

# Winslow Environmental News

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FEATURED COMPANY

## KOSAN BIOSCIENCES: TAXOL, TAKE TWO

BY FELICIA REED

Although the incidence of cancer is still rising, the death rate for all cancers has been

**KOSAN BIOSCIENCES**

declining – thanks to better testing, early diagnosis, and to improved chemotherapy drugs.

Among the newest and most successful of these drugs is paclitaxel, better known as Taxol, a derivative of the bark of Pacific yew trees. Used to battle advanced ovarian and breast tumors as well as certain lung cancers and Kaposi's sarcoma, Taxol works by halting the uncontrollable cell division that allows cancers to grow.

Because it targets dividing cells, healthy or malignant, Taxol causes unpleasant side effects like most other chemotherapy drugs.

Please see *KOSAN* page 7

## Cancer and the Environment: A Complex Skein of Interactions

BY ELLEN PFEIFER

IN HINKLEY, CALIFORNIA, MANY RESIDENTS WERE SUFFERING FROM LUNG CANCER AND OTHER ILLNESSES AS THE RESULT OF EXPOSURE TO HEXAVALENT CHROMIUM IN THE AIR, SOIL AND GROUNDWATER. DISCOVERED AND DOCUMENTED BY ERIN BROCKOVICH, THE CONTAMINATION RESULTED IN A HUGE LEGAL JUDGMENT AGAINST POLLUTER PACIFIC GAS AND ELECTRIC—NOT TO MENTION AN ACADEMY AWARD-WINNING MOVIE. AT THREE MILE ISLAND IN PENNSYLVANIA WHERE A NUCLEAR ACCIDENT TOOK PLACE IN 1979, MEDICAL RESEARCHERS FOUND THE SUBSEQUENT INCIDENCE OF CANCER AND LEUKEMIA WAS TWO TO TEN TIMES HIGHER IN PEOPLE WHO LIVED DOWNWIND



*The nuclear accident at Three Mile Island in 1979 caused an increased incidence of cancer for those living downwind.*

of the nuclear plant than in those living upwind.

Such notorious examples of contaminant-related cancers, plus the higher rates of cancer in industrialized countries make it increasingly plausible that environmental pollutants are contributing causes of the disease. But while there is scientific proof that radiation and certain chemicals are indeed carcino-

genic, there are still many complex unanswered questions about the connection between cancer and the environment.

### How significant a role?

Taking a broad view, epidemiologists assert that “environmental factors play a role in more than half

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MARKETBEAT PAGE 2

### Environmentalists Lead Energy Debate

Spotlight is turned on alternative sources and conservation efforts



PORTFOLIO UPDATE PAGE 6

### Townsend to Lead United Natural Foods

Current president is considered “the ideal candidate” by many observers

## 2002 MOSKOWITZ PRIZE

At this year's SRI in the Rockies conference, the annual Moskowitz Prize was awarded to the authors of a Dutch paper documenting no significant statistical difference between returns from socially responsible investment funds and conventional mutual funds.

Established by the Social Investment Forum in 1996, the Moskowitz Prize is highly coveted in the SRI community and is awarded for outstanding research related to social investing. This year's winning paper, *International Evidence on Ethical Mutual Fund Performance and Investment Style*, was written by Rob Bauer and Roger Otten of the Limburg Institute of Financial Economics (LIFE) at the University of Maastricht, in collaboration with Kees C. G. Koadijk of the Centre for Economic Policy Research (CEPR) at Erasmus University, Rotterdam. Their research examined 103 ethical mutual funds in the United Kingdom, Germany, and the US between 1990 and 2001 and applied the multi-factor Carhart model. First utilized in 1997, the Carhart model is a diagnostic tool for comparative analysis of fund performance.

To download a copy of the 2002 award winning paper, go to:  
[www.socialinvest.org/Areas/Research/Moskowitz/Default.htm](http://www.socialinvest.org/Areas/Research/Moskowitz/Default.htm).

MARKETBEAT

# Green Grassroots Drive a New Energy Agenda

BY JACKSON W. ROBINSON

Energy policy promises to be a hot topic when Congress reconvenes early in 2003. With the oil-fueled Republican Party now in control of the House of Representatives, Senate, and White House, whatever energy legislation emerges is sure to favor increased fossil fuel production. While this is a daunting prospect for environmentalists, a national debate on energy could, in fact, throw the spotlight on the compelling arguments for conservation and alternative energy. It could showcase the environmental and economic advantages being enjoyed by more forward-looking EU and Asian nations. It could spread the word about the massive negative consequences for the American economy that will be the likely result of dependence on fossil fuels. And it could build momentum for the grassroots environmental activism that is flourishing outside the Beltway.

