

Argyle Conversations

by ARGYLE EXECUTIVE FORUMSM

featuring

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On April 14, 2011, Dimitri Drone, partner at PwC, and Lauren Everhart, senior content associate at Argyle Executive Forum, met at PwC's New York offices to discuss the M&A environment in the pharmaceutical industry.

Dimitri Drone Dimitri Drone is the leader of PwC's Transaction Services Life Sciences sector. Dimitri advises corporate clients on the structuring of complex merger & acquisition transactions, alliances, partnerships and joint ventures, as well as minority and early-stage investments to successfully integrate and address accounting, financial reporting, corporate finance, and valuation challenges. In addition, he is a leading advisor within the firm to clients on valuation principles, methodologies and critical assumptions employed in various business enterprise, intangible asset and security valuation exercises across the spectrum of companies in the pharmaceutical and life science sectors.

Dimitri, a CPA and a CFA, received his MBA in finance and economics from the University of Chicago and his BS in accounting from Bucknell University.

Lauren Everhart Lauren Everhart is a senior content associate and project manager at Argyle Executive Forum. In this role, Lauren manages content development, editorial speaker recruitment, and execution for 15+ annual business events. She also manages Argyle Executive Forum's relationship with over 20 of its content and event partners. Lauren has been with Argyle Executive Forum since 2008. She holds a Bachelor of Arts from The State University of New York at Albany and a JD from New York Law School.

LAUREN EVERHART: The imminent patent cliff is top of mind for most people in the pharmaceutical space. How did we end up here?

DIMITRI DRONE: Several decades ago, the pharmaceutical industry was in a stealth growth phase. Research labs were productive, and we were just beginning the era of the blockbuster drug, in areas such as gastrointestinal, cardiovascular, as well as depression and other CNS diseases. Increased emphasis on sales and marketing enabled companies to grow many of their drugs into blockbusters, with annual sales in excess of \$1 billion. The prescription for a successful drug was to follow the leader—namely, to quickly come up with your own version of a blockbuster drug, then promote the category as well as your own offering to grow the entire pie and your share within that market. Some of the best-known and most widely prescribed drugs on the market were not the first to file. Rather, they were able to learn from those already in the market and use their marketing heft once approved. Key to this era was an acceptance of multiple products treating the same or similar ailment.

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Over this period though, several competitive forces were emerging that would pose significant challenges for the pharmaceutical companies in the years to come, namely the rising influence of the payers (insurance companies as well

as the government), combined with the emergence of both pharmacy benefit managers (PBMs) as well as generics. Fast forward to today and the ability to bring multiple compounds to market in the same therapeutic area with similar product profiles is no longer possible. Companies have had to scale back their marketing and promotional efforts from government scrutiny of such practices. Generic companies and others are masters at challenging patents. When combined with pharmacies swapping in generics, branded drugs can lose up to 90 percent of their sales once patent protection has been lost.

As a result, over the past decade, those emulating successful strategies of the past have found that it doesn’t work anymore. Even if one can come up with another drug, the reimbursement environment is unattractive. Many of the high profile drugs that never come to market are killed off as they can’t demonstrate how they are different/better than what is already on the market, and accordingly, the reimbursement profile will not provide for a sufficient return. As a result, companies are trying to spend their time in less developed areas—in oncology, for instance—where there are big markets and a lot of opportunity. However, there are much greater risks in these areas, and unfortunately, very few breakthroughs have occurred. Many turn to M&A as a result.

Let’s delve a little deeper into acquisitions. How might M&A play an even bigger role as pharma companies continue to navigate the current environment?

On average, reports suggest it takes in excess of a decade and \$1 billion to bring a drug to market. It’s been widely publicized that many companies have significant products with patent expirations occurring through 2014, so in the next four years we’ll see an unprecedented amount (in terms of

dollar value) of drugs coming off patent. There is a shortage of promising late-stage compounds across companies right now, and investors are most focused on what will drive top-line growth over the next five-to-ten years. So for those with limited near term prospects in-house, they're going to look outside the company. As you can imagine though, with so many companies in the same predicament, it's become a pretty heated M&A market for companies with attractive late-stage pipelines. They are scarce assets right now, often with rich price tags.

