

Acquisitions versus product development: An emerging trend in life sciences

Are late-stage deals the right prescription for the ailing pharma industry?



By 2012 drugs representing over \$74 billion in sales will lose patent protection and therefore face the possibility of competition from generic manufacturers.¹ This “patent cliff,” combined with the current uncertainty surrounding healthcare reform, is causing pharmaceutical companies to reevaluate their business development strategies.

The recent mega-mergers of Pfizer and Wyeth and Merck and Schering-Plough point to an increasing trend of consolidation in the pharmaceutical industry. As consolidated pharmaceutical companies increase combined revenues, they also continue to look for ways to bolster their R&D pipelines and reduce SG&A costs by rationalizing their combined sales and eliminating other corporate overhead. According to recent Deloitte analysis of M&A deal activity in the pharmaceutical and biotech sectors, there is an increasing preference for later-stage compounds in both mergers and acquisitions and pharmaceutical-biotech strategic alliances.

The rationale for acquisitions and pursuing products in the later stages of development has been proven in the past by many pharmaceutical companies. Acquirers or licensees can cut costs while leveraging their clinical development capabilities to accelerate the filing and launch of compounds with a higher likelihood of demonstrating approvable efficacy profiles.

However, while later-stage compounds have lower scientific risk, later-stage deals and associated higher deal valuations pose potentially greater financial risk. This is because executing and integrating later-stage deals presents a unique set of challenges, and missteps can have a high cost, including delaying product launch or, worse, compromising the entire program.

Pharmaceutical and biotech executives can benefit from understanding factors driving the industry to later-stage deals and the issues that can arise in later-stage deals, including more complex financial, valuation, operational, tax, and integration issues

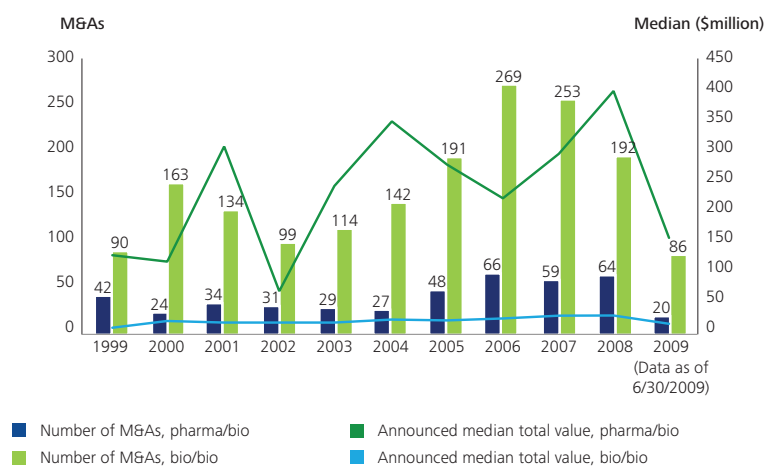
¹ “U.S. Pharmaceutical Market Trends: Tremendous Slowdown,” Doug Long, *IMS Health*, July 2009, <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/...?vgnextoid=bd34c71e81a32210VgnVCM100000ed152ca2RCRD&vgnextfmt=default>.

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A look at the trend

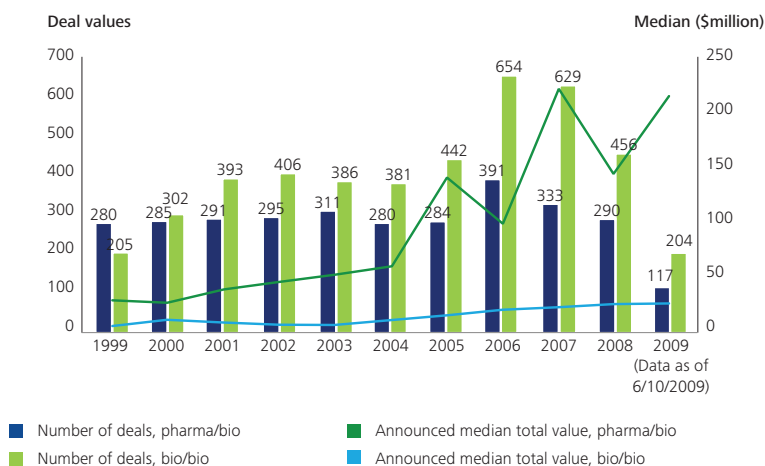
According to data compiled by Deloitte, the median value of deals in which a pharmaceutical company acquired a biotech firm rose from \$80 million in 2000 to \$400 million in 2008 (Figure 1).² This substantial growth reflects greater maturity and perceived worth of target companies and their pipelines.

