Conference Summary

Pharmaceutical Executive Summit: Emerging Strategic and Financial Issues in the Pharmaceutical Industries - November 3, 2015

11:30 a.m. **Registration**

12:00 p.m. **Luncheon and Welcoming Comments**
Peter Young, President and Managing Director, *Young & Partners*
William Looney, Editor-in-Chief, *Pharmaceutical Executive*

12:30 p.m. **Luncheon Keynote Speaker and Fireside Chat**

Navigating the Changing Pharma Landscape
Brenton L. Saunders, President and CEO, *Allergan plc*

A Fireside Chat with Brent Saunders
Peter Young, President and Managing Director, *Young & Partners*
Brenton L. Saunders, President and CEO, *Allergan plc*

1:30 p.m. **Challenges and Opportunities in the Pharma and Biotech M&A Market**
Peter Young, President and Managing Director, *Young & Partners*

2:00 p.m. **Orphan Drugs: The Path Going Forward**
Dr. Spielberg, Editor-in-Chief of *Therapeutic Innovation and Regulatory Science* and former Deputy Commissioner for Medical Products, *the Food and Drug Administration*

2:30 p.m. **The Pharmaceutical Market: Trends, Issues and Outlook**
Doug Long, Vice President, *IMS Health Inc.*

3:15 p.m. **Coffee Break**

3:30 p.m. **Strategy Case Studies: Building a Specialty Biopharmaceutical Company**
Richard Hoyt, Vice President of Business Development and Licensing, *Mallinckrodt Pharmaceuticals*

4:00 p.m. **Strategy Case Studies: Building Multiple Strategic Platforms**
Amit Hasija, Vice President, Head of North America Business Development *Sanofi*

4:30 p.m. **Speaker Roundtable**
Moderator: Peter Young, President and Managing Director, *Young & Partners*
Participants: Executive Summit Speakers

5:30 p.m. **Cocktail Reception**

Navigating the Changing Pharma Landscape

BRENTON L. SAUNDERS
CHIEF EXECUTIVE OFFICER AND PRESIDENT
ALLERGAN PLC

It is my pleasure to address this 11th Annual Pharmaceutical Executive Summit as the keynote speaker. If you look at the global biopharma industry today, there have been enormous changes occurring in the biopharma industry that are both positive and negative. Truly breakthrough innovations have been very positive for the industry. These developments have been profound and are having an enormously positive impact. On the other hand, issues around pricing and changes in health care systems are examples of challenges in the industry.

The pharmaceutical industry constituents have to think about their business models and how they have to change. M&A is at an all-time high, in part driven by the changes in the industry and pharma business models, a renewed focus on growth, the need to compensate for revenues from expiring patents, participation in on-going therapy area / segment consolidation, high levels of acquisition currency & cheap financing conditions, and the use of financial engineering.

We now are entering a golden age for the biopharma industry as we go from a chemistry foundation to a biology orientation that is resulting in break-through drug innovations that we should look on with great pride as an industry. These are doing great things for patients, particularly in specialty pharmaceuticals. Although some of these new drugs are expensive, the benefits to the patients and the positive effect on the health care system are enormous.

What are we doing at Allergan? We have been focusing on the growth of our top line by making the right investments in R&D, finding various routes to creating new products, managing our business well, and using M&A to participate in the consolidation that is happening in the industry.

There are four components to the Allergan business model. We want to be the leader in our seven core therapeutic areas, focus on customer intimacy, be a development powerhouse, and have an "open science" model. We feel we are doing well in all four areas. The "open science" model is different from the traditional model of development followed by pharma historically. We are very open-minded about where we get new drug opportunities. Many new developments are coming from well-funded, professionally managed biotech companies. Under our "open science" model, we are not burdened by the 'not invented here' syndrome, source new medicines from a broad range of sources, and reinvest in this new and vibrant ecosystem both internally and externally, to be a development powerhouse.

A Fireside Chat with Brent Saunders

PETER YOUNG, PRESIDENT AND MANAGING DIRECTOR, YOUNG & PARTNERS
BRENTON L. SAUNDERS, PRESIDENT AND CEO, ALLERGAN PLC

Young: Let's go back a bit in time to when you grew up in South Whiteside Township and went to Parkland High School in Allentown, PA. What was it like growing up close to Allentown with a urologist father and a mother who started and ran a geriatric care agency?

