"Something's Gotta Give"
Possible M&A and Commercialization Trends in Life Science from 2005 Forward

by David Schulman and Martyn Postle

Backing into the Future

Not surprisingly, articles that predict industry trends are often "authoritative" but less often "right." Nevertheless, there is value to examining possible industry trends and why they might come about, if only eventually. Even if wrong on timing or repetition of theme, these sorts of examinations help focus attention on more likely versus less likely potential opportunities. This article attempts to focus on just those types of potential opportunities in the life science industry.

Current Industry Conditions

The life science industry, from development-stage biotechnology companies to the elite group of large multinational pharmaceutical companies, is continuing to undergo substantial changes on a global basis that in one way or another relate to:

- Product Development Timeline: there are long lead times between the identification of promising compounds and any ultimate product regulatory approval and market launch, up to as many as 10 to 12 years for successful drugs;
- Clinical Costs: there are high clinical development costs required to obtain regulatory approval for "blockbuster" (meaning greater than $1 billion in sales per year) drugs;
- Emphasis on Blockbuster Drugs: many larger pharmaceutical companies have been emphasizing larger, blockbuster-type drugs to the exclusion of smaller, less profitable drugs, which has had an adverse impact on the image of some companies (e.g., "lifestyle" and "me-too" drugs at the expense of smaller drugs for real unmet medical needs);
- Product Regulatory Approval: a stringent regulatory approval process in the United States, European Union, and Japan often has resulted in fewer approvals in recent years and delayed approvals for some headline drugs (e.g., AstraZeneca's Exanta);
- Dearth of Capital for Private Companies: all but the most promising of biotechnology companies, both in the European Union and the United States, have experienced a tightening of available capital;
- Limited Window for IPOs: again, all but the most promising of biotechnology companies have been shut out of the IPO process, and this problem is particularly acute in the European Union;
- Pricing Pressure: increased same-therapeutic-class competition, lower approved reimbursement pricing for certain non-U.S. markets, and parallel importing have all served to heighten pricing pressure in select areas; and
- IP Protection: concern is mounting over the insufficient length of remaining IP exclusivity available for a given pharmaceutical product as a result of patents, EU

supplemental protection certificates, EU data use, Hatch-Waxman extensions, and the like after product launch.

Most Likely Trends

So what is next? This section summarizes the most likely global life science industry trends that, from 2005 onwards and ranked from most to least likely, may result from the industry conditions described previously:

Most Likely

1. Non-Core Product and Development-Stage Compound Divestitures. A number of regional and international pharmaceutical companies have been going through the process of identifying "core" therapeutic areas with the idea of shedding non-core/smaller-revenue launched prescription products and over-the-counter products as well as promising development-stage compounds that no longer satisfy internal investment criteria. This trend, which appears to be accelerating in the United States and Europe, has opened up an opportunity for smaller companies to bolster their own late-stage drug development pipelines and add additional launched products to their marketing portfolio. The trend is also being driven by industry consolidation. As large pharmaceutical companies become even larger through consolidation, even "medium sized" products are now considered too small. Leading venture capital firms are also paying close attention to this trend, with an eye to investing in product portfolios that have been "incubated" in a large pharma environment and, though no longer considered attractive by the selling pharmaceutical company, may have much upside and a lower risk of failure (when compared with early-stage investing). Anecdotally, a few larger pharmaceutical companies have appointed managers whose sole charge is to implement these types of divestiture programs. This trend emanates from (a) the desire of pharmaceutical companies to focus on fewer, larger-sale/blockbuster drugs, (b) the interest of other pharmaceutical and biotechnology companies to pick up "core" products for those acquirers, and (c) the willingness of venture capital firms to fund these types of acquisitions. In effect, this trend involves placing non-blockbuster products and compounds in more appropriate platforms, where proper management and focused marketing can increase their therapeutic use and related sales.
2. Blockbuster Alliance Deals. Many industry analysts view Pfizer's array of co-promotions with smaller pharmaceutical companies and biotechs (which commenced with the 1996 co-promotion of Lipitor, currently an $8 billion-plus a year drug), as the compelling reason why smaller life science companies should team up with large pharmas. In return for joining with a large pharma to share the clinical development and post-launch marketing costs and to access "best in class" large pharma resources, the licensing company gains (a) up-front milestone payments, often as much as $100 million, together with equally significant back-end milestones, (b) a potential significant equity investment, (c) attractive royalty streams, and (d) the greater possibility of achieving the full sales potential of a given drug candidate. While there may not be many of these deals in any one year, achieving this kind of alliance represents the goal of many life science companies with potential product-licensing candidates.
3. Non-Blockbuster License Deals. There appears to be a growing number of biotechs who are seeking to license both "core" and non-"core" compounds to VC-funded biotechs and mid-size pharmas interested in locating products with potential sales of $50 million to $500 million per year. This trend emanates from (a) the desperate need for some licensing biotechs to receive even modest up-front milestone payments, up to $5 million to $10 million, as a means of supplementing dwindling sources of VC

