unusual bleeding. Subsequent reports of decreased systolic function, heart failure, and leukemia prompted the FDA to institute a “black box” warning in 2005.

Valuation

Based on an NPV calculation, we come up with a fair value of \$6.00 per share for Opexa. This valuation only takes into account sales for Tcelna for SPMS, and assumes that Merck Serono exercises its option agreement.

U.S. Market	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Total Patients with Multiple Sclerosis	450,000	463,500	477,405	491,727	506,479	521,673	537,324	553,443	570,047	587,148	604,762	622,905	641,592	660,840	680,665	701,085	722,118
Secondary-Progressive MS Patients (N.A.)	157,500	162,225	167,092	172,105	177,268	182,586	188,063	193,705	199,516	205,502	211,667	218,017	224,557	231,294	238,233	245,380	252,741
Total Patients with Multiple Sclerosis	472,500	486,675	501,275	516,314	531,803	547,757	564,190	581,115	598,549	616,505	635,000	654,051	673,672	693,882	714,699	736,140	758,224
Secondary-Progressive MS Patients (RoW ex. Japan)	165,375	170,336	175,446	180,710	186,131	191,715	197,466	203,390	209,492	215,777	222,250	228,918	235,785	242,859	250,145	257,649	265,378
Penetration % (N.A.)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.8%	3.6%	7.2%	9.4%	10.8%	11.3%	11.8%	12.3%	12.3%	12.3%	12.3%
Patients treated (N.A.)	0	0	0	0	0	0	3,385	6,973	14,365	19,235	22,784	24,557	26,417	28,366	29,217	30,093	30,996
Penetration % (RoW ex. Japan)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.5%	3.0%	4.0%	4.5%	5.0%	5.5%	6.0%	6.0%	6.0%	6.0%
Patients treated	0	0	0	0	0	0	0	3,051	6,285	8,631	10,001	11,446	12,968	14,572	15,009	15,459	15,923
Revenue per patient	\$0	\$0	\$0	\$0	\$0	\$0	\$60,000	\$61,800	\$63,654	\$65,564	\$67,531	\$69,556	\$71,643	\$73,792	\$76,006	\$78,286	\$80,635
Annual Sales (\$MM)	\$0	\$0	\$0	\$0	\$0	\$0	\$203	\$619	\$1314	\$1827	\$2214	\$2504	\$2822	\$3168	\$3361	\$3566	\$3783
Royalties received	0%	0%	0%	0%	0%	0%	8%	10%	12%	12%	15%	15%	15%	15%	15%	15%	15%
Total Royalty Revenue to Opexa (\$MM)	\$0	\$0	\$0	\$0	\$0	\$0	\$16	\$62	\$158	\$219	\$332	\$376	\$423	\$475	\$504	\$535	\$567

Discount Rate (15.0%)	
NPV (\$MM)	\$574.8
Probability of commercialization	35%
NPV	\$201.2
Diluted Shares Outstanding	33,188,416
NPV Per Share	\$6.06

The Company’s lead product, Tcelna, is initially in clinical trials to treat SPMS. There are approximately 450,000 people in North America who have MS, and approximately 35% of patients with MS have SPMS. Given the current development timeline (assuming top-line results reported in 2016 and assuming the Company needs to run an additional phase 3 clinical trial for two years). Our model assumes a very conservative penetration rate of 10.8% by 2024 for North America and 4.5% for the rest of the world outside of Japan. We are assuming a cost per therapy of \$60,000, in line with current treatment costs for SPMS. We are also assuming that Merck Serono will exercise its option agreement and have applied royalty step ups at \$500M, \$1B, and \$2B in annual sales. We apply a 15% discount rate and a 35% probability of commercialization of the Company’s therapy. Dividing this total by the current diluted shares outstanding of 33.2 million gives a per share value of \$6.06.

Using a sensitivity analysis, we have provided multiple scenarios using various discount rates and commercialization probabilities:

		Probability of Commercialization						
		20%	25%	30%	35%	40%	45%	50%
Discount Rate	3%	\$490.5M	\$613.1M	\$735.7M	\$858.3M	\$980.9M	\$1,103.5M	\$1,226.1M
	6%	\$333.5M	\$416.9M	\$500.2M	\$583.6M	\$667.0M	\$750.3M	\$833.7M
	9%	\$230.4M	\$288.0M	\$345.6M	\$403.2M	\$460.8M	\$518.4M	\$576.0M
	12%	\$161.6M	\$202.0M	\$242.4M	\$282.8M	\$323.2M	\$363.6M	\$404.0M
	15%	\$115.0M	\$143.7M	\$172.4M	\$201.2M	\$229.9M	\$258.7M	\$287.4M
	18%	\$82.9M	\$103.6M	\$124.3M	\$145.0M	\$165.8M	\$186.5M	\$207.2M
	21%	\$60.5M	\$75.6M	\$90.8M	\$105.9M	\$121.0M	\$136.2M	\$151.3M
	24%	\$44.7M	\$55.9M	\$67.1M	\$78.2M	\$89.4M	\$100.6M	\$111.8M
	27%	\$33.4M	\$41.8M	\$50.1M	\$58.5M	\$66.8M	\$75.2M	\$83.5M

Risks

There is no guarantee that the Company's phase 2b trial for SPMS will show statistically significant efficacy. There is no guarantee that the Company will achieve its primary endpoint in its current clinical trial. However, the Company has shown promising efficacy data in previous trials in both RRMS and SPMS, which likely increases the probability of successful results from its current phase 2b trial for SPMS.

