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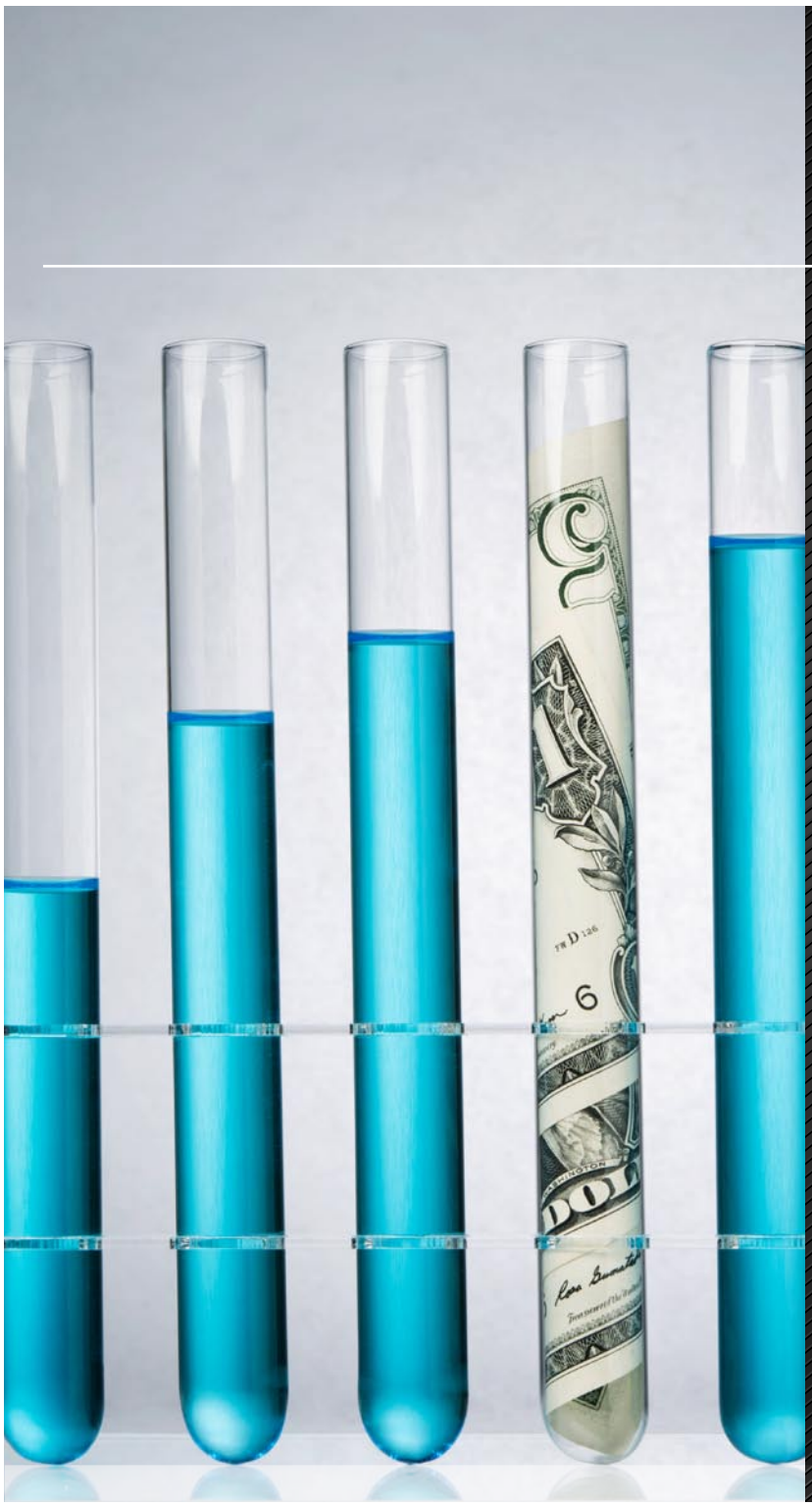

TalkingPoint

CREATING SHAREHOLDER VALUE THROUGH M&A IN THE LIFE SCIENCES SECTOR

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James C. Greenwood, President & CEO of the Biotechnology Innovation Organization (BIO), moderates a discussion on creating shareholder value through M&A in the life sciences sector between Gregory K. Bell, group vice president at Charles River Associates, Benjamin E. Clark, a partner at Deloitte & Touche LLP, and Diane J. Romza-Kutz, a partner at Thompson Coburn LLP.