Saunders: I grew up in a fairly rural area where most of the kids worked on farms and everyone valued hard work. I credit my parents for instilling these values in me. We did not get an allowance and had to work to earn any spending money. This was an important part of my upbringing and created a strong work ethic. Having a father who was a doctor and a mother in health care services probably helped me have an early sense of the health care system and how one helps patients.

Young: I understand that you and your brother started a number of businesses from the time you were 6 or 7 years old, including a shampoo business, a moving company, and a lawn mowing/snow plowing business that became S&S Landscaping with 50 clients. Often you can tell a lot about successful people by what they did when they grew up. What drove your desire to be entrepreneurial and run businesses early on?

Saunders: To be fair, I do not know what drove us to be entrepreneurial early on. Perhaps it was my parents' lessons in work ethic. In addition, my identical brother and I just were more interested in working for ourselves rather than for anyone else. No one really pointed us in that direction, so I guess it was just in our DNA. But it was a great learning experience.

Young: I also understand that your 1975 Chevy Station Wagon with 100,000 miles on the odometer was the company car and that you sold S&S Landscape. Are both of these statements true and was the sale of S&S Landscape your first M&A deal?

Saunders: My first company car was a 1970 station wagon and it served us well in the business. And yes, when my brother and I went to college we had to figure out what to do with the landscape business and we did sell the business to a company. I guess it was my first M&A deal.

Young: Any lessons learned from that experience that became useful to you later on in life?

Saunders: There were a lot of lessons learned from that time. Two lessons come to mind. First, we learned that hiring friends did not give us the best results. We learned that is was better to hire people who were hard working and who we could work well with. We also learned that customer intimacy was key to making our business successful and to find additional ways to serve clients that could produce higher margins. These lessons have proven to be useful in my business life.

Young: A university president of my undergraduate college who later became the commissioner of baseball once said that a person's success and impact is not primarily a function of the person's IQ and talent, but more by whether that person has a passion and drive to put in the effort and to stretch themselves to achieve a goal. Those people who know you have said that a defining aspect of Brent Saunders is that he gives it his all. Is this a true characterization and is this a characteristic that you look for in the executives (or your lawn mowing employees)?

Saunders: That trait is an important trait that I look for in employees. We look for people who have passion and are willing to take prudent risks and champion their ideas. There are lots of very intelligent people who we look at, but passion and the willingness to take prudent risks are important traits that we look for.

Young: Is it true that your first foray into the pharmaceutical industry was in college when you and your brother patented a formula for ingrown toe nails that your grandfather invented and sold your "Nail EZ" product by mail?

Saunders: Yes it is true. In fact, it was just a combination of salicylic acid and menthol and really worked.

Young: CEOs of pharmaceutical companies come from many different backgrounds. In your case, you started in compliance working for the Thomas Jefferson University Health System and later for PriceWaterhouseCoopers in their compliance

advisory services group. How important is compliance when it comes to the knowledge and background that a pharma CEO has to have to be successful, on an absolute and relative basis compared to the other skills such as R&D, marketing and financial?

Saunders: I took a bit of a risk by starting in the compliance area because there were very few if any compliance officers in the pharma industry. However, it gave me a very good perspective on some very important aspects of the pharma industry and was a great way for me to start out. Of course, compliance has become even more important today.

Young: The first move into the corporate world was when Fred Hassan, then CEO of Schering Plough and who, by the way, was keynote speaker a few years ago at this Pharmaceutical Executive Summit, chose you to be the SVP and Global Head of Compliance and Business Practices in 2003. You then went on to run the consumer health care business of Schering-Plough and manage the integration of Schering-Plough into Merck & Co. Was this phase of your career a defining change in the trajectory of your career or was it when you were chosen to be the CEO of Bausch & Lomb, then owned by Warburg Pincus?

Saunders: I first met Fred when I was a partner of PWC in compliance consulting and had a very lucrative and comfortable position. When Fred asked me to join Schering Plough it was a big risk for me, but it was a great turning point in my career and gave me a route to running a business.