Merck-Serono may never exercise its option, even if results from SPMS trials are positive. If Merck-Serono does not exercise its option, then OPXA could have to fund further development of Tcelna, which could result in additional equity raises and dilution to shareholders.

Even if statistically significant efficacy and safety are proven, Tcelna may not be commercially viable. There is a risk that it will either be too costly or time consuming to mass produce the Company's Tcelna therapy. However, OPXA has produced over 850 Tcelna doses to date, thus increasing OPXA's manufacturing expertise and decreasing this risk.

Opexa relies on third parties to conduct the clinical trials for Tcelna. If the third parties fail to perform their obligations in a timely or competent manner development and commercialization of the device could be delayed. Delays in this process could also cause the Company to need additional capital.

Management

Neil K. Warma, President and Chief Executive Officer, Director

Neil K. Warma was appointed President and Chief Executive Officer of Opexa Therapeutics, Inc. in June 2008, and is a Member of the Board of Directors. He has more than 20 years of executive level experience in the life sciences industry in the U.S., Europe and Canada. Prior to joining Opexa, Mr. Warma served as President & CEO and a member of the Board of Directors of Viron Therapeutics Inc., a privately-held clinical stage biopharmaceutical company developing a novel class of protein therapeutics. While at Viron, Mr. Warma positioned the company as a leader in the treatment of serious inflammatory disorders.

Previously, Mr. Warma held several senior management positions at Novartis Pharmaceuticals at its corporate headquarters in Basel, Switzerland, in international policy and advocacy and in global marketing. In addition, Mr. Warma was co-founder and President of MedExact USA, Inc., an Internet company providing clinical information and services to physicians and pharmaceutical companies, which was ultimately sold to a large public European firm.

Mr. Warma obtained an honors degree specializing in neuroscience from the University of Toronto and an International M.B.A. from the Schulich School of Business at York University in Toronto. He currently serves on the Board of Directors of the Biotech Industry Organization (BIO) Emerging Company Section and on the Board of Directors of BioHouston, Inc.

Karthik Radhakrishnan, Chief Financial Officer

Karthik Radhakrishnan was appointed as the Chief Financial Officer in March of 2013. Mr. Radhakrishnan joined the Company with over 10 years of healthcare capital markets experience and most recently was a Vice President at ING Investment Management in New York. While at ING from 2007 to 2012, he was responsible for healthcare investments in the small & small-mid cap core/growth products that are part of the Fundamental Equity product line. Previously he was the senior analyst at Eagle Asset Management from 2005 to 2007, responsible for large cap growth healthcare. Prior to this, Mr. Radhakrishnan served in various analyst positions including Senior Analyst at The Dow Chemical Company where he worked from 2002 to 2005.

Mr. Radhakrishnan served as a member of the Board of Trustees at Cares Foundation, a non-profit organization serving the Congenital Adrenal Hyperplasia community from 2008 to 2011. Mr. Radhakrishnan is a CFA charter holder and has an MBA degree from the University of Michigan, a Masters in Engineering from the State University of New York and a Bachelors degree from the Indian Institute of Technology.

Donna R. Rill, Chief Development Officer

Donna Rill has nearly 30 years of extensive clinical and research laboratory experience in cell and gene therapy research and clinical application, immunological techniques and assessment, microbiology, diagnostic virology, experimental design and method development and implementation. She brings her expertise in the areas of laboratory development and operations, FDA cGMP (current Good Manufacturing Practices) and regulatory compliance, quality control/assurance system development and clinical Standards of Practice. She has worked to design, and qualify cGMP Cell & Gene Therapy Laboratories, cGMP Vector Production facilities, and Translational Research Labs at St. Jude Children's Research Hospital, Texas Children's Hospital and Baylor College of Medicine.

Ms. Rill has held the positions of laboratory director of cell and gene therapy, Translational Research Center for Cell and Gene Therapy, Baylor College of Medicine; associate scientist/lab manager of the Bone Marrow Transplant Research Laboratory, and the GMP Cell & Gene Therapy Laboratories, St. Jude Children's Research Hospital; education coordinator and clinical instructor, department of clinical laboratory, LeBonheur Children's Medical Center and University of Tennessee Center for the Health Sciences.

Ms. Rill received her B.S. in medical technology from the University of Tennessee, Memphis.

Kenny Frazier, Vice President of Clinical Development and Regulatory Affairs

Kenny S. Frazier has more than 24 years of experience in clinical development including six years in contract research organizations and eighteen years in biotech and large pharma. Prior to joining Opexa, Mr. Frazier served as the head of clinical operations for Lexicon Pharmaceuticals, a mid-sized biopharmaceutical company focused on the development of novel compounds in large and orphan indications. Mr. Frazier managed operational activities of early (FIH) development through late stage phase 3 clinical trials across a number of therapeutic areas including diabetes, oncology, rheumatoid arthritis, and irritable bowel syndrome.

Prior to Lexicon, Mr. Frazier led clinical operations for Tanox, Inc., a small biotechnology company focused on the development of monoclonal antibodies for the treatment of peanut allergies and HIV. Prior to Tanox, Inc., Mr. Frazier spent six years as Director of Clinical Operations with DuPont Pharmaceuticals where he led the development of field operations, drug safety and project management to support clinical trials in cardiovascular, rheumatoid arthritis, HIV, CNS and oncology.

Mr. Frazier holds a Bachelor of Science degree in Biology from Texas Tech University.

Additional Information

Legal: Pillsbury Winthrop Shaw Pittman LLP

Auditor: MaloneBailey, LLP

Transfer Agent: Continental Stock Transfer & Trust Company

[Company Information](#)

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