Editorial

Increasing clarity

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The fates of biotechnology companies, like those in many other dynamic industries, depend on the outcome of future events, which can be difficult to predict. Seemingly late-stage issues such as regulatory uncertainty dissuade investors, stalling innovation and company growth. Accordingly, increased definition of regulatory processes and opportunities for profitable investment exit can improve the financing climate, and drive innovation. In my editorials earlier this year I have commented on the numerous uncertainties the biotechnology industry faced. What a difference a few months makes! Recent events have clarified several important issues.

Although obtaining financing in biotechnology has seldom been described as easy, the situation is far better now than it was a year ago. With a large number of companies having less than a year's cash on hand, there was a strong fear that a majority of biotechnology companies would go bankrupt. This fear was not realized, and it appears that companies were able to adjust their burn rates and fundraising activities to accommodate the financial challenges. While many jobs were cut and R&D scaled back, mass-bankruptcy now seems unlikely and the industry stands well positioned for growth.

The passage of the health reform bill has also had a profound impact. Important issues such as the approval pathway for generic biologics and data exclusivity for branded biologics are now better defined. The FDA has been empowered to approve follow-on biologic drugs, and biologic manufacturers have been granted 12 years of exclusivity. For more discussion on biologic exclusivity, see the two commentaries on the topic in issue 16.1.[1,2]

These important clarifications are offset by some important unresolved issues: The Small Business Innovation Research program, which is an important source of gap financing between academic and development-stage research for American companies, is overdue for reauthorization. While the US congress has failed to renew the program, it appears that the program will continue to be extended through annual 1-year 'punts'. Another pressing issue is approval time for biologic drugs. While the FDA approved 16 biologic drugs in 2009 – reversing a declining trend – it appears that approval times are increasing. So it appears that while development-stage funding and follow-on biologic approval are becoming better-defined, other issues may be taking their place as key issues.

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REFERENCES

1. Pitts, P.J. (2010) Why data exclusivity is the new patent protection. *Journal of Commercial Biotechnology* 16(1): 3–4.
2. Wroblewski, M.S. and Jex, E.A. (2010) Follow-on biologic drug competition – No need for new marketing exclusivities. *Journal of Commercial Biotechnology* 16(1): 5–7.

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