Emerging Trends in Biotech/ Pharmaceutical Collaborations

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Industry Drivers

A number of forces are driving pharmaceutical companies to seek strategic partnering deals with biotechnology companies, including heightened regulatory caution and rising research and development costs. Since peaking in 1996, when the FDA approved 53 new drugs, the annual number of new drugs approved for marketing has steadily declined.[1] In 2007, the FDA approved only nineteen new drugs.[2] This decline can be attributed primarily to a more cautious regulatory climate caused by recent high-profile safety issues.[3] As a result of the heightened bar to obtain FDA approval, the life sciences sector has been plagued by a dearth of new product flow. All players in the industry—even large pharmaceutical companies—have been affected. Notably, only Novartis and GlaxoSmithKline (GSK) released more than one drug in 2007.[4]

At the same time that approvals are declining, research and development costs continue to rise. Since 1996, R&D spending by pharmaceutical manufacturers has increased 187 percent, from $16.9 billion to $48.5 billion. Recent estimates calculate that average R&D costs are now $1.318 billion per new molecule approved by the FDA.[5]

As a result of the declining returns from their R&D investments, life sciences companies have a strategic need to maintain a broad product pipeline at all stages of development. They are filling these pipelines by in-licensing an ever-increasing number of compounds. This increased demand has created a seller's market, where smaller biotechnology companies with novel therapeutic products in development are often able to negotiate licensor-favorable terms in licensing and collaboration agreements.

Emerging biotechnology companies, like large pharma companies, have strong incentives to enter into collaboration deals. Small biotechs are facing tight capital markets as it has become increasingly difficult for them to raise capital. Venture capital financing in the biotechnology sector declined 68 percent from Q1 '07, a quarter in which biotech companies raised $1.5 billion in 40 financing deals, compared to Q1 '08, in which only $480 million was raised in 33 deals.[6] Moreover, second quarter 2008 financings have dropped even further—VC investment in biotechnology has dropped 65 percent as compared with Q1 2008. Exacerbating the pressures on private biotech companies is the outright frozen IPO market. The IPO market for biotech companies was very active in 2007, with 28 IPOs that raised approximately $2 billion, more than double the amount raised in 2006.[7] In contrast, public financing in 2008 has come to a screeching halt. This challenging IPO market means that mergers/acquisitions have become the exit strategy of choice. Though M&A activity declined slightly in 2007 (commensurate with the surge in IPOs during 2007), a resurgence in M&A activity is expected during the latter part of this year and in 2009.

In addition to these financing challenges, biotechnology companies face challenges similar to pharmaceuticals with respect to heightened regulatory scrutiny and escalating R&D expenses. In combination, these factors motivate emerging biotech companies to seek strategic partnering and collaboration deals with larger biotechnology and pharmaceutical companies. Strategic partnering and collaboration deals present an opportunity for an emerging biotech company to reduce the financial and regulatory uncertainty inherent in developing and commercializing drug product candidates. Furthermore, these deals allow a smaller company to access the financial resources and multidisciplinary expertise of a larger life sciences company. This is especially useful for an emerging biotech company developing a product aimed at a large patient population, where clinical trials and commercialization are particularly costly and complex.[8] For most biotechs, their initial goal is simply to generate good data to support a successful

product development plan. Once they have adequate clinical data in hand, biotechs can then seek out larger partners who can support the high cost of developing drug products through Phase III clinical trials.

