

SEPSIS AND ENDOTOXEMIA

Market Update – February 2011



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Recent Announcements

22 Nov. 2010

Spectral Diagnostics acquires Canadian Distribution Rights for Toraymyxin™

The Company announced that it has acquired the right to market and sell Toraymyxin™ (PMX) - a therapeutic hemoperfusion device that removes endotoxin from the bloodstream of critically ill patients.

This acquisition is consistent with Spectral's intent to position the use of its proprietary EAA™ diagnostic that measures endotoxin levels in whole blood and PMX as the first sepsis "theranostic". Both products are approved for sale by Health Canada.

The Company notes that this agreement consolidates their exclusive access to a North American market with a value estimated in excess of \$1 billion and that their market development activities will begin in the current year.

In October 2010, Spectral announced the initiation of the **EUPRHATES** (*Evaluating the Use of Polymyxin B Hemoperfusion in a Randomized controlled trial of Adults Treated for Endotoxemia and Septic shock*) trial in the United States. In a press release of 3Q'2010 results, Spectral noted that this trial was on-track to have 15 sites enrolling patients by early 2011.

25 Jan. 2011

Eisai - Phase III Study for Eritoran Does Not Meet Primary Endpoint

Preliminary findings from the **ACCESS** (*A Controlled Comparison of Eritoran and Placebo in Patients with Severe Sepsis*), have led the Company to announce that it would not submit marketing authorization applications for regulatory authorities in the United States, EU and Japan before the end of their fiscal year (March 31, 2011).

The planned primary endpoint was all-cause mortality at Day 28 of the study. The Company will continue to analyze the data and re-stated its commitment to addressing critical areas of need, such as sepsis.

ACCESS began enrolling the first of its 2,000 planned severe sepsis patients in November 2007 in more than 150 sites globally. This study targeted early-onset severe sepsis in adults as confirmed by evidence of infection, evidence of SIRS, sepsis-associated organ dysfunction and an APACHE II score of 21-37. Study drug was to be administered no later than 12 hrs. after the first qualifying organ dysfunction was observed.

Study Updates From [clintrials.gov](http://www.clintrials.gov)¹

AstraZeneca CytoFab[™] (ovine polyclonal fragment)

First announced in June 2010, the planned Phase II dose ranging study, is actively recruiting in 43 sites globally (US, Canada, Germany, Spain, Australia) with primary outcome data forecasted August 2011 with an estimated study completion date moved forward to October 2011.

Agennix Talactoferrin alfa

OASIS (*A Phase 2/3 Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of Talactoferrin Alfa in Patients With Severe Sepsis*) was posted on Jan. 7, 2011 and was not yet recruiting subjects at the time of this update.

Estimated enrolment of 1,280 subjects is slated to begin in April of this year with data collection being targeted for January 2014. The primary endpoint is all-cause mortality by Day 28 of the study.

Eli Lilly Xigris[™] (drotrecogin alfa)

The long-running **PROWESS-SHOCK** trial is due to complete in November 2011. The Company launched this trial in March 2008 after the EMA stated that risk/benefit balance of the drug required further clarification.

Estimated enrolment is 1,600 adults with severe septic shock and high risk of death. The primary efficacy endpoint is 28 day all-cause mortality with primary outcome data expected in June 2011.

In a paper² published in the March 2010, the authors' state:

“After this trial, we will be able to confirm the efficacy of this compound or if it should be abandoned.”

¹ In [clintrials.gov](http://www.clintrials.gov) listings, Primary Completion date refers the final data collection date for primary outcome measure. Study Completion date is later allowing for the collection of longer-term and/or secondary outcome measures.

² Eliézer Silva, Luiz Francisco Poli de Figueiredo, and Fernando Colombari* *PROWESS-SHOCK TRIAL: A PROTOCOL OVERVIEW AND PERSPECTIVES* SHOCK, Vol. 34, Supplement 1, pp. 48-53, 2010

The lead author Dr Eliézer Silva served as the Brazilian coordinator for the **PROWESS-SHOCK** Trial from January 1 to December 31, 2009.

Lilly's collaborative study with George Washington University on 12 patients with End Stage Renal disease (*Safety and Dose Finding Study of Xigris in Hemodialysis Patients-Xigris 1003*) is due to complete in January 2011.

APROCCHS (*Activated Protein C and Corticosteroids for Human Septic Shock*) is a randomized, placebo-controlled study actively recruiting to enrol 1280 subjects in 4 centers in France. It is sponsored by a collaboration of University of Versailles. Assistance Publique - Hôpitaux de Paris and the Ministry of Health, France with a scheduled completion of date of March 2012

Canadian investigators are examining the role of Xigris[™] as a possible disease-modifier in the toxemia of pregnancy in two separate prospective observational studies. The smaller 40 subject trial has a listed completion date of Dec. 2010 with the larger 2,000 subject trial reading out in Dec. 2011.

Looking Forward

The 31st International Symposium of Intensive Care & Emergency Medicine, March 22-25, 2011 in Brussels promises to be an interesting and potentially informative meeting ... particularly the morning session of March 24th. Among the scheduled topics will be an update on Lactoferrin (Dr. Phil Dellinger) and a presentation on Eritoran study results by the lead investigator, Dr. Steven Opal.

Medwell View

Despite the optimism expressed in Eisai's initial press release, Eritoran's future as a sepsis therapeutic seems dubious. In the absence of strongly positive signals generated by planned or ad-hoc analyses, negotiations with Regulatory Authorities on a path to market authorization will be prolonged. **ACCESS** investigators (and others) will press for the release of additional data from this study and Dr. Steve Opal's planned presentation in Brussels could be an important event in this process.