Figure 1: Trends in pharma-biotech M&A deals
Number of all M&As and median total value by year — pharma/bio versus bio/bio (1999 – Q2 2009)



The median value of out-licensing deals also rose during the same period, but peaked in 2007 — from about \$25 million in 2000 to \$230 million in 2007, according to Deloitte research (Figure 2).³ This substantial growth — notwithstanding the economic upheavals and the resulting downward trends in both M&A and out-licensing deal values in 2008 and 2009 — reflects the need for pharmaceutical companies to generate near-term revenue, as well as the premium being placed on targets with later-stage products in development.

Figure 2: Trends in biotech out-licensing deal values
Number of deals and median total value by year — pharma/bio versus bio/bio (1999 – Q2 2009)

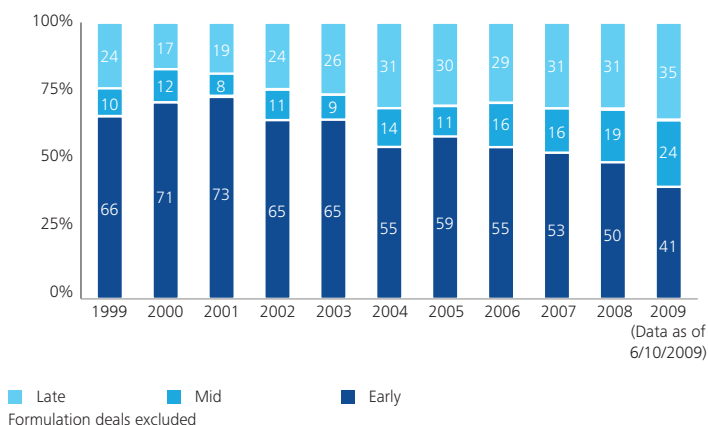


² "Trends in Biotech M&A: Distribution of Pharma/Bio and Bio/Bio Mergers & Acquisitions, 1999 – Q2 2009," Deloitte Recap.

³ "Alliance Trends: Distribution of Pharma/Bio and Bio/Bio Out-Licensing Deals, 1999-Q2 2009," Deloitte Recap.

In addition, the percentage of alliances that involved compounds in the mid-to-late stages of development also increased dramatically, from 27 percent of all deals in 2001 to 59 percent in 2009 (Figure 3).⁴

Figure 3: Biotech out-licensing: distribution by stage
Percent distribution by stage at signing for all deals by year (1999 – Q2 2009)



Why it's happening

We believe several factors, both positive and negative, are driving the trend to later stage deals. The patent cliff and associated competition from generic manufacturers are causing a laser-like focus on near term revenue growth and profitability. This makes it increasingly difficult for pharmaceutical companies to fund early-stage research with the inherent uncertainty of reaching commercialization, compelling them to shift to later-stage targets or whole company acquisitions.

The specter of healthcare reform also adds additional complexity to the drug development process. Some industry experts estimate that the cost of bringing a new drug to market is over \$1 billion,⁵ and once synthesized, most compounds take more than 10 years to gain FDA approval.⁶ The uncertainty regarding future drug reimbursement, the increased focus on drug efficacy, and the potential impact of a government-run payer program reduces companies' willingness to fund early stage clinical development.

Recent disarray in the capital markets means fewer financing alternatives are available for emerging biotechnology companies. In addition venture capital funds are focusing their financial resources on select portfolio companies. Therefore many biotech companies are facing a funding crisis and can't finance their clinical programs forcing them sell off programs or the company as a whole, creating a buyer's market.