James C. Greenwood
President & CEO

Biotechnology Innovation Organization (BIO)

James C. Greenwood is President and CEO of the Biotechnology Innovation Organization (BIO) in Washington, DC, which represents more than 1200 biotechnology companies, academic institutions, state biotechnology centres and related organisations across the United States and in more than 30 other nations. Mr. Greenwood represented Pennsylvania's Eighth District in the US House of Representatives from January 1993 through January 2005. A senior member of the Energy and Commerce Committee, he was widely viewed as a leader on health care and the environment. He can be contacted on +1 (202) 962 9200 or by email: info@bio.org.

Gregory K. Bell
Group Vice President

Charles River Associates

Dr Gregory K. Bell frequently testifies as an expert witness on damages in intellectual property, finance and antitrust litigation in courts and arbitration proceedings in North America, Europe, Asia and Australia. Dr Bell's business consulting engagements focus on the economics of business strategy, working with firms to develop sustainable competitive advantages in specific product markets. He has led numerous projects concerning game theory and competitive strategy, global launch strategy, product pricing and positioning, capital budgeting and real options and cost-benefit analyses. He can be contacted on +1 (617) 425 3357 or by email: gbell@crai.com.

Benjamin E. Clark
Group Vice President

Deloitte & Touche LLP

Benjamin Clark has 21 years of experience with Deloitte and 17 years as a dedicated M&A specialist advising both domestic and cross-border financial and strategic buyers and sellers on many aspects of acquisitions and divestitures including – due diligence, accounting structuring, financial reporting, transaction and financing documents and the preparation of carve-out and pro forma financial statements. He has served clients in a wide range of industries including many sectors of the healthcare and life sciences industries. He can be contacted on +1 (213) 688 4166 or by email: beclark@deloitte.com.

Diane J. Romza-Kutz
Partner

Thompson Coburn LLP

Diane Romza-Kutz helps life sciences companies develop new products and bring them to market amid a scatter of regulatory land mines that can delay or destroy the path to profits. Ms Romza-Kutz works with companies in the businesses of food, dietary supplements, animal health, prescription/over-the-counter drugs, biologics, medical devices, tobacco and agribusiness – clients that all face a similar framework of crisscrossing federal, state and local regulations. She can be contacted on +1 (312) 580 2224 or by email: dromzakutz@thompsoncoburn.com.

Greenwood: How would you describe recent M&A activity in the life sciences sector? What impact is it having on the space and how are companies responding?

Bell: The nature of the life sciences industry guarantees vibrant M&A activity. The binding constraint on growth in life sciences, the lifeblood for economic and therapeutic success, is products and product candidates. Today, as products become more complex, involving gene therapies, delivery mechanisms, and hybrid drug-device and drug-diagnostic combinations, the technical capabilities that may be required to bring new products to market may span one or more organisations. This need adds additional impetus for M&A activity and other forms of corporate associations beyond the standard push provided by gaps in product pipelines. The need for new products is no secret to existing and hopeful life sciences companies. They race to identify new candidates, competing vigorously for the talent that might unlock the next first-in-class option. They explore new technologies, expanding into biologics or diagnostic screening options to unlock new options. They look toward companies that can provide new formulations or delivery mechanisms to optimise existing options. And they are always searching for new partners or acquisitions to strengthen their pipelines.

Clark: While overall, announced global life sciences deal volume decreased from 1470 transactions between January and November 2014, to 1407 between January and November 2015, the total deal value increased significantly from $333bn to $506bn in the same period, based on our analysis of Thomson Reuters M&A data. The primary driver of the increase was the approximately $192bn attributed to Pfizer's announced acquisition of Allergan. That said, some deals and many potential IPOs may have been put on hold due to market conditions during the autumn. It appears that elevated levels of deal activity and rising valuations are prompting industry players to evaluate their portfolios and generate shareholder value, resulting in a combination of investing in focused areas of care, divesting low growth assets, and increasing scale.