Speculation around Xigris™ will increase as the Company moves toward the completion of the **PROWESS-SHOCK** trial in H2'2011. If the Critical Care community as a whole hold views similar to those of Dr. Silva, a negative outcome for this trial could lead to a re-examination of the drug's clinical utility by critical care organizations and reimbursement status by cost-conscious payors. Arguably, further declines in unit volumes and sales revenue could lead Eli Lilly to reconsider the commercial future of this product.

AstraZeneca appears to have made the progress expected in the execution of their clinical trial programs. We will watch with interest the projections around recruitment rates and study completion dates which have moved in recent weeks.

Acquisition of Canadian distribution rights from Toray consolidates Spectral Diagnostics' North American market for their sepsis "theranostic". The combination of the EAA™ diagnostic and a novel therapeutic approach of removing a sepsis trigger (endotoxin) via a method that minimizes systemic complications in patients with confirmed severe sepsis.

Figure 1. summarizes the currently estimated dates for the availability of efficacy data from the clinical trial programs of selected sepsis therapeutics.

We note that Spectral appears to be the best positioned of all near-term market entrants for novel sepsis therapies by virtue of their initiation of a Phase III registration study and their forecasted date for efficacy data of January 2013. Bearing in mind that PMX is medical device; the regulatory

review process may be of shorter duration than might be expected for either small molecule or biological NCE's³.

Agennix has recently amended its clinical development plans for Fortis-M (non-small cell lung cancer) and talactoferrin alfa (severe sepsis) to conserve the EUR 76m funds raised in October 2010.

The revised strategy now calls for the **OASIS** study of talactoferrin alfa to be a Phase II/III trial rather than Phase III trial originally slated for Q1 2011.

It is believed that this approach will provide additional information on the compound and build on the positive results from the previous Phase II trial prior to commencing the larger and more expensive Phase III trial.

Further, the Phase II results will enable Agennix to modify the design of the Phase III stage, if required, to improve the likelihood of success in the pivotal element of the study. The revised strategy will result in a one-year delay in the initiation of the Phase III trial.

Adhering to the forecasted start/finish dates for this study will be a challenge given that other studies of similar magnitude⁴ have suffered from prolonged patient recruitment and delayed study completion dates.

Based on the EUR 19.2m reduction in R&D, the Company is projected to have sufficient funds for operations until mid-2012. However, if the related party loan is not extended or converted into equity, there is a possibility that the Company will not have completed the first part of the Phase II/III trial for talactoferrin. This would leave the Company facing another highly dilutive/expensive financing or dependent on the demands of potential partners for talactoferrin.

³ New Chemical Entity

⁴ Eritoran (**ACCESS**) or Xigris™ (the **PROWESS** series of trials)







Figure 1. Comparison of Primary Completion Dates for Selected Sepsis Therapeutics

Company	Product	Study Acronym	Study Phase	Estimated Enrolment	Indication	Primary Efficacy Outcome	Start Date	Primary Completion Date
Spectral Diagnostics	PMX column	EUPHRATES	3	360	Septic shock / endotoxemia	28-day mortality (all cause)	Jun 2010	Jan 2013
Agennix	Talactoferrin	OASIS	2/3	1280	Severe sepsis	28-day mortality (all cause)	Apr 2011	Jan 2014
AstraZeneca	CytoFab™		2	300	Severe sepsis / septic shock	Ventilator-free days	Oct 2010	Aug 2011
	CytoFab™		2	20	Severe sepsis / septic shock	Safety / Tolerability of 2 Doses	Jul 2010	Aug 2011

Upcoming Value-Driving Milestones in Sepsis

A range of key clinical and business development events in the sepsis space are forecast to occur over the next 30 months that have the potential to influence share prices and valuation. While precise timing of events is difficult to predict, management of the leading sepsis players has provided the following general guidance regarding their sepsis programs.

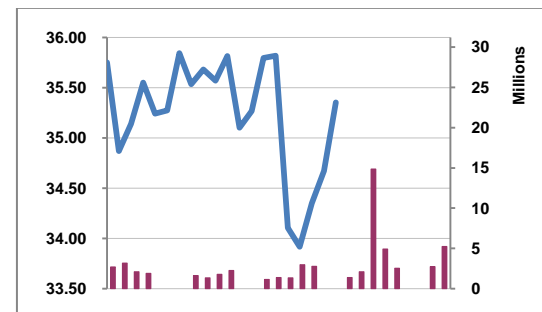
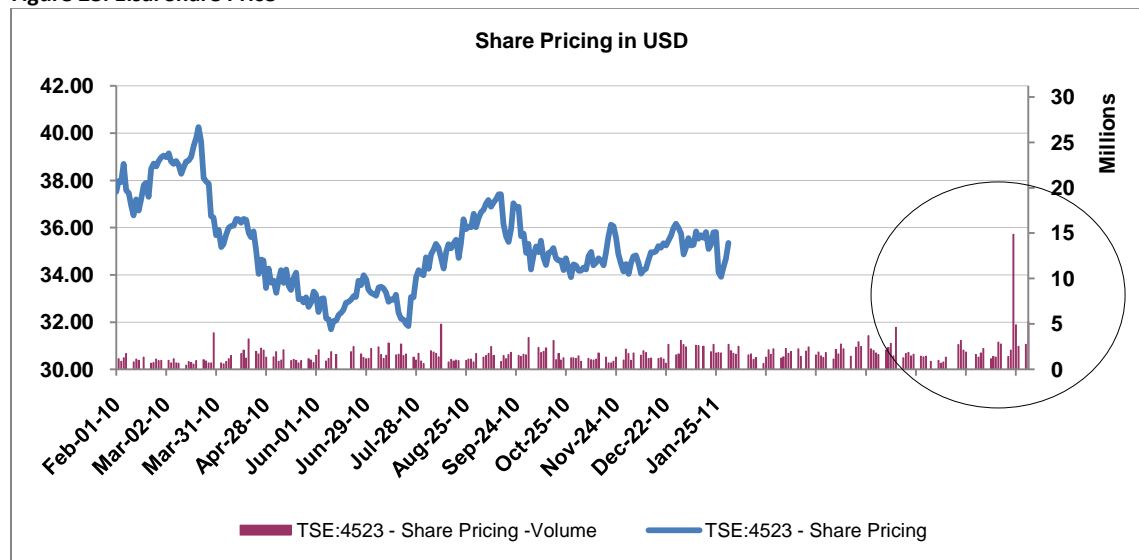
Figure 2: Key Milestones in Sepsis Space

