

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported) July 14, 2011

Spherix Incorporated

(Exact name of registrant as specified in its charter)

(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
Delaware	0-5576	52-0849320
(Address of principal executive offices)		(Zip Code)
6430 Rockledge Drive, Suite 503, Bethesda, Maryland		20817
Registrant's telephone number, including area code		<u>301-897-2540</u>

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 7.01 Regulation FD Disclosure.**

On July 14, 2011, Dr. Robert A. Lodder, Jr., President, will be presenting to individual funds in Boston, MA. The presentation is available on the Company's website at [www.spherix.com](http://www.spherix.com), is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

**Section 9 – Financial Statements and Exhibits**

Item 9.01 Financial Statements and Exhibits

Exhibits

99.1 Spherix Incorporated Overview Presentation, July 14, 2011

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Spherix Incorporated  
\_\_\_\_\_  
(Registrant)

**By:**

/s/ Claire L. Kruger  
\_\_\_\_\_  
Claire L. Kruger  
CEO

Date: July 14, 2011

**Exhibit 99.1: Spherix Incorporated Overview Presentation, July 14, 2011**



**Spherix Incorporated (NASDAQ: SPEX)**  
**July 14, 2011**

# Forward-Looking Statements

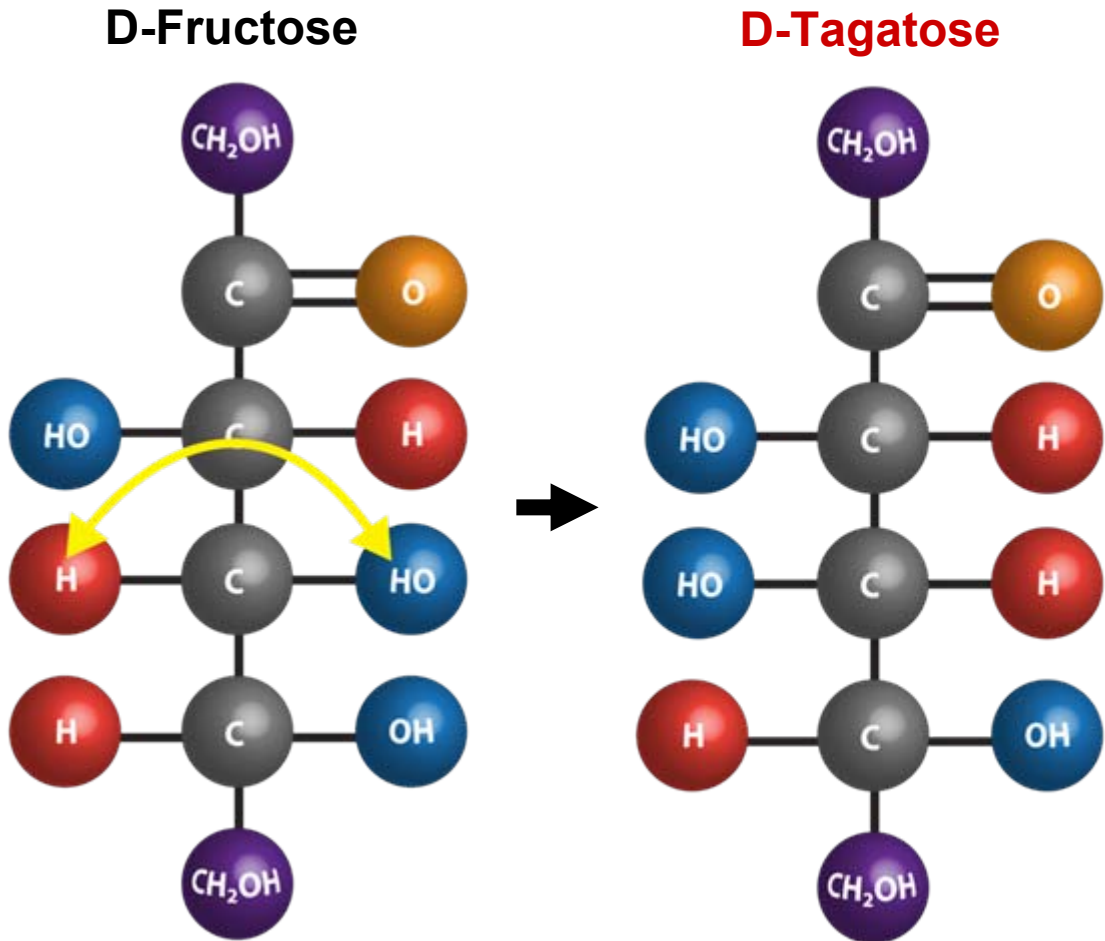
This presentation contains forward-looking statements made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements, including statements relating to planned clinical study design, regulatory and business strategies, plans and objectives of management and growth opportunities for existing or proposed products, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. The risks and uncertainties include, without limitation, risks that product candidates may fail in the clinic or may not be successfully marketed or manufactured, we may lack financial resources to complete development of D-tagatose, the FDA may interpret the results of studies differently than us, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends, our continuing efforts to develop D-tagatose may be unsuccessful, our common stock could be delisted from the Nasdaq Capital Market, and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission. You are cautioned not to place undue reliance on any forward-looking statements that speak only as of the date of this presentation. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this presentation or to reflect the occurrence of unanticipated events.

