With recovery from the 2009 recession now underway, good deals are back on the drawing board. The challenge will be to paint over legacy risks and fill the canvas with the right mix of assets at the best price for long term shareholder gains.
Business developers and the investors and analysts who specialize in the “art of the deal” are pharma’s window on the future—the canaries in the coal mine who can sniff both danger and opportunity from the faintest dry breeze of incentive. Every year, Pharm Exec assembles a diverse “brain trust” of experts who meet to identify trends in the M&A and licensing fields and make predictions of the industry’s health as a driver of next-stage innovations in medicine. On February 1, we convened our latest panel of eight—drawn from a mix of big and “stealth” pharma, biotechs, and the investment banks—to calculate damage from the recent market decline and lay out new milestones for progress in this year’s apparent path to recovery.

What follows is a summary of the group’s discussion, covering a wide range of strategic questions: Does 2010 mark the end of the financing drought and a return to robust deal making? Will the caution and sobriety induced by the Great Recession lead to stronger and more lasting collaborations? Is licensing an adequate substitute for Big Pharma’s newfound skepticism about the contributions from in-house R&D? How will the 2009 bumper crop of megamergers affect the number and price tags for deals in key therapeutic areas like oncology, primary care, and specialty? And what are the new markers for success in biotech’s effort to secure fresh capital?

Our panel did find common cause around a single truth: The search for real value—value that can be differentiated against the competition—is irresistible, in good times and bad. And although the circumstances of each deal are unique, the driver that will bring people back to the table in 2010 is still a simple one: Big Pharma is looking to snag marketable new products at minimal risk, while small biotech has to raise money. Let the games begin.

—William Looney, Editor-in-Chief

Pictured, from left: Wael Fayad, Forest Labs; Jeff Brennan, Targacept; Mary Tanner, Peter J. Solomon Co.; Ben Bonifant, Campbell Alliance; Dennis Purcell, Aisling Capital; Barbara Ryan, DeutscheBank; Doug Giordano, Pfizer; Alex Scott, Eisai
William Looney: Forward-looking forecasts like the Campbell Alliance Dealmakers Intentions Survey indicate that the market for licensing and M&A investment is beginning to improve after a slowdown in 2009. What factors are driving this trend? And, given the importance of long lead times in this industry - is a recovery sustainable?

Dennis Purcell, Aisling Capital: Overall, the sector weathered the recession relatively well. Predictions in early 2009 that up to two-thirds of small biotechs would end up insolvent by year-end proved untrue. Companies did a remarkable job in conserving cash through the financing drought, and as a result the runway for future growth has been extended. However, larger structural challenges remain in play. We need a revival in the equity markets, and the venture capital community has to come back to the table, especially as the hedge funds that helped support biotech in the past have mainly dropped out. The key issue for 2010 is that biotech companies are going to have to return to the financing arena; if the market doesn’t respond, we face the prospect of a “double dip”—another round of winnowing that will expose all but the most promising players to a cash crunch. This will negatively impact the sector overall, and lead to fewer opportunities for productive collaborations.

Ben Bonifant, Campbell Alliance: Our survey shows that the volume of deals picked up significantly in the last quarter of 2009, and that momentum is extending into this year as well. The impact of recession and the reluctance to lend has resulted in a more selective approach, however, with the greatest optimism centered on the potential for transactions around the in-licensing of products in Phase II of the development cycle. Conversely, we are seeing reluctance to engage in riskier transactions involving Phase III products, where the cost of failure is higher. Overall, I’d say the theme for 2010 is a flight to quality, at a stage where the value proposition to the payer community can still be shaped, involving therapeutic classes—like oncology and CNS—that serve an unmet medical need.

Wael Fayad, Forest Labs: The patent cliff facing the industry intensifies the search for new products to fill the gap, and thus we expect an upswing in licensing and M&A deals this year. Deal activity and value will follow the highest quality assets, not necessarily those only in late-stage development. Companies are looking for more certainty. To assure that, you need to spread the risks linked to the time and cost of obtaining market authorization across more assets that you license or acquire after they have been sufficiently “de-risked.” This can be an extremely cost-effective way to build a pipeline.