### Energy is blowing in the wind

Among the points environmentalists will emphasize in any Congressional discussions will be the growth and remarkable success of wind energy in Europe. For example, wind-powered electricity generation grew at 40% in Europe over the last twelve months, according to a study issued last November by the European Wind Energy Association and reported by Dow Jones International News. Germany led the European Union (EU) in this ramp-up, building 1,896 megawatts (MW) of wind power in 2002. Wind now accounts for 6% of Germany's electricity production, and German installations account for 50% of Europe's total wind capacity of 20,477 MW.

Neighboring Denmark is even more committed to wind. It is currently generating 18% of its electricity needs from wind with a stated goal of producing 25% by the end of the decade. Not surpris-

ingly, two of the world's leading wind-turbine manufacturers (Vestas and NEG Micon) are headquartered in Denmark. These two companies command almost 50% of the world market, a market that is growing at 25% annually. What this means is that wind power not only benefits Denmark by lessening its dependence on foreign fuels, but it also fosters economic growth and job creation, eliminates unhealthy air emissions, and improves the country's balance of payments. Surely this is an ideal energy policy model for the United States to study in view of our national priorities to advance energy self-sufficiency, stimulate economic growth, and reduce ever-rising health costs.

### Japan and Toyota: producing the cars of the future

As Danish companies have become the leading global manufacturers of wind turbines, market research firm J.D. Power says that Japan's Toyota is on the verge of becoming the world's largest (and most profitable) automobile company. Responding to the energy crisis of the 1970's and increasing restrictions on exhaust emissions, Toyota fully incorporated environmental considerations into its research and development programs. Today, Toyota is the world's leading manufacturer of hybrid electric cars and just delivered its first fleet of fuel cell cars whose only emission is water. While full scale commercial production of fuel cell cars is years off, Toyota is well ahead of its American counterparts and is the odds on favorite to be the world leader in fuel cell vehicles that will replace conventional automobiles.

### Will a myopic America be left behind?

In the meantime, the U.S. is unwilling to wean itself from a fossil fuel-dominated energy portfolio. What's more, national leaders seem oblivious to the

emerging, innovative, and prosperous energy companies in the EU and Japan, the second and third largest economies in the world. With companies like Toyota about to become the biggest and most profitable manufacturer of cars, we need to recognize that foreign companies are capable of dominating the rapidly emerging alternative energy industries. Should that occur, the U.S. economy loses a big opportunity to enhance growth, productivity, and security.

#### **Environmental activists to the rescue**

Fortunately, grass roots movements are actively promoting alternative energy and conservation.

Last year, for example, San Francisco voters approved a \$100 million bond proposal to pay for

energy related initiative.

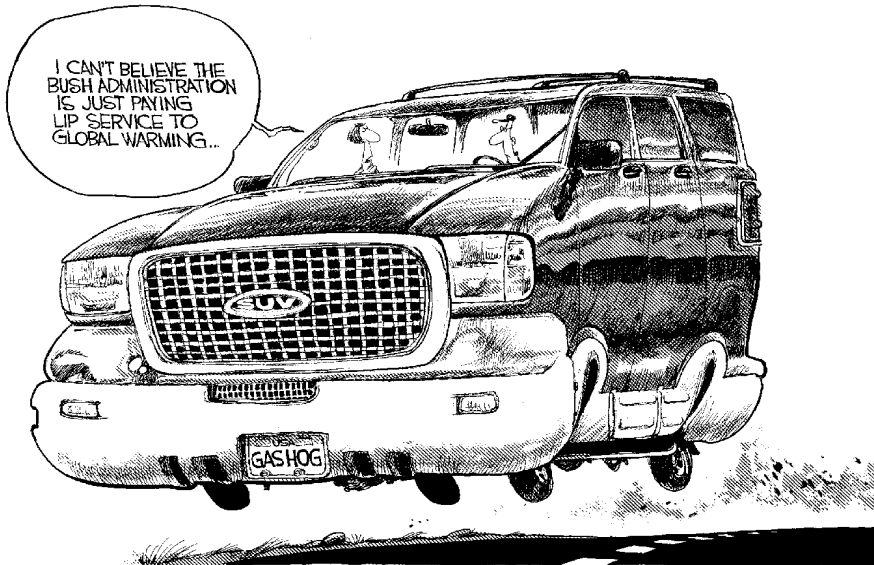
On another front, public opinion throughout the country is turning against Sport Utility Vehicles (SUVs), the gas guzzling and dangerous vehicles that constitute Detroit auto manufacturers' largest remaining profit centers. All sorts of unlikely activists, including senior citizens and ministers, are spreading the word, sometimes tagging SUVs in their grocery store parking lots for excessive gas consumption and pollution. With so much negative publicity, it's no wonder that General Motors is now taking out full-page ads offering "... Five Years Interest-Free SUVs". It's quite clear however, that five years of interest free loans will significantly reduce profitability. And that may be just the