- **Core expertise in scientific and technical aspects of drug and food development**
- **Operates two subsidiaries**
  - **Biospherics: Pharmaceutical development of D-tagatose and pipeline products**
    - **Dyslipidemias**
    - **Atherosclerosis**
    - **Metabolic Syndrome and Diabetes**
  - **Spherix Consulting: Scientific consulting on food and drug approvals for clients worldwide**

- **D-tagatose and SPX-106 show promise in multiple clinical applications**
  - **Hypertriglyceridemia (\$26 billion treatment market)**
  - **Diabetes (\$175 billion treatment market)**
- **Preclinical and Phase 2 data show significant lowering of triglycerides**
  - **Much faster and less expensive development pathway vs. diabetes**
  - **Clinical development program initiated**
- **Cash position sufficient to fund initial triglyceride studies**
- **Phase 3 study demonstrated statistically significant reductions in HbA1c in patients with mild Type 2 diabetes**
  - **Pursuing partnership(s) for further clinical development**

# What is D-tagatose?

- Naturally occurring L-epimer of D-fructose with an inversion at C4
- Spherix used chiral carbohydrate research to create L-sugars that are not metabolized, but retain sweetness
- Blocks lipid formation from carbohydrates
- Does not stimulate insulin production





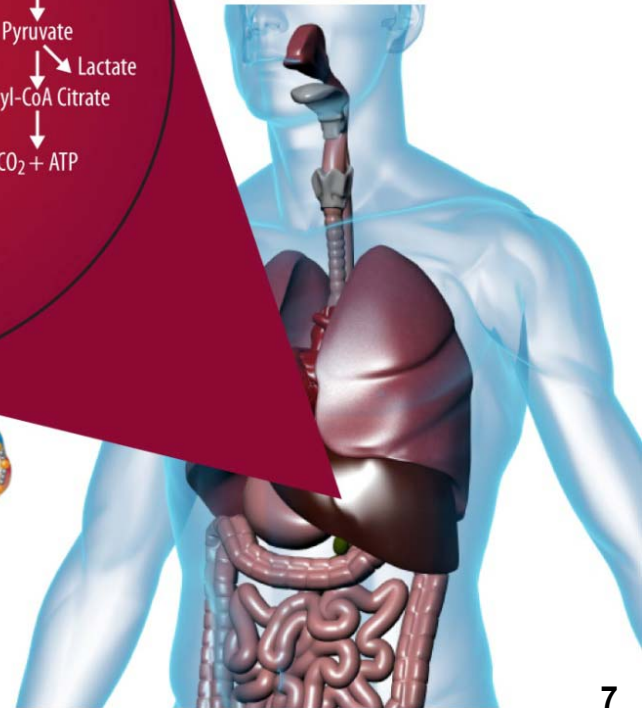
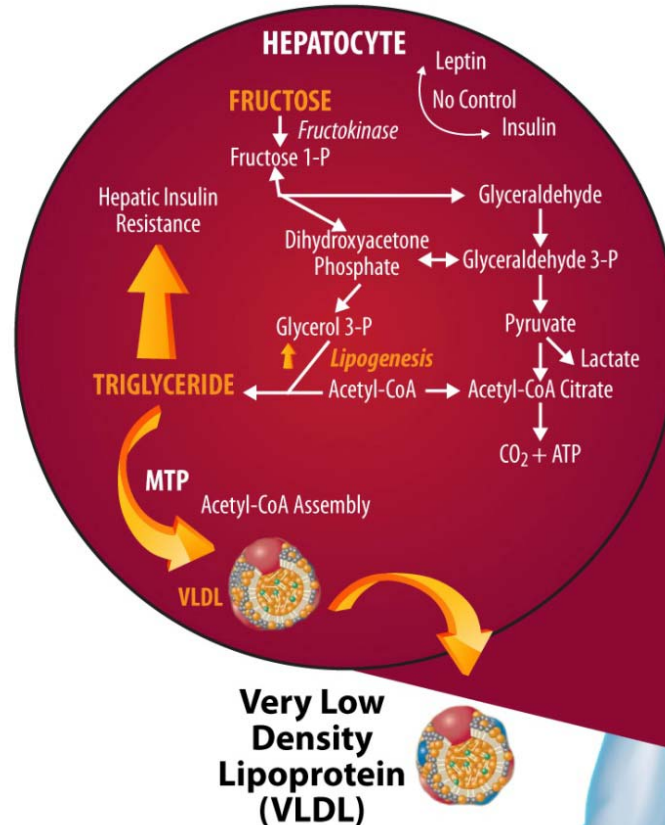
# The D-Tagatose Difference

