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PAGE 1 OF 7

Coley Shares Soar on Buyout

Pfizer Boosts Vaccine Pipeline With $164M Deal For Coley

By Donna Young
Washington Editor

In an effort to boost its vaccine and biological development pipeline, Pfizer Inc. is acquiring Coley Pharmaceutical Group Inc. in a deal worth about $164 million.

News of the acquisition sent Coley shares (NASDAQ:COLY) skyrocketing 160.3 percent Friday, up $4.81, to close at $7.81.

Under the terms of the agreement, Pfizer will pay $8 per share for Coley's outstanding common stock. Shareholders holding about 27 percent of Coley shares have agreed to tender their shares in the offer, the company said. The acquisition is expected to close in early 2008.

Wellesley, Mass.-based Coley specializes in developing vaccines and drugs that stimulate or inhibit Toll-like receptors (TLRs) to target cancer, asthma and autoimmune diseases.

See Coley, Page 4

First Success From SD Pharma Takeover

Adventrx's Emulsion Navelbine Found Equal; NDA Talks Near

By Randall Osborne
West Coast Editor

Adventrx Pharmaceuticals Inc.'s positive data from the marketing-enabling trial with its vein-saving emulsion equivalent for Navelbine (vinorelbine), the vinca alkaloid against non-small-cell lung cancer, sends the company to the FDA for discussions next month.

A new drug application could come as early as the first half of 2008, said analyst Brian Lian, with CIBC World Markets, who predicted that progress with the compound – called ANX-530 – will drive the stock near term, along with possible partnership news.

Stephen Dunn, analyst with Dawson James in Boca Raton, Fla., told *BioWorld Today* that although the ANX-530's potential is "financially not huge, they acquired a

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European Group Again Nixes Application For Natalizumab

From Staff Reports

The up-and-down story of Tysabri (natalizumab) as a treatment for Crohn's disease took another downturn when a European group for the second time recommended rejecting marketing authorization requested by Elan Corp. plc, of Dublin, Ireland, and Biogen Idec, of Cambridge, Mass.

The Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMEA), again said no to the marketing authorization for natalizumab as a treatment for Crohn's disease. That decision came on the companies' appeal following a previous negative opinion adopted by the CHMP earlier in 2007.

The second negative opinion now sends the issue to the European Commission, which determines marketing authorizations in the European Union. The commission

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OTHER NEWS TO NOTE

• **Abbott**, of Abbott Park, Ill., said the European Committee for Medicinal Products for Human Use has issued a positive opinion recommending approval of Humira (adalimumab) for the treatment of moderate to severe plaque psoriasis. Psoriasis will be the fifth disease indication for HUMIRA. Humira was developed by the former Cambridge Antibody Technology, of Cambridge, UK, now part of MedImmune Inc.

• **Alios BioPharma Inc.**, of South San Francisco, and the Cleveland Clinic today announced that they have entered into an exclusive worldwide license agreement focused on development of small-molecule RNase L activators for the treatment of a broad range of viral diseases such as chronic hepatitis B and hepatitis C, HIV, influenza and others. The technology also is applicable to the treatment of cancer for both solid tumors and hematological malignancies such as leukemia. The agreement grants Alios exclusive worldwide rights to Cleveland Clinic patents, technology and preclinical small molecules relating to RNase L activation. Under the terms of the agreement, Alios will provide the Cleveland Clinic an up-front license fee, various development, regulatory and commercial milestones, and royalties on net sales. In addition, Alios will sponsor ongoing research at the Cleveland Clinic for a period of two years. Alios will continue the research and development of those compounds with the goal of advancing molecules toward clinical development for both chronic and acute viral diseases and for cancer. The agreement covers the use of RNase L activators for all human, veterinary and agricultural applications. Financial terms were not disclosed.

• **Argos Therapeutics Inc.**, of Durham, N.C., said it has granted exclusive research and development rights based on its regulatory T-cell technology to Johnson & Johnson subsidiary **Therakos Inc.**, of Exton, Pa. Terms of the agreement were not disclosed.

