

Spherix, Inc.

(SPEX-NASDAQ)

SPEX: Shifting Focus To Triglycerides Makes Sense...

UPDATE

Current Recommendation	Outperform
Prior Recommendation	N/A
Date of Last Change	02/08/2010
Current Price (06/24/10)	\$1.26
Target Price	\$3.50

Spherix announced that it was shifting focus on the company's phase III candidate from type-2 diabetes to triglyceride lowering. This may come as a surprise to some Spherix investors; however, the strategy move makes sense to us considering the bar moved significant higher for approval of new type-2 diabetes drugs following the new FDA guidelines on cardiovascular safety established in March 2008. This was after Spherix has already designed the current phase III protocol. The new path to market for triglycerides will be cheaper and quicker for the company. In the meantime, Spherix will look to partner D-tagatose for type-2 diabetes with a larger pharmaceutical organization. This partnership becomes more likely after the phase III NEET data is released later this summer.

SUMMARY DATA

52-Week High	\$2.24
52-Week Low	\$1.01
One-Year Return (%)	-31.72
Beta	0.83
Average Daily Volume (sh)	22,407

Risk Level	Average,
Type of Stock	Small-Value
Industry	Med-Biomed/Gene
Zacks Rank in Industry	6 of 17

Shares Outstanding (mil)	17
Market Capitalization (\$mil)	\$22
Short Interest Ratio (days)	1.50
Institutional Ownership (%)	7
Insider Ownership (%)	18

Annual Cash Dividend	\$0.00
Dividend Yield (%)	0.00

5-Yr. Historical Growth Rates	
Sales (%)	-55.7
Earnings Per Share (%)	N/A
Dividend (%)	N/A

P/E using TTM EPS	N/A
P/E using 2009 Estimate	N/A
P/E using 2010 Estimate	N/A

Zacks Rank	3
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ZACKS ESTIMATES

Revenue (millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	0.4 A	0.3 A	0.4 A	0.3 A	1.4 A
2010	0.3 A	0.3 E	0.3 E	0.4 E	1.3 E
2011					11.4 E
2012					11.5 E

Earnings per Share

(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	-\$0.14 A	-\$0.11 A	-\$0.15 A	-\$0.21 A	-\$0.62 A
2010	-\$0.13 A	-\$0.15 E	-\$0.16 E	-\$0.14 E	-\$0.57 E
2011					\$0.07 E
2012					\$0.03 E

Zacks Projected EPS Growth Rate - Next 5 Years %	N/A
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WHAT'S NEW

Spherix Shifting D-Tagatose Development to Triglycerides...

On June 23rd, Spherix announced it will explore triglycerides as a potential therapeutic indication for D-tagatose, pending review of the ongoing phase III NEET (Naturlose Efficacy Evaluation Trial) program currently focusing on the treatment of type-2 diabetes. We note that reduction in triglycerides in a secondary endpoint in the ongoing NEET program. We expect results from NEET later this summer.

D-tagatose offered up encouraging triglyceride lowering efficacy in the phase II program conducted by Spherix. The unblinded data from the phase II program show a 21% reduction in triglycerides from the patients who received 7.5 g tagatose compared to the patients who received 2.5 g tagatose. The patients had a mean triglyceride level of 180 mg/dl, which falls in the "borderline high" range, according to National Cholesterol Education Project guidelines, and triglycerides were reduced by -38 mg/dl on average. The triglyceride levels of 172 patients have been monitored for 6 months on therapy as part of the trial.

The NEET program will offer up interesting data with respect to the triglyceride lower effects of D-tagatose. NEET was designed to study type-2 diabetics early in the treatment process (first-line). Therefore, the majority of patients can come into the phase III NEET program have yet to proceed in disease development to where their diabetes is significantly impacting cardiovascular endpoints. This "borderline high" patient population, with a triglyceride level between 150 mg/dL and 200 mg/dL will give Spherix excellent insight into how the drug may treat patients with severely elevated levels of triglycerides, such as over 500 mg/dL.

...Why the Shift...

Management came to the conclusion to shift focus to triglycerides after careful analysis of the above unblinded phase II data on D-tagatose in triglycerides, and the realization that the cost burden of developing drugs specifically for diabetes has increased significantly due to the evolving and more stringent FDA guidelines on cardiovascular safety. The new FDA guidelines, established in March 2008, two years after Spherix designed the protocol for NEET, for approval of a new treatment for type 2 diabetes require:

- ✓ Independent cardiovascular endpoints, including cardiovascular mortality, myocardial infarction, and stroke, and can include hospitalization for acute coronary syndrome, urgent revascularization procedures, among others.
- ✓ Trials should be large enough to conduct an appropriate meta-analysis, and include higher risk cardiovascular patients, including those with relatively advanced diseases, elderly patients, and patients with renal impairment, as well as the ability to explore sub-groups such as age, sex, and race.
- ✓ A minimum of 2 years on therapy.
- ✓ The incidence of cardiovascular events occurring with investigation drug compared to the control group should be no greater than 1.8x under a two-sided 95% confidence interval.