- **May provide a safety advantage over current agents**
  - **Approved as GRAS by FDA; approved as Novel Food in EU; ADI “not specified” by JECFA**
- **Provides lipoprotein and glycemic control through a mechanism of action unlike any agent currently marketed in the U.S.**
  - **“Sugar blocker” with potential fat, liver and gut mechanisms that may modify blood lipid and post-prandial glucose levels**

# Proposed Mechanism of Action in Lowering VLDL and Triglycerides

Tagatose follows fructose pathway in the liver

- **D-Tagatose lowers blood lipoprotein and glucose levels**
  - Triglycerides reduced
  - VLDL reduced
  - LDL reduced
  - HDL essentially unchanged
  - TC reduced
- **D-Tagatose does not cause myopathy / rhabdomyolysis**
- **D-Tagatose does not stimulate insulin secretion**



# Pharmaceutical Pipeline Compounds Formulated with D-Tagatose

	Preclinical	Phase 1	Phase 2	Phase 3	Marketed
<b>NEET Study (D-Tagatose)<sup>1</sup></b> <i>Type-2 diabetes</i>				<i>Phase 3 Completed</i>	
<b>Dose Ranging Study (D-Tagatose)</b> <i>Type-2 diabetes</i>			<i>Phase 2 Completed</i>		
<b>SPX 7233801</b> <i>atherosclerosis</i>					
<b>SPX 8522876</b> <i>dyslipidemias</i>					
<b>SPX 10624258 “SPX-106”</b> <i>metabolic syndrome</i>					
<b>SPX 8818309</b> <i>obesity</i>					
<b>SPX 8818440</b> <i>diabetes</i>					

1. Proceeded directly from phase 1 to 3 due to FDA GRAS approval

- **Biospherics' goal to diversify pipeline by licensing in new drug candidates**
- **The Company has preclinical cardiovascular and metabolic drug candidates licensed from UKRF**
- **The Company is seeking and examining:**
  - **Later, clinical-stage compounds:**
    - **Phase 1 and Phase 2**
  - **Orphan drugs:**
    - **Developed specifically to treat a rare medical condition**
    - **7 years of data exclusivity in addition to patent life in US**
    - **In the US and EU, may be easier to gain marketing approval**

***Metabolic syndrome*** is a combination of medical disorders that increase the risk of developing cardiovascular disease and diabetes. It affects one in five people, and prevalence increases with age.

