

Morgan Lewis



Emerging Life Sciences Companies

second edition

Chapter 2

Realizing Value from New Venture Spin-Outs

Chapter 2

REALIZING VALUE FROM NEW VENTURE SPIN-OUTS

Increasingly, Big Pharma is seeking to realize the latent value of intellectual property (IP) and potential products that have been “put on the shelf.” These potential products often do not promise a sufficient upside to garner high priority in the Big Pharma research and development (R&D) pipeline, or they may simply lie outside the company’s core competency or strategic focus. One way to realize value is through a simple sale to another pharmaceutical or biotechnology company focusing on that therapeutic area. However, the obvious acquisition candidates may only be willing to pay for a product further down the FDA approval pipeline or may be working on a competing methodology and favor their in-house approach without objectively analyzing which approach is better. An alternative way to realize value from these assets is through a new venture spin-out.

While Big Pharma will not likely spin out its blockbuster drug candidates, profitable businesses can be built with smaller or niche-market biotechnology, pharmaceutical, diagnostic, or device products. Generally, a spin-out involves the transfer of IP by the Big Pharma parent company to a newly created company (Company) in exchange for equity in the Company. While it is nice to receive a return on Company equity, the ultimate success for Big Pharma in a new venture spin-out is to be able to take a product that is “on the shelf” and turn it into a revenue-generating product for its sales force.

Experienced venture capitalists do not see these new venture spin-outs as castoffs but as a tremendous opportunity to take advantage of the Big Pharma R&D system. The Company can be capitalized with private equity and other venture financing (see Chapter 4: How to Be Touched by an Angel and Chapter 5: Preparing a Venture Capital Term Sheet) and continue the development of technology, free of the resource allocation, planning decisions, and other constraints of the parent. The Company can focus on and nurture its technology and often license or otherwise acquire synergistic IP from other Big Pharma companies or other sources. The Company can also use stock options, higher-level titles, and a greater entrepreneurial spirit to lure new talent to the enterprise.

Some of the key issues to keep in mind in structuring a new venture spin-out are discussed in the following sections.

Structuring IP Transfer

In order for the Company to be fundable, it must have the complete right to use any transferred IP for its intended field of use, subject to termination only under very limited conditions.

Whether the transfer of technology from the parent to the Company is structured as an assignment or a license, defining its terms involves a delicate negotiation in which the parent often must negotiate with itself. At this stage, an internal champion or an executive recruited from outside should be designated to represent the interests of the Company, and experienced venture capital counsel should be engaged on its behalf to provide a reality check on the one-party negotiation process. Issues to focus on include (i) the ideal business structure for the Company, (ii) the IP to be transferred/licensed, (iii) the scope of the Company's exclusive field of use, (iv) rights to the technology outside the exclusive field of use, (v) rights to improvements by the Company and the parent, and (vi) any "strings attached," such as any right of the parent to market or co-market products developed from the transferred IP. These strings can often be what makes or breaks the Company's ability to be funded by a venture capitalist.

Valuation

The Company's premoney valuation is a key component in the venture capital investment decisionmaking process. Factors in this valuation will include (i) market value for companies at a similar stage of development, (ii) R&D expenses attributable to the technology, (iii) value of the technology if sold to a third party, and (iv) negotiations with the investors. Before the venture capital investment, this value will be represented by Company stock issued to the Big Pharma parent plus a pool of Company equity (usually 15%–20% postfinancing) reserved for the Company's initial management and future employees. The Big Pharma parent should be flexible with valuation and seek the best venture capital partner (rather than the cheapest) for the Company in order to increase the likelihood of achieving its long-term goals (e.g., realizing value from underutilized IP and bringing new products to market).

Continuing Relationship

The Company and the Big Pharma parent are likely to have a continuing relationship. Typically, the Big Pharma parent will have a representative on the Company's board, and the Company will draw initial members of its management and scientific teams from the Big Pharma parent. In addition to IP, the parent may contribute hard assets (e.g., equipment), third-party contracts, and infrastructure services (e.g., HR, accounting, regulatory) for a transition period, and even temporarily share facilities with the Company. It may be desirable to conduct limited joint R&D if both companies are interested in the same improvements for different fields of use. In order to promote a healthy and functional future relationship, care should be taken up front to focus on the respective rights of the parties when it comes time for the Company to seek strategic alliances with pharmaceutical companies other than the parent.