Company	H1/11	H2/11	H1/12
			
		Full data set from Phase 3 clinical trial of Xigris™ for treatment of adult patients with severe septic shock (>1,600 patients)	Results of French “APROCCHS” trial of Activated Protein C and Corticosteroids for Human Septic Shock (1280 patients)
		Results of global Phase 2b clinical trial of CytoFab™ for treatment of adults with severe sepsis (300 patients) Results of Japan Phase 2 clinical trial of CytoFab™ for treatment of adults with severe sepsis (20 patients)	
	Commence Phase 2 portion of Phase 2/3 clinical trial of Talactoferrin in adults with severe sepsis (350 patients) Announce licensing partner for Talactoferrin in treatment of sepsis		
	File for CE Mark approval in Europe for CytoSorb in the treatment of severe sepsis	Commence randomized, controlled pivotal US study of CytoSorb for treatment of severe sepsis	
		Interim Analysis of “EUPHRATES” Phase 3 trial	

Value Impact of Key Milestones

Eisai – On January 25, 2011, Eisai announced preliminary data analysis results that septic shock treatment Eritoran did not meet the primary endpoint of reduction in 28-day all-cause mortality in the highly-anticipated Phase 3 ACCESS trial. According to Eisai’s announcement, the Company will not seek regulatory approval for the drug in Japan, the US and Europe before the end of FY 2011. The Company has announced that it is preparing a detailed analysis of clinical data to determine how to proceed, indicating that the Company may not abandon development of Eritoran. The market consensus share target return was revised to -11.2% (representing approximately ~YEN 100B reduction in market capitalization). The market’s swift reaction demonstrates the significant level of pipeline stress placed on Eisai as they are facing the loss of the global Aricept franchise and possess a debt-constrained balance sheet, in order to maintain the Company’s stated target of a 33% cash payout ratio. With the loss of US patent protection on Aricept and the removal of future potential Eritoran sales, the Company’s payout ratio is likely to rise significantly above the stated ratio, leaving the Company with no choice but to cut dividends.

Figure 28: Eisai Share Price



Source: Capital IQ

Company Overview

Name: BTG plc
Type: Public Company
Website: www.btgplc.com
Ticker: LSE:BGC
Location: London, United Kingdom

Business Description

BTG plc, a specialty pharmaceuticals company, engages in the development and commercialization of life science technologies primarily in the United States, Europe, and Asia. It focuses on medicines that are used in critical care situation, and to treat cancer, neurological, and other disorders. The company's product pipeline comprises Vraxaze glucarpidase for the treatment of delayed methotrexate elimination; Varisolve polidocanol endovenous microfoam, a Phase 3 clinical trial product to treat varicose veins; OncoGel paclitaxel aqueous gel injection, a Phase 2b product candidate for the treatment of oesophageal cancer; and Angiotensin therapeutic vaccine, which is in Phase 2a clinical trials to treat hypertension. Its products pipeline also includes Prolarix, a Phase 2a product for primary liver cancer; Acadra acadesine, which is in Phase 1/2 clinical trials to treat B-cell chronic lymphocytic leukaemia; BGC20-0134, a Phase 1 clinical trial product for multiple sclerosis; and BGC20-1531, a Phase 1 clinical trial product to treat migraine headache. The company offers BeneFIX for the treatment of haemophilia B; CroFab, an antidote used to treat mild or moderate envenomation from Crotalid snakes, which include rattlesnakes; two-part hip cup, a prosthetic hip joint replacement; Campath, a anti-lymphocyte antibody to treat B-cell chronic lymphocytic leukaemia; DigiFab, an antidote to treat patients with digoxin toxicity or overdose; and three-part knee, a unicompartmental knee joint replacement. The company was founded in 1948 and is headquartered in London, the United Kingdom.

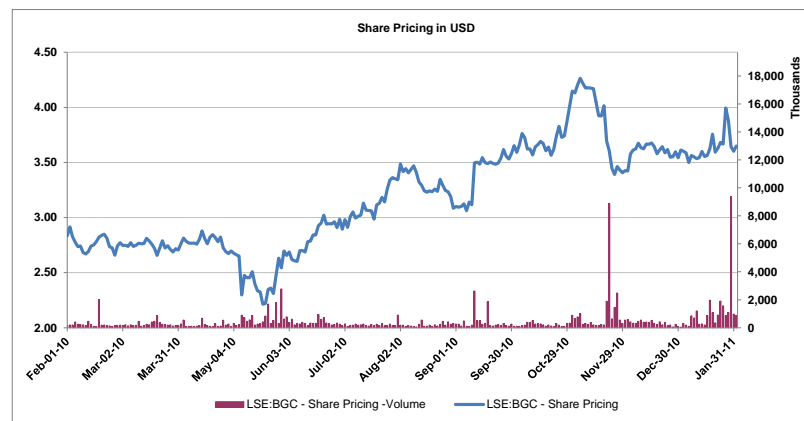
Trading Statistics (Currency: USD)