• **DeCODE genetics**, of Reykjavik, Iceland, launched deCODEme, a service that enables individuals to get a detailed look at their own genome. Subscribers who send a cheek swab can learn what their DNA reveals about ancestry, body traits and genetic variants associated with higher or lower average risk of disease. The information will be continually updated as new discoveries are made.

• **Discovery Laboratories Inc.**, of Warrington, Pa., said the FDA has accepted the firm's Nov. 1 submission as a complete response to the April 2006 approvable letter for Surfaxin (lucinactant), natural human lung surfactant with KL-4 peptide, for the prevention of respiratory distress syndrome in premature infants. The FDA set May 1, 2008 as its target date to complete its review of the new drug application for the product.

• **DSM Pharmaceutical Products**, of Parsippany, N.J., and **Crucell NV**, of Leiden, the Netherlands, have granted licensing rights for their PER.C6 cell line to **Daiichi Sankyo**, of Tokyo. Financial terms of the agreement were not disclosed.

• **Endo Pharmaceuticals Inc.**, of Chadds Ford, Pa., and **Penwest Pharmaceuticals Co.**, of Danbury, Conn., said they have filed a lawsuit against **Impax Laboratories Inc.**, of Hayward, Calif., in the U.S. District Court for the District of Delaware related to Impax's abbreviated new drug application for Opana ER (oxymorphone HCl) extended-release tablets CII. The lawsuit alleges infringement of certain Orange Book-listed U.S. patents that cover the Opana ER formulation. It also seeks a declaratory judgment stating that Impax has no legitimate basis to trigger the Hatch-Waxman ANDA patent litigation process because the FDA has rescinded its acceptance of the application.

• **GeoPharma Inc.**, of Largo, Fla., disclosed second-quarter results for its reporting period ending September 30, listing total revenues of $6 million compared to $6.8 million in the first quarter. The firm, which has won approval of its first generic drug, the veterinary product carprofen, said it is making progress on 12 ANDAs and other drugs in the pipeline.

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OTHER NEWS TO NOTE

• **Helix BioPharma Corp.**, of Aurora, Ontario, said that the firm's CEO position will no longer be jointly held by Donald Segal and John Docherty. Segal will assume the role of CEO, and Docherty will take the position of president. Segal is a founding partner, and Docherty joined the company in 1999.

• **Humanetics Corp.**, of Minneapolis, said Congress has awarded the company an additional $3.8 million from the fiscal year 2008 Defense Appropriations Act, signed by President Bush. This award to Humanetics brings the total funding received by the company from the Department of Defense to slightly less than $7 million. The 2008 funding will be used by Humanetics to continue development, clinical testing, regulatory approval, manufacturing and commercialization of a number of medical radiation countermeasures. The firm's lead candidate, BIO 300, is undergoing large animal efficacy and human safety trials. The company also is working with several preclinical lead candidates which are showing promising early results.

• **Immunicon Corp.**, of Huntingdon Valley, Pa., said that it has received a notice from the Nasdaq stock market informing the firm that it does not comply with the continued listing requirements. That rule requires that Immunicon have a minimum of $10 million in stockholders' equity to continue listing its securities on the Nasdaq global market. The firm has until Nov. 27 to submit a plan for regaining and sustaining compliance with the listing requirements.

• **Inflazyme Pharmaceuticals Ltd.**, of Vancouver, British Columbia, said its shareholders approved the sale of the majority of its research and development assets to **Biolipox AB**, of Stockholm, Sweden. Of the votes cast, 98 percent voted for the sale. In return for the sale, which includes the PDE inhibitors, the LSAIDs and the Protein Therapeutics technology, Inflazyme receives $4 million in cash and up to $7 million in potential milestones plus royalty payments, which include $1.5 million upon a decision to enter a Phase IIb clinical study with a PDE inhibitor; $2.5 million upon a decision to initiate a Phase III study with a PDE inhibitor; $3 million upon a decision to begin a Phase III clinical study with an LSAID; and a royalty of 1.25 percent on net sales of the first PDE inhibitor commercialized. Inflazyme also may receive up to 35 percent of the proceeds from the subsequent sale or licensing of the Protein Therapeutics technology if that happens within 12 months of the asset sale.

