

## Spherix, Inc.

(SPEX-NASDAQ)

***SPEX: Phase III Data Shows Signs  
 Tagatose Works, But More Analysis Needed.***

### UPDATE

On October 7, 2010, Spherix released top-line data from its phase III program testing D-tagatose as a monotherapy in treatment-naïve patients with Type-2 diabetes. The data was mixed, but we believe the underlying results show the drug works. Questions remain on dosing and patient criteria, but we believe the majority of these can be handled by an improved trial design for the second phase III program. The biggest challenge that remains is securing a development partner for Type-2 diabetes and the cost necessary to conduct a safety registration program acceptable by the U.S. FDA. We remain optimistic on the development of D-Tagatose. We believe the market misunderstood the phase III NEET data and there are several plausible reasons why results in India failed whereas the U.S. succeeded. There is clearly a path forward here and the market is missing that.

<b>Current Recommendation</b>	<b>Outperform</b>
Prior Recommendation	N/A
Date of Last Change	02/08/2010
Current Price (10/13/10)	\$0.97
<b>Target Price</b>	<b>\$2.50</b>

### SUMMARY DATA

52-Week High	\$2.03
52-Week Low	\$0.95
One-Year Return (%)	-50.78
Beta	0.51
Average Daily Volume (sh)	954,006

Shares Outstanding (mil)	17
Market Capitalization (\$mil)	\$16
Short Interest Ratio (days)	1.40
Institutional Ownership (%)	5
Insider Ownership (%)	15

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

5-Yr. Historical Growth Rates	
Sales (%)	-56.1
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	4
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Risk Level	Average,
Type of Stock	Small-Value
Industry	Med-Biomed/Gene
Zacks Rank in Industry	14 of 15

### 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 A	0.3 E	0.4 E	1.3 E
2011					6.4 E
2012					6.5 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 A	-\$0.15 E	-\$0.12 E	-\$0.54 E
2011					-\$0.24 E
2012					-\$0.20 E

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

### *Top-Line Data From Phase III NEET Program Released...*

On October 7, 2010, Spherix released top-line data from its phase III program testing D-tagatose as a monotherapy in treatment-naïve patients with Type-2 diabetes. The data was mixed, but we believe the underlying results show the drug works. Questions remain on dosing and patient criteria, but we believe the majority of these can be handled by an improved trial design for the second phase III program. The biggest challenge that remains is securing a development partner for Type-2 diabetes and the cost necessary to conduct a safety registration program acceptable by the U.S. FDA.

Below is a table of the top-line data:

<b>Patient population</b>	<b>2 months</b>	<b>6 months</b>	<b>10 months</b>
U.S. PP	-0.4* (n=51)	-0.6* (n=29)	-1.1* (n=20)
U.S. ITT LOCF	-0.3* (n=100)	-0.3* (n=101)	-0.4* (n=101)
India PP	-0.1 (n=150)	0.0 (n=117)	-0.2 (n=72)
India ITT LOCF	-0.2 (n=253)	-0.1 (n=254)	-0.2* (n=254)
Global PP	-0.2 (n=201)	-0.2* (n=146)	-0.4* (n=92)
Global ITT LOCF	-0.2* (n=353)	-0.2* (n=355)	-0.2* (n=355)
Global ITT (7.5<HbA1c<9.0)	-0.3 (n=175)	0.1 (n=134)	-0.5* (n=92)

PP = Per-Protocol; ITT = Intent-to-Treat; LOCF = Last Observation Carried Forward

\* p<0.05; all other figures do not have statistical significance

The phase III data from NEET (Naturlose Efficacy Evaluation Trial) show that D-tagatose was more effective in the U.S. population than in the Indian population, as the PP patients in the U.S. who were treated with D-tagatose had a reduction in HbA1c of 0.4% at two months, 0.6% at six months and 1.1% at 10 months on therapy (p<0.05). Results in the Indian PP population show essentially no change in HbA1c after 2, 6, or 10 months. We have several theories as to why the U.S. population offered such impressive results when the Indian population did not.