Last (Delayed Quote)	\$ 3.60	Shares Out. (mm)	325.61
52 wk High/52 wk Low	4.34079 / 2.40442	Avg. Vol - 3 mo (mm)	0.86

Financial Information (Currency: USD)

Market Capitalization (mm)	\$ 1,172.78	LTM Revenue (mm)	\$ 151.89
Cash & ST Invst. (mm)	\$ 100.37	LTM EBITDA (mm)	\$ 24.97
Technology Value (mm)	\$ 1,086.77	LTM Net Income (mm)	\$ 15.08

Last Updated February-01-11



Sepsis-Related Technologies and Products

- CytoFab (AZD9773), an investigational ovine polyclonal antibody fragment that neutralizes TNF-alpha
- Status: Two Phase 2 trials for CytoFab in the treatment of severe sepsis underway: 1) Phase 2 initiated June 2010 in Japan; 20 subjects; anticipated completion Sept 2011, and 2) a global Phase 2b initiated Oct 2010; 300 subjects; anticipated completion Oct 2011

Strategic Positioning

- Dec 2008: BTG acquired Protherics and the license for CytoFab
- Dec 2005: Protherics and AstraZeneca announced late-stage licensing agreement for CytoFab; under the agreement Protherics to receive an initial payment of £16.3M, a £7.5M equity investment to be paid in cash, and milestone payments up to £171M, excluding royalties; under the agreement AstraZeneca is responsible for clinical development and Protherics for bulk manufacturing

Recent Key Events

- Jan 2011: BTG acquired Biocompatibles International, a medical technology company in the field of drug-device combination products, for £170M. The acquisition strengthens BTG's product portfolio and pipeline in specialist products
- July 2010: AstraZeneca to file for approval for CytoFab in U.S.; EU filing date extended from 2014 to 2015 in order to strengthen submission
- June 2010: Two additional Phase 2 studies announced; including a smaller study (20 subjects) in Japan and a larger study (300 subjects) in NA, EU and Australia
- July 2009: Phase 2 dose-escalation study in 74 severe sepsis patients completed; no data has been published to date

Upcoming Milestones

- Sept 2011: Estimated study completion date of first of two new Phase 2 clinical trials for CytoFab in the treatment of severe sepsis; primary endpoints are safety/tolerability
- Oct 2011: Estimated study completion date of Phase 2b clinical trial for CytoFab to compare the efficacy and safety of two dosing regimens in adult patients with severe sepsis
- 2015: Projected MAA submission (EU) and NDA submission (U.S.) dates

Company Overview**Name:** Eli Lilly & Co.**Type:** Public Company**Website:** www.lilly.com**Ticker:** NYSE:LLY**Location:** Indianapolis, United States**Business Description**

Eli Lilly and Company develops, manufactures, and sells pharmaceutical products worldwide. It offers neuroscience products to treat schizophrenia, manic episodes, and bipolar maintenance; depression and diabetic peripheral neuropathic pain; attention-deficit hyperactivity disorder in children, adolescents, and adults; depression, bulimia nervosa, and obsessive-compulsive disorders; and bipolar depression and treatment-resistant depression. Eli Lilly distributes its products principally through independent wholesale distributors, as well as directly to pharmacies. The company was founded in 1876 and is based in Indianapolis, Indiana.

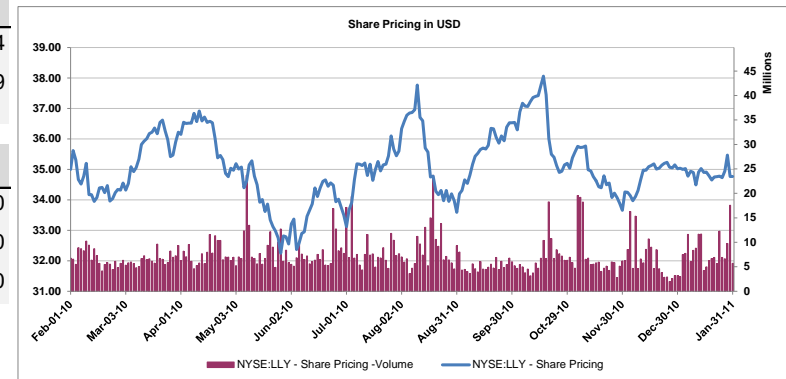
Trading Statistics (Currency: USD)

Last (Delayed Quote)	\$ 35.10	Shares Out. (mm)	1153.14
52 wk High/52 wk Low	38.08 / 32.02	Avg. Vol - 3 mo (mm)	7.29

Financial Information (Currency: USD)

Market Capitalization (mm)	\$ 40,094.78	LTM Revenue (mm)	\$ 23,076.00
Cash & ST Invst. (mm)	\$ 6,140.10	LTM EBITDA (mm)	\$ 8,091.80
Technology Value (mm)	\$ 41,084.18	LTM Net Income (mm)	\$ 5,069.50

Last Updated February-01-11



Sepsis-Related Technologies and Products

- Xigris (Drotrecogin alpha (activated)); a recombinant activated protein C, inhibits Factors Va and VIIIa in the coagulation cascade; also inhibits PAI-1 and tumor necrosis factor production

- Status: Phase 3 confirmatory trial for Xigris in adult patients with severe sepsis initiated Mar 2008; 1,500 subjects; anticipated completion Nov 2011; APROCCHS (Activated Protein C and Corticosteroids for Human Septic Shock) study currently recruiting subjects at four centers in France; 1280 subjects targeted