Coley

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Pfizer has been partnering with Coley for the past two years on the biotech's lead TLR9 agonist drug candidate PF-3512676 for the treatment of cancer.

However, the program suffered a clinical setback in June when Pfizer decided to discontinue two Phase II and two Phase III clinical trials of PF-3512676 in lung cancer after an interim analysis of the Phase III studies showed there was no evidence that the compound produced additional clinical efficacy over that achieved with the standard cytotoxic chemotherapy regimen alone. (See *BioWorld Today*, June 21, 2007.)

That setback, CEO Robert L. Bratzler said Friday during a conference call, "shifted" Coley's product commercialization timeline.

"Our access to milestone and royalty revenues necessary for funding drug development and fortifying our pipeline was delayed," he said.

The firm recognized that its "most significant value-creation opportunity," VaxImmune, a vaccine adjuvant currently being evaluated in 35 clinical studies for cancer, infectious disease and biowarfare defense, was "at least five years out," Bratzler said.

So, he explained, the company evaluated various options that would accelerate future value creation without dilution and without unduly compromising the development of the firm's early stage drug candidates.

As Coley considered its strategic alternatives, Bratzler continued, "we could not overlook the potential synergies that could be derived from our relationships with our stellar list of global pharmaceutical partners," which includes GlaxoSmithKline plc, Merck & Co. Inc. and Novartis AG.

Since signing its licensing agreement with New York-based Pfizer in 2005, he said, the pharmaceutical maker has "consistently demonstrated" that it is a "supportive, dedicated and world-class partner."

Among the many reasons the acquisition of Coley by Pfizer was so attractive, Bratzler said, was "the fact that the two companies share a strategic commitment to the future potential of innovative vaccine technology and immunologic treatments of a broad range of diseases. Moreover, Pfizer possesses the resources as well as the scientific and clinical expertise to maximize the potential of Coley's proprietary TLR-based product candidates across the full range of applications, both for use as vaccine adjuvants as well as novel therapeutics."

When the acquisition deal closes, Bratzler noted, Pfizer will own the biotech's second- and third-generation vaccine adjuvants "exclusively . . . for their use in both therapeutic and prophylactic vaccines across the full range of applications."

Coley's vaccine adjuvant platform not only will enable Pfizer to broaden its development program, he contended, but also will add "immunological horsepower" to the pharmaceutical maker's vaccine portfolio.

Despite the setback in June with PF-3512676, Bratzler said, development of the compound as a treatment for cancer "remains unchanged."

"Pfizer is totally committed to this program," he maintained. "That's one of the reasons we were obviously very excited about the prospects of joining forces in this transaction with Pfizer."

Pfizer currently is investigating PF-3512676 in a Phase II clinical trial in combination with Tarceva (erlotinib) for the treatment of refractory non-small-cell lung cancer and a Phase I clinical trial in combination with Pfizer's anti-CTLA4 antibody, tremelimumab, for the treatment of advanced melanoma.

Coley announced last month that Pfizer had nominated a second-generation TLR9 agonist compound discovered by the biotech for future clinical development against cancers. (See *BioWorld Today*, Oct. 31, 2007.)

"We see tremendous synergies and potential applications for our drug candidates in the areas of cancer, inflammation, autoimmune and infectious diseases – all key therapeutic areas for Pfizer," Bratzler affirmed. "We don't think we could have found a more committed or a more qualified partner to progress our pipeline in our pioneering technology. We believe that under Pfizer's direction, our mission of developing TLR-based medicines that improve human health, prolong life and alleviate suffering will be achieved." ■

Adventrx

Continued from page 1

whole bunch of product candidates from SD Pharmaceuticals Inc. that are all based on this [nano-emulsion technology]," and the success with vinorelbine helps validate the April 2006 merger.

Shares of Adventrx (AMEX:ANX) closed Friday at 64 cents, down a penny.

In taking over SD, of Carlsbad, Calif., San Diego-based Adventrx gained worldwide intellectual property rights, excluding rights for China, Taiwan, Hong Kong and Macau, to a portfolio of eight oncology and infectious disease therapeutic product candidates, including ANX-530 which had been the subject of an earlier license agreement between the firms.