Spherix' phase III NEET program was not designed under these newly designed FDA guidelines. The NEET program enrolled 332 patients, plenty sufficient to show separation on the key primary endpoint of change in HbA1c after 6 months, but far short of what is necessary to satisfy the FDA's hurdle on cardiovascular safety. It is our estimate that a cardiovascular safety program designed to meet the FDA's new requirements above would take several years (min 24 months active protocol), several thousand (we estimate at least 5,000) patients, and tens of millions of dollars (we estimate at least \$60 million) to achieve an NDA filing.

As such, continued development of D-tagatose as a treatment for type-2 diabetes will require the involvement of a larger pharmaceutical partner with deeper resources. Management plans to pursue this potential partnership later in 2010 once the full phase III data from NEET has been released. We remind investors that the blinded interim analysis from NEET demonstrated incidences of responders (achieving an HbA1c target of <6.5%) at 1, 2, 4 and 6 months of treatment to be 4%, 13%, 19% and 18% respectively. Because the trial was randomized 1:1 in terms of drug and placebo, approximately 50% of the patients received placebo.

In the meantime, Spherix will end the phase III NEET program once the data for the 6 month efficacy endpoint has been collected. Originally the program was designed to continue for another 6 months to assess overall safety. However, since this 6 month follow-up period will fall short of the new FDA requirements on cardiovascular safety, management thought it prudent to save the costs and prepare for the next step in D-tagatose's development. We note that to date, there have been no D-tagatose related serious adverse events (SAEs) in the phase III program.

Analysis of the NEET program will include key secondary variables of triglycerides, LDL, HDL, glucose and insulin profile, and body weight. This analysis will be paramount in developing a phase III program specifically focusing on triglycerides in 2011. And importantly, a phase III triglyceride program does not require a rigorous cardiovascular safety program as outlined above and required for diabetes. In our view, this new strategy results in a quicker and cheaper path to market for D-Tagatose in the U.S.

Outside the U.S., the market for D-tagatose remains attractive. The EMEA has not established the cardiovascular safety hurdle for new diabetes drugs as high as the U.S. FDA. And, in areas such as India, Japan, and China where diabetes is becoming an enormous problem. These countries, with their already carbohydrate rich diets and growing pallet for American sugary beverages, are experiencing a boom in type-2 diabetes incidence. A sugar-blocker like D-tagatose offers a very interesting therapeutic agent, and one for which we believe Spherix could partner separately from the U.S. opportunity.

...The Triglyceride Market...

Pending conversations with the U.S. FDA, and the outcome of the phase III NEET program, Spherix will probably seek to meet with the U.S. FDA later in 2010 to discuss the next steps for development. The phase III NEET program essentially counts as a phase I safety assessment for triglycerides. Spherix must conduct some preclinical trials to establish the mechanism of action, and then the company can proceed into phase II dose-ranging studies perhaps in late 2011 or 2012. We suspect that D-tagatose for triglycerides will be formulated into an oral pill, as opposed to the powder sachets currently being used in NEET. A QD or BID dosing would put the product on par with the dosing for statins and fenofibrates.

We point investors to the phase III program for the recently approved Lovaza (omega-3-acid ethyl) at GlaxoSmithKline, or the ongoing phase III program at Amarin Pharmaceuticals with AMR-1010 (ethyl EPA) as a potential roadmap for D-Tagatose approval. Spherix will most likely conduct two phase III programs, one in patients with very high (>500 mg/dL) triglycerides and another in patients with in mixed dyslipidemia, in roughly 500 patients. The primary endpoint will be reduction in triglyceride levels at say 12 to 24 weeks, as well as secondary endpoints in LDL, HDL, and BMI.

The global dyslipidemia market in 2009 stood at roughly \$26 billion. The market is dominated by statins, including Pfizer's Lipitor, AstraZeneca's Crestor, and generic simvastatin (Merck's Zocor). These product totaled sales over \$22 billion last year. Specifically for triglycerides alone, fenofibrate drugs such as Abbott's TriCor and TriLipix, dominate the segment with sales over \$2 billion in 2009. Niacin products totaled sales of roughly \$1 billion last year. However, the new kid on the block is Glaxo's Lovaza, an omega-3-acid ethyl "fish oil". And, despite what patients describe as a horrible fishy smell and aftertaste and four single very large (1g) pills a day, the new drug delivered \$702 million in sales in 2009. Lovaza has gained rapid acceptance as a treatment for triglycerides due to the significant lack of effect in this area of statins, and the side-effects and potential contra-indications for niacin and fenofibrate molecules. A drug like D-tagatose, with an improved profile over Lovaza, could be a meaningful share gainer in the market.

