Section 1 Company Profile

Stem Cells Inc. (Ticker: STEM) is a biotechnology company engaged in the clinical development of its proprietary HuCNS-SC delivery technology to treat diseases of the central nervous system (per their website).
Their most promising research is in the area of treatment of chronic spinal cord injury using transplanted neural stem cells as a therapeutic agent. This report will address only this research area – as a matter of awareness, the company is undertaking other studies as well. Other than the spinal cord therapeutic, the most promising is the study with Age-Related Macular Degeneration (AMD). Initial result of this study is expected mid to late 2015.

Section 2 Timeline

06/2014: Close enrollment to Phase I/II Clinical trial
10/2014: Phase II Proof of concept clinical trial upto 52 subjects.
12/2014: Phase I/II clinical trials complete -- 12 Subjects
12/2014: First subject transplanted in Phase II trial.
10/2015: Phase II Clinical trial complete.
12/2017: 4 Year trial complete???

Section 3 Risks

Cash:

A small biotech always needs source of cash for continuing research. At the end of 2014, the cash balance was 25 Million. With an operating expense expected to be around 35 Million for 2015, we are looking at a 10 million deficit. This can either be raised by acquiring more debt or issuing more equity. In either case, the equity value could be diluted significantly. Furthermore, looking at 2016 and beyond, I see a similar pattern emerging unless the trials produce significant results at the end of 2015.
Most of the generated cash is acquired from issuing new equity. Twenty million plus has been generated by issuing equity every year since 2012. This should theoretically dilute the equity price, however looking at prices at the beginning of each of these years, we see the stock trading at $.83, $1.50, 1.34 and 1.04 in years 2012/13/14 and 15 respectively. This introduces a risk that the company will keep issuing equity without market repercussions – which is unsustainable. Recent downtrend in 2015 however suggests that the company might have a harder time tapping into the equity markets for more cash.

Phase I/II trial results:

The data from the trial (at the end of year 1), in our opinion, provides lackluster results. Looking at the 4 test results (Out of 12) – so assuming 8 out of 12 subjects didn't have any changes to their initial condition – they do not seem to provide overwhelming evidence that the cells actually restore normal functionality after the transplant.
Subject 1 (Classified as AIS A, defined to be completely impaired with no motor or sensory function) shows reduced sensation to touch.
Subject 3 (also classified as AIS A), shows dramatic improvement in the feel of a light touch in his thoracic region.
Subject 4 (Classified as AIS B, defined to have preserved sensory function but not motor function), shows no improvement in the sensory function area.
Subject 7 (Classified as AIS B) showed dramatic improvement in the sensory function.
Data on Motor function is not available.

Overall results suggest that there was no deterioration of existing conditions; however significant improvement from the base condition was not seen. This study lasted for a year. Longer 4 year study in progress with these subjects – however, it is not expected that the outcome will be any different than the outcomes reported in the first year.

Phase II Clinical trial expectations:

If Phase I/II trial is any indication, we are not expecting much out of this clinical trial. However, we foresee the results of this study being the biggest catalyst for the stock price (and for the company, for that matter!).

Takeover Target:

Depending on the result of the Phase II clinical trial outcome, we do see the potential of this company being acquired by a bigger pharma/research conglomerate. There can be three outcomes from the study:
1. Amazing results. HuCNS-SC delivery technology delivering 20 million STEM cells cures spinal cord injury (SCI).
2. So-So results. HuCNS-SC delivery technology acts as a therapeutic agent in cases of SCI.
3. Lackluster results. HuCNS-SC delivery technology shows no improvement in cases of SCI.

While we are not expecting a miracle cure, the expectation will be that this trial fall in the region of So-So results. This should leave the stock price relatively unchanged or even slightly higher.
At a price of around $.5 per stock, the company would have to issue almost twice or three times the equity it had been issuing in the past as a source of cash. This is not sustainable. This is the opportunity where the bigger research companies can buy STEM for a discount and continue the research if the results show any positive glimmer.

Section 4 Valuation

Assumptions:

Based on the reported cost of phase I/II trials, we deduced that the cost/patient would be around $167,000 for the single transplant. Assuming the surgery to implant the cells cost around $100K, the cost of implant would be around $67K.
Since the costs of manufacturing the stem cells keep going down (as reported in 2014 10K), after approval, the simple cost of cell production should fall down to around $40K/patient. It is also assumed that more production will result in further cost reduction to manufacture these cells.
Assuming that the company sells these cells with a 40% margin, the cost of cells/patient would be: $56,000. (Plus obviously the cost of surgery). This would leave the profit margin to be around $16K/patient.
Number of people with spinal cord injury (SCI) in US: Approx 300,000
Number of new cases with SCI every year: Approx 12,000
We are also assuming 10% market penetration in the first year. Since there are no competitors in this area, we assume that market penetration in Y2=20%, Y3=50%, Y4 till Y8 70%. Ramp down years will have a much lower market penetration, hence in Y9, 50% and Y10, 30%.
The valuation is also solely based on US numbers. Worldwide SCI numbers would be much larger – and so would equity valuation if we considered worldwide numbers.

Method used:

Based on the above assumptions, cash flow was projected from now until 2030 at which time the project is terminated. We used a Risk-Adjusted net present value (rNPV) formula to calculate the risk adjusted net present value of the project. The discount rate we used was 20%.

Average likelihood of a new molecular (or biologic) entity (NME) of making it to FDA approval after it passes Phase I is around 20%. Once it passes phase II trials, the likelihood goes up to 30%. Once it passes phase III, it will have a 67% chance that it'll eventually make it to FDA approval. After Phase III, 81% of the NME's will finally get approved. We used these numbers to come up with the risk adjusted NPV of the projected cash flow. Outstanding debts, RSUs/Warrants, SG&A (assumed to be around 30% of cash flow) was subtracted to arrive at the cash flow to equity. With around 105 million shares outstanding we calculated the value of each share to be around $5.15.

Conclusion:

In our assessment, the future of this company is heavily dependent on the phase II clinical trial. If the trials are not successful, the company will have difficulty tapping into the equity markets for more funds. At this juncture, either a private fund or a big pharma/research entity will likely assume responsibility.
However, on the flip side, if the clinical trials do produce good results, there is a potential for a huge upswing to the stock price.

Recommendation:

This stock should not be a huge part of your portfolio. Since the catalyst is the clinical trial, and the stock seems to be highly mispriced, we recommend a buy rating to this stock. Recommended purchase time would be between August to the end of September 2015.