

operational control of the organization. If the company is successful, the venture capitalists also receive a significant portion of the downstream financial windfall (based on their percentage of ownership and terms agreed upon when they made their investment in the company). Ideally, the company itself benefits from the support and business strategy knowledge of the venture capital firm. The founders of the company may be kept on board in some capacity to enable further advancement of the company's programs, but this is not always the case. As noted earlier, many company founders form companies with the intent of selling out to venture capital once the science and business has advanced into early clinical trials. (Most venture capital firms will only invest in programs that have reached clinical trials.) Employees of small biotechnology companies would be well advised to stay aware of the intentions of company owners with respect to venture capital plans, especially once a viable clinical candidate has been identified.

The discovery, development, and eventual commercialization of a novel therapeutic require a great deal more than scientific expertise. Internal corporate dynamics can, and often do, play a major role in determining whether or not a new drug will reach patients in need. Corporate cultures that are not conducive to the near constant information flow will be far less efficient and less able to move their programs forward. Navigating the changing business environment can also be a significant challenge. The pharmaceutical business climate is not static, and organization must adapt to survive as competitor compounds reach the market, patient populations shift in size and age, and new business models become available (e.g., CROs, academic drug discovery centers). For smaller companies, the added hurdle of funding research and development programs in an increasingly constrained financial environment must be overcome. Science alone cannot win the day, but when coupled with the right environment, resources, and organizational structures, new medications can be developed to help patients in need.

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## QUESTIONS

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1. What are the three major facets of a pharmaceutical company?
2. What are some of the business climate factors that can impact a pharmaceutical company?
3. What are some of the non-monetary impacts of mergers and acquisitions?
4. What is the purpose of a contract research organization?
5. What are some of the potential risks of working with a contract research organization?
6. How did the Bayh–Dole act of 1980 impact academic and non-profit research communities?