funding, and (b) the interest of other pharmaceutical and biotechnology companies in augmenting their drug pipelines. To date, regional pharmaceutical companies in Europe do not appear to have been strong participants as licencees in this trend, but as their traditional source of co-promotion and co-marketing opportunities from large pharmas continue to dwindle, this will have to change.

Next Likely

4. Strategic Consolidation. Whether it is further consolidation among large pharmas (such as Sanofi/Aventis or Pfizer/Pharmacia) or even among biotechs (such as the roll up of Vernalis, British Biotech, and Ribotargets in the United Kingdom), there are a number of reasons to expect this trend to continue, including: (a) for large pharma combinations, a view that scale and global reach in key therapeutic areas matter, (b) for biotech combinations, a need to build therapeutic strength and conserve financial resources, and (c) in the case of large pharma acquisitions of biotechs, a recognition that sometimes it is more cost-effective (if not always more efficient) to acquire whole companies rather than co-promote or in-license select compounds. Of course, as with all M&A, it is always difficult to gauge how receptive target management teams will be to this type of strategic M&A, which invariably involves head-count reduction and resolution as to who leads the combined entities. Indeed, the post-merger post-mortem carried out by industry analysts usually focuses far more on the cost reductions achieved (measured by a comparison of actual historic operating expenses) rather than on revenue enhancements or R&D productivity gains (measured by hypothetical forecasts) simply because of the absolute measure of the former.
5. Antitrust-related Product and Compound Divestitures. In many strategic M&A transactions, each of the companies involved will have launched products and/or compounds in development that the relevant antitrust and competition law authorities will view as involving unacceptably high "anti-competitive" market concentration. In these situations, the regulators will require that "overlap" products and compounds be divested. Typically, only the largest pharmaceuticals are considered eligible buyers by the antitrust regulators, given the concern that smaller players may not be effective competitors with the combined companies post-closing. These transactions often result in complicated three-way negotiations among the buyer and seller, in the first instance, and the regulator, thereafter. It is important to bear in mind that the regulators often insist on numerous pro-buyer adjustments to the agreements, all in the name of greater competition. As the pace of industry M&A increases, so should these divestitures, which generally represent wonderful opportunities to augment product pipeline and sales growth.
6. Increasing VC Investment. In spite of all the well-publicized expense and timing difficulties associated with backing successful launched pharmaceutical products, the fact remains that there continues to be a high unmet demand for new health care solutions that offer attractive profits for those fortunate enough to deliver in this area. Accordingly, venture capital firms continue to search for ways to invest in this industry in risk-appropriate ways, such as by investing in non-core dispositions and restructurings as described previously in Trend 1 (e.g., Advent International's investment in Viatris, Apax Partners' investment in Medeus Pharma plus divestments from SSL International, and 3i's recent acquisition of Betapharm Arzneimittel). Assuming the pace of strategic M&A and IPOs and overall exits picks up, more venture capital investing—which helps fuel early-stage product development—should be a consequence.