- 1) Management noted that the Indian population has significantly lower BMI than the U.S. population at trial enrollment. Many – if not all – of the patients in the U.S. were Type-2 diabetics with metabolic syndrome (diabetes as a result of high BMI or obesity / poor diet), whereas it is likely that a high percent of the patients enrolled in India (10-20%) may have been Type-1 diabetics with relatively healthy body weight and vegetarian diets. Patients in the U.S. saw their HbA1c drop during the 8-week diet and exercise run-in period. Conversely, management saw a number of patients in India have skyrocketing HbA1c levels (to 15%+) during the run in period and at the beginning of the trial due to changes in diet and exercise. These significant outliers – presumably Type-1 diabetics – could have dramatically swayed the results for the Indian ITT and PP population. We note the enrollment criteria only specified patients be treatment-naïve with HbA1c levels between 6.6% and 9%. No metabolic tests were done to confirm Type-2 vs. Type-1. In the U.S., the differences are pretty well understood. This is not the case in India, and we believe the dramatically different patient characteristics of a few patients impacted the overall study results.

- 2) Significant differences in diet may have also played a meaningful role in the dramatic variation between U.S. patients and Indian patients. The U.S. high fat / high simple-sugar diet creates a substantially different normal gut flora than in India where the population has a low fat / high complex carbohydrate diet. Changes in gut metabolism most likely played a key role in the D-Tagatose mechanism of action and further metabolism by the liver. We have not seen the adverse event rates from the trial; however, management noted that the Indian placebo population had a 25% adverse GI reaction. We can only guess that gut metabolism played a major role in the outcome. Management plans to study the D-Tagatose mechanism of action in animal and cell culture studies in 2011. Once management knows more on how exactly D-Tagatose works, the company should be able to better design a clinical study to show the best efficacy results.
- 3) Finally, management noted a greater percent of the Indian population had an HbA1c below 7.5% at the start of the trial. In fact, over 50% of the Indian patients enrolled were between 6.6% and 7.5%. Normal is considered below 6%. Guidelines set by the ADA encourage maintenance below 7%. At the start of the trial, Spherix was dealing with an Indian population already near or below goal, and thus it became increasingly more difficult to improve in this "less sick" population.

The table above shows mean reduction in HbA1c at 3 points in time for the U.S., Indian, and Global population. However, as we theorized above, key differences in the Indian population had an important impact on the mean results. We are looking forward to seeing some additional analysis from the data in 2011 (either at a medical conference or journal) which looks at standard deviation, outliers, and median HbA1c changes.

### ***...Responder Analysis Paints Better Picture...***

Statisticians know the mean is highly influenced by outliers. Global responder analysis paints a much better picture in our view of the median efficacy of the drug:

Responders	HbA1c < 6.5%		HbA1c < 7%	
	D-Tagatose	Placebo	D-Tagatose	Placebo
<b><i>...Percent of Patients</i></b>	24%	10%	60%	25%
	n/s		p=(0.03)	

We believe having 60% of the patients achieve an HbA1c below 7% (ADA guidelines) is a very meaningful, and clearly shows D-Tagatose is efficacious.

### **What's Next For Spherix?**

The company is still wrapping up analysis of the phase II dose-ranging study with D-tagatose. Final analysis should be complete by the end of the year. This data should show the effects of lower doses of D-tagatose in relatively the same patient population as studied in NEET. Therefore, we caution investors that the phase II efficacy results may not impress. However, the results will give management a better understanding of the dose-response and adverse event rates with 5g vs. 15g of D-tagatose TID.

Spherix is looking to secure a development partner for D-tagatose in Type-2 diabetes. Results from NEET are mixed, but with further analysis we can clearly see signs of powerful efficacy. We are anxiously awaiting the safety and tolerability data from NEET and the ongoing phase II program. Commercializing the drug in Type-2 diabetes is far too expensive for Spherix to undertake alone. FDA guidelines requiring a cardiovascular outcomes safety program mean Spherix has to partner with someone with deep pockets and a commitment to metabolic diseases. This should be the chief focus of the company over the next several months. We believe the company can secure a partner in 2011, although given the requirements that still lie ahead, we expect the deal will be heavily back-end loaded. The upfront payment will most likely disappoint investors believing that D-Tagatose is a multi-hundred million dollar drug. It very well may be, but it is going to cost Spherix' development partner a significant amount of time and money to find out, and that means too much risk to pay Spherix a big upfront payment.

