

What is SB-509 Worth?

Estimating the Net Present Value of SB-509

Recent news flow from Sangamo (SGMO) has been dominated by the CROI presentations (see my previous reports on the [first two](#) and [last two](#) presentations). While the HIV program has been producing exciting data, it has obscured Sangamo's lead program in diabetic neuropathy. With CROI over, it is likely that investors will start to focus back on SB-509 as both the company's lead program and most important upcoming catalyst.

The company has guided for top-line data of the phase II trial (SB-509-901) in the second half of 2011. This trial has taken the insights derived from the SB-509-601 trial to limit the patients to those with moderate to moderately severe diabetic neuropathy. It was this sub-set of patients that seemed to have the most significant response in the 601 trial. While all patients demonstrate nerve fiber growth, the NIS-LL improvements were most pronounced in this moderate severity sub-set. While perhaps too early, this note attempts to quantify the value of SB-509 as if it were approved in the United States for the treatment of moderate and moderately severe diabetic neuropathy patients.

Additional Quality Research

For another take on Sangamo, you can check out this [report](#) at the Biotech Investment Paradigm. It provides a good overview of Sangamo technology and its lead clinical programs.

Contents

Estimating the Net Present Value of SB-509	1
Additional Quality Research	1
How Many Patients?	2
Modeling a Feedback	2
The Net Present Value of SB-509	2
Additional Research	3
Base Case Table	3
Disclaimer	3



How Many Patients?

Perhaps a little ironically, even though the target population is relatively narrow, it is quite difficult to estimate the actual size of the potential patients. The [National Diabetes Statistics](#) estimates that in 2011 25.8 million Americans suffer from diabetes. The key question is how many of those have diabetic neuropathy?

This is actually a much more difficult question than many realize as researchers disagree as to the clinical definition of diabetic neuropathy. [Feldman, Schefner and Dasche](#) have reviewed the literature and found a series of observations. First, eventually 50% of all diabetes patients will develop some form of diabetic neuropathy. Second, the onset of

neuropathy is correlated with the duration of diabetes. Third, in a study of UK diabetics, the incidence of diabetic neuropathy was 28.5%. Fourth, a Pittsburgh Epidemiology of Diabetes Complications Study of 400 patients with diabetes reported that the prevalence of neuropathy in the cohort was 34%. Finally, a separate [study UK diabetics](#) found that the incidence of diabetic neuropathy was 30% in hospitals and 20% in community patients.

So a perusal of the scientific literature gives differing yet similar incidence rates. It seems that 34% is on the high side and 20% is likely low. A reasonable working estimate is perhaps 25%. This might be low but it is better to be slightly more conservative to ensure reasonable expectations.

The base case model would produce sales of \$2.9 billion in 2025 and a net present value (assuming an 9% yearly discount) of \$4.4 billion.

Modeling a Feedback?

If successful, SB-509 will slow if not reverse the course of the disease. While this is great for patients, it also creates a modeling issue as the size of the addressable market will increase over time. In other words, the current incidence rate is an equilibrium based on the rate at which patient progress through the disease severities. When used on patients, SB-509 will slow the movement from the moderate population to the more severe conditions. As such, the 25% incidence rate will likely increase over time.

As a way to model this feedback, the model assumes that after three years of treatment half of the patients treated with SB-509 will not progress and will remain in the treatable sub-set. So if treatments start in 2016, then in 2019 half of those treated patients will remain. In addition, half of the patients treated in 2017 will be added to the 2020 pool and so on. This method allows the model to capture this feedback, while not overplaying its possible effects.

The Net Present Value of SB-509

The base case table on page 3 presents what I believe to be the best estimates as to the value of SB-509. I use the current estimates of the number of diabetics in the United States and assume that 25% have some form of diabetic neuropathy. Of the diabetic neuropathy patients, I assume that 30% are in the treatment sweet spot (I also model a feedback described in the sidebar). Additionally, I assume that the drug hits the market in 2016 (although 2017 would not be too surprising) and that a year of treatment costs \$5,000 (with a 3% yearly increase). Finally, I assume a peak market penetration of 20% reached in 2024. This model would produce sales of \$2.9 billion in 2025 and a net present value (assuming an 9% yearly discount) of \$4.4 billion.