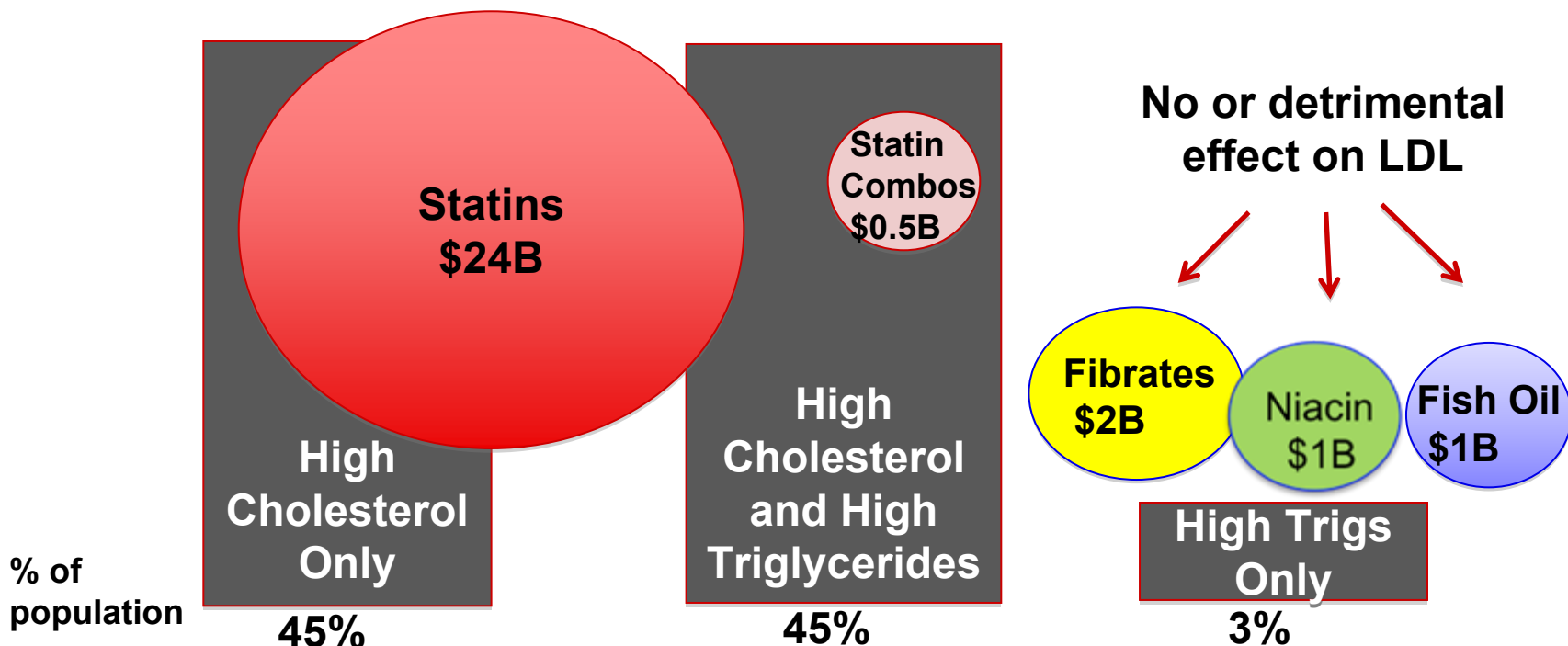
***US National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP) (2001)*** requires at least three of the following:

- ✓ **central obesity: waist circumference  $\geq 102$  cm or 40 inches (male),  $\geq 88$  cm or 36 inches (female)**
- ✓ **dyslipidemia: TG  $\geq 1.7$  mmol/L (150 mg/dl)**
- ✓ **dyslipidemia: HDL-C  $< 40$  mg/dL (male),  $< 50$  mg/dL (female)**
- ✓ **blood pressure  $\geq 130/85$  mmHg**
- ✓ **fasting plasma glucose  $\geq 6.1$  mmol/L (110 mg/dl)**

- **In the U.S. alone, more than 100 million people have elevated triglycerides, defined as more than 150 mg/dl**
- **Approximately 10 million are poorly served by current drug regimens**
- **The U.S. market for triglyceride-lowering drugs is in excess of \$4 billion**
- **The path to commercialization is shorter than for an oral antidiabetic drug**

# Large and Growing Triglyceride Market Opportunity

- A growing epidemic of metabolic syndrome and dyslipidemia supports blockbuster products in an area with limited competition
- Unmet needs still exist due to: adverse events with niacin, lack of robust cardiovascular benefit with fibrates, and unwanted lipid effects of raising the bad LDL cholesterol (fish oils) or decreasing the good HDL cholesterol (fibrates)
- Need new safe agents for use in patients with both high cholesterol and high triglycerides

