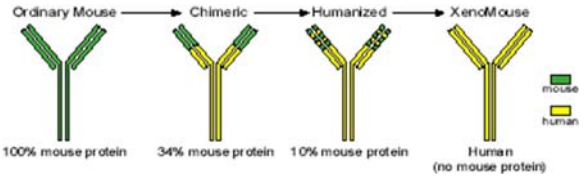
Abgenix and the ABX-EGF Project [1]



Abgenix

In early 2000, Abgenix was a pre-market life sciences company based in Fremont, California. The venture was founded about 1994 and had gone public in 1996. The company's core technology was a genetically engineered XenoMouse.

The XenoMouse was a strain of transgenic mice with 100% human protein. The technology offered a platform for producing antibodies that could potentially treat multiple disorders, such as cancer, transplant rejection, and inflammation. Compared to traditional mouse-protein development of antibodies, the XenoMouse offered advantages of lower rejection rates, lower side effects, and faster development time.

Early antibody-based drugs such as Rituxan (Genentech-IDEC; approved in the U.S. in 1997) and Herceptin (Genentech; approved in 1998) were rapidly transforming the immuno-oncology market. Herceptin was priced at an average of $20,000 for a treatment cycle. In 1999, Genentech reported $188 million sales for Herceptin and $279 million for Rituxan, up from $163 million each in 1998.

To date, Abgenix had generated its revenue via out-licensing the use of its technology, while bringing projects through the development pipeline. The company currently had four drugs based on XenoMouse technology in preclinical, Phase 1, Phase 2, and Phase 3 trials. Drugs that successfully complete Phase 3 trials commonly are submitted to regulatory authorities such as the U.S. FDA, which might or might not approve market introduction. For most projects, Abgenix planned to sell their rights so that the company would not have to invest in bringing the drugs to market.

Over time, the company had worked with multiple partners and licensees, including biotech firms such as Amgen and Genentech, established pharmaceutical companies such as Abbott and Pfizer, early stage genomics companies such as Curagen and HGS, and others such as the U.S. Army.

Most development stage companies in the industry followed the out-licensing strategy or were acquired by larger firms. However, a few such as Amgen, Regeneron, and IDEC moved into long-term independent commercialization.

Decision: ABX EGF project

A key current decision for Abgenix concerned its ABX-EFG development project, which targeted an epidermal growth factor (EGF) receptor. Some studies estimated over 500,000 annual cancer cases in the U.S. that involved over-expression of EGF. In the early preclinical trials, ABX-EGF had eradicated pre-formed human cancer tumors in all test mice; the project had just entered Phase 1 small scale human trials.

The antibody value chain has eight stages: (1) target discovery; (2) target validation; (3) antibody creation; (4) preclinical development; (5) clinical development (Phases 1 to 3); (6) process development; (7) manufacturing; and (8) marketing. Currently, Abgenix focused on stages three through five.

The licensing or acquisition value of a drug project typically increased as it moved up the value chain, commonly with a major bump between Phase 2 and Phase 3 clinical trials. Many products failed in preclinical and Phase 1 and 2 clinical trials. Failures also occurred in Phase 3 trials but were less common.

If ABX-EGF reached the market, the drug would be likely to face multiple competitors. At least two pharmaceutical firms, the $18 billion company AstraZeneca and the smaller venture OSI, had projects based on traditional small cell molecules that were moving through trials. In addition, a drug from a small biotech firm, ImClone, had reached Phase 3 trials, which it had licensed to Merck KgaA of Germany for non-U.S. rights. The biotech pioneer Genentech also had an Avastin project under way.

There was substantial downside and upside uncertainty even if ABX-EGF reached the market. Analysts suggested that an ABX-EGF drug might be limited to second line treatment status, for use after failure of other drugs for colorectal cancer. At the same time, the drug might prove to be valuable in combination with other cancer medicines.

Abgenix options for ABX-EGF

- **Aventis out-license**: The $5 billion dollar pharmaceutical company, Aventis, was interested in taking over the project, paying Abgenix a royalty based on successfully reaching testing and commercialization milestones.

[1] This note draws on the HBS case "Abgenix and the XenoMouse" (Robert Dolan, 2001), as well as additional public information.

- **Bio-tech partnership:** Immunex, a profitable biotech company with about $500 million revenue that emphasized the oncology market, was offering a partnership, with an initial payment and then splitting costs and profits over time.
- **Solo for now:** Abgenix was considering moving ahead on its own with ABX-EGF for the time being and delaying a decision until completing Phase 2 trials.

Financial structures [2]

- **Aventis out-license**: Abgenix would receive $5 million on signing; $5 million if the drug reached the beginning of Phase 2 trials; $8 million if the drug reached Phase 3; and $10 million if approved by the FDA and entered the market. Aventis would be responsible for all development and commercialization activities and costs. One estimate placed likely time to market at five years. If the drug reached the market, analysts estimated a sales profile of $20 (year 1), $70 (year 2), $135 (year 3), $250 (year 4), $330 (year 5), $450 (year 6), $540 (year 7), $620 (year 8), $700 (year 9), and $700 (year 10). Abgenix would receive a 10% royalty on all sales.
- **Immunex partnership**: Immunex would pay $5 million on signing and $5 million if the drug reached the beginning of Phase 2 trials. The two companies would co-design the Phase 2 trials, while Immunex would take the lead if the drug reached Phase 3, also taking primary responsibility for marketing the drug if approved. Abgenix and Immunex would split costs and revenues. Because Immunex had a smaller market footprint than Aventis, analysts estimated that it would achieve about 20% lower sales than the established pharmaceutical company.
- **Abgenix-Immunex partnership development costs:** Current estimates were that development costs for an Abgenix-Immunex partnership over a five year pre-market horizon were likely to increase from $10 million in year 1; $20 million in year 2; $25 million in year 3; $35 million in year 4; and another $35 million in year 5 after FDA approval and before entering the market. An additional $15 million would be needed for marketing launch. After launch, ongoing cost of goods sold was likely to be about 10% of sales plus 25% of sales for selling, general, and administration expenses.

Stage probabilities

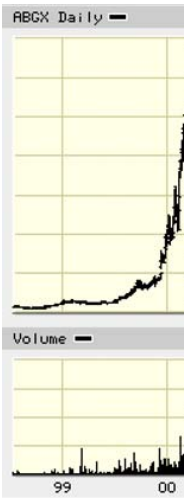
Abgenix had assessed the likelihood of reaching clinical and market milestones. The company forecast an 85% chance of reaching Phase 3a trials; 75% of reaching Phase 3b; and 40% of reaching the market.

Decision: For Abgenix and its investors, what are the strengths and challenges of the three options?

Exhibit 1: Abgenix Financials
(source: company 10-k report)

	1999	1998	1997	1996	1995	1994
Revenue ($ million)	$12.3	$3.8	$2.0	$4.7	$6.2	$6.2
Cost of goods sold	$21	$18	$11	$9	$12	
Selling, general, administration	$5	$3	$4	$3	$3	$2
R&D	$21	$18	$11	$9	$12	$8
Operating income	-$14	-$17	-$13	-$7	-$8	-$4
Net income	-$20	-$17	-$36	-$7	-$8	-$4
Cash & short term investments	$57	$17	$15	$10		
Assets	$149	$24	$22	$14		
Long term debt	$0.4	$2	$4	$2		
Liabilities	$12	$7	$13	$6		
Equity	$137	$17	$9	$8		
Employees	73	60	57			

Exhibit 2: Abgenix Stock Trend



[2] Note: The figures in this section are for illustrative use; they do not map to the actual details.