Deal Activity in 2007

The forces driving partnering activity continued to rise in 2007, causing an increase in the number of strategic alliances. The number of strategic alliances rose approximately 3 percent in 2007.[9] However, the total deal value of these alliances decreased to $19.7 billion, a decline of 10.5 percent ($2.3 billion) from 2006.[10]

The six most active licensees during 2007 were Novartis, Johnson & Johnson, GlaxoSmithKline, Merck, Roche, and Pfizer.[11] These six companies alone signed 118 deals, comprising 14 percent of all deal activity.[12] In terms of total deal value, GSK was the biggest deal maker of the year, with four deals valued between $640 million and $1.52 billion. As in past years, the largest deals in 2007 involved late stage products, with thirteen of the top eighteen deals involving clinical stage products.[13] Interestingly, however, the largest deal of the year was for products still in the discovery phase of development. Ablynx signed a deal with Boehringer Ingelheim for $1.8 billion, covering the discovery, development, and commercialization of up to 10 nanobody-based products in a variety of therapeutic areas.[14] Given the current licensor-friendly market, Ablynx was able to negotiate $88 million upfront and retain co-promotion rights in Europe despite the very early stage of the licensed products in development.[15]

Regional partnering also became a more prominent feature in the deal-making landscape in 2007, particularly with licensors in China, India, and the Middle East.[16] This follows the increasing trend of pharmaceutical companies outsourcing R&D to lower-cost countries.[17]

China saw rapid growth in the number of deals, with 13 deals in 2007 compared to only eight deals in 2006. An illustrative example is the August 2007 drug discovery and development collaboration between Eli Lilly & Co. and China-based Hutchison MediPharma.[18] Under the deal, Hutchison will receive drug discovery milestone payments of $20-29 million per candidate, and potential royalties on sales of any product commercialized from the collaboration.[19] Hutchison received an undisclosed upfront payment and will also receive annual R&D support payments.[20] Hutchison also retained the right to develop any candidate that Lilly passes on.[21] This deal is representative of Lilly's continuing efforts to move its research and development efforts, including clinical trials, to China, India, and eastern European countries.[22] Lilly "now conducts a significant proportion of its research in foreign laboratories, with 20 percent of it based in China," where Lilly's largest foreign R&D team is based.[23]

India also saw growth in the number of deals for 2007, though deal activity in India is already more than double that of China.[24] While India is traditionally known for its generic pharmaceutical industry, the country is engaged in a concerted effort to expand its pharmaceutical industry into proprietary products.[25] The 2007 deal between GlaxoSmithKline and India-based Ranbaxy Laboratories underscores India's recent efforts to develop proprietary drugs of its own. Ranbaxy is already known as a major manufacturer of generic pharmaceuticals, and is one of the largest generic manufacturers in the world.[26] In fact, Ranbaxy and GSK have been involved in multiple disputes arising from Ranbaxy's attempts to market generic equivalents of GSK's drugs, including Valtrex, Imitrex, and Ceftin. With the recent drug development deal with GSK, Ranbaxy is pursuing an entry into proprietary medicine. The 2007 deal expands on a previous collaboration between GSK and Ranbaxy, where Ranbaxy had limited responsibility conducting optimization chemistry required to progress drug leads to the candidate selection stage.[27] The new agreement enhances the collaboration, increasing both Ranbaxy's drug development responsibilities and its rights to potential downstream product revenue.[28] Ranbaxy also negotiated rights to advance lead drug candidates beyond the initial selection stage, through completion of clinical proof of concept trials.[29] Ranbaxy could receive over $100 million in potential milestone payments if it develops a product that GSK eventually markets.[30] Ranbaxy will also receive double digit royalties on worldwide net sales.[31] Furthermore, Ranbaxy retained the right to co-promote products in India.[32] Through the broad collaboration, GSK will access Ranbaxy's talented R&D team and is expected to develop more products for patients faster while Ranbaxy will benefit from GSK's vast global drug discovery and development experience.[33]

Deal Structures

Deal structures continue to become more complex. For example, half of the deals between large pharmaceutical companies and biotech companies with late-stage products (*i.e.*, in Phase II or III of clinical trials) included a co-promotion and/or profit sharing structure.