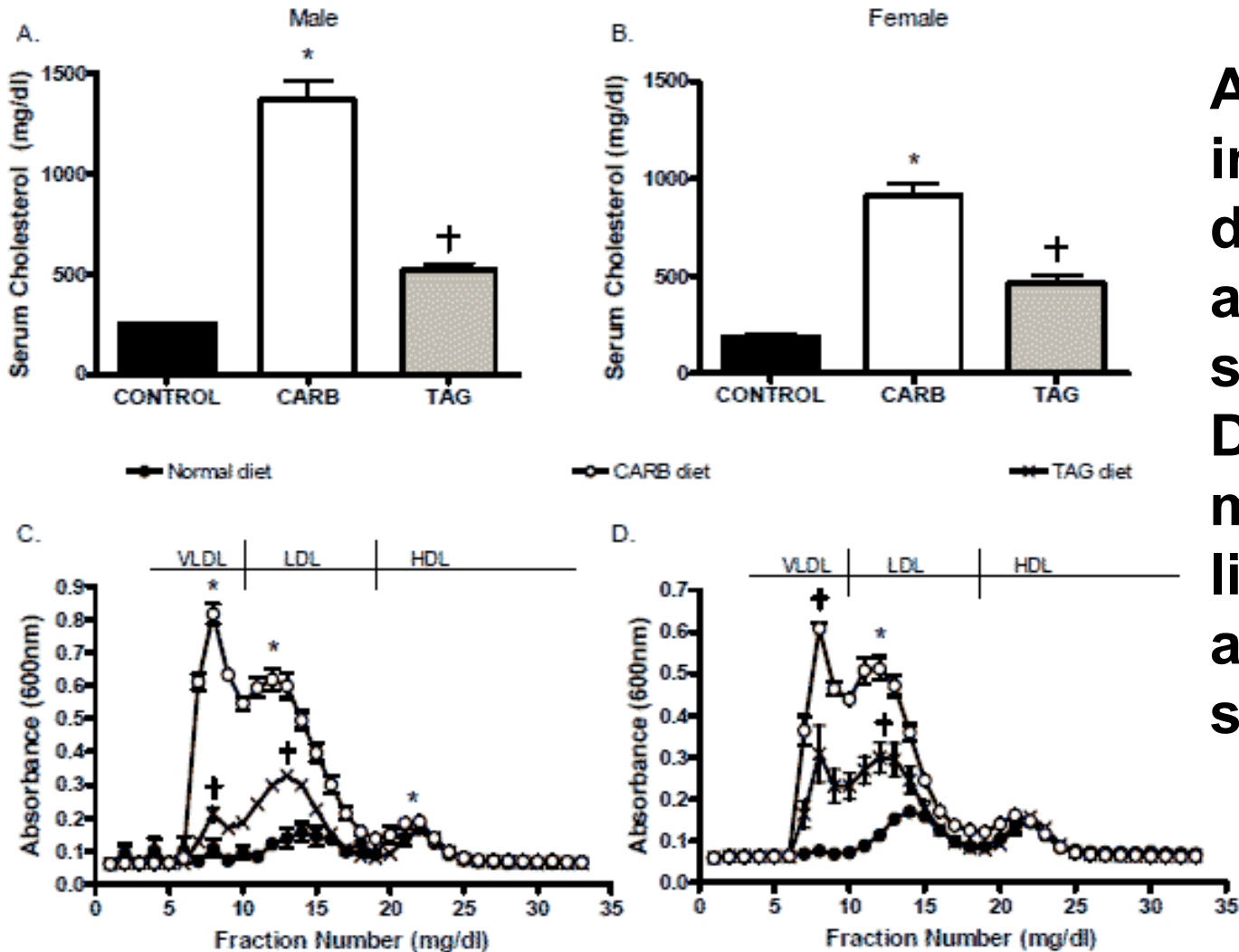


# The Metabolic Diseases Crisis- Hypertriglyceridemia

- **In the US alone, >100 million people have elevated triglycerides (> 150 mg/dl)**
- **Associated with other lipid abnormalities and the metabolic syndrome**
  - **abdominal obesity, insulin resistance, low high-density lipoprotein (HDL), and hypertension, which are linked to coronary artery disease**
- **Preclinical work and interim Phase 2 D-tagatose data support pursuit of this indication for development**
- **Good commercial opportunity! Large, but poorly-served market due to side effects of current products, with few competitors and low promotional intensity**



# Tagatose Effects on Triglycerides LDLr Knockout Mice



Animal studies in a model of diet-induced atherosclerosis suggested D-tagatose might reduce lipoproteins and atherosclerosis.

