Athersys Equity Analysis

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Catalyst for the stock price either way should be around December 2015 or before (See below)

Business case

Athersys Inc. (Ticker: ATHX) is a small cap biotech firm engaged in development of various stem cell therapeutic agents utilizing proprietary MultiStem technology. This technology offers off the shelf therapy for various inflammatory and immune, neurological, and cardiovascular disease areas, as well as certain other conditions. This represents an opportunity where therapies can be used safely for conditions currently lacking effective standard of care.

The company is currently in various stages of testing therapies for Ischemic stroke (Phase 2), Acute Myocardial infraction (Phase 2), Acute respiratory distress syndrome (Phase 2A), Hematopoietic Stem Cell Transplant (Phase 1) and Inflammatory Bowel Disease.

This analysis is based solely on the study for Ischemic stroke, and the projections of cash flow based on the results of this study.

The motivation for this study lies in the fact that each year about 15 million people suffer from stroke worldwide. Ischemic strokes comprise of 85% of all strokes. The standard care for this type of stroke is a clot dissolving thrombolytic agent (tPA), which must be administered within 3 to 4 hours of the episode. 95% of cases don't arrive in time to the hospital for this treatment to be administered. Furthermore, tPA is not a therapeutic agent – It only dissolves the clot. This study attempts to validate MultiStem as an agent that can be administered well outside the 4 hour window and that it has beneficial quality of life improving function.

Timeline

Study Start Date:	October 2011
Estimated Study Completion Date:	December 2015
Primary Completion Date:	March 2015

Interim results were released by the company on April 2015 (http://www.athersys.com/releasedetail.cfm?ReleaseID=907107). Interim results will be discussed in the risk section below.

Risks

Cash

Biotech research companies without a commercial product are cash burners. Without a viable source of revenues, they depend largely on venture capital, debt financing or Equity issuance.

At the end of 2014, the net cash used in operating activities was around $27 million. Cash (equivalents) were reported to be around $26 million. Without additional sources of funding, the company at this rate of cash burn could sustain itself for about another year.

If Chugai Corporation makes an additional $7 Million payment to Athersys in Q3 2015, this will signify the validity of preliminary results. This could be a significant price catalyst around October 2015.

Notice that in 10Q for mid 2015, the cash (equivalents) was reported to be around $32 million. This increase in cash position came primarily from an agreement with the Chugai Corporation. Chugai is also currently reviewing the interim study for phase 2 before making an additional $7 million payment to Athersys.

Major source of cash for Athersys remains to be equity issuance. This will certainly dilute the existing shareholders value – the valuation model takes this into account and assumes that approximately $20 million of equity will be issued every year until 2018.

Warrants issued by the company are almost all non-exercisable; hence cash from this is not expected to be significant.

Cash positions of this company at this time do not appear to represent a major risk to company operations.

Phase 2 Interim results

The primary objective for phase 2 study was to establish:

- Frequency of dose limiting adverse events
- Stroke recovery based on global test analysis including modified Rankin Scale (mRS), NIHSS, and Barthel Index (BI)

There was no known instance of dose limiting adverse event.

Overall, not a miracle drug to treat ischemic stroke. However a lot of positive outcomes and cost lowering treatment could potentially make it as a standard treatment.

The study revealed the fact that given the criteria (mRS ≤1, NIHSS ≤1, and BI ≥95%), almost 17% more of the control group achieved this milestone (P value of .03). Also very positive are the facts that the patients recovered faster, had lower mortality rates, and lower adverse effects – all with a very low P value. The most important finding of the study, is however, downplayed by the presented data. The MultiStem treated group also had a significantly lower level of circulating CD-3^{+} T-cells at two days following dosing ($p < 0.01$), suggesting a reduction in the inflammatory response post-stroke. Given the fact that recurrent ischemic stroke and transient ischemic attack are common problems in primary care, with stroke survivors averaging 10 outpatient visits per year – and a strong correlation between inflammation markers and a recurring Ischemia – this therapy holds a lot of promise. Sources:
http://www.aafp.org/afp/2007/0801/p382.html
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1868538/
A little concerning is the P value of the overall study at .07, however given all the individual low P values, the phase 2 study should have the potential to progress this product into phase 3 research.

Valuation

Projecting the cash flows from the Ischemic stroke study shows the valuation to be around $4/share. Share dilution (from the company issuing more equity in the future) has been built into the model.

Catalyst

Q3 2015 : Chungai Corporation milestone royalty payment. Payment signifies the validity of P2 interim data.

Q4 2015 : Full year study data to be released.

Dates TBD: Phase 3 interim data will also act as catalysts.

Recommendation

At the current equity price of 1.32, the stock is a strong buy before the catalyst dates. Depending on the results of Phase 2 and possibly Phase 3 studies, this stock could also be a part of a core long term portfolio.