Upfront payments for all clinical phase transactions increased from 2006. The most dramatic rise occurred

in discovery phase deals, where payments more than doubled in 2007.[34] In contrast, upfront payments for marketed products continued to decline, reflecting the lower value of such products in the increasingly competitive marketplace.[35]

Early Stage Deals

Traditionally, biotech companies have been hesitant to out-license their technology too early.[36] As a drug target proceeds through the various stages of development and clinical testing, its commercial potential increases as the risk of failure decreases.[37] Biotech companies generally receive less for their technology at earlier, riskier stages of development.[38] Consequently, biotech companies seek to balance their present need for resources against the increased value they could receive for their technology at a later date, assuming it doesn't fail along the way.[39]

Even with the risks inherent in unproven targets, early stage collaborations are increasing. As large pharmaceutical companies continue their efforts to fill their product pipelines at all stages, deals involving products in pre-clinical development increased 12 percent over 2006 (from 137 to 154 deals).[40] These early stage deals generally feature option-based structures, where the licensee/pharma company seeks to mitigate its risk by minimizing upfront payments while committing to larger milestone payments upon demonstration of proof of concept.[41] However, despite pharma's preference for a risk-based structure, the current licensor-friendly environment has driven pharmas to agree to significant upfront payments to secure deals with biotech companies owning good technology and intellectual property with potential application in large therapeutic areas. For example, in July 2007, Alnylam Pharmaceuticals, an emerging Massachusetts-based biotech company, entered an early-stage license and discovery deal with Roche Pharmaceuticals, with a total deal value of $957 million.[42] The deal is IP-centric with a grant to Roche for broad access to Alnylam's intellectual property and know-how to develop treatments in limited disease areas. In exchange, Roche paid $288 million upfront, and also paid $43 million for just under 5 percent of Alnylam's outstanding common stock.[43] This large sum was the largest initial payment of any biotech/pharmaceutical collaboration during 2007, and is noteworthy given that the rights granted to Roche cover only undeveloped targets.[44] Moreover, the deal is non-exclusive, and only grants Roche the rights to use Alnylam's intellectual property in the fields of oncology, respiratory disease, metabolic disease, and certain liver diseases, so long as the disease target in that area hasn't already been exclusively licensed to a third party.[45] Most importantly, Alnylam retained the right to license its intellectual property to third parties in fields not covered by the Roche license.[46] Overall, this deal is particularly attractive for Alnylam, since it excludes their core disease areas in cardiovascular, autoimmune and central nervous system, and infectious diseases.[47]

Due to the significant risks of failure, the structure of early-stage collaborations is a heavily negotiated deal point. Pharmaceutical companies nearly always insist on an "opt-in" approach. With this approach, the pharma seeks to delay making a large investment (or opt-in decision) until the biotech company has demonstrated proof of concept. For example, in the Alnylam/Roche deal discussed above, the agreement only covers Alnylam's existing IP. Roche would have to pay more for rights to new IP developed by Alnylam or to expand the collaboration into other therapeutic areas.[48] Before expanding into new therapeutic field, Roche must first complete Phase II studies of a drug candidate in one of the already granted fields.[49] Once its first Phase II studies are complete, Roche has the option of paying Alnylam a fee in order to expand development into a new therapeutic area.[50] As for future developed IP, Alnylam only has a duty to negotiate a license for its technology in "good faith," but it has no obligation to actually grant any license to Roche.[51] The opt-in structure of this deal benefits Roche because it allows it to postpone further investment until Alnylam's early-stage technology has been proven to work.

While pharma companies often insist on this opt-in approach, biotech companies work hard to retain rights to their proprietary products or technologies if their pharma partner decides not to proceed with development. Biotech negotiators also should insist on including well-defined timelines or specific milestones for triggering pharma's opt-in decisions. This is crucial in early-stage target discovery deals because so much of the true value of the development pipeline is unknown at the time the deal is negotiated. For example, in August 2006, ChemoCentryx and GlaxoSmithKline signed a collaboration agreement that included terms covering "returned licensed products," *i.e.*, indications that GSK has decided not to fund as part of the collaboration.[52] As part of the $1.5 billion deal, ChemoCentryx will develop up to six drug candidates targeting chemokine and chemoattractant receptor targets through clinical proof of concept.[53] GSK then has an exclusive option to license each product for further development and commercialization on a worldwide basis.[54] But if GSK passes on this option, or fails to exercise the option within 90 days, it loses all rights

to the candidate and ChemoCentryx may then continue development and commercialization of these "refused candidates," either alone or with a third party.[55] Furthermore, under the "returned licensed products" provisions in the deal, if GSK exercises its option but then ceases development of a candidate for any reason, GSK will forfeit all of its rights to the candidate.[56] This deal strategically protects ChemoCentryx's interest in seeing its products commercialized and thereby maximizing its revenue.