# Tagatose Effects on Triglycerides LDLr Mice (2)

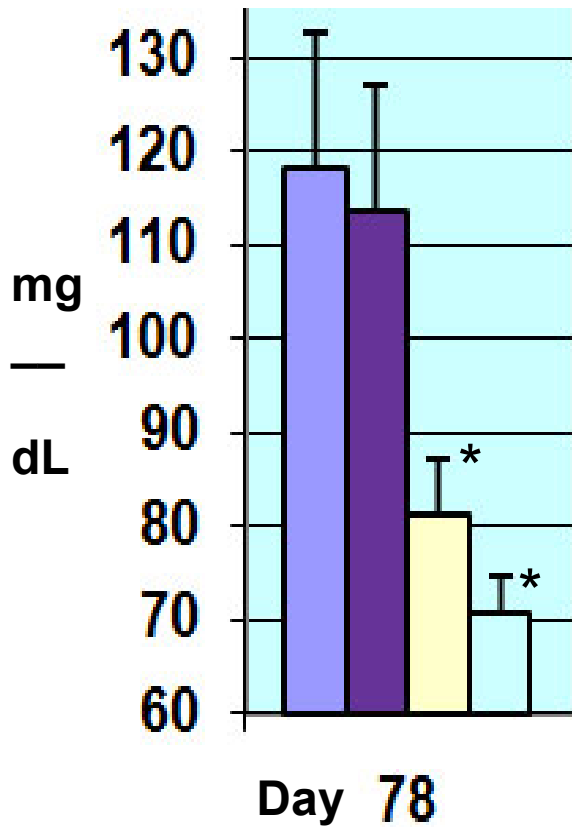
Tagatose administration reduced triglycerides, adiposity and body mass.

Gender	Diet	Body weight (g)	Rate of body weight gain (g/week)	Tibialis anterior (mg)	Total triglycerides (mg/dl)	Adiposity index (%)
M	NORMAL	30.18 ± 0.36	0.28 ± 0.03	57.80 ± 3.50	110.3 ± 19.9	3.35 ± 0.27
	CARB	40.30 ± 1.78 *	0.97 ± 0.06	58.80 ± 2.73	822.4 ± 147.5 *	6.70 ± 0.77 *
	TAG	27.30 ± 0.42	0.17 ± 0.03	57.83 ± 2.20	162.3 ± 29.2	1.72 ± 0.13
F	NORMAL	24.43 ± 1.10	0.30 ± 0.05	35.25 ± 7.41	79.1 ± 15.5	2.71 ± 0.57
	CARB	30.56 ± 0.98 *	0.68 ± 0.05	43.14 ± 2.06	326.2 ± 37.3 *	5.39 ± 0.41 *
	TAG	24.06 ± 0.73	0.19 ± 0.02	42.40 ± 2.50	54.1 ± 8.0	1.60 ± 0.32

Data are mean ± SEM from N = 5/6 mice/group).

# LDLr -/- Mouse Treated with Sugar and Drug Mixtures for Nine Weeks

## Triglycerides



- Water
- Glu/Fruc
- Glu/Fruc/Tagatose
- Glu/Fruc/Tagatose / SPX-106

### TRIGLYCERIDES

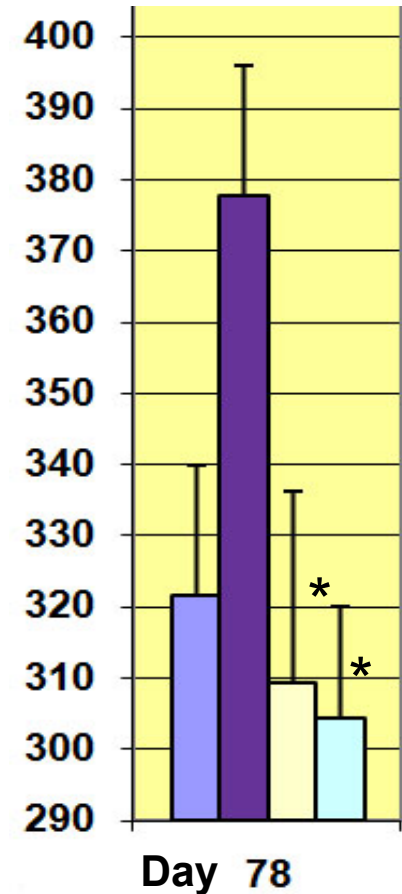
- $p=0.035$  for tagatose vs. water
- $p=0.046$  for tagatose vs. glucose / fructose
- $p=0.009$  for tag/SPX106 vs. water
- $p=0.011$  for tag/SPX106 vs. glucose / fructose