Recent Key Events

- Feb 2009: FDA working with Lilly to further evaluate the incidence of severe bleeding and death in patients who received Xigris; FDA will communicate results of study and recommendations upon completion of the review; timeline uncertain but likely to take several months

- Mar 2008: Recruitment commenced for second, large confirmatory Xigris trial to maintain original approval for treatment of severe sepsis in adult patients; target enrolment of 1,500 subjects from 182 sites worldwide

Strategic Positioning

- Xigris is the only approved pharmaceutical therapy indicated for the treatment of severe sepsis in adult patients

- Xigris increases the risk of bleeding and has a series of contraindications including active internal bleeding, hemorrhaging stroke and trauma with life-threatening bleeding

- Sales figures for 2009 were US\$127M, 2008 US\$161M; sales have been hindered by small eligible patient population due to contraindications and high relative cost of treatment (US\$1,700 per day)

- Annual reassessments from EMEA are required; as a result of these reviews and remaining questions over the current risk-benefit profile, a new trial focused on patient selection and safety assessments was initiated

Upcoming Milestones

- Nov 2011: Forecasted completion date for Xigris Phase 3 confirmatory trial

- Mar 2012: Anticipated completion date of APROCCHS (Activated Protein C and Corticosteroids for Human Septic Shock) clinical trial in France (1280 subjects)

Company Overview

Name: Eisai Co. Ltd.

Type: Public Company

Website: www.eisai.co.jp

Ticker: TSE:4523

Location: Tokyo, Japan

Business Description

Eisai Co., Ltd. manufactures and markets pharmaceutical drugs, over-the-counter drugs, and pharmaceuticals production systems and equipment primarily in North America, Europe, and Asia. Its primary products include Aricept, which is in Phase 1 clinical trials to treat Alzheimer's disease; AcipHex, a proton pump inhibitor that is in Phase 3 clinical trials. Eisai also offers consumer healthcare products, food additives, and chemicals. The company was formerly known as Nihon Eisai Co., Ltd. and changed its name to Eisai Co., Ltd. in 1955. Eisai was founded in 1941 and is headquartered in Tokyo, Japan.

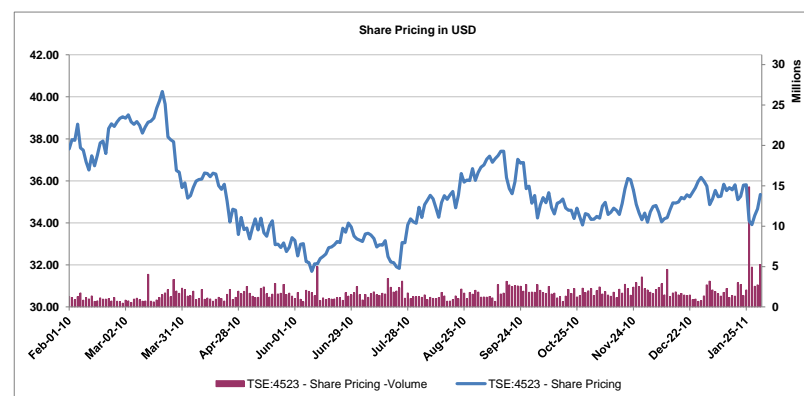
Trading Statistics (Currency: USD)

Last (Delayed Quote)	\$ 35.35	Shares Out. (mm)	284.94
52 wk High/52 wk Low	45.1114 / 33.6709	Avg. Vol - 3 mo (mm)	2.22

Financial Information (Currency: USD)

Market Capitalization (mm)	\$ 10,073.27	LTM Revenue (mm)	\$ 9,819.32
Cash & ST Invst. (mm)	\$ 2,168.60	LTM EBITDA (mm)	\$ 2,190.76
Technology Value (mm)	\$ 12,629.35	LTM Net Income (mm)	\$ 590.81

Last Updated February-01-11



Sepsis-Related Technologies and Products

- Eritoran (Eritoran tetrasodium (E5564)); structurally similar to lipid A, acts as a TLR4 antagonist to block excessive reaction of the innate immune system to endotoxin
- Status: ACCESS clinical trial for use of Eritoran in severe sepsis did not meet primary endpoint of reduction in 28-day all-cause mortality

Recent Key Events

- Jan 2011: Preliminary findings from ACCESS Phase 3 trial for use of Eritoran in severe sepsis indicate the primary endpoint of reduction in 28-day all-cause mortality was not met. Plans to file for regulatory approval in the US, EU and Japan have been dropped
- Mar 2010: Review of interim efficacy of Phase 3 ACCESS trial did not reveal safety concerns and enrolment of patients continued; recommended increasing enrolment from 1,500 to 2,000 subjects
- Jan 2010: Phase 2 trial data published; results indicated Eritoran was well-tolerated in patients with severe sepsis (300 subjects)

Strategic Positioning

- In wake of Eritoran failure and loss of US patent protection on top-seller Aricept (Nov 2010), Eisai announced it will submit simultaneous applications in the US and EU in Q12011 for anti-epileptic drug perampanel

Upcoming Milestones

- Eisai will continue to analyze the preliminary Phase 3 ACCESS data to determine Eritoran next steps

Company Overview

Name: Toray Industries Inc.
Type: Public Company
Website: www.toray.co.jp
Ticker: TSE:3402
Location: Tokyo, Japan