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RAMIREZ



Michael Ramirez, Copley News Service

solar panels, wind power, and energy efficiency strategies for public buildings. This alternative energy initiative had broad support from, among others, labor unions, the Chamber of Commerce, American Lung Association, and environmentalists.

Similarly, a coalition of the six New England states and the five eastern Canadian provinces recently made the commitment to reduce regional greenhouse gas emissions. On the receiving end of unhealthy pollution blown in from Mid-western coal burning utilities, the Northeast region is taking action locally to set an example for the rest of the country. Energy efficiency and renewable technologies are the key components of this

beginning of the bad news.

Having largely ignored the energy and pollution alarms of the last 30 years, American automobile companies are now locked in a life and death struggle with some of their Japanese and EU competitors. Wedded to oil, American energy companies may be similarly at risk.

With or without the help and leadership of U.S. government and industry, we believe the growth of the alternative energy industry is inevitable. The combination of international demand and competition, continuing technological innovation, and grass roots initiatives will set the course no matter how shortsighted our national leaders may be. □

# O'NATURALS TAKES ON McDONALDS

Frustrated by the lack of healthy alternatives to the typical fast food fare, Stonyfield Farm's founder and CEO Gary Hirshberg and wife Meg



have partnered with Mac McCabe, former interim CEO for Northeast Co-ops, to develop a better option. The result is O'Naturals — a healthy quick service restaurant. Privately financed through friends, family and angel investors, O'Naturals opened its first location in Falmouth, Maine in May 2001. Now 18 months in operation, it is demonstrating similar unit economics to conventional quick service restaurants. With the original location reaching profitability ahead of schedule, the company will launch its second location in Acton, Massachusetts in mid-January 2003. A third location is coming to Portland, Maine in March of 2003. While McDonald's may not have to worry about O'Naturals "eating its lunch", the public's growing appetite for healthy fare is already causing the fast food giant some angina pains. We believe O'Naturals is in the vanguard of the coming culinary revolution, which will ultimately lead to dramatic changes in the menus of all quick service restaurants. Move over French Fries and cheeseburgers; make room for baked veggie chips and turkey wraps. (We can't wait to have an O'Naturals around the corner!) For more information, please visit O'Natural's web site: [www.onaturals.com](http://www.onaturals.com).

CANCER continued from page 1

of all cancers" according to the Harvard Medical School's Consumer Health Information. "Sun exposure and smoking are the major contributors, accounting for about 40 percent of all deaths. All other environmental factors (excluding diet) combined — including pesticides, air pollution, and asbestos — account for less than 10 percent."

What is key is the amount of exposure.

"The degree of risk from pollutants depends on the concentration, intensity, and duration of exposure," says the American Cancer Society.

cer from air pollution or food additives is minute."

## Still cause for concern

That said, there is nonetheless concern that the incidence of cancer is rising (even as mortality rates are declining). What's more, the geographical disparities in cancer rates — both between different parts of the world and within individual countries — have given researchers much to ponder. Why, for example, should there be breast cancer hot spots in Cape Cod, Massachusetts or on Long Island, New York? Why should incidence of non-Hodgkin's lymphoma in the U.S. have increased 75% since 1973—

### TOP 10 LIST OF ENVIRONMENTAL LINKS TO CANCER ACCORDING TO THE US ENVIRONMENTAL PROTECTION AGENCY

RISK	FACTOR RISK
1. Excessive sun exposure	.1 in 3
2. Cigarette smoking (one pack or more per day)	.8 in 100
3. Natural radon in indoor air at home	.1 in 100
4. Outside radiation	.1 in 1,000
5. Environmental tobacco smoke (in room with a smoker)	.7 in 10,000
6. Human-made chemicals in indoor air at home	.2 in 10,000
7. Outdoor air in industrialized areas	.1 in 10,000
8. Human-made chemicals in drinking water	.1 in 100,000
9. Human-made chemicals in most foods (including pesticides)	.1 in 100,000 or less
10. Chemical exposure at uncontrolled hazardous waste sites	.1 in 10,000 to 1,000,000