Full results from the crossover comparison, 31-patient trial, which was designed to prove a pharmacokinetics match with London-based GlaxoSmithKline plc's Navelbine, should be available in the first quarter of next year, and will be submitted for disclosure in an upcoming medical conference. Approved for use in NSCLC alone or with cisplatin, Navelbine and its generic versions sold about $200 million in 2006.

The equivalence in the Adventrx trial was determined by comparing areas under the curve (AUC, or how much drug is circulating in the body over time) and maximum plasma concentrations (Cmax, or top concentration of drug in the blood at a specific time). If the upper and lower bounds of the AUC ratio's and the Cmax ratio's 90 percent confidence interval ranged from 0.80 to 1.25, then ANX-530 and Navelbine were considered equivalent.

In the first week, patients got either ANX-530 or Navelbine. After a "washout" period, they were dosed with the opposite drug during the second week. The FDA has said a single successful study of that type could support a Section 505(b)(2) NDA.

Vinorelbine, which also has shown activity in breast, ovarian and other cancers, works by disrupting microtubule formulation. By delivering the drug as an emulsion, ANX-530 cuts down on vein irritation from intravenous delivery.

The below-dollar stock price is a far cry from Adventrx's 52-week high of $2.98, shares having tumbled 79 percent last month, closing at $2.02, on news that a comparison of the firm's CoFactor (also known as ANX-510) to leucovorin missed its primary endpoint of reducing serious hematological or gastrointestinal adverse events associated with the chemotherapy drug 5-fluorouracil. (See *BioWorld Today*, Oct. 2, 2007.)

CoFactor is the active metabolite of leucovorin and is intended to boost the efficacy and decrease the toxicity of 5-FU by allowing more stable binding to the drug's target enzyme. Adventrx still has a Phase II trial with 5-FU in breast cancer, but a Phase III trial with 5-FU and Avastin (bevacizumab, Genentech Inc.) in metastatic colorectal cancer was discontinued earlier this month. The stop came after advice from the trial's data safety monitoring board, which cited a slow accrual rate and the fact that analysis of Phase IIb data showed no significant differences between the treatment arm and control arm with regard to either safety or efficacy.

The CoFactor breast cancer trial will complete enrollment this year and produce data in the second half of 2008. CIBC analysts are not optimistic, but Dunn is keeping the faith. "I personally don't think CoFactor is dead yet," he said, pointing to differences in administration between trials (bolus in the U.S., infusion in the European Union) that could explain outcomes.

"You're not going to have a problem if you're using infusion, but with a bolus, you overload the leucovorin. That's where you get the benefit of using CoFactor," Dunn said.

Along with ANX-530 and CoFactor, Adventrx has ANX-514, an emulsion of the chemotherapy drug Taxotere (docetaxel, Sanofi-Aventis Group), slated late this year to begin a bioequivalence study that also aims at approval through the 505(b)(2) pathway.

Dunn also sees promise in ANX-201 (Thiovir), a preclinical reverse transcriptase inhibitor for HIV. The pyrophosphate analogue delivers thiophosphonoformate and phosphonoformate (foscarnet) in capsule form.

"Foscarnet works very well in HIV patients, but it's intravenous, so they have to go to the hospital," Dunn said. In March, Adventrx signed a deal with Pharmatek Laboratories Inc., of San Diego, for the manufacture of ANX-201, and Phase I/II combination trials in HIV patients are expected to begin in the third quarter.

Adventrx reported a third-quarter loss per share of 7 cents, in line with analyst estimates, and finished the period with about $39 million in cash and cash equivalents. CIBC estimated a cash burn in the fourth quarter between $4 million and $6 million, for a full-year net loss of about $22 million. ■

OTHER NEWS TO NOTE

• **Schering-Plough Corp.**, of Kenilworth, N.J, said it has received antitrust clearance from the U.S. Federal Trade Commission for its planned acquisition of **Organon BioSciences NV**, of Oss, the Netherlands, from **Akzo Nobel NV**, of Amsterdam, the Netherlands. The $14.4 billion acquisition was announced in March. Schering-Plough still needs to secure certain regulatory approvals, including clearance from the U.S. Federal Trade Commission but expects the transaction to be completed by year-end. Separately, Schering-Plough said that the European Commission approved the 48-week standard dose of Pegintron (peginterferon alfa – 2b, 1.5 mcg/kg once weekly) and Rebetol (ribavirin, 800 – 1,400 mg daily) combination therapy for retreating adult patients with chronic hepatitis C whose prior treatment with interferon alpha (pegylated or nonpegylated) and ribavirin combination therapy or interferon alpha monotherapy did not result in a sustained response.