Keep in mind that M&A has been prevalent in the industry for the past decade. While synergies are usually not the driver of a transaction, there is usually the ability to eliminate some overlap—for example, the acquirer doesn't need another salesforce, or competing R&D

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programs can be consolidated into one. Even where there are synergies, companies try to mitigate their risk in other areas. One trend in that regard is the use of contingent consideration, which is closely aligned with how pharmaceutical companies already transact as it relates to licensing, collaboration and other alliances in the sector. Paying in stages enables the acquirer to lessen the risk it takes on, as future payments are tied to some form of success. Taking another page from the alliance textbook would be to acquire an existing partner—the acquirer already has in-depth knowledge of the target company and underlying compounds, given the pre-existing relationship.

We also expect to see a number of companies focusing on smaller, more frequent bets, in hopes that the potential for “singles and doubles” will help them achieve success with less risk. For example, compounds that qualify for orphan-drug status might be attractive, given the small patient populations with limited competition and potential additional avenues to product approval. There's also an increased emphasis on waiting until a target's compounds have been approved, although that usually comes at an additional cost.

Historically, acquirers focused much of their attention on scientific due diligence, but we're seeing much more emphasis on understanding the market, tied to commercial and financial due diligence, as well as the potential reimbursement profile of drug candidates.

Lastly, it seems as though everyone is focusing more of their diligence efforts on overseas targets.

Historically, the U.S. has been the market of choice for the pharmaceutical sector. Why, has that been the case and might that change over the next five-to-ten years?

As a relatively advanced healthcare market from a global standpoint, the U.S. was typically viewed as a market you had to be in, given close to half of pharmaceutical revenues were historically generated in the U.S. However, with a lack of new products, the U.S. is saturated. Now, there are still those that

find the U.S. attractive, but they are often global companies headquartered outside of the U.S. that need to expand their presence here.

But the U.S. is losing its dominance. Other countries are growing at much higher rates, particularly the BRIC countries—Brazil, Russia, India and China. Their populations are very significant, and individuals within those populations are accumulating more wealth. As people in those countries obtain more wealth, they become very focused on things that their counterparts in the West are accustomed to, like healthcare. So, improving health becomes something that is of great interest to them, and that, in turn, makes them a very viable market for pharmaceutical companies.

The other factor contributing to companies' interest in BRIC countries is that there's a lot of uncertainty in the U.S. regarding healthcare reform and the FDA. There have been challenges associated with getting drugs approved and there are a number of changes being proposed in the FDA. This uncertainty is leading many companies to other

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markets. Also, many global companies possess a lot of cash and available resources outside of the U.S., as they have generated profits in overseas markets for years. For instance, even for drugs that are sold in the U.S., often times the intellectual property is outside the U.S., or manufacturing for the products occurred outside of the U.S. A lot of the profits gained from blockbuster drugs reside overseas and, in many cases, pharmaceutical companies are looking at investing those profits in overseas acquisitions.

Something that's interesting about this international growth is that every country has its own unique characteristics, which means that companies are looking to enter new or unfamiliar areas. For instance, big pharmaceutical companies with a very limited generic presence in the U.S. may enter into generic markets in China or Brazil. They'll enter an unfamiliar area by acquiring one of the more significant generic players in those markets. This gives them a foundation to build off in establishing a local presence. As companies expand in foreign markets, many of them are faced with the question, do we build it or do we buy it? They're quickly going to need to buy it because if they don't, someone else will. In countries where it's a bit of a land grab, you want to clearly establish yourself as one of the front runners. The way to do that is to buy one of the top two or three companies in that country. You also gain localized institutional knowledge by acquiring companies in other countries as opposed to building it yourself. Of course, there are many new challenges that acquirers face in these markets, not the least of which is dealing with FPCA.

Given the state of the sector domestically and the current environment for investment overseas, what's your outlook on pharma/biotech M&A for the next three-to-five years?

International deals will be very much front and center. When you look at the M&A activity that's

occurring in the U.S., a fair amount is foreign companies looking to enter the U.S. market. I think that trend will continue because the U.S. market is so significant and so well developed; if you're a global player, you need to have a significant U.S. presence. But for those that are already in the U.S. in a meaningful way, one of the pillars of their strategy will be to look abroad. Another pillar will be to look at more niche areas, such as going after orphan drugs, which potentially have a quicker road to market and more pricing power.

I think we'll see more conversions of partnerships and alliances to outright M&A, as companies look to buy out preexisting partners. Companies need to spend money to address the patent cliff, but you need that money to be spent efficiently and effectively. If companies can create better odds of having that money yield a return, they'll go after it. It might mean taking more shots on goal rather than always going for the homeruns. Or it might be going into foreign markets that are already built up, where there's a lot of pent up demand, and leveraging a local company. When you overlay a company's institutional knowledge of bringing drugs to market and global infrastructure and products, this could be a nice channel for growth. ■

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