Of course, I am sure people are upset with some of my assumption. If, for instance, you assume an initial price of \$1,000 then the NPV drops to \$900 million but a \$10,000 yearly price tags up the NPV to \$8.9 billion. Keeping my \$5,000 initial price but modeling only a 10% peak penetration reduces the NPV to \$3.4 billion from the \$4.4 billion base case. Of course, a more optimistic assumption of 30% peak penetration increases the NPV to \$8.3 billion. So there is obviously a range of values depending on the assumptions with which you are most comfortable. Clearly, I think my base case represents a reasonable set of values and clearly paints a favorable picture of the value of SB-509 (remember this is only for the United States market).

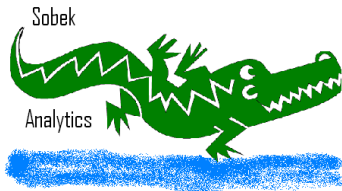
We can take the base case and play with it even more to get a sense of what potential partners might be willing to pay. Keep in mind that this is layering another set of assumptions on the first set of assumptions but it is interesting to play with the numbers to get a sense of value. It seems clear that a partner would not pay the full NPV as there are risks associated with the program. So assume that potential partners assign a 30% chance of success, which would create a risk adjusted NPV of \$1.3 billion. Also, assume that the partner is willing to buy 80% of the value (which would be just over \$1 billion). Again, the partner would not want to pay full price and would expect to get a 25% return on its invested capital. That implies a total commitment of \$850 million to get 80% of US rights of SB-509 for the treatment of diabetic neuropathy. How much would SGMO get in this scenario? Well, that would depend on the costs of trials but a reasonable guesstimate (what is one more assumption between friends?) is \$200 million. So my base case implies that a sensible deal for US rights to SB-509 would be milestones of \$650 million with SGMO royalties at 20% and the partner paying all development costs. Again, one could alter these partnership parameters (perhaps trials cost less or SGMO want a higher percent) or you could use one of the other cases. To me the actual value matters less than understanding how it was calculated. Understanding how these values interact help us better value future deals.

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Additional Research

If you would like access to the files used to create these estimates, you can contact me at dsobek@sobekanalytics.com. I will forward you the excel spreadsheet that contains the base case and some additional models. Feel free to alter the estimates to fit your personal assumptions about the market.

Disclaimer

I am not a certified financial analyst. All the information provided in this report is my interpretation and may contain errors. Please, do not invest based solely on my opinions as it is critical for all investors to conduct their own due diligence and invest in ways that best fit their own needs. In addition, I am long SGMO shares.

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Year	Initial US Market Size ¹	Percent with DN (25%) ²	Moderate Severity Sub-set	Market Penetration	Price of Treatment	Total Sales	Discount	NPV of Revenues*
2011	2580000	6450000	1935000	0	0	0	1	0
2012	26058000	6514500	1954350	0.00	0	0	0.90	0
2013	26318580	6579645	1973894	0.00	0	0	0.81	0
2014	26581766	6645441	1993632	0.00	0	0	0.73	0
2015	26847583	6711896	2013569	0.00	0	0	0.66	0
2016	27116059	6779015	2033704	0.01	5000.00	50.8426112	0.59	30.02205
2017	27387220	6846805	2054041	0.03	5150.00	264.457842	0.53	140.5437
2018	27661092	6915273	2074582	0.05	5304.50	550.230986	0.48	263.1738
2019	27937703	6984426	2095328	0.08	5463.64	858.607942	0.43	369.6026
2020	28217080	7054270	2116281	0.10	5627.54	1190.94646	0.39	461.3971
2021	28499251	7124813	2137444	0.13	5796.37	1548.677	0.35	539.9903
2022	28784243	7196061	2158818	0.15	5970.26	1933.30642	0.31	606.692
2023	29072086	7268021	2180406	0.18	6149.37	2346.42178	0.28	662.6988
2024	29362807	7340702	2202210	0.20	6333.85	2789.69437	0.25	709.1029
2025	29656435	7414109	2224233	0.20	6523.87	2902.11905	0.23	663.9118
						Total NPV of Future Sales*	4447.13	

*These are in millions of US dollars.

¹ Derived from <http://diabetes.niddk.nih.gov/dm/pubs/statistics/>

² Estimated from http://www.medscape.com/viewarticle/467524_2 and <http://www.uptodate.com/contents/epidemiology-and-classification-of-diabetic-neuropathy>