For those targets that are cash constrained in bringing their compounds through the remaining regulatory hurdles, valuations will be relatively attractive to buyers. Pharmaceutical companies would be remiss to pay a significant premium in such cases, particularly when three to four years of earnings drag are already anticipated from the funding of continued losses.

⁴ Ibid.

⁵ "The New Drug War," Henry I. Miller, *The New York Post*, February 5, 2009, http://www.nypost.com/seven/02052009/postopinion/opedcolumnists/the_new_drug_war_153617.htm.

⁶ FDA Approval Process, FierceBiotech, http://www.fiercebiotech.com/topics/fda_approval_process.asp.

Executives see early-stage discovery and research occurring outside

The trend among pharmaceutical companies to focus on later-stage opportunities is reinforced by the apparent expectations of life sciences leaders concerning who will pursue discovery and early-stage research. In a 2008 Deloitte survey of 360 senior executives, 44 percent said that over the next decade most discovery and early-stage research will be conducted outside large life sciences companies.

This sentiment holds true in the largest companies, with 52 percent of executives surveyed from companies with revenues of \$15 billion agreeing. It was reflected across sectors, as well, with 58 percent of respondents from pharmaceutical R&D firms and 67 percent from biotechnology companies agreeing.⁷

Some ways to be a successful acquirer

Given these dynamics, we believe an acquirer's competitive advantage lies in its ability to position itself as the partner of choice. As it vies for targets, an acquirer can differentiate itself from competitors in various ways, including:

Understanding why to pursue a deal. Clearly understanding the goals of a transaction allows the acquirer to be a proactive partner rather than a reactive acquirer. Is the company looking to replace "lost" revenues, acquire a drug to leverage an existing sales force, enter a new or adjacent therapy area? Answering these questions will allow the acquirer to focus on and execute a particular strategy, whether it is looking for a strategic acquisition, a co-promote opportunity with an existing on-market drug, or a licensing agreement for a promising drug in clinical trials rather than trying to do everything and not achieving anything.

Appreciating the difference between a candidate and an opportunity. For a transaction to occur, both buyer and seller must achieve their own respective goals. To maximize the chance of success, the acquirer must appreciate the difference between a candidate and an opportunity. A candidate is a target that represents a theoretical strategic fit for the acquirer. An opportunity occurs when the proposed transaction also meets the

strategic needs of the seller. Rigorous and honest analysis must be conducted by the acquirer to ensure time is not wasted pursuing theoretical candidates without regard for the seller's needs and motivations.

Dating before the dance. The only winner in an auction or competitive bid situation is the seller — and the financial advisor. Establishing relationships with potential targets that either preempt auctions or provide a leg up when you can't avoid one can create an advantage in acquiring attractive assets.

Being a well-oiled machine. In a competitive market, the seller has the ability to control the deal's cadence. Organizations that are not aligned internally to analyze, review, and approve deals will have difficulty meeting the time constraints of a competitive process. In contrast, companies with a defined review and decision-making process will be able to identify the important issues early and reach conclusions quickly, putting them ahead of the curve competitively.

Embracing uncertainty. As a process of discovery, due diligence means peeling back the layers of the onion to get to the heart of the target's future prospects. The further along the target's compound is in the development process, the greater the number of layers to peel back. A buyer can't ever fully evaluate implications of all due diligence components, whether within its own organization or the target's. However, preparing detailed alternative scenario analyses can go a long way towards assessing and quantifying future risks and understanding potential value.

Demonstrating that, even more than usual, cash is king. More than ever, the ability for an acquirer to bring cash to the table will improve its chances of consummating a deal. Greater proportions of cash are likely to win out when there's a struggle between the target's life-or-death need for cash and its hesitancy to take on the valuation risk of the buyer's equity.

⁷ "The future of the life sciences industries: Transformation amid rising risk," Deloitte white paper, 2009.

