

Managing change in biotech: setbacks and failures

Mary Ann Rafferty

When faced with a setback, how can biotech companies effectively manage staffing challenges?

One of the toughest challenges faced by biotech companies is having a promising lead experimental drug fall flat in the final stages of clinical trials. In the San Francisco Bay Area alone this past year, companies such as Nuvelo, Telik, Renovis, Dynavax Technologies and Threshold Pharmaceuticals have all experienced precipitous drops in their stock prices after once-promising experimental drugs yielded disappointing results in clinical trials (Table 1).

Previous articles on managing change in biotech companies focused on changes in startups¹ as well as changes that occur during mergers and acquisitions². This article addresses the kinds of changes that accompany adverse events such as product failures, regulatory action that puts clinical studies on hold and the withdrawal of R&D funding by a pharmaceutical partner.

Strategies for setbacks

Many of the people working in biotech companies hold advanced degrees and have highly specialized technical and nontechnical expertise. They typically strongly value human life and hold a deep commitment to creating new therapeutics, medical devices or diagnostics that improve medical treatments or meet unmet medical needs. The above-average intellect and high values combine in a way that arouse passion and develop a force that propels teams forward into scientific and medical frontiers.

Research and clinical studies in oncology, for example, are not for the faint of heart. With few exceptions, this complex and puzzling disease or composite of diseases continues to confound researchers and clinicians and defy

Mary Ann Rafferty currently heads a leadership development consulting practice working with companies in the biotech industry.
e-mail: maryannrafferty@comcast.net

Table 1 Five San Francisco Bay Area biotech companies saw their stocks tumble after once-promising experimental drugs yielded disappointing results in clinical trials

Company	Lead drug candidate	Indication	Date of news	Share drop
Renovis (S. San Francisco)	NXY-059	Stroke	10/26/2006	76%
Nuvelo (San Carlos)	alfimeprase	Blood clots	12/11/2006	79%
Telik (Palo Alto)	Telcyta	Lung, ovarian cancer	12/26/2006	71%
Dynavax Technologies (Berkeley)	Tolamba	Ragweed allergy	1/8/2007	30%
Threshold Pharmaceuticals (Redwood City)	glufosfamide	Pancreatic cancer	2/26/2007	57%

Source: *San Francisco Chronicle*, May 11, 2007

effective medical interventions that result in a cure. When adverse events occur, the long-term efforts of highly talented, passionate, driven staff can come to a halt with little notice. At these times, company leaders and employees experience strong emotions—disbelief, disappointment, bewilderment, painful frustration. Usually, the immediate and pressing priority for the company's leadership is evaluating any and all strategic and tactical alternatives and addressing a variety of complex business decisions. At the same time, employees are reacting to the news and are eager to learn exactly how this turn of events will affect their projects and their employment.

From a practical perspective, company leaders are wise to look squarely at the goals, milestones and timelines against the most reasonable horizon, usually 18–24 months. Next, they must evaluate the skills and expertise necessary for achieving these goals in the projected time frames. This review can lead to a clear picture of staffing requirements and provide a sound basis for difficult staffing decisions.

The kind of instability that accompanies such adverse events can prompt significant employee retention challenges, especially in functions where talent supply-and-demand pressures are high, such as project management, regulatory affairs, clinical operations,

pharmaco-vigilance and toxicology. This is especially true in the Bay Area, where opportunities exceed available qualified staff in these specialized areas. Companies must identify staffing vulnerabilities and design and execute retention measures to secure the specialized talent they need, both transitionally and beyond. Meaningful retention or 'stay' bonuses tied to the achievement of specific milestones or to remaining with the company until a future date can help to meet the staffing needs of the company and provide incentives for employees during uncertain times.

According to Gary Pisano, "Even when a drug gets to phase 3 trials, the probability of failure can be as high as 50 percent (depending on the therapeutic category)."³ Biotech companies tend to be highly resilient, able to reinvent themselves—they tough-out these disappointments. The passion, intellect and determination of committed scientists and clinicians remain undaunted, even emboldened by the challenges of drug development.

COMPETING INTERESTS STATEMENT

The author declares no competing financial interests.

1. Rafferty, M.A. *Nat. Biotechnol.* **25**, 479–480 (2007).
2. Rafferty, M.A. *Nat. Biotechnol.* **25**, 689–690 (2007).
3. Pisano, G. *Science Business: The Promise, the Reality, and the Future of Biotech* (Harvard Business School Press, Cambridge, MA; 2006).