



GENENTECH (DNA)

Today Genentech will come up with figures on its revenues and earnings.

Analysts expectations: Analysts are expecting the firm to show adjusted earnings a share of **26 cents, with revenues of \$1.49 billion**, for the first half of 2005, compared to a net earnings of **16 cents a share on operating revenues of \$1.13 billion** for the second quarter. The focus will be on the stars, i.e., **Avastin** and **Rituxan** – the current engines that continue to bring positive momentum of the stock. (Subscribers: read Prohost Faxletter that will be posted Tomorrow morning.)

The giant is a real giant.

ADVANCED KIDNEY CANCER

BAYER (BAY) AND ONYX (ONXX) *Completed the submission of NDA for sorafenib*

Bayer and **Onyx** completed the submission of a New Drug Application (NDA) with the FDA for sorafenib (**BAY 43-9006**) for patients with advanced renal cell carcinoma (RCC), or kidney cancer. Bayer felt encouraged by Phase 3 results. Pending the FDA's acceptance and favorable review the firms' expect to launch the cancer drug in the first half of 2006.

*Sorafenib was accepted by the FDA into the **Pilot 1 Program** for continuous marketing applications. The Pilot 1 Program was designed for therapies that have been granted Fast Track status and have the potential to provide important therapeutic benefit over available therapies. Under the Pilot 1 Program designation, the FDA is committed to reviewing each "reviewable unit" of the submission within a six month timeframe.*

The sorafenib submission is based on an ongoing Phase 3 trial in patients with advanced kidney cancer. Results from the study - the largest randomized, placebo-controlled trial ever conducted in advanced renal cell cancer -- were presented in May at the 41st Annual Meeting of the American Society of Clinical Oncology (ASCO).

Sorafenib is currently available to patients throughout the United States through a treatment protocol known as the Advanced Renal Cell Carcinoma Sorafenib (ARCCS) study. To be eligible, individuals with advanced kidney cancer may not have been previously treated with sorafenib. Physicians who are interested in becoming investigators should call **1-866-639-2827**. Interested patients should discuss this with their doctor or call the number above. A similar trial will start in Europe shortly, and Bayer and Onyx are in discussions with regulators about similar programs in other territories.

Phase 3 Results Presented at ASCO *Progression-free Survival Doubled*

At ASCO sorafenib was shown to double progression-free survival (PFS) when compared to placebo. As assessed by independent radiologic review, PFS was doubled to a median value of 24 weeks in patients receiving sorafenib as compared to 12 weeks for patients receiving placebo (p-value < 0.000001). More than 900 patients with advanced kidney cancer, who had previously failed one prior systemic therapy, have been randomized in this ongoing multi-national Phase III study.

The pivotal trial was initiated in the fourth quarter of 2003 after the FDA completed a Special Protocol



Assessment (SPA). Previously, the companies announced that patients enrolled in the Phase 3 kidney cancer trial who were receiving placebo could "cross over" to drug treatment based on the clinical and statistical significance of the PFS data. The study is ongoing, and patients will continue to be treated and followed for survival.

Thus far, **769 patients have been evaluated for safety**. Drug-related adverse events (all grades) were similar to what has been observed in previous clinical trials and included: rash, diarrhea, hand foot syndrome, hair loss, itching, nausea, hypertension, and fatigue.

Sorafenib, is the first **oral** multi-kinase inhibitor that targets serine/threonine and receptor tyrosine kinases in both the tumor cell and tumor vasculature. In preclinical models, sorafenib targeted members of two classes of kinases known to be involved in both tumor cell proliferation (tumor growth) and tumor angiogenesis (tumor blood supply) - two important cancer growth activities. These kinases included RAF kinase, VEGFR-2, VEGFR-3, PDGFR-b, KIT, FLT-3 and RET.

Prohost comments: Sorafenib is a new generation drug that has the chance to become a blockbuster in the kidney cancer market. In clinical trials it offered hope to hopeless cases, which is the case now and will be the case after marketing in the U.S. and Europe and the rest of the world.

It is not too soon to congratulate the developing firms and to conclude that the drug's efficacy will have the chance, after marketing, to increase as a result of increased oncologists' familiarity with the products and its use in combination therapy in various protocols. Kidney cancer is a nasty malignancy.