Due diligence considerations

A key to good due diligence is to focus on deal value drivers early. If the assumptions that drive value aren't valid, the negotiations will likely be difficult and the deal may never succeed. The issues present in later-stage deals are often more complex. For example, many companies that reach later-stage development have already entered into licensing or other transactions that will need to be evaluated in the due diligence process to help establish the value of the transaction.

Obviously the acquirer will want to address all interested parties as part of its due diligence process. Most sellers attempt to restrict those communications until the very end of the due diligence process. They don't want their strategic partners to know until they're absolutely sure they have a deal. But if the retention of a key strategic relationship is essential to the deal, confirmation of that can't wait until the end. Deals often fall apart in the very final stages as a result of a negative reaction by key stakeholders to the proposed deal.

In addition, later-stage deals can have regulatory or compliance issues, some of which can, or should, kill the deal



Other due diligence considerations include:

Picking the right team. It is very important that due diligence team composition accurately reflect the development stage of the target's compounds. A team conducting due diligence on a later-stage compound must include sub-teams with deep expertise in critical functions such as clinical operations, safety, regulatory affairs, chemistry, and pharmacology. In an ideal case, these sub-teams are led by the people who have accountability for functional delivery if the transaction successfully closes.

Looking beyond information provided by the target. Due diligence disclosures typically provide limited information. However, it may be possible for the due diligence team to supplement this information. For example, think of a target's clinical trial contract research organization (CRO) operations. If development teams within different therapeutic areas have worked with the CRO in the past, then it may be possible to gauge the quality of the CRO's work, the rigor of its standard operating procedures, and willingness to collaboratively resolve issues.

Conducting disciplined due diligence. In the face of fierce competition for promising targets, business development teams may be tempted to compromise on the thoroughness of due diligence. To manage the risk associated with crippling due diligence omissions, acquirers should establish a list of due diligence "non-negotiables" prior to undertaking any M&A activity. Such a short-list of functions and activities that must be fully understood before making an offer can help the acquirer manage the risk while allowing the business development team to operate autonomously.

New purchase price allocation rules

Purchase price allocation considerations begin with the changes in the business combination accounting rules under Statement of Financial Accounting Standard 141R. While a number of changes in this accounting standard can impact pharmaceutical deals, two specific ones are likely to affect many deals — they relate to in-process R&D (IPR&D) and to contingent consideration.

Under previous rules, a portion of the purchase price was allocated to IPR&D and then immediately written-off. Under the new rules, IPR&D will remain on the books as an intangible asset to be either written off when a project is abandoned or amortized upon commercialization.

Under the old rules, companies generally recorded contingent consideration — which is prevalent in pharmaceutical deals either in the form of an earn-out or upon the achievement of certain milestones — as additional goodwill when the contingency was resolved. Under the new rules, cash-settled contingent consideration is recorded as part of the initial acquisition price at its fair value. This is generally based on the present value of probability-weighted future payments, with subsequent changes in fair value recognized in the income statement each quarter until the contingency is resolved.

Both of these changes will increase the level of disclosure required relating to the status of products in development and to the performance of the acquired entity. They may also create more volatility in post-acquisition earnings.

Potential tax issues

Acquirers also should carefully consider the tax implications of later-stage deals. Later-stage target companies typically have significant tax net operating losses and R&D tax credits. However, acquiring companies shouldn't assume that these tax attributes will be available to them without limitation after the deal is done. The tax law places annual limitations on the use of these tax attributes when there is a change in the ownership of 50 percent or more of a company. As such, the purchase of the stock of a late stage company will limit the ability of the buyer to use the acquired company's net operating losses and tax credits. The limit is generally equal to the equity value of the acquired company multiplied by a rate published by the IRS. The rate is currently around 4.5 percent, so the annual limitation can be quite small. However, the analysis may not be limited to just the buyer's acquisition.

Biotech and pharmaceutical development companies often are funded by venture capital in the form of common and preferred stock investments. If the amount of these equity transactions causes 50 percent or more of the company's ownership to change hands over a three-year period, the company's tax attributes may already be subject to an annual limitation. Typically, these transactions occur at times when the company needs funding to survive and, therefore, the value of the company is very low. As such, if there were a prior ownership change, the annual limitation may be very small, and a buyer is likely to be bound by the lower limitation.

