CORPORATE DEVELOPMENT

GENENTECH: DON'T SELL THE COMPANY SHORT

SAN FRANCISCO—The tissue plasminogen activator (t-PA) saga has been the Genentech (So. San Francisco, CA) story over the past year. There is more, however, to Genentech's business development strategy. Two announcements made here in January—the planned development and distribution of the first product under a reciprocal agreement with the Japanese pharmaceutical company Mitsubishi Kasei (Tokyo), and a collaboration with California Biotechnology (CalBio, Mountain View, CA) to develop lung surfactant—demonstrate that Genentech is balancing long-term in-house product development with a broader business strategy which better utilizes its manufacturing and marketing capabilities.

Without question, Genentech has over the past few months had to come to grips with the less-than-anticipated market response to its anti-clotting drug t-PA. Although its version—the only one on the market in the U.S.—is indeed the largest selling new therapeutic in pharmaceutical history (first-year sales hit nearly $190 million), neither the company nor financial analysts are pleased. After an initial surge, low demand has halted manufacturing, and Genentech has now set aside capital to cover the possibility that some of the drug already warehoused will go stale before it is sold. This resulted in estimated flat earnings for the fourth quarter, an announcement that drove the stock down.

Company chairman and CEO Robert Swanson acknowledges that Genentech expected a faster acceptance of thrombolytic therapy by cardiologists. "In 1988," he points out, "only 30 percent of those who qualify for thrombolytic therapy were given any drug." But he also is quick to mention that "among those, almost all got t-PA." Competition from the alternative therapy streptokinase, and t-PA's high cost are not, in his view at least, key concerns.

The company has responded by stepping up its marketing efforts; including a planned increase in its sales force in 1989 from 200 to over 300, and a widening of its sales effort beyond hospitals to include regular calls to office-based internists and cardiologists. Swanson believes this will help overcome what he terms "misconceptions"—especially at the smaller hospitals—about t-PA's side effects, namely stroke. "The actual rate of stroke," he says "is well within the label claim and is no greater, in fact, than the controls," about 0.9 percent. Genentech also filed in September with the Food and Drug Administration for a reduced mortality claim, which would allow more aggressive advertising of t-PA's life-saving benefits.

Peter Drake of Vector Securities (Chicago, IL) believes that the company's response to the t-PA sales slowdown is both "doing what's appropriate under the circumstances," and "getting the bad news out of the way." However, he takes issue with Swanson's claim that the slowdown will be a one-quarter phenomenon, instead seeing it stretching into 1989. His sales projections for t-PA are "bearish" over the next three years at $150 million, $120 million, and $140 million, respectively.

Denise Gilbert (Montgomery Securities, San Francisco, CA) thinks the company "has a mistaken impression of its sales penetration potential." She observes that "Genentech's history has been to be naive about sales. Look at its expense projections for sales and R & D—they've always been low." She also thinks "the company must wake up to the fact that its R & D group is dwindling." And although she thinks a 15-20 percent increase in sales is possible, she also expects a price cut due to the Beecham Group's (Middlesex, U.K.) introduction of the competitive thrombolytic agent Eminase later this year.

As for its human growth hormone, the other major drug already commercialized, Gilbert believes that its other indications—to treat small stature due to chronic kidney disease and certain nutritional disorders—are "small markets." And if the Orphan Drug Act is amended, its seven-year exclusivity in existing markets may be threatened by the five other growth hormone entrants.

Enter the two new agreements: According to Peter Drake, speaking before the formal announcement of the in-licensing deals, "Depending on the product (or more likely, the series of products) and the stage of development, this could be a wildcard." The Mitsubishi agreement is to develop and market argatroban—a small molecule that acts as a novel clot-inhibiting agent that blocks enzymatic thrombolytic activity in the brain. It is the first product announced under a broad, classic licensing arrangement signed quietly in June 1986. For Genentech, it means eventually taking advantage of its already-in-place marketing capability.

The CalBio agreement on lung surfactant—a mixture of lung-specific proteins currently being developed as a potential treatment for infant respiratory distress syndrome (IRDS)—calls for Genentech to oversee final development, clinical trials, and regulatory activities. Genentech will also have exclusive North American manufacturing and marketing rights. Company president Kirk Raab said Genentech began putting a team together to begin manufacturing preparations Christmas week, after the deal was worked out. He also points out that the company's manufacturing facilities are not being idled by the halt in t-PA production. "We are producing products for clinical trials," he notes. "As with any sophisticated fermentation and recovery process, yields are evolutionary. Take CD4, where demand for raw materials and active product will be significant, and our work on γ-interferon, which could be a commercial product in a few years. We don't want to get into the clinic first without having addressed manufacturing questions."

—Mark Ratner