

Breakthrough Appendicitis Diagnostic Blood Test & New rDNA Drugs

Stock Price Performance & Volume: APPY



Key Statistics (mrq ended March 31, 2009)

Business	Bio Science
Stock Price (5/1/09)	\$1.76
Stock Symbol (Nasdaq:CM)	APPY
Avg. Daily Trading (90 day)	259,000
Shares Outstanding/Fully Diluted	31.7M / 36.9M
52 Week Low/High	\$1.05 - \$7.80
Public Float, est.	29.9M
Market Capitalization	\$55.8M
Insider Holdings	19%
Institutional Holdings, est	38%
Revenues (ttm)	\$528K
EPS (ttm)	(\$0.31)
Cash & ST Investments (mrq)	\$15.1M
Total Assets (mrq)	\$21.8M
Total Liabilities (mrq)	\$6.3M

Management & Headquarters

Daryl Faulkner, Executive Chairman & CEO

Greg Pusey, Vice Chairman

Dr. Robert Caspari, COO & Chief Medical Officer

Jeff McGonegal, Chief Financial Officer

Dr. Mark Colgin, Chief Scientific Officer

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AspenBio Pharma Highlights

- The company is advancing toward commercialization of **AppyScore™**, the world's first blood test to aid in the diagnosis of human appendicitis and plans to file a 510(k) application with the FDA by the end of Q2 2009.
- Several studies, including a pilot study and recently completed formal FDA trial, demonstrated **AppyScore's** sensitivity and negative predictive value is greater than 90% when used along with other common modalities typically used in diagnosing appendicitis.
- Recent senior management additions (Faulkner & Caspari) have added extensive leadership, diagnostic and regulatory experience.
- Novel and **patented** recombinant DNA ("rDNA") single-chain technology for animal therapeutics: producing a **new class** of recombinant drugs which mimic natural reproductive hormones for animals of economic importance.
- **Two bovine drugs** submitted for FDA clearance to be commercialized in accordance with a long term development and marketing agreement with **Novartis Animal Health** (NYSE:NVS).

AspenBio Pharma Overview

AspenBio Pharma, Inc. is dedicated to the discovery, development and marketing of novel patented diagnostics to aid physicians in making more accurate medical decisions. Additionally, a cornerstone of our business has also been bringing innovative therapeutics to market to enhance animal reproduction. All product development is focused on large worldwide markets that target previously unmet clinical needs.

Market Opportunity: Better Test for Appendicitis

In the U.S. alone, it is estimated that more than 10 million people annually enter hospital Emergency Departments ("ED") with abdominal pain potentially related to appendicitis. In addition to physical exam and lab tests, the use of Computed Tomography ("CT") as a screening tool for diagnosing appendicitis has grown substantially over the last 10 years.

While considered the best diagnostic method currently available, the cost, time, and safety concerns associated with CT make it an undesirable screening tool. A CT scan can also be difficult to read in children and young adults. Diagnosis in women with abdominal pain is also more difficult due to common gynecological conditions having symptoms similar to appendicitis. Recent published studies have also raised health concerns about the possible harmful effects of radiation levels in CT scans which increase with multiple scans. One abdominal CT scan exposes a patient to a radiation dose equivalent to more than 500 chest X-rays.

About the Human Appendix & Appendicitis

The **Appendix** is a 3 1/2-inch-long tube of tissue that extends from the large intestine. It contains specialized tissue that can produce antibodies, as well as grow and protect digestive bacteria.



Appendicitis is an inflammation of the appendix. Left untreated, an inflamed appendix can eventually burst or "perforate," spilling infectious materials into the abdominal cavity, which can be fatal unless treated quickly.

Out of the 10 million annual ED patients, approximately 310,000 have their appendix removed. Historically, due to limited effectiveness of diagnostic tools, an estimated 8%-14% of patients are determined, upon having surgery to have had a normal appendix, i.e., one that did not require removal. Total hospital charges for the surgical removal of a normal appendix are estimated to exceed \$400 million annually in the US.