Mary Tanner, Peter J. Solomon Co.: I’d describe the financial landscape as “bipolar.” We have to reconcile the desire for recovery with the hard fact that the real cost of capital is often going to be higher than the potential rate of return on your investment. And most of the Big Pharma stocks are still trading at historic lows. I am not convinced that an upturn in dealmaking is sustainable until we have some normalization of the financial landscape, as it is the cost of money and the poor measurability of risks to investors that really drives the calculation around opportunity.

Barbara Ryan, Deutsche Bank: Deal activity has to continue as a consequence of the move by Big Pharma to externalize the traditional R&D function. This is an industry that on its own has a better than 50 percent failure rate for compounds in Phase III. The big companies with cash have to look farther afield—the challenge is sifting and finding that strong Phase III licensing candidate, as pickings are slim everywhere right now.

William Looney: So is there a consensus that the number of deals is not the real issue, but rather a broader trend toward “strategic bifurcation, where the focus is on separating out the good deals: those grounded in strong science, that target favored therapy areas, provide clear patent terms, and allow for competitive differentiation that appeal to payers?

Jeff Brennan, Targacept: For a more collaborative relationship between Big Pharma and biotech, you need greater alignment on what the ideal licensing package should include. Biotech’s strength is identifying the unmet medical need in complex diseases, and figuring out how to get proof of con-
cept [PoC] with novel mechanisms to the patient as quickly and efficiently as possible. Pharma's strength is in Phase III development, CMC and commercialization. Over the years, biotech companies have been told by pharma that their PoC-stage licensing packages don’t meet the internal standards for a PoC designation. To be sure, some of this is part of the negotiation dance, but it is also becoming a “box-checking” exercise. Overall, it can affect the value and complicate the probability of successfully licensing our compounds.

To adapt to this, we are seeing biotech companies focus on fewer compounds in order to produce a more robust licensing package. This too can have unintended consequences. The biotech company spends considerably more money on each program, so there are fewer PoC candidates. Those PoC packages that are successful are in high demand and in response in-licensing costs have risen dramatically.

Doug Giordano, Pfizer: This dynamic ought to be of concern to us, as the emphasis on late-stage projects combined with a tight cost structure means that the early work that must take place to drive future innovation is being neglected. It’s another impediment to the basic discovery trench work that we rely on to yield the next generation of products.

Alex Scott, Eisai: What is driving the tighter scrutiny is the dictates of a changing market. The most important aspects are customer and payer expectations about value. In evaluating any deal, you have to ask first if the compound has been advanced under the old development approach, which emphasized meeting clinical endpoints and securing FDA registration; or under today’s rubric, where the product is designed with the value proposition in mind for each stakeholder. A lot of candidates fail to register on the competitor-differentiation scale. By the time a product is in Phase III, building that broader case for reimbursement from scratch is virtually impossible.

Doug Giordano, Pfizer: Another factor is the importance companies now place on diversification of the revenue stream, away from a singular focus on small molecule R&D. This is creating opportunities for profitable deals in new areas like established off-patent products, which Pfizer is re-positioning not as a shrinking, end-of-life-cycle portfolio, but as a growth asset. It’s a tremendous new opportunity for partnering: taking older branded medicines with a track record in one market and introducing them to a new generation of patients in China, Brazil, and other high-potential countries. Cephalon just announced acquisitions that establish it as a leading European player in new generic formulations and related drug delivery technologies; this is another example of using the M&A card to leverage existing asset strengths. These deals create a more stable overall revenue base, which in turn allows more head room for higher risk innovations. But they also require a more diverse negotiating skill set than is the case under the traditional playbook built around licensing of a Phase II. The risk-to-return profile is markedly different.