Source: Harvard Medical School's Consumer Health Information at [www.intelhealth.com](http://www.intelhealth.com)

Quoting statistics from the U.S. Environmental Protection Agency (EPA), the Harvard Medical School report lists the Top 10 Environmental Links to Cancer. Compared to voluntary activities such as sun exposure and tobacco use, the other "factors contribute much less significantly to cancer development." (See accompanying table.) "To illustrate the significance of some of these numbers, consider that the lifetime risk of dying from a fall is four in 1,000, and the lifetime risk of death by drowning is three in 1000. By comparison, the risk of developing can-

an upsurge not entirely attributable to the AIDS epidemic (AIDS infection makes a victim much more susceptible to NHL)?

Environment must play some role, but what exactly that is will only be known after meticulous and intricate detective work.

## Breast Cancer: many risk factors

To understand the difficulty of assessing the environment's role in carcinogenesis, consider the case of breast cancer.

There are many known risk factors associated

with the development of breast cancer. Most of these "are related to exposure to estrogen and other hormones involved in a woman's menstrual cycle," reports the Silent Spring Institute which researches the environment and women's health. "Early menstruation, late menopause, having children late in life, never having children, and never breast-feeding" are known risk factors because they all increase the lifetime exposure of breast tissue to estrogen. Other contributors to increased estrogen levels are "alcohol use, lack of physical exercise, higher body mass after menopause, and obesity." Synthetic hormones also increase estrogen concentrations.

However, "less than half of breast cancer risk is explained by these known risk factors," the institute maintains. Genetic susceptibility also plays a part. In about five to 10 percent of cases, the recently discovered breast cancer genes BRCA1 and BRCA2 can dramatically increase risk.

#### **Endocrine disruptors and chemicals: a toxic cocktail**

Estrogens plus defective genes can deliver a double whammy. According to the National Institute of Environmental Health Sciences (NIEHS), "estrogens can cause genetically altered breast cells to divide more rapidly than normal cells, resulting in a tumor. And, in animal studies, breast cancer-causing chemicals do not produce a significant increase in tumors unless estrogen is present."

Among the chemical pollutants researchers are studying in relation to breast cancer are endocrine disruptors (EDCs), "compounds that mimic or otherwise interfere with natural hormones," according to the Silent Spring Institute. "EDCs that mimic estrogen are of particular concern."

Organochlorine pesticides, some of which are EDCs, have been particularly pervasive in the environment. These "long-lasting chemicals concentrate as they pass up the food chain and are stored in the

body fat of animals, fish, and humans," reports the Program on Breast Cancer and Environmental Risk Factors (BCERF) at Cornell University. At Mount Sinai School of Medicine in New York, researchers funded by NIEHS have found that breast cancer patients had significantly higher chemical residues of the pesticide DDE (a breakdown product of DDT) in their blood stream than healthy women. Now banned, DDT is just one of a long list of organochlorines that also includes the still legal dieldrin, chlordane and heptachlor, lindane, beta-hexachlorocyclohexane, and hexachlorobenzene. These products are found in termite control products, fungicides, and prescription-strength anti-lice shampoos.

Scientists are also investigating whether the age at which exposures to carcinogens take place can ratchet up the potential for harm. So, for example, puberty is "marked by significant hormonal changes and steady growth of breast tissue. During this time of rapid cell division and differentiation, breast tissue may be especially sensitive to the effects of cancer-causing agents," states the NIEHS. "Recent findings from both human and animal studies seem to support this theory. For example, when pubescent female rats are exposed to aromatic hydrocarbons—chemicals that are typically found in exhaust fumes—virtually all of the rats develop breast cancer." Conversely, "mature breast cells, such as those found in females after pregnancy, appear to be more resistant to the effects of carcinogens and can more easily repair damage caused by carcinogens," affirms the BCERF program.

#### **So much still to learn**

"Breast cancer takes many years to develop – up to 30 years or more – because of the many changes that must occur before a normal cell becomes a cancerous cell that divides out of control," says the BCERF project. To unravel the intertwining causes and to pinpoint the role of environmental chemicals will continue to challenge scientists for many years. □

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**Epidemiologists assert that environmental factors play a role in more than half of all cancers. Sun exposure and smoking are the major contributors.**

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## PORTFOLIO UPDATE

### United Natural Foods

(NASDAQ: UNFI)

DAYVILLE, CT – In early December, United Natural Foods announced the appointment of Steven Townsend, a 20-year veteran of the company, as the new Chief Executive. Michael Funk, the previous CEO, took over as Chairman of the Board of Directors.