Romza-Kutz: Recently, we have seen the definition of deals in the life science sector begin to expand to other industry lines falling within the broader definition of life sciences to include animal health, holistic medicines and healthy foods, to name a few. Couple this with what appears to be a slightly higher level of activity in the area and we can see a better financial picture for life science companies going forward. Companies need to respond to this 'loosening' of monies as evidenced by increasing investor interest by well thought out market positions and establishing a realistic market value for the technology they are developing. The days of inflating or overvaluing current and future market positions are long over.

Greenwood: What factors are driving increased levels of deal-making? What strategies are companies using to identify and leverage deal-making opportunities with a view to generating long-term value?

Clark: Rising demand for generic, biosimilar and specialty drugs and the need to replace expiring blockbusters appear to be significant drivers in the consolidation of branded pharma, generic pharma and biotech players of all sizes. A shift from volume-based to value-based reimbursement, increased regulatory oversight, aging populations in key markets, growing prevalence of chronic diseases and rapid technological innovation appear to be spurring horizontal and vertical M&A activity. It has become apparent that targets must be chosen carefully as realising synergies and generating shareholder value can be much more difficult if the target is a business with priorities and strategies that conflict with an acquirer's core business.

Romza-Kutz: Like in years past, a driver of the increased deal making is the need to diversify technology platforms for larger companies, enhance technology platforms for mid-size companies and the continued need of emerging technology to develop a compound to a degree and licence it out to drive revenues for other product development. In addition, large pharma, although much more consolidated than in years past, still needs viable candidates in its pipeline, particularly phase two and three products. More deals means a better valuation for the companies engaged in those deals. Better valuation means less expensive money for the licensor. Deals are the best way for emerging technology companies to bring their product to market in most disease franchises. The larger partner in the deal usually has the experience or the resources to get the technology through the approval process. Those wishing to in licence are still looking for products which complement the products that they either already have to market, or are close to getting to market. It is highly likely that they will look for products that will strengthen their market position in given disease markets.

Bell: Some of the high-profile recent mergers have been more about financial engineering, particularly the pursuit of advantageous tax status than supplementing or solidifying research pipelines. Certainly there is value in an optimal corporate structure, but companies will be unable to crystallise the associated value potential without new products to sell. Financial engineering aside, products and product technology continue to be the drivers of M&A activity in life sciences.

Greenwood: What M&A deals have caught your attention in particular? What lessons can the sector learn from the outcomes of such deals and the ways in which they are structured and executed?

Romza-Kutz: The most striking deal was the purchase of Jerini by Shire, where the share value at the time of deal closing was higher than when the discussion between the companies began. This suggests that Jerini created competition for itself by generating interest from other companies similar to Shire and that drove the deal and the price of the deal. In addition to Jerini, we have begun to see poor market share human drug products cross into the animal health market where they get revitalised. I strongly suspect that this is a growth area – as is animal health generally – for investors and companies alike.

Bell: From our perspective, the most interesting deals and possibly those with the most risk are the ones that are bringing together technical capabilities to address potential market opportunities. These deals could create blockbusters or yield product opportunities that never make it to market. The value potential in these deals is likely to be tied up in the combined entity's new R&D strategy and how quickly and effectively the capability synergies hoped for by the dealmakers can be brought forward. Another interesting set of deals is the drive for size that continues in the generics business, particularly some of the opportunities that biosimilars could generate. Here the focus will need to be on effectively leveraging size across the generic portfolio and learning how to compete effectively and across national regulatory regimes when it comes to biosimilars.

Clark: The Actavis/Allergan story encompasses many of the factors we have seen driving activity in the industry today. Legacy generics company Watson acquired Actavis for $4.7bn in 2012, taking the Actavis name and creating scale as a global generics company. In 2013, Actavis acquired Irish pharmaceutical company Warner Chilcott for $8.5bn and re-domiciled in Ireland. In 2014, Actavis completed its acquisition of Forest Laboratories for $28bn to enhance its speciality drug footprint, while Allergan was fending off an activist investor and another pharma looking to refresh its pipeline. Actavis announced

its white-knight intentions to acquire Allergan in late 2014 and closed the transaction, valued at $66bn, in early 2015, taking the Allergan name and creating a diversified global pharmaceutical company. Subsequently, in 2015, Allergan agreed to sell its generics business to Teva for $40.5bn and agreed to merge with Pfizer in a deal valued at $160bn. Companies navigating today's market dynamics may look to borrow a page out of the Actavis/ Allergan playbook.