The consequence of this annual limitation is that the post-acquisition combined company may have to recognize taxable income despite acquiring a company with significant net operating losses. For purposes of modeling out future post-acquisition tax cash flows, a buyer needs to carefully assess the availability of any acquired tax

County	Average property taxes	Average home value	Taxes as % of home value	National rank*
Niagara County	\$2,912	\$99,200	2.9%	1
Monroe County	\$2,638	\$90,700	2.9%	2
County	\$3,407	\$120,400	2.8%	3
County	\$2,768	\$108,900	2.5%	4
County	\$1,899	\$75,300	2.5%	6
County	\$2,896	\$115,900	2.5%	7
County	\$2,256	\$93,200	2.4%	8
County	\$1,840	\$76,400	2.4%	9
County	\$145,300		2.4%	10
County			2.4%	11
County			2.4%	12
County			2.4%	14
County			2.3%	16
County			2.2%	17

attributes to avoid any surprises. The tax law in this area is complex, and certain rules can further limit the amount of post-acquisition tax attributes. However, other rules can provide a greater amount of utilization, so buyers should consult with their tax advisors accordingly.

Addressing post-integration priorities

The primary objective of integration activities should be to balance integration speed and scope against the disruption to clinical operations. Achieving this integration objective requires companies to pay close attention to several key factors:

Talent retention. Retention of the target's employees is critical to maintaining continuity of clinical operations. Therefore, it is recommended that product focused employees be "ring fenced" early on during integration planning so they may maintain focus on the execution of product filing plans. However, in order to retain talent in the longer run, it is not enough to declare employees as "off-limits"; the acquirer needs to be able to provide new employees with a compelling career proposition.

Leadership structure and deliverable ownership.

One of the first integration activities should be establishing a clearly defined leadership structure. This is a very sensitive undertaking, one in which the acquirer needs to balance employee retention against ensuring that key positions are staffed by the right people. The greatest benefit of performing this activity early on the planning process is that it results in the clear assignment of regulatory dossier component ownership – for example, of clinical study reports, CMC (chemistry, manufacturing, and controls) filings, and pre-clinical study reports. This clarity is critical to the timely and successful submission of regulatory filings.

Legacy CRO relations. Retention of legacy clinical operation and manufacturing CROs reduces disruption of clinical operations. As a first step in this effort, acquirers can perform a thorough audit of CROs immediately post-close and identify and address capability gaps as soon as possible.

Project management structure. The integration of project management and governance processes and infrastructure provides the project development team with appropriate project oversight and the ability to identify and address potential issues. However, formal project management processes are often perceived as "bureaucratic red-tape" by the employees of a small and nimble biotech. Therefore, it is important to pay close attention to the integration of project management and to focus on finding a way to provide project oversight without the structure and processes that usually accompany project management.

Regulatory, compliance, and document management systems. The early integration of the target's regulatory and compliance systems allows for seamless transition of safety reporting; this is a top priority because delayed/incomplete adverse event reporting can potentially compromise the trial. Furthermore, the prompt integration of documentation systems allows for an early assessment of the completeness and "registration readiness" of prior pre-clinical and clinical research. This allows enough time to conduct additional studies and/or repeat experiments if needed.



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It's never too late to deal — or is it?

With so many complex and rapidly changing dynamics — the patent cliff, healthcare reform, the uncertainty with respect to the efforts of the U.S. Congress, and still-dry capital markets — the trends in life sciences industry consolidation are almost certain to continue, with growing emphasis on later-stage deals. Healthy companies have good cause to pursue deals that promise faster revenue streams and profits. Likewise, cash-strapped companies — particularly smaller firms with rich R&D pipelines — are likely to seek deals rather than go broke.

In such an environment, both buyers and sellers are wise to look beneath the surface for issues that could reinforce or, conversely, sour the deal. Careful examination of the issues described above can help life sciences executives fill the right M&A prescription — one that leads to healthier outcomes for all involved.

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