And Next Likely

7. U.S. IPO Market. In 2004, a handful of biotechs were able to go public on the U.S. public markets, with Eyetech being among the most successful in terms of post-IPO price run-up. Although this state of affairs was by no means a strong showing, the IPO experience in Europe, generally, was even less successful. Nevertheless, there is a growing feeling that increasingly there will be a handful of very attractive biotech IPO candidates. It may even be the case that certain of these European biotechs may seek U.S. listings if their growth stories are compelling enough and the European markets do not generate their own successful biotech IPO stories. Anecdotally, some European biotechs see the United States as their only hope for an IPO, even though they appreciate that they will not get much "share of voice" from U.S. biotech analysts in the much larger U.S. market, which could hinder future share performance.

8. Securitizations/Financings of Royalty Receivables. As mentioned previously, a number of biotechs are struggling to raise additional rounds of venture capital-backed financing. Assuming that these biotechs remain privately held because the IPO markets do not open up in any meaningfully greater way, a subset of these biotechs who have engaged in licensing deals that ultimately generate royalties may become eligible to "sell off" or pledge some or all of their royalty streams in return for immediate cash. These deals may take the form of outright sales, securitizations, or traditional borrowings. The important point to keep in mind is that, if this trend increases above its current pace, a key segment of the biotech community will be able to access capital through securitizations and financings as well as (a) venture capital-led rounds, (b) IPOs, and (c) licensing deals.

9. Acquisition of Product Tails by Biotech Companies. In contrast to those biotech companies seeking to exchange cash flow for cash as described previously in Point 8, some of the stronger biotechs are looking to exchange cash for cash flow through the inclusion of acquired product tails from pharma companies as part of out-licensing agreements for high potential products. Some see this as the best method to "wean" themselves off the requirement for periodic equity injections from a fickle equity market, while more see this as a logical step in their evolution from a discovery company to a niche pharmaceutical company.

10. Insolvency and Default and In-Licensed IP. A number of major M&A and blockbuster alliance deal valuations assume continued access to in-licensed intellectual property from "up-stream" licensors. In many cases, this intellectual property has been the subject of one or more separate sublicenses and the ultimate "down-stream" exploiter of the intellectual property has no contractual privity with the ultimate "up-stream" owner. Significantly, in these situations the insolvency of the ultimate "up-stream" owner of the critical intellectual or a default under the head license may enable the owner to terminate the rights of the "down-stream" licensee, effectively barring the "down-stream" licensee from continuing the marketing and sale of the drug under various U.S. and European laws. As many biotechs continue to face difficulties in obtaining satisfactory financing, "up-stream" owner insolvency and defaults may become a trend that will require licensees to review ways to minimize or eliminate this risk.

11. Minority Investments. Large pharmaceuticals may increase their willingness to make minority investments in publicly traded biotechs in return for greater access to new technology and products. While some of the major pharmaceutical companies have operated venture arms in the past (such as GlaxoSmithKline, Eli Lilly, and Johnson & Johnson), many of them were reluctant, as an institutional matter, to make these sorts of minority investments (sometimes for fear that it would be difficult not to continue to fund or because the large pharmaceutical company might be exposed to control person liability under applicable U.S. securities laws); there are increasing signs that this trend

is changing. Two factors may be at work: (a) by and large, the large pharmaceuticals generally have not had bad experiences (such as exposure to controlling person liability), and (b) large pharmaceutical companies have continuing needs to bolster their product offerings, and these sorts of equity offerings may be part of the cost. Those pharma companies that have historically operated venture arms have managed their investments in isolation from the rest of the business. That may change if companies perceive a benefit from linking their venture investments to the objectives of their licensing groups. In a related development, several biotechs with very promising late-stage compounds have been able to negotiate extensions of credit, via established credit facilities, from the large pharma collaboration partner.

Conclusion

Due to a number of industry factors, life science participants will continue to find the need and the means to reshuffle ownership and financing of single pharmaceutical products, therapeutic portfolios, and whole companies in a variety of M&A, licensing, and financing transactions. While the timing and frequency of the various trends described in this article ultimately may prove hard to accurately predict, the need for change in the life science industry appears to be a constant for the time being.

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