### CHOLESTEROL

- $p=0.05$  for gluc/fruc vs. tagatose
- $p=0.01$  for gluc/fruc vs. tagatose / SPX106

n=10 per group

## Total Cholesterol



# Peak Factor Analysis Results for the LDLr $-/-$ Mice

- The SPX-106/tagatose combination is the most effective of the treatments for lowering *triglycerides*.
  - The SPX-106 dose is responsible for lowering most of the triglycerides in the blood, followed by tagatose.
  - D-tagatose lowers triglycerides by -3.1 mg/dl per g/kg/dose of the sugar, while the SPX-106 lowers triglycerides by -372 mg/dl per g/kg/dose of the drug. Both glucose and fructose raise triglycerides.
- The SPX-106/tagatose combination is the most effective of the treatments for lowering *cholesterol*.
  - The SPX-106 concentration is responsible for lowering most of the cholesterol in the mice blood, followed by tagatose.
  - D-tagatose lowers cholesterol by -3.9 mg/dl per g/kg/dose of the sugar, while the SPX-106 lowers cholesterol by -629 mg/dl per g/kg/dose of the drug. Both glucose and fructose raise cholesterol.

- **Objective**
  - Evaluate dose-response effect of minimal doses of D-tagatose (2.5, 5.0 or 7.5 grams dosed 3-times daily) on glycemic control in subjects with Type 2 diabetes not well controlled by diet and exercise
  - 2.5 grams was comparator
- **Design**
  - Multi-center, single-blind, randomized, parallel group clinical study; 6 months duration
  - 34 patients in each of the 3 groups for a total of 102 evaluable patients
- **Clinical Endpoints**
  - Primary: HbA1c ( $\Delta 7.5\text{g}-2.5\text{g} = -0.2\%$ )
  - Secondary: LDL, HDL, TG, glucose, insulin, body weight
    - 7.5 g reduced triglycerides by -42 mg/dl vs. the 2.5 gram dose (EE) and -31 mg/dl ( $p=0.03$ ) (ITT) at 3 months which remained -29 mg/dl at 6 months
    - Mean triglyceride level was 180 at start of trial

# Phase 2 Dose Response Triglyceride Results

- **By the end of the six-month trial, the 7.5 g dose reduced serum triglycerides vs. the 2.5 g dose by -42 mg/dl from a mean of 180 mg/dl in the Evaluable Efficacy (EE) population (-23%)**

# Phase 2 Dose Response Triglyceride Results

- **Unlike some other drugs, D-tagatose lowered triglycerides without elevating VLDL**
- **D-tagatose in the 7.5 g dose reduced LDL vs. the 2.5 g dose by -11 mg/dl by the third month of treatment**
- **The reduction essentially held steady at the six-month end-of-study visit (-10 mg/dl). HDL was unchanged, increasing only between 0.3 and 1.4 mg/dl over the entire course of the study vs. comparator**

# HbA1c and Body Mass Index

	<b>HbA1c</b>	<b>BMI</b>	<b>TG</b>
<b>HbA1c</b>	1	0.722	0.801
<b>BMI</b>	0.722	1	0.718
<b>TG</b>	0.801	0.718	1

Values are Pearson product-moment correlation coefficients,  $p \leq 0.10$

**Levels of glycated hemoglobin (HbA1c ) are directly correlated to levels of triglycerides (TG) and body mass index (BMI). When one of these measures is elevated, the others are likely to be elevated as well. As a result, hyperphagia could, in effect, lead to “fat cell burn-out”.**