Profit Sharing and Co-Promotion

In 2007, over half of biotech/pharma collaboration deals had some form of profit sharing structure, and such deals are becoming increasingly common. Most profit sharing deals also include a cost sharing component. These profit/cost sharing deals are beneficial to both parties—biotechs retain the ability to reap the rewards of developing a highly successful product, while pharmas are able to further hedge the risk of inventing in emerging technology by reducing their financial obligations. Negotiations over profit sharing terms usually revolve around the following issues: defining the "costs" to be shared between the parties; determining what internal (*e.g.*, full-time employees) and external costs will be included; how "profit" will be calculated; and how initial product launch costs will be treated. The last factor, product launch costs, is critical for smaller biotech companies, since they generally cannot absorb these enormous costs, which occur before their products start making any revenue.

Like profit sharing, co-promotion options are also becoming more common in biotech/pharma collaborations. Co-promotion is a marketing practice where a drug manufacturer agrees to use another company's sales force, in addition to its own, to promote the same branded pharmaceutical product. Negotiations over co-promotion terms often include the following points: determining the time period over which the option can be exercised; defining the triggers for the co-promotion option; and determining whether and under what circumstances the biotech can opt-out of the co-promotion option. For each of these issues, it is critical for negotiators to have a strong understanding of the parties' commercialization plan, including:

- What commercialization activities are within the scope of the plan?
- Who is permitted to update the plan?
- How often may the plan be updated?
- Who reviews and approves the commercialization budget?
- Who is the target audience for the commercialization activities?
- Who is responsible for training the sales force?

The risk of co-promotion is that the emerging biotech companies will underestimate the resources needed to effectively market and sell their products.[57] In such cases, co-promotion options may harm the licensors as they find themselves unprepared to handle a national product launch. When this happens, the collaboration will often end in a merger as the larger partner seeks to regain control of the product prior to the product launch.[58]

The recent collaboration agreement between Affymax and Takeda Pharmaceuticals illustrates many of the profit sharing and co-promotion issues discussed above. In June 2006, Affymax entered into a $535 million licensing and collaboration deal for their Phase II anemia treatment, Hematide.[59] In exchange for an exclusive worldwide license, Takeda paid $105 million upfront and will make up to $430 million in development and regulatory milestone payments.[60] Affymax and Takeda also agreed to share development and promotion costs, where the terms varied by region. Globally, Takeda is responsible for final packaging and distribution of the commercial product, while Affymax is responsible for manufacturing and supplying the drug substance to Takeda.[61] Within Japan, Takeda is covering all of the development and commercialization costs.[62] Takeda will receive all the profits from Japanese sales, while paying a "double-digit" royalty to Affymax.[63] In the United States, the companies will share development costs, though Takeda will bear the "vast majority" of these costs.[64] Importantly, if the drug is approved in the United States, Affymax can build its own sales force for co-promotion of Hematide, and the two companies will share equally in US profits for the product.[65] Balanced commercialization terms such as the ones negotiated in the Affymax-Takeda deal are becoming more common, even where the smaller biotech company lacks any sales and marketing infrastructure at the time the deal is negotiated.