What's Next...

Spherix expects to release the results from the NEET program later this summer. Follow the data release, management will request a meeting with the U.S. FDA. This is when we expect partnership talks to heat up, as any potential partner for type-2 diabetes may want to be involved in the discussion with the U.S. FDA on the cardiovascular safety program requirements, or on what is necessary to proceed in triglycerides. We do not believe that Spherix needs to partner D-tagatose for the triglyceride preclinical or phase II program. However, any potential diabetes partner will most likely want an opt-in or right-of-first-refuse for this indication. As such, Spherix has the potential to bake in significant future milestone into any partnership besides upfront cash. We expect discussion regarding D-tagatose commercialization outside the U.S. will proceed concurrently and potentially with different parties. The wildcard event would be if the U.S. FDA tells Spherix they do not need to conduct a cardiovascular safety program for D-tagatose because the drug has already been designated GRAS (generally recognized as safe) for as a food ingredient. This would be an enormously positive event.

PROJECTED FINANCIALS

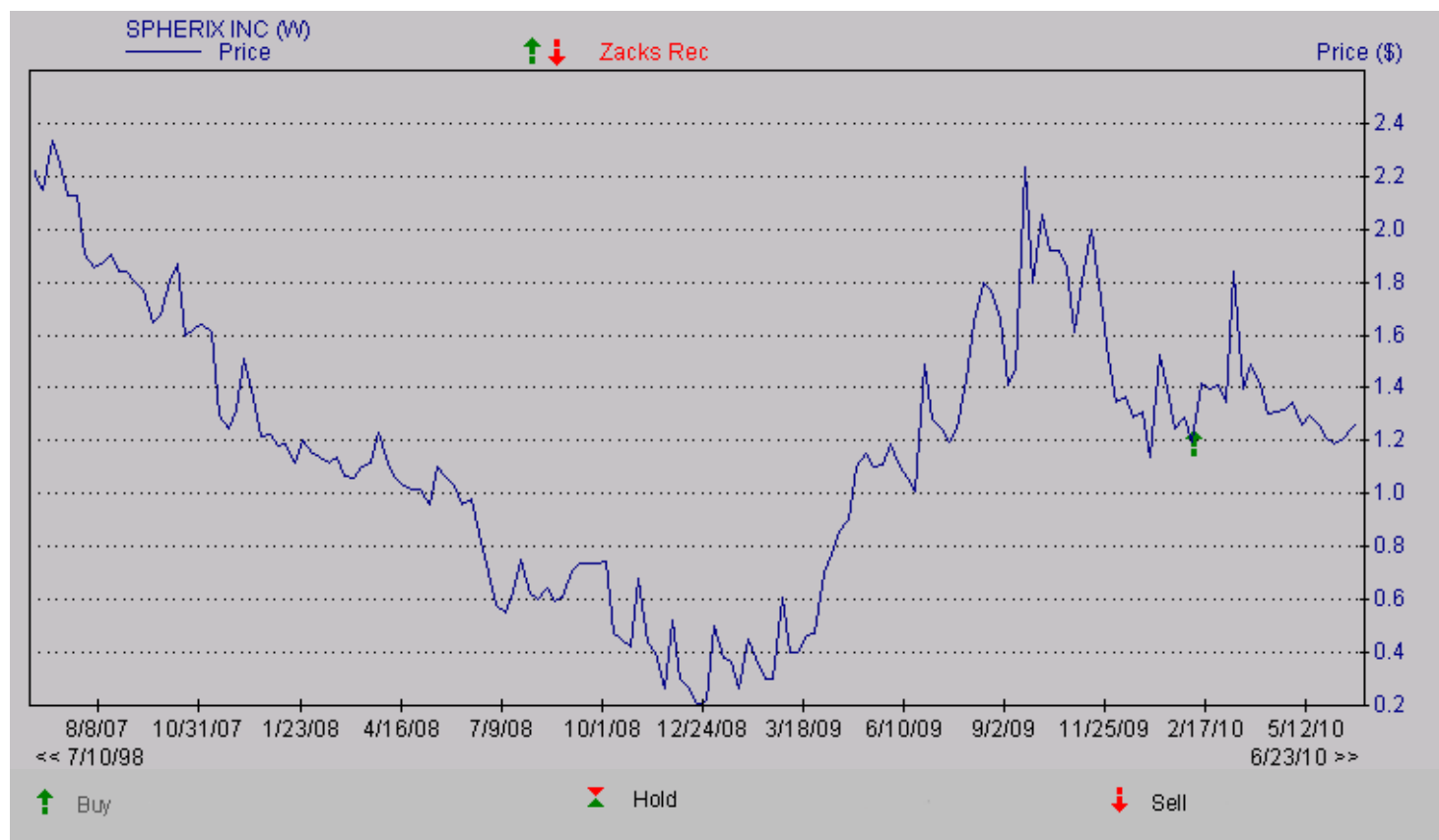
Spherix, Inc. Income Statement

	2008 A	2009 A	Q1 A	Q2 E	Q3 E	Q4 E	2010 E	2011 E	2012 E	2013 E
<i>D-tagatose (U.S. Sales)</i>	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0.0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	-	-
D-tagatose (Royalties)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0.0	\$0.0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	-	-
Collaborations & Milestones	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$10.0	\$10.0	\$15.0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	0.0%	50.0%
Health Sciences	\$1.0	\$1.4	\$0.3	\$0.3	\$0.3	\$0.4	\$1.3	\$1.4	\$1.5	\$1.5
<i>YOY Growth</i>	563.2%	32.5%	-7.8%	-9.7%	-20.7%	39.0%	-2.0%	5.1%	7.1%	0.0%