On the triglyceride front, management plans to push forward with animal studies and a phase I / II program in 2011. Unfortunately, no triglyceride efficacy data can be extrapolated from the phase III NEET program. The patient population's mean triglyceride level was 170 mg/dl. AHA guidelines list below 150 mg/dl as normal, with anything below 200 mg/dl listed as "acceptable". The NEET population really offered no opportunity for improvement.

## OVERVIEW

### *Shifting Focus To Triglycerides Makes Sense...*

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.

We note that patients in the phase II program were enrolled for diabetes, not for having high triglycerides. In fact, the patients had a mean triglyceride level of 180 mg/dl, which falls in the "borderline" range, according to National Cholesterol Education Project guidelines. The NCEP considers "high" to be >250 mg/dl. Still, triglycerides were reduced by -38 mg/dl on average in the phase II trial. This is very impressive. The triglyceride levels of 172 patients have been monitored for 6 months on therapy as part of the trial. This "borderline" 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.

### *...The Triglyceride Market...*

Pending conversations with the U.S. FDA, Spherix will probably seek to meet with the U.S. FDA during the fourth quarter 2010 to discuss the next steps for development in triglycerides. Much of the preclinical work for D-tagatose was conducted under assumptions the product would be used as a food additive. Requirements are more stringent for pharmaceutical products, so Spherix must meet with the FDA to iron-out the necessary plans for cell culture, animal and human toxicology work. Nothing here is of significant cost or reason for concern, but the information must be obtained for the NDA filing. The verified path to market is something the company's potential diabetes development partners are surely interested in prior to signing a deal.

The phase III NEET program essentially counts as a phase I safety assessment for triglycerides. Spherix will conduct the necessary preclinical toxicology and carcinogenicity work throughout 2011, and then seek to proceed into phase I / II dose-ranging studies perhaps in late 2011 or 2012. The recent \$5 million cash-raise in October 2010 will help management fund these studies. 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 was 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.

## **Maintaining 'Outperform' Rating / Lowering Target to \$2.50**

We remain optimistic on the development of D-Tagatose. We believe the market misunderstood the phase III NEET data and there are several plausible reasons why results in India failed whereas the U.S. succeeded. There is clearly a path forward here and the market is missing that.

Our target is moving from \$3.50 to \$2.50 based on the dilution from the recent \$5.25 million financing. The offering was a 24% dilution to existing shareholders with another potential 12% dilution on the warrants. The company issued shares of its Series B Convertible Preferred Stock and warrants to purchase shares of its common stock in a registered offering to institutional investors. Each share of Series B Convertible Preferred Stock is convertible at the option of the holder, at any time during its existence, into 800 shares of common stock at a conversion price of \$1.25 per share of common stock for a total of 4.2 million common shares. In connection with the offering, the investors received warrants to purchase up to 2.1 million shares of common stock. The warrants have an exercise price of \$1.50 per warrant share, and are exercisable immediately upon issuance and terminate 60 months after the date of issuance.