- **Objective**
  - Evaluate 15 grams of D-tagatose dosed 3-times daily on glycemic control in subjects with Type 2 diabetes not well controlled by diet and exercise
- **Design**
  - Multi-center, double-blind, placebo-controlled study
  - 494 treatment-naïve patients randomized
  - 34 sites in the U.S., 23 sites in India
    - 102 patients enrolled in the U.S., 254 patients enrolled in India
  - Entry HbA1c between 6.6% and 9.0% (avg. 7.5%)
    - $\leq 6\%$  considered normal,  $\geq 8\%$  considered high, ADA recommends  $\leq 7\%$
- **Clinical Endpoints**
  - Primary: HbA1c
  - Secondary: TG, LDL, HDL, body weight, glucose, insulin,

**NEET Study (Protocol 70971-004)**

Statistically significant reduction of HbA1c in US ITT and PP at all time points

## Reduction in HbA1c Over Time

Patient population	2 months	6 months	10 months
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

- **Patients with  $\geq 1$  treatment-emergent adverse events in the active group (163) was comparable to the placebo group (166)**
  - **No serious adverse event deemed treatment related**
  - **No episodes of hypoglycemia or pancreatitis were reported among any trial subjects**
- **The study was not powered for significance in secondary endpoints (e.g., triglycerides)**

- **Patents include:**
  - Ten national filings based on PCT publication # 2010/054001 as anti-metabolic, atherosclerosis, obesity & diabetes methods and composition with a 2<sup>nd</sup> pharmaceutical agent
  - US patent # 5,447,917 D-tagatose as anti-hyperglycemic agent
  - US patent # 5,356,879 D-tagatose as anti-hyperglycemic agent
- **New Chemical Entity Exclusivity (Hatch-Waxman) – U.S.**
  - 5-year exclusivity (no aNDA's accepted) usually granted to new drug products containing chemical entities never previously approved by FDA either alone or in combination
  - Essentially ~6 years exclusivity (base case)
- **Pediatric Exclusivity – U.S.**
  - 6 months exclusivity for conducting studies in pediatric population
  - Added to end of all existing marketing exclusivity and patent periods
- **New Chemical Entity Exclusivity – E.U.**
  - 10 years exclusivity granted to NCE in European Union

- **Claire L. Kruger, Ph.D., Chief Executive Officer**  
Toxicologist with 20 years of consulting experience; primary area of expertise is in pharmaceuticals, consumer products and foods, where she provides scientific, regulatory, and strategic support to clients in both the US and international regulatory arenas
- **Robert A. Lodder, Ph.D., President**  
Founder of InfraReDx, Inc., Prescient Medical, Inc., and Escent Technologies, Inc.  
Professor of Pharmaceutical Sciences at the College of Pharmacy, University of Kentucky Medical Center. Joint appointments in Electrical & Computer Engineering and in Chemistry.  
Inventor with over 100 publications and 17 patents.
- **Robert L. Clayton, Chief Financial Officer**  
16 years of experience in finance and accounting, including 5 years in public accounting; previously served as Director of Finance and Controller for Spherix
- **Katherine M. Brailer, Corporate Secretary and Director of Administrative Services**  
25 years of experience in all aspects of administrative services, including 10 years as an Officer of Spherix

# Near Term Milestones

Milestone	Initiating
• Perform additional animal studies on hypertriglyceridemia	1Q'11
• File IND for SPX-106 / D-tagatose combination at FDA	4Q'11
• Begin human study with SPX-106 / D-tagatose in hypertriglyceridemia	1Q'12
• Engage partner for D-tagatose in diabetes to continue development	Ongoing

Cash (3/31/11)	\$6.5 million
Working Capital (3/31/11)	\$6.6 million
Revenue (2010)	\$1.4 million
Estimated Cash Burn (2011)	approx. \$4.5-\$5.5 million
Shares Outstanding (3/31/2011)	2.56 million
Warrants Outstanding @ \$32.5	110,435
Warrants Outstanding @ \$28.75	8,283
Warrants Outstanding @ \$15.0	210,000
Warrants Outstanding @ \$15.625	12,600
Warrants Outstanding @ \$8.125	12,807
Warrants Outstanding @ \$8.00	213,450

\*Unaudited

- **D-tagatose and SPX-106 show promise in multiple clinical applications**
  - **Hypertriglyceridemia (\$26 billion treatment market)**
  - **Diabetes (\$175 billion treatment market)**
- **Preclinical and Phase 2 data show significant lowering of triglycerides**
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- **Phase 3 study demonstrated statistically significant reductions in HbA1c in patients with mild Type 2 diabetes**
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