Total Revenues	\$1.0	\$1.4	\$0.3	\$0.3	\$0.3	\$0.4	\$1.3	\$11.4	\$11.5	\$16.5
<i>YOY Growth</i>	563.2%	32.5%	-7.8%	-9.7%	-20.7%	39.0%	-2.0%	755.7%	0.9%	43.5%
Direct Costs / CoGS	\$0.4	\$0.4	\$0.1	\$0.1	\$0.1	\$0.1	\$0.4	\$0.3	\$0.4	\$0
<i>Gross Margin</i>	61.2%	66.9%	70.8%	66.7%	66.7%	68.8%	66.6%	97.4%	96.5%	97.6%
Research & Development	\$4.0	\$6.8	\$1.3	\$1.8	\$1.8	\$1.7	\$6.6	\$5.5	\$6.0	\$6.5
<i>% R&D</i>	390.3%	502.6%	938.2%	600.0%	600.0%	425.0%	496.3%	48.2%	52.2%	39.4%
Sales, General & Admin	\$3.1	\$3.3	\$1.1	\$1.0	\$1.1	\$1.1	\$4.3	\$4.5	\$4.8	\$5.0
<i>% SG&A</i>	305.6%	240.24%	306.36%	333.33%	366.67%	275.00%	319.0%	39.5%	41.7%	30.3%
Operating Income	(\$6.5)	(\$9.2)	(\$2.1)	(\$2.6)	(\$2.7)	(\$2.5)	(\$10.0)	\$1.1	\$0.3	\$4.6
<i>Operating Margin</i>	0%	0%	-	-	-	-	-748.7%	9.6%	2.6%	27.9%
Interest & Other Income	\$0.3	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1	\$0.4	\$0.8
Pre-Tax Income	(\$6.2)	(\$9.1)	(\$2.1)	(\$2.6)	(\$2.7)	(\$2.5)	(\$10.0)	\$1.2	\$0.7	\$5.4
Taxes	(\$0.6)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0.0	\$1.1
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%	5.0%	20.0%
Net Income	(\$4.1)	(\$9.1)	(\$2.1)	(\$2.6)	(\$2.7)	(\$2.5)	(\$10.0)	\$1.2	\$0.7	\$4.3
<i>Net Margin</i>	0%	0%	-	-	-	-	-748.6%	10.5%	5.8%	26.2%
Reported EPS	(\$0.29)	(\$0.62)	(\$0.13)	(\$0.15)	(\$0.16)	(\$0.14)	(\$0.57)	\$0.07	\$0.03	\$0.21
<i>YOY Growth</i>	-	-	-	-	-	-	-7.6%	-112.0%	-50.7%	503.2%
FAS-123R Expense	\$0.1	\$0.1	\$0.0	\$0.1	\$0.0	\$0.1	\$0.1	\$0.3	\$0.4	\$0.5
<i>EPS Impact of FAS-123R</i>	<i>(\$0.01)</i>	<i>(\$0.01)</i>	<i>(\$0.00)</i>	<i>(\$0.00)</i>	<i>(\$0.00)</i>	<i>(\$0.00)</i>	<i>(\$0.01)</i>	<i>(\$0.02)</i>	<i>(\$0.02)</i>	<i>(\$0.02)</i>
Weighted Ave. Shares Out	14.3	14.7	17.2	17.3	17.4	17.6	17.4	19.5	21.0	22.5

Source: Zacks Investment Research, Inc.

Jason Napodano, CFA

HISTORICAL ZACKS RECOMMENDATIONS



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