## PROJECTED FINANCIALS

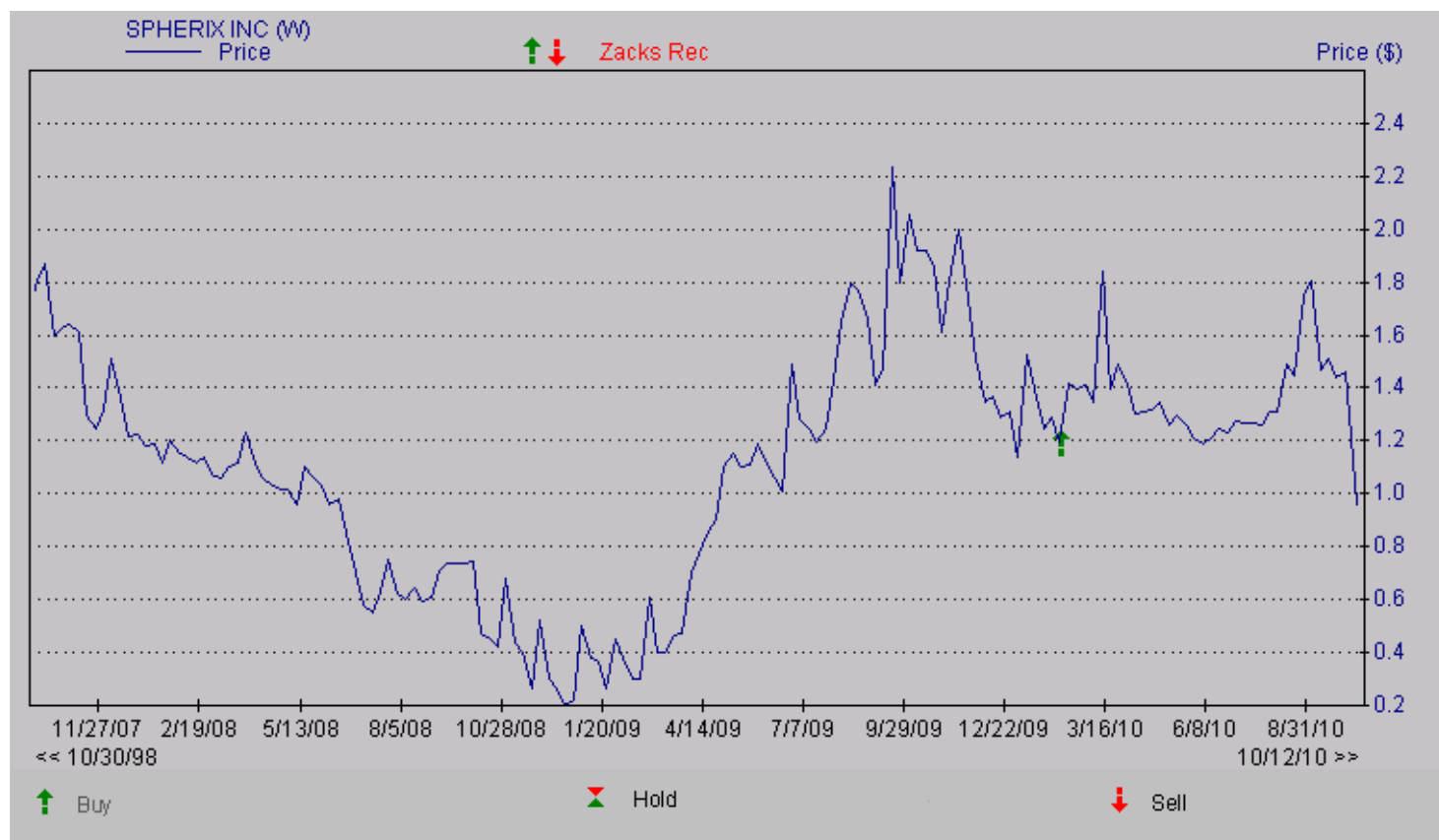
### Spherix, Inc. Income Statement

	2008 A	2009 A	Q1 A	Q2 A	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>	-	-	-	-	-	-	-	-	-	-
<b>D-tagatose (Royalties)</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0.0</b>	<b>\$0.0</b>
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	-	-
<b>Collaborations &amp; Milestones</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$5.0</b>	<b>\$5.0</b>	<b>\$10.0</b>
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	0.0%	100.0%
<b>Health Sciences</b>	<b>\$1.0</b>	<b>\$1.4</b>	<b>\$0.3</b>	<b>\$0.3</b>	<b>\$0.3</b>	<b>\$0.4</b>	<b>\$1.3</b>	<b>\$1.4</b>	<b>\$1.5</b>	<b>\$1.5</b>
<i>YOY Growth</i>	563.2%	32.5%	-7.8%	-1.5%	-15.4%	25.1%	-1.4%	4.5%	7.1%	0.0%
<b>Total Revenues</b>	<b>\$1.0</b>	<b>\$1.4</b>	<b>\$0.3</b>	<b>\$0.3</b>	<b>\$0.3</b>	<b>\$0.4</b>	<b>\$1.3</b>	<b>\$6.4</b>	<b>\$6.5</b>	<b>\$11.5</b>
<i>YOY Growth</i>	563.2%	32.5%	-7.8%	-1.5%	-15.4%	25.1%	-1.4%	377.8%	1.6%	76.9%
Direct Costs / CoGS	\$0.4	\$0.4	\$0.1	\$0.1	\$0.1	\$0.1	\$0.5	\$0.3	\$0.4	\$0
<i>Gross Margin</i>	61.2%	66.9%	70.8%	65.7%	68.8%	65.3%	65.9%	95.3%	93.8%	96.5%
Research & Development	\$4.0	\$6.8	\$1.3	\$1.5	\$1.6	\$1.6	\$6.1	\$5.5	\$6.0	\$6.5
<i>% R&amp;D</i>	390.3%	502.6%	938.2%	472.2%	500.0%	444.4%	452.2%	85.9%	92.3%	56.5%
Sales, General & Admin	\$3.1	\$3.3	\$1.1	\$1.2	\$1.2	\$1.2	\$4.7	\$5.0	\$5.2	\$5.5
<i>% SG&amp;A</i>	305.6%	240.24%	306.36%	376.02%	375.00%	333.33%	349.5%	78.1%	80.0%	47.8%