Scope of Rights Granted

When negotiating an exclusive license with their pharmaceutical partner, the smaller biotech company must be careful to exclusively license only those rights to its technology and intellectual property that the collaborators will need to further develop and commercialize the licensed products. The biotech negotiators should have the company's next deal in mind, retaining sufficient rights to enter into

additional licenses utilizing or otherwise exploiting the same technology and intellectual property. For example, the biotech may want to use the same technology/IP to collaborate with a second partner to develop targets for a disease not covered by the collaboration with their first pharmaceutical partner. In contrast, the larger pharmaceutical company will often insist on rights of first negotiation or rights of first refusal for future products or technologies developed by the biotech. But, as demand from pharmaceutical companies for product development collaborations increases, biotech companies have gained increasing leverage to retain significant rights to further license their technology and intellectual property in commercially viable fields or significant territories.

Diligence Obligations

Especially when negotiating a licensing agreement that includes profit sharing terms, the biotech licensor needs to ensure that its product/technology does not "sit on the shelf." In the past, licensing agreements generally required pharmaceutical licensees only to make "commercially reasonable efforts" to develop and commercialize products. But this limited obligation is difficult to enforce, which allows pharma companies to potentially shelve the development of the licensed product without any consequences—they could effectively stop development without losing their exclusive rights to the biotech's product or access to the licensed intellectual property.

The current negotiation leverage enjoyed by biotech licensors means that they can often request (if not demand) more than "commercially reasonable efforts." Biotech companies may seek to negotiate specific, objective development milestones that the licensee must *diligently* meet. Furthermore, biotech's new leverage means that it can insist on including certain consequences if the licensor's diligence obligations are not met, such as the right to terminate the license. Alternatively, the biotech licensor may negotiate a discretionary right to convert the license from exclusive to nonexclusive, thereby enabling the biotech company to license to other parties. For example, in November 2005, Incyte and Pfizer signed a collaboration agreement worth $803 million ($40 million upfront, $20 million interest free loan, up to $743 million in milestone payments, and undisclosed royalties), where Pfizer received exclusive worldwide development rights to Incyte's oral CCR2 antagonist in all therapeutic areas (except multiple sclerosis and one undisclosed indication, which Incyte will develop independently).[66] But the agreement requires Pfizer to comply with several diligence obligations, including: providing quarterly development reports; making "commercially reasonable efforts" for development, regulatory approval, and commercialization; provisions for "Incyte products" within the portfolio; and termination provisions for indications Pfizer fails to pursue ("reverted indications").[67] These licensor-favorable provisions may be useful for Incyte in its efforts to maximize revenue from the collaboration by forcing Pfizer to take concrete, affirmative steps toward commercialization or risk losing rights to Incyte's technology.

Equity

Collaboration deals between emerging biotechnology companies and large pharmas often have some type of equity feature included in the deal. Most common is for the pharma to take an equity stake in the biotech, paying cash in addition to any upfront payments and other payments already negotiated. The critical issues in such a deal are size of the equity stake and the timing of the payments. For example, the licensee/pharmaceutical might pay for an initial equity stake when the deal closes, and also retain the right to purchase further equity in the licensor/biotech when certain events or milestones occur. In the ChemoCentryx/GlaxoSmithKline deal discussed above, GSK agreed to pay $63.5 million upfront, of which $38.5 million is in cash, and the additional $25 million is for stock as part of a Series D financing.[68] Furthermore, GSK agreed to invest in ChemoCentryx common stock if ChemoCentryx holds an initial public offering.[69]

Alternatively, rather than taking an immediate equity stake, the licensee/pharmaceutical might loan money to the licensor/biotech, where the note is secured by stock in the biotech company. Usually, the pharmaceutical company will provide an interest-bearing note that is convertible into stock of the licensor/biotech. Ariad and Merck entered into such a deal in July 2007. As part of the licensing and collaboration agreement, the companies will split the costs of global development. But once Ariad has spent $150 million on development costs, Merck will then provide up to $200 million in interest-bearing notes to cover the remainder of Ariad's development obligations.

Conclusion

Escalating research and development costs combined with increased regulatory scrutiny will continue to pressure pharma companies to partner with emerging biotech companies as a means of filling their product pipelines.[70] These continued pressures mean that demand for technology developed

by biotech companies will continue to increase, and that biotechs will retain substantial leverage to achieve licensor-favorable terms in any collaboration agreement with pharmaceutical licensees. Furthermore, as capital markets recover, this leverage will expand as biotechs realize alternatives to collaborating with big pharmaceutical companies are available. As such, both the number and value of biotech/pharma collaborations should increase in the coming years.