Chrohn's Disease

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usually follows CHMP recommendation, and the companies said they expect to hear from the EC during the first quarter of 2008.

In August, the FDA's Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee voted 12-3 in favor of Tysabri's use in Crohn's disease patients who have failed or cannot tolerate existing therapies. The chief issue before the panel was whether Tysabri, a recombinant anti-alpha4 integrin monoclonal antibody, had an appropriate risk/benefit profile for the CD population.

The chief issue before the panel was whether Tysabri, a recombinant anti-alpha4 integrin monoclonal antibody, had an appropriate risk/benefit profile for the CD population.

The drug was pulled from the market in February 2005, only a few months after gaining approval for multiple sclerosis, and ongoing trials in MS and CD were halted after two patients contracted progressive multifocal leukoencephalopathy (PML), a potentially fatal brain infection. Further analysis and review by the agency led to the drug's return to the market, with limited use in MS patients.

As part of its recommendation, the FDA joint advisory panel suggested that the companies conduct additional analyses to determine the CD population most inclined to benefit from Tysabri treatment and look at longer-term safety data. Panel members also stated the need for strict postmarketing surveillance.

Biogen's and Elan's marketing application for Tysabri in CD was based on data from two Phase III induction studies and one maintenance study.

Though the first Phase III study failed to show a statistically significant difference in clinical response rates, defined as CDAI (Crohn's Disease Activity Index) reduction of 70 or more from baseline, a subsequent subset analysis demonstrated that patients with elevated CRP had a higher clinical response rate compared to placebo.

The second study, which specifically enrolled patients with elevated CRP, yielded positive results, showing response rates of 48 percent compared to 32 percent for patients in the placebo arm. ■

OTHER NEWS TO NOTE

• **Singulex Inc.**, of Hayward, Calif., signed a collaboration with researchers at Washington University School of Medicine in St. Louis to increase the clinical utility of validated and recently discovered biomarkers in human disease. Singulex also said the firm will get a $900,000 Phase I/II Fast Track Small Business Innovation Research contract from the National Cancer Institute to create biomarker assays to help predict patient response and therapeutic efficacy of cancer therapies in development. Scientists at Washington University will be part of Singulex's Erenna Technology Access Program (ETAP) to develop biomarker assays for both validated and putative biomarkers in important disease areas, including breast cancer, Alzheimer's disease, diabetes and stroke. ETAP allows early access for institutions and companies to Erenna, the company's biomarker detection platform system, which incorporates biomarker detection and optimized immunoassays.

• **ThromboGenics NV**, of Leuven, Belgium, said it has begun preclinical development of an anti-VPAC antibody for thrombocytopenia. Thrombocytopenia, which is the reduced number of platelets in blood, is a common severe side effect of chemotherapy and increases the risk of bleeding and severity of hemorrhage. Researchers at the University of Leuven and ThromboGenics have developed a novel therapeutic approach, showing that the inhibition of VPAC could stimulate the production of platelets. VPAC is a receptor present at the surface of bone marrow cells called megakaryocytes, which, when mature, produce platelets.

• **UCB SA**, of Brussels, Belgium, said it has been informed by the European Medicines Agency that the Committee for Medicinal Products for Human Use adopted a negative opinion on the market authorization application in the European Union for Cimzia (certolizumab pegol) in the treatment of patients with Crohn's disease. UCB plans to appeal, and a decision is expected during the first half of 2008. Cimzia is a pegylated anti-TNF, for which UCB filed a biologics license application in early 2006. The drug was approved in Switzerland for Crohn's disease in September of this year, and UCB said preparation for a U.S. regulatory submission for Cimzia in treating rheumatoid arthritis is ongoing.