Prior to his new appointment, Mr. Townsend directed the company's day-to-day business as President, operating out of UNFI's headquarters in Connecticut. For some time, he had been handling many of the Chief Executive's responsibilities because Mr. Funk, as CEO, was based in Northern California. This additional executive experience made Townsend an ideal candidate for the new role, according to observers.

During his tenure, Funk distinguished himself by steering the East Coast division through a challenging turnaround and by guiding the company's overall strong performance. Although investors might view the change with some trepidation in the

short-term, analysts close to the company believe that the transition will be relatively seamless and performance for the year should not be affected negatively.

### Art Technology Group

(NASDAQ: ARTG)

CAMBRIDGE, MA – Art Technology Group, a developer and marketer of online customer relation applications, announced the appointment of a new CEO, Robert Burke. Mr. Burke comes to ARTG after a 25-year career with Digital Equipment, where he headed the Systems Integration business. Current CEO Paul Shorthose will remain as Chairman of the Board and will work alongside Burke focusing on several customer and marketing-related initiatives. Former CEO Jeet Singh is leaving both the Board of Directors and his most recent position as Chief Strategy Officer.

The company's restructuring of management is part of a plan to boost growth. Because it is still early in the turnaround process, analysts are forecasting minor losses in EPS for the fourth quarter, but they also maintain that the downside is limited. The company boasts good technology and happy customers but needs higher confidence levels that earnings will improve. According to Paul Shorthose, "The Company is well positioned today with world-leading technology, a who's who customer list, a team of extraordinary, committed employees, and an ecosystem of global systems integrators...and other strategic partners."

### PolyMedica Corporation

(NASDAQ: PLMD)

WOBURN, MA – In early December, PolyMedica Corporation announced updated guidance for the third quarter ending December 31, 2002. The Woburn, MA-based company best known through its Liberty Medical brand name, also provided guidance on the Company's financial performance for the FY '03 fourth quarter ending March 31, 2003.

For the FY '03 third quarter the company reaffirmed its previous guidance for net revenues of \$89-91 million and revised guidance upwards for diluted earnings per share of \$0.79-\$0.81 (previously the company expected to report EPS of \$0.76-\$0.78). This revision was based on a reduction in previously announced investigation-related expenses from \$0.08 per share to \$0.05 per share. Estimated EPS before investigation-related expenses remains unchanged at \$0.84-\$0.86.

For the company's fiscal fourth quarter, PolyMedica expects net revenues in the range of \$93-95 million and diluted EPS of \$0.83-\$0.85. This estimate is based on an estimated \$0.05 per share of legal and related expenses associated with previously announced investigations (before these expenses EPS is expected to be \$0.88-\$0.90).

According to Samuel L. Shanaman, Lead Director and Interim CEO, "We are very much on track to meet our operational performance targets this quarter and have incurred lower-than-expected expenses related to the previously announced investigations."

### Conceptus, Inc.

(NASDAQ: CPTS)

SAN CARLOS, CA – Conceptus announced in late November that Steven Bacich, President and CEO, would step down from those positions. It is expected that he will stay on with the company as Chief Technology Officer. A new CEO should be on board by the first quarter of 2003. Conceptus develops, manufactures and markets a proprietary, permanent birth control device for women that, unlike tubal ligation, requires no surgical incision.

Mr. Bacich directed the company's development of the new device and its approval by the FDA one year earlier than expected by analysts. He also built a strong rapport with Wall Street. According to Mr. Bacich, "With such a large anticipated market, we will be searching for a CEO with significant commercial experience, and a track record of success in marketing to physicians and running a strong consumer education program. With the recent FDA approval of Essure, and the staffing of our U.S. sales and professional education functions, I believe now is the right time to hand over leadership of the Company to a new Chief Executive with the requisite skill set for continued success."

Analysts familiar with the company believe that the CEO succession is in no way reflective of the technology or the current state of business. They do not believe the management reshuffling will have an impact on product milestones or result in any disruption in the business.

*KOSAN continued from page 1*

However, a second generation of drugs, which work much like Taxol, are on the horizon. Known as Epothilones, they may be more effective and produce fewer side effects. Among the companies working hard to bring an Epothilone to commercialization is Kosan Biosciences, Inc. (Nasdaq:KOSN) of Hayward, California. Its candidate, Epothilone D or KOS-862, is an outgrowth of research spearheaded by Dr. Samuel Danishefsky at the Sloan-Kettering Cancer Center. It is about to begin Phase II clinical trials.