Young: Later you ended up running Bausch & Lomb which was clearly a turnaround situation, turned it around and sold it to Valeant, and then went on to run Forest Laboratories and merged it with Actavis. Can you comment on the timing of all of these divestitures. Bausch & Lomb was private equity owned and would be sold in any scenario but Forrest was not. What was the argument for a merger versus you continuing to run Forest as an independent company?

Saunders: I am proud of what my teams accomplished at both of those companies. In the case of Forest, the combination of Forest with Actavis created a lot of business and shareholder value for all parties, so it made sense to do that deal.

Young: There are many who say that the role of M&A in pharma is too pronounced and that companies are paying too much and are operating in a valuation bubble. There are others who say that M&A has an important role, but one that can vary significantly depending on the circumstances of each company. What is your opinion?

Saunders: M&A has always played an important role in the progress of the pharma industry and will continue to have an important role. Although the industry has gone through many mergers, it is still very fragmented if you look at the data. Also, it has many inefficiencies that can be solved with scale. In addition, the insurance companies and hospitals are becoming increasingly concentrated as a result of mergers, so that will be one of the drivers of further consolidation of biopharma companies.

Challenges and Opportunities in the Pharma and Biotech M&A Market

PETER YOUNG
PRESIDENT AND MANAGING DIRECTOR
YOUNG & PARTNERS

Introduction

The last few years have been a positive period overall for both the Pharma and Biotech industries on many fronts. Most importantly, there has been a renaissance with regard to the escalation of the number of new drugs approved and under development for both pharma and biotech companies.

Many of these are driven by new methods, such immune-related oncology drugs, personalized medicine, stem cells, and biologics. We are also witnessing the development of a greater number of drugs that cure diseases rather than just extend life.

The valuations of both pharma and biotech companies in the public and M&A markets soared up until August/September of this year in part because of these positive developments. This was despite the setback in public valuations this year due to the negative publicity about drug pricing.

The Changing Pharma Business Model

For many years pharmaceutical companies used their internal research and development capabilities to develop and commercialize, with reasonable success rates, drugs in a 6 to 10 year timeframe. Given the length of the remaining patent life once the drug was commercialized, the cost of developing that drug, and product pricing in the market place, the economics of drug development and sales were attractive and growth and profitability was high. A multitude of changes occurred that have disrupted that business model.

The pharma companies, large and small, have been forced to shift their strategies and to revamp the way they approach R&D and access to new drugs. Current strategies range from diversification, large scale mergers, exiting the pharma industry, geographic expansion, regional consolidation, pursuit of biologics, expansion of generics, movement into vaccines, pursuit of orphan and niche drugs, or movement away from primary care indications to specialized areas, etc.

Generic pharma companies are facing a different set of factors. They have benefited from the patent expirations and the drive by payers to reduce costs. Although, the demand for low-cost drugs has been enormous, the decreasing number of blockbuster drugs coming off patent has reduced the opportunities for generic producers. All of these developments are forcing generic pharmaceutical companies to go into new areas and to consolidate.

Pharma M&A

In the first three quarters of 2015, 37 deals were completed worth $190 billion versus 51 deals completed worth $80.4 billion during all of 2014. This represents a dramatic increase in the dollar activity and an increase in the annualized pace in terms of the numbers of deals. The $68 billion acquisition of Allergan by Actavis contributed significantly to the dollar amount of this year's nine month total.

Activity has been particularly high in the U.S. and Europe.

Drug makers are acting as both buyers and sellers, forming strategic alliances, swapping assets, shoring up their core businesses, exiting non-core units, and seeking tax inversion advantages.

As of September 30, 2015, the value of the deals announced but not closed was $54.7 billion (24 deals), an indication that there is a solid pipeline of deals ahead of us.

Notable announced transactions include Teva's acquisition of Allergan's Global Generic Pharmaceuticals Business for $40.5 billion. In addition, there have been a number of large unsolicited offers, such as Mylan's offer for Perrigo and Shire's offer for Baxalta.