<b>Operating Income</b>	<b>(\$6.5)</b>	<b>(\$9.2)</b>	<b>(\$2.1)</b>	<b>(\$2.6)</b>	<b>(\$2.6)</b>	<b>(\$2.6)</b>	<b>(\$9.9)</b>	<b>(\$4.4)</b>	<b>(\$5.1)</b>	<b>(\$0.9)</b>
<i>Operating Margin</i>	0%	0%	-	-	-	-	-735.7%	-68.8%	-78.5%	-7.8%
Interest & Other Income	\$0.3	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1	\$0.4	\$0.8
<b>Pre-Tax Income</b>	<b>(\$6.2)</b>	<b>(\$9.1)</b>	<b>(\$2.1)</b>	<b>(\$2.6)</b>	<b>(\$2.6)</b>	<b>(\$2.6)</b>	<b>(\$9.9)</b>	<b>(\$4.3)</b>	<b>(\$4.7)</b>	<b>(\$0.1)</b>
Taxes	(\$0.6)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0.2	\$0.0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%	5.0%	20.0%
<b>Net Income</b>	<b>(\$4.1)</b>	<b>(\$9.1)</b>	<b>(\$2.1)</b>	<b>(\$2.6)</b>	<b>(\$2.6)</b>	<b>(\$2.6)</b>	<b>(\$9.9)</b>	<b>(\$4.3)</b>	<b>(\$4.5)</b>	<b>(\$0.1)</b>
<i>Net Margin</i>	0%	0%	-	-	-	-	-735.4%	-67.2%	-68.7%	-0.7%
<b>Reported EPS</b>	<b>(\$0.29)</b>	<b>(\$0.62)</b>	<b>(\$0.13)</b>	<b>(\$0.15)</b>	<b>(\$0.15)</b>	<b>(\$0.12)</b>	<b>(\$0.54)</b>	<b>(\$0.24)</b>	<b>(\$0.20)</b>	<b>(\$0.00)</b>
<i>YOY Growth</i>	-	-	-	-	-	-	-13.3%	-56.3%	-15.7%	-98.3%
FAS-123R Expense	\$0.1	\$0.1	\$0.0	\$0.0	\$0.0	\$0.1	\$0.1	\$0.2	\$0.3	\$0.3
<i>EPS Impact of FAS-123R</i>	(\$0.01)	(\$0.01)	(\$0.00)	(\$0.00)	(\$0.00)	(\$0.00)	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.01)
Weighted Ave. Shares Out	14.3	14.7	17.2	17.2	17.3	21.5	18.3	22.5	23.5	24.5

Source: Zacks Investment Research, Inc.

Jason Napodano, CFA

## HISTORICAL ZACKS RECOMMENDATIONS



## DISCLOSURES

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