# Realizing Value from Big Pharma New Venture Spin-Outs

Steven M. Cohen, Partner, Morgan Lewis

Increasingly, Big Pharma is seeking to realize the latent value of its intellectual property (IP). Pharmaceutical companies develop dozens of drug candidates for each product that it can fully fund through the clinical trial process. Thus, many potential viable products have been or are in jeopardy of being "put on the shelf." These potential products often do not promise 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 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. One 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 intellectual property by the Big Pharma "parent" company to a newly created company (Newco) in exchange for equity in Newco. While it is nice to receive a return on Newco equity, the ultimate success for Big Pharma in a new venture spin-out is often to have the product development work completed and the product turned into a revenue generating product for its sales force.

Experienced venture capitalists do not see these new venture spin-outs as cast-offs, but as a tremendous opportunity to take advantage of the Big Pharma R&D system. Newco can be capitalized with private equity and other venture financing and continue the development of technology, free of the resource allocation, planning decisions and other constraints of the former parent. Newco can focus on and nurture its technology and often license in or otherwise acquire synergistic intellectual property from other Big Pharma companies or other sources. Newco can also use stock options, higher level titles and 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:

**Structuring IP Transfer.** In order for Newco to be fundable, it must have the complete right to use the transferred IP for its intended field of use, subject to termination only under very limited conditions. Whether structured as an assignment or a license, defining the terms of the technology transfer from the parent to Newco involves a delicate negotiation in which the parent company often negotiates with itself. An internal champion or an executive recruited from outside must be designated to represent the interests of Newco. At this stage, experienced venture capital counsel should be engaged on behalf of Newco to provide a "reality check" on the one-party spin-out negotiation process. Issues to focus on include: (1) intellectual property to be transferred, (2) scope of Newco's exclusive field of use, (3) rights to the technology outside exclusive field of use, (4) right to improvements by each of Newco and parent and (5) "strings attached" such as any right of the parent to market or co-market products developed from the transferred IP. The "strings attached" can often be the term that makes or breaks Newco's ability to be funded by a venture capitalist.

**Valuation.** Newco's pre-money valuation is a key component in the venture capital investment decision-making process. Factors in this valuation will include (1) market value for companies at a similar stage of development, (2) R&D expense attributable to the technology, (3) value of the technology if sold to a third party and (4) negotiations with the investors. Before the venture capital investment, this value will be represented by the Newco stock issued to the parent company plus a pool of Newco equity (usually 15-20% post-financing) reserved for Newco's initial management and future employees. The parent should be flexible with valuation and seek the best venture capital partner (rather than the cheapest) for Newco in order to increase the likelihood of achieving its long-term goals (e.g., realizing value from underutilized IP, bringing new products to market and achieving a return on its equity).

**Continuing Relationship.** Newco and the parent company are likely to have a continuing relationship. Typically, the parent will have a representative on Newco's board and Newco will draw initial members of its management and scientific team from the parent. In addition to intellectual property, the parent may contribute hard assets (such as equipment), third-party contracts, infrastructure services for a transition period (HR, accounting, regulatory) and even temporary facility sharing. It may be desirable to conduct limited joint R&D if both the parent and Newco 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 Newco to seek Big Pharma strategic alliances.

Please join us on Wednesday, June 22, 2005 from 9:30 a.m. to 10:45 a.m., for a panel at BIO focused on new venture spin-outs. The panelists include:

Ting Pau Oei, who was the point person for Johnson & Johnson's new venture spin-out program, and who will discuss J&J's approach to alternative means of maximizing value from its R&D efforts. Ting Pau, who is now a partner at L Capital, a life sciences venture capital firm, will also describe why L Capital considers new venture spin-outs from Big Pharma to be an attractive investment opportunity.

Geert Cauwenbergh, CEO of Barrier Therapeutics, one of the most successful recent new venture spin-outs. Prior to being the founder of Barrier, Dr. Cauwenbergh was Vice President for Technology Transfer, J&J Consumer and Personal Care Products and previously Vice President Research and Development, J&J Skin Care Center. Barrier began by licensing a group of dermatology products from J&J in various phases of clinical development in May 2002 with funding by blue chip venture capital firms led by JPMorgan Private Equity and TL Ventures. Barrier successfully completed an IPO in May 2004 and a secondary offering in February 2005, in which J&J was able to begin to realize cash proceeds from its Barrier equity.

Howard Weisman, a founder and President of ESP Pharma. ESP Pharma began operations in May 2002 with the acquisition from Wyeth of four late stage or marketed cardiovascular drugs, including its flagship product, Cardene I.V., and was funded by blue chip venture capital firms: Domain, Apax and NEA. By the end of 2004, the Company had grown revenues to $90 million which was helped by the purchase in 2003 of the I.V. Busulfex, a specialty oncology drug. In January 2005, Protein Design Labs of Fremont, California announced it had agreed to purchase ESP Pharma. The total purchase price was $325 million in cash and $175 million in stock.

For more information about new venture spin-outs, please join us at BIO or contact Steven Cohen, Princeton Office, at scohen@morganlewis.com.