BIOTECH BUSINESS

Biotech-Pharma Partnerships Reach All-Time High

ith access to capital a nagging concern for most biotechs, and big pharma unable to develop a robust portfolio, alliances between the two have become a standard for doing business. In 1993, 69 alliances had been formed between biotech and big pharma. By 2004, the number reached 502 — and **BY AMANDA** that trend is expected to **BROWER** continue. According to a new report by Deloitte Research, "Critical Factors for Alliance Formation," more than 70 percent of small biotech companies surveyed plan to participate in even more alliances over the next three years

— blurring the boundaries be-

tween pharma and biotech.

Supply-and-demand factors, however, are starting to take hold. Big pharma is finding that the number of alliances to be had with biotechs whose products are farther along in development is starting to dwindle. This opens an opportunity for smaller biotechs with products in earlier stages of development to form alliances now —not in five years when their products are closer to approval. Deloitte reports that because alliance formation has become so competitive, biotechs can be selective when choosing a partner and are able to choose from an average of eight candidates for each alliance deal.

A Wharton research study has determined that drugs produced by pharma-biotech alliances are 30 percent more likely to succeed in gaining FDA approval. What makes these drugs so much more successful?

"One of the key components big companies bring to the table is experience — both in managing robust clinical trials and in navigating the regulatory process with the U.S. Food and Drug Adminis-

tration, European Union, or other regulatory bodies," says Eric Bolesh, senior

analyst at Durham, N.C.-based Cutting Edge Information. "In theory, the combination of science [on the part of the smaller partner] and development expertise

[on the part of the larger partner] leads to more effective drug testing and approval efforts."

Summarizing a report focusing on the biotech-pharma relationship, "Building Pharmaceutical-Biotechnology Alliances,"Bolesh notes that "For companies that have never received an FDA approval letter, designed an advertising campaign, or managed a sales force, the business of development and marketing can be daunting."

Merck, for one, has been aggressive in developing alliances. In 2002, Merck completed 32 part-

Primary reasons for pharma-biotech failures Percentage of respondents naming reason as source of failure



nerships — a 68 percent increase compared to 1999. In 2004, one third of Merck's human health sales were from licensed products, patents, and formulations.

Some biotechs prefer to be acguired than to risk having a bigger company pull it around. Witness this spring's flurry of activity, including Pfizer's acquisition of Vicuron Pharmaceuticals, which focuses on infection-fighting drugs, and GlaxoSmithKline's purchase of Seattle-based Corixa, which already was in partnership with GSK.

As more and more alliances are

formed, Cutting Edge estimates that only 1 out of every 3 deals will meet expectations. And often, partnerships fail. "Product failure is the leading cause of deal failures, and that is understandable many experimental products simply don't work," says Bolesh.

"But many partners point to causes of deal failures that are avoidable," he continues. These include poor communication, poorly negotiated terms, poorly defined partner roles, ineffective alliance leadership, and weak partner or internal commitment.

Specialty pharmacy spend up 22% in 2005

Costly new biotech drugs are increasing the overall cost of healthcare, according to a new survey by Aon Consulting, an employee benefits consulting firm. The survey, based on data provided by 79 leading medical, dental, pharmacy, and vision vendors, found that overall expenditures for specialty drugs will increase 22.5 percent this year — nearly 75 percent higher than the general pharmacy trend rate of 13.1 percent. Specialty drugs currently represent 5 percent of overall pharmacy spending, a figure that will certainly climb as many of the 800-plus potential new biotech drugs in the pipeline come to market.

Aon defines specialty drugs as not just biotech therapies, but other higher-priced products as well. The annual cost of these drugs — used to treat such conditions as cancer, anemia, multiple sclerosis, and rheumatoid arthritis — can cost \$10,000 to \$250,000 annually, often require special handling, and necessitate administration by a professional.

In a press release, Aon Senior Vice President & National Practice Council Leader Randy Vogenberg, RPh, PhD, noted that specialty pharmacy is an increasingly important issue for employers. "These drugs offer significant advances in treating rare diseases and increasingly common disorders but are very costly due to lack of generic competition and inconsistent benefit plans across managed care organizations." Aon's suggestions for managing specialty drug costs include analyzing claims and other data to develop a proactive strategy and using evidence-based medicine to guide diagnosis and treatment.

Higher specialty drug prices will play a role in how employers will design benefit plans. Aon Senior Vice President Bill Sharon, calling increases of this proportion "alarming," says the trend may force employers to cut coverage in other areas, such as "lifestyle" drugs and procedures like gastric bypass surgery, to compensate.

E&Y: Biotech To Be Profitable in 4 Years

Ernst & Young's annual report on the state of biotech industry, "Beyond Borders 2005," optimistically predicts that the industry as a whole is on track to become profitable by 2009. According to the report, the industry is on an upswing — about 365 drugs are in later stages of development compared with 290 in 2003.

Currently, biotechs market 230 drugs. Revenues rose 17 percent in 2004 to \$54.6 billion. Twenty new biotech medicines were approved in 2005, nine of which are expected to bring in revenues of \$3 billion this year. Capital markets were kind to biotech in 2004, with companies raising \$16.9 billion.

Chit-chat

Shopping sprees: Cephalon acquires a midstage cancer drug in its \$160 million purchase of Salmedix, and Genentech gets a manufacturing facility in a \$408 million purchase of a plant Biogen Idec once planned to make natalizumab (Tysabri) in.... While regulatory bodies and medical groups drag their feet on a meaningful drug registry, UnitedHealth Group, with nearly 13 million members, is working on its own — one that would provide nearly real-time data on claims for almost all drugs approved since 2004.... A congressional report found that up to half of drug makers receiving fast-track status have not followed through on agreements to conduct postmarket studies. BH

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