Greenwood: What advice can you offer to life sciences companies on conducting effective due diligence and managing transactional risks when conducting deals?

Bell: From our perspective, strategic due diligence is the most important and most overlooked aspect of due diligence. Here, the focus needs to be three-fold. What are the scientific, clinical and technical opportunities? What is the market potential associated with those opportunities? How will we need to be organised, managed and led in order to realise that potential? Due diligence checklists should be subordinated to the vision, strategy and structure paradigm which will be the foundation of sustainable, long-term value creation through M&A activity.

Clark: It is important to remain objective during the deal lifecycle and stick to your strategy, rather than rushing in and overpaying for the sake of doing a deal. If red flags develop, do not be afraid to walk away from a deal. The wrong deal may hurt shareholder value much more than no deal. In addition, be sure that diligence streams are coordinated and not operating in silos due to compressed timelines. The collective team should be working together to assess points of failure and potential mitigation plans across the financial, legal, operational, technological and regulatory threads.

Romza-Kutz: Creating virtual deal rooms for due diligence is important, as well as indexing what is placed in those e-rooms, but it's often the key players that drive the technology to the point of deal interest. It is rare deal where the players don't matter, so take the time to meet and get to know the key drivers in the potential transaction. Managing risks starts with a willingness to recognise where the risks can occur. No one likes to think of risk when faced with a potential deal that drives assets and revenues into the respective deal partners businesses. However, making a list of where risks occur, evaluating the likelihood of realising each of these risks and establishing a response for the identified risks leads to much better deal outcomes.

Greenwood: How much of an impact has the growth of emerging markets had on the life sciences M&A space? Do you expect to see an increase in cross-border activity going forward?

Clark: In markets such as China, India and Brazil, there have been steady increases in population, standard of living and access to health care, creating opportunities for entry or expansion into these countries. Growth is not just limited to the traditional emerging markets, but can also be found in countries such as Mexico, Venezuela, the Philippines and Eastern Europe countries, where a rise in government health reform and consumer focus has driven increased health care spending. While we believe there will be an increase in cross-border activity, companies should be prepared to tackle the nuanced commercialisation, operational and regulatory challenges – including anti-bribery regulations – that accompany these new territories.

Romza-Kutz: Emerging markets are still relatively untapped in terms of opportunities and market penetration. This is really a function how life science products, whether it is drugs, devices biologics or animal health products are paid for. This is a problem that has

to be addressed fairly quickly as evidenced by the 2015 Ebola outbreak. Life sciences companies play in the global market and will continue to do so, therefore cross-border activity will continue to increase in the near future.

Bell: Emerging markets won't be the real value driver in life sciences M&A. There is no doubt that emerging markets can be attractive targets for established life sciences companies with valuable products. Local companies often possess the skills, knowledge and relationships needed to open an emerging market for a portfolio of therapies. Of course, it is not only through M&A activity that the large multinationals are able to capture the value of an emerging market; M&A is only one of the forms of corporate association that may be used. Those companies who are best able to identify and effectively integrate emerging market opportunities will realise a significant jump on competitors for at least local if not global sales.

Greenwood: With tax authorities now taking action against so-called 'inversion transactions', what advice would you give firms looking to restructure and maximise the tax implications of their deals?

Bell: We believe that 'inversion transactions' can create value, but long-term and sustainable value creation will remain with products and product technologies. It will be difficult to realise value from a transaction that is focused on inversion value. The upheavals and costs associated with integration, particularly on the R&D side of the merged entity, could easily eradicate large chunks, if not all, of the value from inversion. If inversion is driving the deal, those concerned with long-term, sustainable value creation would be advised to look elsewhere.