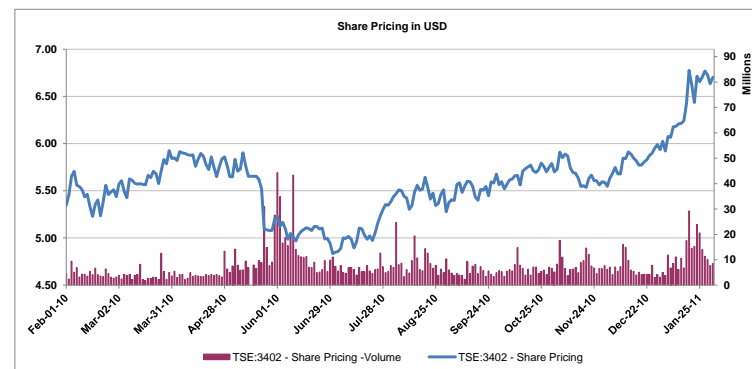
Business Description

Toray Industries, Inc. and its subsidiaries provide fibers and textiles, plastics and chemicals, IT-related products, carbon fiber composite materials, environment and engineering products, and life science products. It has operations in Europe, North America, and Asia. Toray Industries formed a joint development agreement with Daimler AG to develop components made from carbon-fiber reinforced plastics for series production vehicles. The company was formerly known as Toyo Rayon Co., Ltd. and changed its name to Toray Industries, Inc. in January 1970. Toray Industries was founded in 1926 and is headquartered in Tokyo, Japan.

Trading Statistics (Currency: USD)				
Last (Delayed Quote)	\$	6.70	Shares Out. (mm)	1629.38
52 wk High/52 wk Low		6.92322 / 5.15559	Avg. Vol - 3 mo (mm)	8.81

Financial Information (Currency: USD)					
Market Capitalization (mm)	\$	10,920.52	LTM Revenue (mm)	\$	17,654.00
Cash & ST Invst. (mm)	\$	851.57	LTM EBITDA (mm)	\$	1,791.77
Technology Value (mm)	\$	17,064.66	LTM Net Income (mm)	\$	204.43

Last Updated February-01-11



Sepsis-Related Technologies and Products

- Toraymyxin, a selective blood endotoxin removal hemofiltration cartridge that captures endotoxin
- Status: Phase 3 EUPHRATES trial initiated by Spectral Diagnostics June 2010; 360 subjects; anticipated completion 2013

Recent Key Events

- June 2010: Phase 3 EUPHRATES trial initiated by Spectral Diagnostics; 360 subjects recruited
- June 2009: Results of Phase 2 EUPHAS trial announced by Spectral; findings demonstrated that Toraymyxin, when combined with conventional therapy, significantly improved hemodynamics and organ dysfunction and reduced 28-day mortality in patients with severe sepsis and septic shock

Strategic Positioning

- Nov 2010: A long-term, exclusive distribution agreement signed with Spectral to market and sell Toraymyxin in Canada
- Mar 2009: Spectral acquired the US rights to the Toraymyxin device with the strategic intent of applying their proprietary Endotoxin Activity Assay (EAA) to guide the treatment of endotoxemia in severe sepsis patients
- May 2008: Collaboration with Spectral Diagnostics; Spectral to have access to Toray's distributors in China, India, Russia and Canada for the sales and promotion of EAA in combination with Toraymyxin
- July 2007: Toray announced its partnership with Torii Pharmaceutical Co. Ltd for the joint promotion of Toraymyxin in Japan

Upcoming Milestones

- H2 2011: Spectral interim data and analysis from Phase 3 EUPHRATES trial for Toraymyxin in sepsis
- 2013: Anticipated final data and commercial launch of Toraymyxin in U.S. Market by Spectral

Company Overview

Name: Agennix AG
Type: Public Company
Website: www.agennix.com
Ticker: DB:AGX
Location: Planegg, Germany

Business Description

Agennix AG, a biopharmaceutical company, engages in developing therapies in the areas of unmet medical needs to improve the length and quality of life of seriously ill patients primarily in Germany and the United States. The company's lead program, talactoferrin, is an oral targeted therapy in Phase III clinical development for the treatment of severe sepsis and non-small cell lung cancer. Its other clinical development programs include RGB-286638, a multi-targeted kinase inhibitor in Phase I testing for solid tumors; satraplatin, the oral platinum-based compound for prostate and other cancers; and a topical gel form of talactoferrin for diabetic foot ulcers. The company was founded in 1997 and is based in Planegg, Germany.

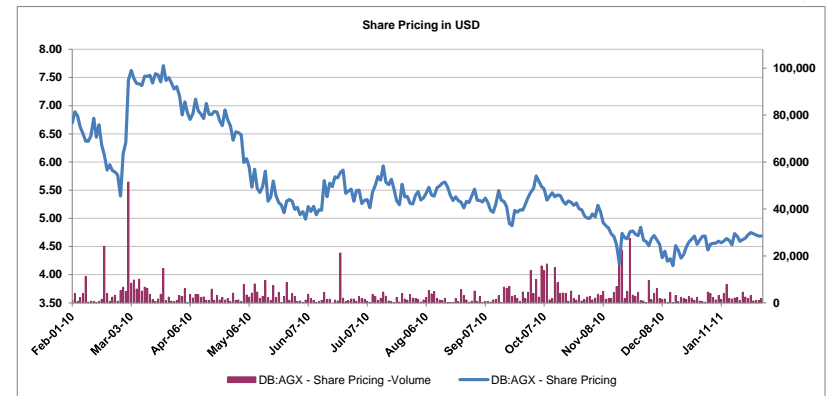
Trading Statistics (Currency: USD)

Last (Delayed Quote)	\$ 4.68	Shares Out. (mm)	41.88
52 wk High/52 wk Low	8.00055 / 3.92904	Avg. Vol - 3 mo (mm)	0.00

Financial Information (Currency: USD)

Market Capitalization (mm)	\$ 196.18	LTM Revenue (mm)	\$ 10.36
Cash & ST Invst. (mm)	\$ 15.01	LTM EBITDA (mm)	-\$ 28.11
Technology Value (mm)	\$ 97.31	LTM Net Income (mm)	-\$ 28.14