CLINIC ROUNDUP

• **BioAlliance Pharma SA**, of Paris, has completed patient enrollment in the pivotal Phase III trial for Loramyc for the treatment of oropharyngeal candidiasis. The trial will include 540 patients enrolled by 40 specialist clinical centers in the U.S., Canada and South Africa. The trial results are expected in the first half of 2008. The company plans to file a market authorization application in the second half of next year, subject to the FDA's regulatory requirements.

• **Peregrine Pharmaceuticals Inc.**, of Tustin, Calif., said its Phase II clinical protocol to study bavituximab in combination with the chemotherapy drug docetaxel in patients with metastatic breast cancer has been approved by the Drug Agency of the Ministry of Labour, Health and Social Affairs of the nation of Georgia. The open label, multicenter safety and efficacy trial is expected to begin enrolling patients by early 2008. The primary objective is to assess the overall response rate to the combination of bavituximab with docetaxel, a chemotherapy drug commonly used in the treatment of metastatic breast cancer. Secondary objectives include measuring time to tumor progression, duration of response, overall patient survival and safety parameters.

• **Thallion Pharmaceuticals Inc.**, of Montreal, presented positive safety and efficacy data from the completed Phase I/II trial of ECO-4601 for the treatment of advanced cancer patients. ECO-4601 was safe and well tolerated up to the maximum dose tested of 480mg/m2/day. Adverse events potentially related to ECO-4601 were nonspecific and common in that type of patient population. Of seven refractory cancer patients who had completed six cycles of treatment, six patients achieved stable disease. The company said it intends to advance ECO-4601 into a Phase II trial in an indication to be selected in the coming weeks, and plans to initiate regulatory filings prior to the end of the fourth quarter in order to begin a Phase II trial. ECO-4601 is a novel small molecule derived from a nonpathogenic microorganism

• **Vivus Inc.**, of Mountain View, Calif., has initiated the second of two pivotal Phase III studies of its investigational drug Qnexa in overweight and obese patients with comorbidities including hypertension, dyslipidemia or Type II diabetes. The CONQUER study (OB-303) will enroll patients with a body mass index ranging from 27 to 45, including patients with Type II diabetes regardless of BMI. The co-primary endpoints will evaluate the differences between treatments from baseline to the end of the treatment period, in mean percent weight loss and in the percentage of subjects achieving weight loss of 5 percent or more.

FINANCINGS ROUNDUP

• **Affymetrix Inc.**, of Santa Clara, Calif., has entered into an agreement to sell $275 million worth of 3.5 percent unsecured senior convertible notes due in 2038. It granted the underwriter, JF Morgan Securities, an over-allotment option to purchase up to $41.25 million aggregate principal amount of additional notes on the same terms and conditions.

• **HistoRx Inc.**, of New Haven, Conn., has secured $6 million in a Series B private equity financing round. Current investor Brook Venture Partners led the round. Other participants included another Series A investor, Navigator Technology Ventures, as well as three new investors: The Roche Venture Fund, Commons Capital and Maven Capital. HistoRx will use the funds to advance its portfolio of proprietary tissue-based diagnostic products developed from its AQUA biomarker analysis platform.

• **MicroIslet Inc.**, of San Diego, has entered into an agreement to sell common stock to a private trust for gross proceeds of $1 million. The company has agreed to sell an aggregate of approximately 2.35 million shares and to issue to the investor warrants to purchase an aggregate of approximately 1.3 million shares. The warrants have an exercise price of $0.60 per share and are exercisable for five years beginning in one year. The company expects to use the proceeds of the financing for working capital purposes.

• **Pipex Pharmaceuticals Inc.**, of Ann Arbor, Mich., has received approximately $7.3 million in gross proceeds through the exercise of warrants to purchase the company's common stock. The company said it now should have enough funds to last into 2008 when it hopes to obtain FDA approval for its anticopper drug candidate Coprexa and/or its serum-free copper diagnostic device, FreeBound. A new drug application is expected to be filed for Coprexa yet this year, and a pre-IDE package was submitted for FreeBound in October.