Alex Scott, Eisai: The advent of the customer-focused business model also means that company culture must bend to the art of the deal. This is important because, as has been noted, good acquisition or licensing opportunities are scarce. When they do arise, speed in both evaluation and execution is critical to sealing the deal with partners that often have multiple options. Further on, you have to avoid the mindset of insisting that an acquisition or licensee fit into some existing structure instead of working to place the new asset where it can have the most impact. We say at Eisai that our partnering strategy combines the resources of a large company with the ingenuity and flexibility of the smallest startup. This is an appealing message to the diverse constituencies with whom we work.

William Looney: Building on the selectivity theme, which therapeutic areas today pose the best opportunity for deals?

Ben Bonifant, Campbell Alliance: Our survey found that twice as many people expect to do a deal on oncology products compared to other categories. CNS therapies ranked second in level of interest. We also saw a sharp drop in expectations for primary care medicines that require extensive resourcing through the sales force. For example, few companies are interested in deals involving cardiovascular drugs, which we as-
cribe to the many competing therapies in the category and the challenges of differentiating value.

Alex Scott, Eisai: I’d say it’s not the therapy that counts so much as the value metric. If you have a product in any therapy area that has an interesting new mechanism of action and the Phase I work is solid, then that by itself is a good value point to the investor.

Wael Fayad, Forest Labs: We look for good products across all therapeutic areas including primary care, hospitals, and specialty markets. We think there is still an opportunity to improve on existing therapy, including therapeutics prescribed by primary care physicians. However, what you can no longer do is settle for an incremental improvement, as substantive differentiation is being demanded by the market to justify the value of new products.

Mary Tanner, Peter J. Solomon Co.: Therapy areas go in and out of fashion. The low hanging fruit in many categories has been plucked, but beyond that we just don’t know where the best leads are likely to take investors five or ten years from now. The standard for risk is ratcheting ever higher. That is why there is such strong interest in oncology deals, because progress in developing biomarkers will ensure that the clinical benefits from a new therapy are targeted to the right patient. It promotes certainty by defining the potential size of the market and providing a rationale for the cost.

Dennis Purcell, Aisling Capital: One reason that funds are scarce is that it is harder for the investor to make bets around a frayed business model. The world’s biggest selling drug is Pfizer’s Lipitor, yet the company has decided to abandon the cardiovascular segment entirely—that’s like Gallo saying it wants to quit the wine business. It demonstrates how fickle management can be, and the challenge of defining what kind of start-up company you want to capitalize today to attract the attention of a Pfizer five years from now. With so much in flux, we risk a big disconnect between the companies being funded and what the big in-licensors want in terms of new product candidates. If a venture capitalist could get that equation right, then we are back to the days of a 35 percent or more return on investment.

William Looney: What requirements are important to ensure that your company is seen by target constituencies as the “partner of choice?”

Wael Fayad, Forest Labs: We spend a lot of time and effort on business development, as licensing and partnerships are to us equivalent to what others call R&D. We see two critical measures in securing our reputation as a good partner. First, you must have the skills, resources, and track record to move
a project forward and achieve commercialization. This is a key confidence builder. The second has to do with company culture. It’s inherent in the task of a good business development team to challenge assumptions and introduce new partners that can threaten the established code of behavior. This is not easy to do, especially in large organizations. The Forest culture is outwardly focused by design, and every employee is taught to look beyond his job description to find ways to add value. In practice, this means that we never approach a potential deal without placing a priority on “active listening”; competitive research, including stakeholder analysis; and respect—in the latter case, for the know how and expertise that each partner brings to the collaboration.

Jeff Brennan, Targacept: The Big Pharmas are all different, and so too is biotech. As a small biotech, we are looking for long term relationships that in most cases should include some type of R&D collaboration. We want to make sure our potential partners take the time to understand first who we are and what our goals are. Targacept’s mission is to provide superior treatment options for complex diseases, improving patient lives by developing new medicines that exploit the unique role of NNRs [neuronal nicotinic receptors] that regulate CNS activity. In most cases, we want to be an active contributor as we progress compounds forward in collaboration with our partners. Sometimes we can see the market and assess prospects differently—maybe better—than a Big Pharma would.