Last Updated February-01-11



Sepsis-Related Technologies and Products

- Talactoferrin alfa, a recombinant form of human lactoferrin; effectiveness has been demonstrated in treatment of both non-small cell lung and renal cancer and severe sepsis
- Status: Phase 2 portion of Phase 2/3 clinical trial for talactoferrin in severe sepsis to be initiated Mar/Apr 2011 (350 subjects); Phase 3 portion to be initiated quickly after Phase 2 completion, with plans to run a second Phase 3 trial consecutively

Recent Key Events

- Jan 2011: Additional data from initial Phase 2 trial for talactoferrin in severe sepsis released; data showed the reduction of all-cause mortality was sustained at three and six months
- Nov 2010: Revised clinical trial plan for talactoferrin in severe sepsis includes completion of a Phase 2/3 trial prior to initiation of the second Phase 3 trial
- Feb 2010: Additional positive long-term mortality data from Phase 2 released; results showed talactoferrin also reduced all-cause long-term mortality compared to placebo
- Dec 2009: Study results from Phase 2 trial for treatment of severe sepsis released; reduction in mortality was seen both in patients with and without cardiovascular depression
- Late 2008: Two Phase 3 trials for use of talactoferrin alfa in cancer treatment initiated in US; expanded to Europe in 2010
- Apr 2008: Phase 2 trial for use of oral talactoferrin for treatment of severe sepsis in the presence/absence of cardiovascular depression initiated; 190 subjects recruited

Strategic Positioning

- Re-financing strategy for 2010 includes raising €9.8M in a private placement with existing shareholders (Mar 2010), a €15M loan from major shareholder dievini Hopp Biotech at an interest rate of 6% per annum (July 2010), and a planned rights equity offering; €76M has been raised as of Oct 2010
- Re-financing to put the Company on sound financial ground and create negotiating power with potential partners; the Company is actively seeking a partnership for oral talactoferrin

Upcoming Milestones

- Mar/Apr 2011: Expected initiation of Phase 2 portion of Phase 2/3 clinical trial for talactoferrin in severe sepsis (350 subjects), with Phase 3 portion to be initiated quickly upon completion
- Second Phase 3 trial for talactoferrin in severe sepsis planned to follow completion of first Phase 3 trial, at recommendation of FDA to support potential BLA submission
- 2014: Anticipated completion of Phase 2/3 clinical trial for talactoferrin in severe sepsis

Company Overview

Name: Spectral Diagnostics Inc.

Type: Public Company

Website:

www.spectraldiagnostics.com

Ticker: TSX:SDI

Location: Toronto, Canada

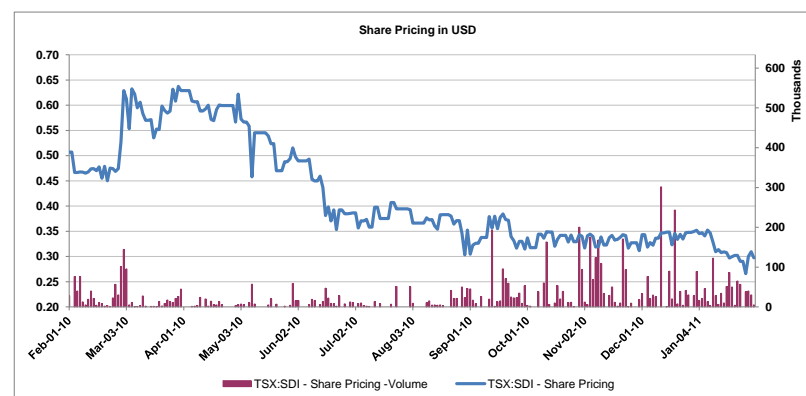
Business Description

Spectral Diagnostics Inc., a medical diagnostics company, manufactures, commercializes, and markets rapid diagnostics and various proprietary reagents. Its lead product, Endotoxin Activity Assay (EAA), is a biomarker for the identification of patients at risk for sepsis. The company also offers RapidWN West Nile Virus IgM Test, an assay that helps physicians in obtaining diagnostic information regarding exposure to the West Nile virus; and Toraymyxin, a therapeutic hemoperfusion device that removes endotoxin from the bloodstream. Spectral Diagnostics Inc. operates primarily in Canada, the United States, and Europe. The company was founded in 1991 and is based on Toronto, Canada.

Trading Statistics (Currency: USD)				
Last (Delayed Quote)	\$	0.30	Shares Out. (mm)	80.55
52 wk High/52 wk Low		0.75567 / 0.267	Avg. Vol - 3 mo (mm)	0.05

Financial Information (Currency: USD)					
Market Capitalization (mm)	\$	23.94	LTM Revenue (mm)	\$	2.90
Cash & ST Invst. (mm)	\$	15.84	LTM EBITDA (mm)	-\$	4.57
Technology Value (mm)	\$	8.79	LTM Net Income (mm)	-\$	5.55

Last Updated February-01-11



Sepsis-Related Technologies and Products

- "Theranostic" consists of diagnostic tool (Endotoxin Activity Assay (EAA)) and therapeutic device (Toraymyxin (PMX)); EAA guides the treatment of endotoxemia, PMX is a selective blood endotoxin removal hemofiltration cartridge that captures endotoxin
- Status: Phase 3 EUPHRATES trial initiated June 2010; 360 subjects; anticipated completion

Strategic Positioning

- Mar 2010: Raise of \$19.5M completed (grew from \$14M prior to closing); funds to be used to advance Toraymyxin towards regulatory approval and commercialization in US
- July 2008: An exclusive distribution agreement signed with BB Medical, a distributor of medical technologies, for EAA in Russia
- May 2008: Spectral to have access to Toray Industries' distributors in China, India, Russia and Canada for the sales and promotion of EAA in combination with Toraymyxin