Universities and nonprofit research institutions are also frequent candidates for a new venture spin-out. A university or research institution will frequently desire to retain the right to use the technology for research purposes and may desire to restrict the time spent by the founding professor.

The following is a detailed outline of various issues to consider when spinning out a new venture.

Reasons for Spinning Out

- A. To free the Company from its parent's resource allocation and planning decisions and other constraints that may not be consistent with its health and growth
- B. Different risk profile—hard-to-justify investment in new market compared with familiar, existing business
- C. Liberate parent from funding responsibilities
- D. Encourage entrepreneurial spirit
- E. Increase focus
- F. Recruit talent that might not be attracted to internal division or venture
- G. Employee ownership

Entity Structure (See Chapter 1: Choosing the Ideal Structure for Your Business Entity)

Technology Transfer Structure

- A. Assignment vs. license
- B. License
 - 1. Exclusive vs. nonexclusive
 - 2. Field of use
 - 3. Retention of rights by parent; license back to parent for certain uses
 - 4. Infringement by third parties; infringement on the rights of third parties
 - 5. Improvements
- C. Ownership issues if continued joint development

Economic Terms

- A. Contributions by parent
 - 1. IP
 - 2. Valuation of the IP
 - a. Function of R&D expenses attributable to the technology
 - b. Function of valuation of technology if sold currently to a third party
 - c. Negotiation with outside investors

- d. Equity vs. royalties; create a “win–win” structure; consider use of convertible preferred stock with liquidation preference equal to agreed-upon current value to preserve cash in the Company
 - e. Use of milestones to adjust consideration to parent (conversion ratio adjustment or issuance of warrant) subsequently if value is ambiguous
 - 3. Other assets
 - a. Furniture, fixtures, and equipment
 - b. Intangible/contracts
 - c. Infrastructure services (e.g., HR, accounting)
 - d. Temporary facility sharing
 - 4. Financial support—seed financing; follow-on funding; commitment to participation in later outside financing round(s)
- B. Contributions by new investors (generally cash for preferred stock)
- C. Equity participation by management—individuals treated as founders?
- D. Continuing commercial relationship between parent and the Company
 - 1. Vendor/customer
 - 2. Support services
 - 3. Joint R&D
- E. Competition between parent and the Company
 - 1. For customers
 - 2. For employees

Governance

- A. Constitution of board of directors
 - 1. Parent represented
 - a. Director
 - b. Observer
 - 2. Management represented
 - 3. Outside investors represented
 - 4. Procedure for selecting independent directors

- B. Protective provisions (e.g., voting, special consent rights of parent)
 - 1. Parent
 - 2. Outside investors

Different Approaches in Commercial and Academic Contexts

- A. Economics
 - 1. Equity allocation
 - 2. Royalties
 - 3. Sponsored research
- B. Governance
- C. Ongoing relationships

Conflicts of Interest

- A. Parties
 - 1. Parent
 - 2. The Company
 - 3. Outside investors
 - 4. Management/founders
 - 5. In the university context—add the academic institution and the faculty member/
principal investigator
- B. Parent on both sides of transaction
 - 1. Watching out for interests of the Company
 - 2. Watching out for interests of management
 - 3. Are interests naturally aligned?
- C. Impact on employees of the Company
 - 1. Can they effectively negotiate?
 - 2. Potential negative impact on future success of the Company
 - 3. Consider designating roles (e.g., founder/management to look out primarily
for interests of the Company, even though it is still employed by parent, and
parent executive to look out primarily for interests of parent)

Human Issues

- A. Who goes with the Company? Who stays with parent?
- B. Can parent tolerate loss of talent?
- C. Alternative arrangements (allowing parent to keep people)
 - 1. Compensation/incentive issues
 - 2. Accentuated conflicts of interest