[HIV - AIDS](#)

INCYTE (INCY)

Reverset for HIV Accepted for presentation

Incyte announced that an abstract describing results from the Phase 2 b study of **Reverset** has been accepted for both oral and poster presentations at the late breaker sessions of the 3rd International AIDS Society (IAS) Conference on HIV Pathogenesis and Treatment to be held in Rio de Janeiro from July 24 to July 27.

The poster describes Study 203. It will be available on July 25. The late breaker oral presentation will be given on **Wednesday, July 27 at 3:20 pm ET**.

Incyte will host a conference call and live webcast to discuss these results on Monday, July 25 at 8:30 am ET. Participants on the call will be: Dr. Cohen, Robert Murphy, M.D., Professor of Medicine, Northwestern University and the principal investigator for Study 203, Paul Friedman, M.D., president and CEO of Incyte, and Richard Levy, M.D., senior vice president, drug development, also of Incyte.

The domestic dial-in number is 877-692-2592 and the international dial-in number is 973-582-2700. Slides accompanying the call, as well as a live webcast of the call, can be accessed on July 25th at www.incyte.com under Investor Relations, Events and Webcasts or go directly to: <http://www.talkpoint.com/viewer/starthere.asp?Pres=110451>.

Incyte will also discuss the results of Study 203 at an analyst meeting in New York City on Tuesday, August 2, from 7:30 am to 9:00 am where it will also report its second quarter financial results.

***Study 203** is a 24 week Phase 2 b double-blind, placebo-controlled trial involving 199 treatment-experienced human immunodeficiency virus (HIV) patients. Safety, tolerability and efficacy of Reverset in treatment-experienced HIV infected patients at (50, 100 and 200 mg once daily) are being evaluated at week two and week 16. At week 16, all placebo patients were randomized to Reverset (100 or 200 mg) to continue to evaluate the safety and tolerability of Reverset. At week 24, patients are allowed to continue on Reverset in an open label extension trial.*

Let's see what the firm will tell.

POSTMENOPAUSAL OSTEOPOROSISNPS PHARMACEUTICALS (NPSP)
NDA for PREOS Accepted by the FDA

The FDA has accepted for review NPS' new drug application (NDA) to market **Preos®** (parathyroid hormone) for the treatment of **osteoporosis** in postmenopausal women.

*Clinical results in the NDA are based upon data from 13 separate studies including an international multi-center Phase 3 trial of approximately 2,600 postmenopausal osteoporotic women who were randomized to receive either a daily subcutaneous injection of 100 micrograms of **Preos®** or placebo, in addition to daily calcium and vitamin D supplements. The application also includes results from Phase 1 and Phase 2 studies with **Preos®** open-label extension studies following the pivotal Phase 3 trial, and combination studies evaluating the use of the drug with other drugs, as well as preclinical data and data related to manufacturing the product.*

A similar application to market **Preos®** in Europe under the brand name Preotact™ is currently **under review** by the European Medicines Agency.

NPS has drug candidates in various stages of clinical development.

PROHOST RESEARCH
P.O.BOX 640 429
Oakland Gardens, Ny 11364
Telephone : 516 678 1335
Fax 718 423 2731
E-mail prohost@aol.com

FORWARD-LOOKING STATEMENT

Prohost is independent publication providing information on biotech companies. Prohost does not accept compensation from companies that are featured or profiled. It is strongly recommended that any purchase or sale decisions to any of the featured companies be discussed with a financial advisor or broker prior to completing any such purchase or sale decision. All statements or expressions are the opinion of Prohost and are not meant to be a solicitation or recommendation to buy, sell, or hold securities. Investing in embryonic companies, micro-cap and growth securities is highly speculative and carries a high degree of risk. It is possible that an investor can lose all of his/her investment in this type of companies that are profiled. The information that Prohost relies on is either through the profiled company, news services, research reports, interviews, or other outside sources that Prohost believes are reliable. Prohost makes no representations, warranties or guarantees as to the accuracy or completeness of the disclosure of the profiled companies and accepts no responsibilities for inaccuracies or misleading content in any material supplied by those clients. There can be no assurance that future events relating to the profiled company will occur as anticipated. The information contained herein is provided as an information service only. Past performance of featured companies does not guarantee the future success of any currently featured or profiled company. We encourage our readers to invest carefully and read the investor information provided by the Securities and Exchange Commission ("SEC") and/or the National Association of Securities Dealers ("NASD"). We also strongly recommend that you read the SEC advisory to investors concerning Internet Stock Fraud, which can be found at: <http://www.sec.gov/consumer/cyberfr.htm>