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3. Hughes, *supra* n.2.
4. In 2007, Novartis released Tekturna and Tasigna while GSK released Tykerb and Altabax. *See* FDA, CDER, *http://www.fda.gov/cder/rdmt/InternetNME07.htm* (last visited Jun. 11, 2008).
5. *See* Joseph A. DiMasia & Henry G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," 28 *Managerial & Decision Econ.* 469, 477 (2007).
6. Cynthia Robbins-Roth, "Biotech's 1st Quarter '08 Fails to Fire Up Market," *BioWorld Today*, Apr. 21, 2008.
7. Burrill, *supra* n.1, at 300.
8. *See* Burrill, *supra* n.1, at 278.
9. *Id*. at 281.
10. *Id*.
11. *Id*. at 282.
12. *Id*. at 282, fig. 10.6.
13. *Id*. at 282–283, fig. 10.7.
14. *Id*. at 283. A nanobody is a type of antibody that is substantially smaller than a normal human antibody.
15. *Id*. at 283.
16. *Id*. at 286.
17. *Id*.
18. Press Release, Hutchison China MediTech Ltd., Chi-Med Announces Drug Discovery and Development Agreement with Eli Lilly and Company (Aug. 20, 2007) [hereinafter Hutchison Press Release].
19. *Id*.
20. *Id*.
21. *Id*.
22. Eli Lilly & Co., 2007 Annual Report, at 109 (2008).
23. *Id*. at 109.
24. *See* Burrill, *supra* n.1 at 286.
25. *Id*.
26. Ranbaxy Labs. Ltd., Corporate Profile, *http://www.ranbaxy.com/aboutus/aboutus.aspx* (last visited June 12, 2008).
27. Press Release, Ranbaxy Labs. Ltd., Ranbaxy Signs a New R&D Agreement with GSK (Feb. 6, 2007) [hereinafter Ranbaxy Press Release].
28. *Id*.
29. *Id*.
30. *Id*.
31. *Id*.
32. *Id*.
33. *See Id*. (comment of Dr. Pradip Bhatnagar, Vice President, New Drug Discovery Research).
34. *See* Burrill, *supra* n.1 at 287, fig. 10.9.
35. *Id*. at 287.
36. Michael B. Harlin & Kevin A. O'Connor, "Leveraging Your Biotech Intellectual Property," 26 *Nature Biotechnology* 607, 607 (2008).
37. *Id*. at 607.
38. *See Id*. at 607; Burrill, *supra* n.1 at 287, fig. 10.9.
39. Harlin & O'Connor, *supra* n.40.
40. Burrill, *supra* n.1 at 290, fig. 10.10.
41. *Id*. at 290.
42. Press Release, Alnylam Pharm., Roche and Alnylam Form Major Alliance on RNAi Therapeutics (July 9, 2007) [hereinafter Alnylam Press Release]; Burrill, *supra* n.1, at 282–283, fig. 10.7.
43. Alnylam Press Release, *supra* n.46.
44. Burrill, *supra* n.1 at 283.
45. Alnylam Press Release, *supra* n.46; Randall Osborne, "Alnylam Captures Potential $1B Roche Licensing Deal," *BioWorld Today*, July 10, 2007.
46. Alnylam Press Release, *supra* n.46.
47. Burrill, *supra* n.1, at 107.
48. Alnylam Press Release, *supra* n.46.
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51. *Id*. at 24.
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55. ChemoCentryx/GSK Agreement, *supra* n.56 at 44.
56. *Id*. at 52–53.
57. Burrill, *supra* n.1 at 293.
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68. ChemoCentryx/GSK Agreement, *supra* n.56 at 53.
69. *Id*.
70. Burrill, *supra* n.1 at 276.