In addition to those patients incorrectly diagnosed with appendicitis, certain studies indicate approximately 18% of patients that have appendicitis are initially misdiagnosed and sent home only to return to the hospital with a more advanced disease or perforation. Once an appendix is perforated, it may become life threatening and the surgery is more complicated. The treatment also becomes more costly and requires a significantly longer recuperation time. Due to the removal of healthy appendixes and/or misdiagnosis, many appendicitis cases result in litigation.

The AppyScore Solution

To address the need for an objective, quantitative, rapid, safe, and economical diagnostic test for human appendicitis, AspenBio plans to seek FDA clearance for its unique blood-based test system, **AppyScore**, as a triage test for hospital emergency rooms. This test incorporates a patented assay that detects a marker in the blood associated with the inflammation seen with appendicitis, and is anticipated to be the first and only such test available in the world focused on this condition.

In both preliminary clinical trials and its formal FDA trial, AspenBio has tested this assay in over a thousand patients and has consistently shown the **AppyScore** blood test, when used in conjunction with other commonly used medical modalities, was able to aid in the diagnosis of appendicitis at a sensitivity and negative predictive value greater than 90%. **AppyScore** also has the potential to significantly reduce the time required to diagnose appendicitis cases due to the speed of the **AppyScore** test results, as well as reduce the number of costly abdominal CT scans and the associated exposure to harmful radiation.

AspenBio Pharma is pursuing an FDA 510(k) clearance as an aid in the diagnosis of appendicitis and plans to file its FDA submission during Q2 2009.

Market Opportunity: Animal Reproduction

AspenBio's other potential high-growth market segment is animal therapeutic reproduction drugs. An attractive attribute of animal therapeutics is lower research and development costs and a more rapid process for FDA clearance when compared to human therapeutics.

Virtually all commercial livestock species and their operators worldwide can benefit from improvements in reproduction rates due to a number of factors. In particular for

the dairy farmer, more consistently pregnant cows mean better returns and enhanced milk production. Currently, an estimated 70% of dairy cows in timed artificial breeding programs fail to conceive or maintain a viable pregnancy after artificial insemination. This results in substantial financial and production losses to the dairy industry and has created an opportunity for new, more effective therapeutic drugs to help improve pregnancy rates.

Significant performance advantages of recombinant hormones over conventional hormone products include: 1) more potent and active at a lower dose; 2) more stable with longer half-life; 3) no disease risk (BSE-Mad Cow) or immunogenic response (unlike conventional animal derived hormones); and 4) economical to produce.

To date, there is **no known competing recombinant platform technology** to AspenBio's recombinant single-chain hormones. The company's first two product candidates are anticipated to be marketed under the long-term development and marketing agreement with Novartis Animal Health, as **BoviPure LH** and **BoviPure FSH**. These drugs have a long patent protection period combined with considerable worldwide market potential. The US market potential for **BoviPure LH**, to be distributed under the Novartis agreement, is estimated to be approximately \$200 million annually.

Recent News & Events 2008-2009

Mar 12: AspenBio intends to proceed with FDA 510(k) application for **AppyScore** as an aid to the diagnosis of appendicitis.

Feb 11: Daryl Faulkner, executive chairman of AspenBio, appointed to additional position of interim CEO. He was former president, CEO and board member of Digene Corp., a Nasdaq-traded company prior to its \$1.6B acquisition.

Feb 11: Robert Caspari, M.D., appointed COO and chief medical officer of AspenBio, with initial responsibilities of managing the development and FDA 510(k) submission for **AppyScore**

Jan 20: Reported preliminary results of **AppyScore** clinical study which demonstrated the relationship between **AppyScore** and appendicitis in patients with acute abdominal pain.

Dec 22: Expanded board of directors with the addition of John Landon, whose career includes more than 30 years experience with the DuPont Company as well as board positions with Cholestech (Chairman) prior to its sale to Inverness Medical, and Digene prior to its sale to Qiagen. ■