William Looney: What do the new business unit [BU] structures initiated through the megamergers of the past several years mean for the business development function? What are the implications for potential partners to Big Pharma in the biotech community?

Mary Tanner, Peter J. Solomon Co.: Companies are working hard to remove the internal organizational and cultural barriers to finding opportunities from external sources. The BU approach aims at the silos that traditionally divided development—the science—from commerce. In practice, it also means there is less reluctance from Big Pharma to do deals directly with each other on specific compounds or therapeutic areas. This is a historic change. Consolidation is one explanation—there are fewer opportunities to spread the seed—and getting costs in line is another.

Doug Giordano, Pfizer: Pfizer had a reputation of being too big, too bureaucratic, and impervious to outside input. Our BU structure is changing this. When we initiate discussions on a deal, a potential partner is going to know who is going to be making the decisions. Our BU managers now carry the responsibility for a compound’s R&D development profile as well as commercializing it—all in one locus of responsibility. Hence there are no “black boxes”; the partner benefits from a direct line of visibility, spanning the pipeline to the market. And each partner is going to see that we listen more and look for ways to accommodate his specialized expertise. This has
enhanced the effectiveness of the business-development function, allowing for faster timing in securing a deal and nimbler execution. It is also improving the content and quality of the transactions we negotiate.

Barbara Ryan, Deutsche Bank: One consequence of the old structure was that companies were unaware they were walking in the dark—the right foot did not know what the left foot was doing. I recall a comment from Judy Lewent, the former CFO of Merck, in which she said that companies were prepared to tolerate an enormous amount of risk internally but wanted zero risk in sealing the deal with an external partner. Clearly this approach is sub-optimal if you want to succeed in partnering today. Business development has to be a core competency and you have to balance the risks.

William Looney: It seems the fundamental issues here are transparency and predictability. Everyone wants a transaction where the elements are clearly defined and build toward a profitable outcome that benefits each party. Strong intellectual property [IP] protections helped drive some of that certainty in the past—is it still an important criteria for successful dealing?

Alex Scott, Eisai: Patent considerations remain critical to reaching a decision to license or acquire. It is all driven by expectations about the length of exclusivity in relation to the overall product cycle, which is eroding fast due to circumstances often beyond our control. If we aren’t looking at a novel molecule in which the IP is well-scrubbed and very clear, then we have to walk away. At Eisai, we spend as much out-of-pocket on our IP investigations as we do on all other aspects of due diligence combined.

Wael Fayad, Forest Labs: IP is a major risk that leads us to decline interest in many opportunities. This is unfortunate, as many of these candidates are winners in other aspects, including having good clinical data and knowing that they could do well in the marketplace by filling an unmet medical need.

Jeff Brennan, Targacept: We devote an enormous amount of energy to understanding all aspects of IP. At the end of the day, we don’t license molecules, we license the intellectual property on and around those molecules that provides exclusivity in the space and in the market.

Barbara Ryan: The right therapeutic niche and a case for differentiation against the competition is necessary in any deal, as it is the only way to counter the slow uptake of new medicines by empowered payers. And you need it to delay the long-term threat posed by creeping therapeutic substitution, which in my view is more dangerous than challenges to the patent because markets are so unpredictable.

Dennis Purcell, Aisling Capital: One big positive is a likely increase in FDA approvals of high-profile large molecule biotech products, which will help expand the arena for good deals. The risk is decreased access to new funding for start-ups.

Wael Fayad, Forest Labs: Personal relationships around a shared commitment and understanding of your partner’s business culture.

Alex Scott, Eisai: More clarity from the FDA on a number of pending issues, such as the pathway for follow-on biologics, will be vital to building confidence on the commercialization and financing side.