Clark: Any transaction or business combination – whether or not resulting in a so-called 'inversion' – should make business sense. If the inversion structure enables the parties to achieve incremental business and tax synergies, that is simply up-side for what is otherwise a justified business decision. If companies are actively looking for target companies with which to accomplish a transaction that results in re-domiciling, they will need to be mindful of the more restrictive rules set forth in recent legislation.

Greenwood: What are some of the post-deal steps life sciences companies can take to maximise the shareholder value they are looking to create?

Bell: The key is a focus on the product pipeline. Companies need to ensure that the potential synergies associated with merged technical capabilities are nurtured and ultimately realised, that there are multiple and balanced product candidates at every stage of the development cycle, and that the R&D infrastructure evolves to ensure effective product and technology development. Tax savings from inversions may offer value to current stockholders, but long-term success requires a concentrated focus on finding and commercialising new products.

Clark: A deal strategy should be well-defined and reinforced throughout the diligence process. When a desirable target is found, it should be grounded in well-defined principles that will drive shareholder value. Shareholder value within life sciences may be derived from cost synergies as a result of increased scale, growth synergies as a result of a combined sales force or expanded footprint, or non-EBITDA synergies such as the inversion transactions we have seen most recently. Effective deals typically establish a knowledgeable leadership team, a clear set of governance systems and a planning process focused on establishing and driving toward the key objectives of the deal. Within life sciences,

three key functions often determine the critical path – quality, regulatory and legal. Defining an enterprise wide blueprint, which also takes into account ongoing initiatives and projects, can help an organisation focus on a cohesive plan. Finally, an ongoing program which tracks progress towards delivering value can mitigate the risk of 'slippage' in capturing shareholder value.

Romza-Kutz: Look for deals and to add technologies that complement a company's existing technology portfolio. Over the years, we have seen a number of companies stop at the first deal, either because it did not go quite as expected or due to a financial shortsightedness. Value can be driven to the shareholder level by planning a deal strategy over a number of years. It should include where you can make deals – more than one – and the valuation those deals could create based on a recurring realistic assessment of the market space the deal would occupy. Creativity also drives shareholder value. Know that when the first deal is done, you should be using the return on that deal to look forward to not only develop more of the company's assets, but identifying where the next deal opportunity lies. Shareholder value can be maximised when the cost of the deal is right.

Greenwood: How do you envisage the proliferation of M&A activity in the life sciences sector over the year ahead? To what extent has it become the dominant force shaping the industry?

Clark: Industry players will likely continue to face pricing, cost and regulatory pressures both in the US and abroad, while looking to reload pipelines and optimise portfolios. The blurring of lines is likely to continue as large pharma companies pursue M&A to obtain innovations rather than develop them internally. The drug itself will remain crucial to the success of a company, but there will likely be a focused effort to extend the value of pipeline products through drug platform technology. Therefore, we may see more technology deals and continued integration between pharma and medtech companies through acquisition, joint ventures and other collaborations.

Romza-Kutz: In the year ahead, emerging countries are going to increase price pressures on generics, which will drive generic deals outside of those emerging markets. You will continue to see large pharma look for opportunities to bring technologies to market for an aging population and 'crisis' diseases such as diabetes where the numbers of diagnosed patients have grown to alarming numbers. You will continue to see large pharma utilising its resources to acquire technology past the phase one stage in human drugs. You will continue to see the emergence of the animal health market through more investments, cross over products and possibly more public offerings. Our need to treat our aging population, rein in out of control or expensive diseases, and to ensure a healthy food supply by safely treating feed animals will be the dominant driver for the next few years to come.

Bell: We believe that M&A activity and other forms of corporate association will continue to grow in significance for the life sciences industry. Technology is changing too quickly for companies to be able to go it alone for the long term. The focus on inversion deals will fade, but the need for M&A activity and other corporate associations founded on product and technology opportunities will persist. In the short-term, we are likely to see more efforts devoted to drug delivery mechanisms and diagnostic screening opportunities. Payors, whether national or commercial health insurers, will continue their push for value. Targeting or delivering existing therapies more effectively not only offers the potential to extend revenues from existing molecules, but they offer pathways by which new innovations could be even more effective from launch. ■