### **Kosan: Gene Engineers**

Founded in 1996 by Dr. Chaitan Khosla of Stanford University and Dr. Daniel V. Santi (now Chairman and CEO), Kosan is an emerging biotechnology company that uses a proprietary technology to genetically modify the structures of polyketides for a variety of pharmaceutical applications – including KOS-862. Polyketides are small molecule organic compounds with a complex chemical structure that are produced by certain soil microorganisms. There are about 10,000 known polyketides in nature. They have been the source for many different drugs, including antibiotics, anticancer drugs, cholesterol-lowering drugs, and immunosuppressants. Some examples of polyketide-derived drugs are the antibiotics Erythromycin and Tetracycline. Such pharmaceuticals represent an annual market of about \$15 billion.

The problem with polyketides is that they exist naturally in only minute quantities. Any technology that attempts to exploit them must first create a way of reproducing them quickly and in large quantity. Kosan, like several of its competitors, has turned to gene engineering to accomplish this task.

### **Epothilones have several advantages**

While they may use the same disease-fighting mechanism as Taxol, Epothilones offer several advan-

tages to the older drug. Despite the complexity of producing them, they are easier to make. They are water soluble. And, in animal studies, they have been shown to be effective against cancer cells that both respond to Taxol and those that are resistant to Taxol.

Not without side effects, Kosan's KOS-862 "is among those Epothilones now under development that are less toxic and more active," says Dr. Alison Hanson, medical monitor of the Kosan clinical trials. She presented Kosan's findings in November at the international Symposium on Molecular Targets and Cancer Therapeutics in Frankfurt, Germany.

In Phase I trials involving 31 patients with advanced solid tumors, Kosan tested the safety of various dosing regimens. With dose escalation continuing, so far "no dose-limiting toxicity has been observed," Dr. Hanson reported. Among the side effects noted were mild peripheral neuropathy, fatigue, and rash. Only one patient experienced hair loss. Patients did not suffer precipitate drops in white blood cell counts known as neutropenia.

Mild to moderate anemia (shortage of red blood cells) was seen in only eight patients. Although the trials were not intended to rate the drug's efficacy in killing cancer cells, one patient with testicular cancer showed measurable improvement.

### **Kosan's KOS-862 may best the competition**

The timetable for development of KOS-862 is slightly behind its immediate competitors. However, the drug's chemical properties and its preclinical and Phase I data suggest that the compound could be superior to Bristol-Myers Squibb's BMS-247550 (aza-Epothilone B) and Novartis's EPO906 (Epothilone B). For example, the Bristol-Myers candidate, now in Phase II, reportedly demonstrated side effects including myelosuppression (decreased

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ability of the bone marrow to produce blood cells), anemia and neutropenia. Similarly, the Novartis product, also in Phase II, demonstrated dose-limiting toxicity manifested in severe diarrhea.

So positive are the prospects for KOS-862 that Kosan and Roche (SWX Zurich) have inked a partnership deal for development of the drug. Terms of the agreement stipulate that Kosan receive \$30 million in upfront payments; further payments upon completion of several clinical, regulatory, and commercial milestones; and a sliding scale royalty on

sales starting at an expected 20%. Moreover, Roche will pay all future clinical trial costs. Importantly, Kosan retains the right to co-develop and co-promote KOS-862 in the United States, an option it can exercise after Phase II trials are completed. Should the company exercise its option, it could realize royalties of 23.5% to 29.5% in the U.S. and 20% in Europe.

Worldwide commercial launch of the drug is expected in 2007 with estimated sales of \$189 million in the first year, \$563 million in 2008, and \$853 million in 2009.

#### **Kosan's other drug candidates**


KOS-862 may be the product closest to commercialization in Kosan's drug catalogue, but there are several other promising pharmaceuticals in the pipeline. These include a line of novel antibiotics being developed in partnership with Johnson & Johnson, two other compounds for cancer, Geldanamycin and Discodermolide, and a gastrointestinal drug, motilides. □

*Felicia Reed is a securities analyst specializing in the Biotechnology sector at Adams, Harkness & Hill, Boston, MA. She covers Kosan with a buy rating.*

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**KOS-862 may be the product closest to commercialization in Kosan's drug catalogue, but there are several other promising pharmaceuticals in the pipeline.**

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