BIO/TECHNOLOGY SEMINAR

MANY ANGLES TO COMPETITIVE ANALYSIS

NEW YORK—Performing competitive analysis is always difficult, but it's a particularly daunting task to forecast winners in biotechnology. "Timing, luck, R&D breakthroughs, commercial partners, and financing have a whole lot more to do with ultimate success than we would like to think. It would be nice if our world were rational, but it's not," lamented Steven Burrill at the *Bio/Technology* seminar on "Assessing Competitive Strength," held here at the end of September. "The biotech companies I work with just don't have a good handle on their competitive position," he added.

Burrill, who is chairman of the national high technology group at Arthur Young (San Francisco, CA), believes financial staying power is the key to corporate success in this emerging industry. Such resources allow a firm to do research and product development, attract and retain key people, build appropriate facilities, buy time in the face of regulatory delays, fight for patent rights, and integrate vertically if so desired.

Wall Street also has trouble analyzing competitive position, according to PaineWebber (New York, NY) vice president Linda Miller. Complicating factors include:

- the tangling interrelationships in biotech;
- the requirement for multidisciplinary, synergistic talents within companies;
- the unclear strength (and value) of patent positions; and
- the increasingly global nature of biotechnology, which means that large, international concerns must be factored into the competitive equation.

When Miller analyzes competitive position, she looks first to technological strength, then to business strategy and operational skills, and finally to product portfolio and financing strategy.

"Companies do not distinguish themselves on the basis of technology," countered Nanette Newell, a founder and principal of the Synertech Group (Research Triangle Park, NC), which is active in the formation of biotech start-ups. "Technology is pretty easy to come by, and for the most part the companies all have pretty good technology." Thus Newell believes that companies set themselves apart via their management, choice of products, and approach to the marketplace.

George Rathmann, president of Amgen (Thousand Oaks, CA), stressed the interrelationship between science and business: "We've all known for some time that the management is probably not as significant as the science if you're going to be a leading biotechnology company. But an outstanding management team wouldn't be there if they didn't have outstanding science." He said that analysts should look for different levels of achievement at different stages in a company's development (see chart). "At the beginning, some things represent wondrous performance for a biotechnology company," he explained. "But if those things are still going on five years later, they probably are a sign of some real problems."

As if analyzing competitive strength in biotech weren't hard enough, there are also a few "wild cards" that the seminar's panelists believe make things even tougher. These include the role of public perception, whether the courts will enforce the rulings of the Patent and Trademark Office, any reallocation of turf between the various offices of the Food and Drug Administration, the real value of strategic partnerships, product liability questions, and the eventual impact of second-generation products.

Amgen's Rathmann suggested that companies choose projects whose commercial feasibility can be determined relatively quickly, and that they phase out programs with interesting science but which do not lend themselves to near-term validation.

—Arthur Klausner

KEY ASPECTS ON WHICH TO EVALUATE BIOTECH COMPANIES AS THEY MATURE

0–2 years	2–6 years	6–8 years	8–10 years
Extent of Financing	Mezzanine Financing	PLA/NDA	Market Franchise
Investor Quality	Corporate Partners	Product Intro	Product Innovations
Venture	IND Filing	Revenues	↑R&D Expense
Corporate	Patent Application	Profits	Internal Cash Generation
R&D Expense	Cash vs. Burn Rate	Direct Marketing	
BOD/SAB/MGMT	Product Utility	Product Pipeline	
Experience	Leadership	↑R&D Expense	
Track Record	↑R&D Expense		
Performance	Resource Allocation		

Data from George Rathmann, Amgen. Key: BOD=board of directors; SAB=scientific advisory board; MGMT=management; IND=investigational new drug; PLA=product license application; NDA=new drug application

RESEARCH PAPER ANALYSIS

t-PA PRODUCED IN MOUSE MILK

An intriguing solution to the difficulties of mammalian cell culture is to genetically program animals to secrete useful substances in their milk (see *Bio/Technology* **5**:874, Sept. '87). In this issue, a group from Integrated Genetics (Framingham, MA) and the U.S. National Institutes of Health reports success in transforming mice to produce biologically active human tissue plasminogen activator (t-PA).

These results demonstrate that no specific signal is required for t-PA synthesis in mammary cells. Importantly, there is no evidence of t-PA mRNA in the blood of the transgenic mice, even during lactation, while the levels of t-PA mRNA reach extremely high levels (100,000 μg/ml) in mammary tissue. Thus the human t-PA secretion signal appears to work normally in mouse mammary cells. The work of Katherine Gordon and her collaborators therefore shows the feasibility of using such systems to obtain high levels of biologically active complex human proteins. This opens the door to large-scale molecular farming of valuable proteins from transgenic domestic animals.

The success of animal production units ultimately depends on the level of start-up costs and the difficulty of defining production quality control for regulatory approval. These obstacles will be countered, however, by the relatively low cost of maintaining a ruminant animal versus a bioreactor cell culture facility. The benefit of engineering animals to secrete altered, highly nutritional milk for human consumption, or for increased efficiency of livestock production, also has economic attraction for the livestock industry (see Church, R. B., *Tibtech* **5**:13–19, 1987). Either way, the main benefiters in the near future are likely to be the dairy industry and the producers of veterinary biologics or industrial enzymes, where regulatory approval may be easier to obtain.

—Robert B. Church