Recent Key Events

- Nov 2010: Long-term, exclusive distribution agreement signed with Toray to market and sell Toraymyxin in Canada
- June 2010: Phase 3 EUPHRATES trial initiated; 360 subjects recruited
- Mar 2010: Private placement for \$19.5M completed
- Feb 2010: IDE approval received from U.S. FDA
- June 2009: Results of Phase 2 EUPHAS trial announced; findings demonstrated that Toraymyxin, when combined with conventional therapy, significantly improved hemodynamics and organ dysfunction and reduced 28-day mortality in patients with severe sepsis and septic shock
- Mar 2009: US Rights for the development and commercialization for Toraymyxin acquired by Spectral

Upcoming Milestones

- H2 2011: Interim data and analysis from Phase 3 EUPHRATES trial for Toraymyxin in sepsis
- 2013: Anticipated final data and commercial launch of Toraymyxin in US Market

Company Overview

Name: Cytosorbents Corporation

Type: Public Company

Website: www.medasorb.com

Ticker: OTCBB:CTSO

Location: Monmouth Junction, United States

Business Description

Cytosorbents Corporation, a therapeutic medical device company, engages in the research, development, manufacture, and commercialization of blood purification technologies that would remove middle molecular weight toxins from circulating blood and physiologic fluids. It is developing two products, CytoSorb and BetaSorb utilizing its adsorbent polymer technology. The company was formerly known as MedaSorb Technologies Corporation and changed its name to Cytosorbents Corporation on May 7, 2010. Cytosorbents Corporation was founded in 1997 and is headquartered in Monmouth Junction, New Jersey.

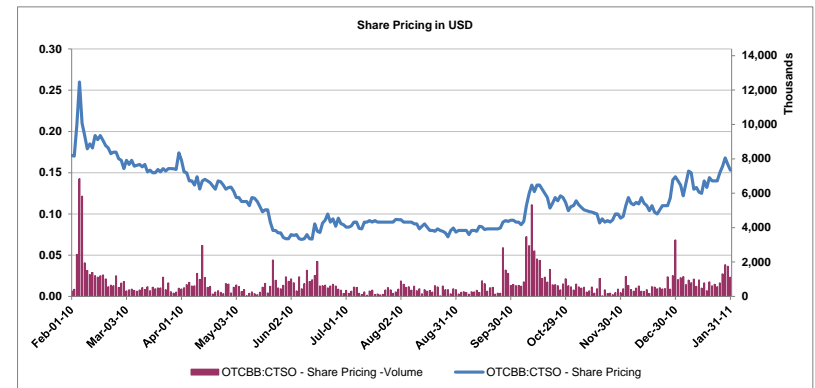
Trading Statistics (Currency: USD)

Last (Delayed Quote)	\$ 0.15	Shares Out. (mm)	118.17
52 wk High/52 wk Low	0.3 / 0.059	Avg. Vol - 3 mo (mm)	0.67

Financial Information (Currency: USD)

Market Capitalization (mm)	\$ 18.08	LTM Revenue (mm)	\$ -
Cash & ST Invst. (mm)	\$ 0.76	LTM EBITDA (mm)	-\$ 2.96
Technology Value (mm)	\$ 18.20	LTM Net Income (mm)	-\$ 2.72

Last Updated February-01-11



Sepsis-Related Technologies and Products

- CytoSorb, hemoperfusion device that filters cytokines and other toxins from the blood via extracorporeal purification; clinical applications include the treatment of sepsis, the prevention and treatment of organ dysfunction, and the prevention and treatment of post-operative complications of cardiopulmonary bypass surgery
- Status: CytoSorb Clinical trial for the treatment of sepsis initiated Dec 2007; 100 subjects; anticipated enrolment completion Q1 2011

Strategic Positioning

- Multiple applications for CytoSorbents' blood purifying adsorbent polymer technology including sepsis, organ transplantation and kidney failure
- Regulatory approval and subsequent commercialization of CytoSorb to initially be focused on European market
- Company low on cash and reliant on non-traditional sources of financing at small amounts, also experiencing difficulty in reaching enrolment targets
- May 2010: \$6M purchase agreement signed with Lincoln Park Capital Fund, a Chicago-based institutional investor; over a 25-month period CytoSorbents will have the right to sell common stock in amounts from \$50,000-\$750,000 for up to an aggregate of \$6M

Recent Key Events

- Feb 2010: \$299K raised through second year participating in New Jersey Emerging Technology and Biotechnology Financial Assistance Program, and \$80K through sub-contracting work for the University of Pittsburgh; funds to be used to support European sepsis study, which reached the halfway point in subject enrolment (50 subjects to date)
- Dec 2009: Clinical trial re-initiated with revised protocol; target of 100 subjects
- Nov 2009: Preliminary clinical data reported; data from 13 subjects demonstrated improvements in many of the secondary and exploratory endpoints of the trial
- Feb 2009: \$109M raised through participation in New Jersey Emerging Technology and Biotechnology Financial Assistance Program and second close of Series B financing
- July 2008: \$4.45M private placement of Series B 10% Cumulative Convertible Preferred Stock closed; the funding is targeted for the German sepsis study
- Dec 2007: CytoSorb clinical trial opened for enrolment in Germany; CytoSorb to be tested in as an adjunctive treatment for acute respiratory distress syndrome and acute lung injury in the setting of sepsis; target of 75 subjects

Upcoming Milestones

- Q1 2011: Anticipated completion of enrolment for CytoSorb clinical trial for the treatment of sepsis