Biotech M&A

Biotech M&A activity has almost always been modest historically, with small spurts of activity from time to time. However, although total dollar value of deals closed in the first three quarters of 2015 was modest, it has exceeded the value of all deals closed in 2014.

In the first three quarters of 2015 there were 19 biotech M&A deals completed worth $15.3 billion. This compares to 27 deals worth $12.7 billion completed in all of 2014. Earn-out deals or "structured acquisitions" involving contingent payments have become increasingly common in biotechnology M&A deals.

As of September 30, 2015, the value of deals announced but not closed was $3.7 billion (7 deals). This suggests a continuation of a solid, but not spectacular M&A market. Valuations are high, however, since there is still intense competition among large pharma and large biotech for products addressing the most attractive targets and indications.

Outlook – Pharma M&A

M&A activity will reach near record levels by the end of 2015. We expect this to continue in 2016, fueled by the massive business restructuring that is happening in pharma and the consolidation that is occurring on both the generic and non-generic sides of the business.

In addition, high stock market valuations have allowed companies to use their shares as an attractive acquisition currency and there have been selective tax inversion attempts. The recent drop and volatility of pharma share prices will have some dampening effect on M&A, but only in a modest way.

Outside of M&A, the need to fill the shrinking drug pipeline is also being facilitated by in-licensing, partnering and joint ventures involving both pharma and biotech companies.

Therefore, in spite of the headwinds from the current ruckus about drug pricing and the volatility of share prices, we believe there will be strong pharma M&A volume ahead of us.

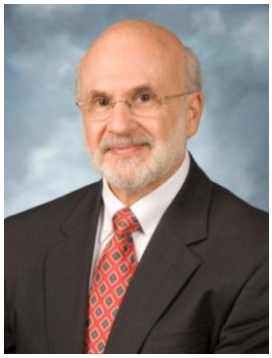
Outlook – Biotech M&A

Biotech M&A will continue to be active but modest, with the primary theme being pharma and big biotech acquisitions of biotech companies for pipeline enhancement. However, M&A dollar volume will continue to be limited, mainly because pharma and big biotech companies are using non-M&A methods to achieve their pipeline goals and because IPO's will likely continue to be an attractive alternative source of funds and shareholder liquidity.

Valuations will continue to be high, with the most promising biotech companies at all stages attracting great interest and high prices.

Orphan Drugs: The Path Going Forward

DR. STEPHEN P. SPIELBERG
EDITOR-IN-CHIEF, THERAPEUTIC INNOVATION AND REGULATORY SCIENCE AND FORMER DEPUTY COMMISSIONER FOR MEDICAL PRODUCTS, THE FDA



Orphan drugs are near and dear to my heart. I view them as a pediatrician, but also look at the point of view of patients, the industry, and the regulatory community. Whereas once, few were interested in orphan drugs, now everyone is interested in developing orphan drugs to treat rare diseases.

The history of orphan drugs goes back to 1908 and Sir Archibald Garrod at Oxford who was looking at "inborn errors of metabolism." He was looking at the disease of alkaptonuria or black urine – which was caused by a missing enzyme.

In the 1960s and 1970s, there was an explosion of interest in inborn errors of metabolism – rare, inherited diseases. New technologies such as gas chromatography, mass spectroscopy, and enzymology allowed scientists to identify the causes of rare diseases, and to begin screening newborns for certain rare diseases. Interventions were limited, however. Scientists were discussing enzyme replacement and gene therapy, but these technologies weren't ready yet. Physicians treated on the basis of pathophysiology. My colleagues and I were able to treat one disease, glutathione synthetase deficiency, which affected 12 people worldwide, with Vitamin E.

In 1983, Congress passed the Orphan Drug Act, which was a good piece of legislation. It provided incentives to treat small populations by providing waived user fees, increased exclusivity, and grants.

Today, we live in an era of enzyme replacement and the beginning of gene therapy. We are able to use small molecules to heal defective proteins as a result of inborn errors of metabolism. Patient advocacy is driving treatment. Patients are using the internet and challenging medical practitioners. The science is advancing inexorably. We are organizing clinical trial networks, although clinical trials in academic medical centers are hard to run because incentives are not in place. Targeted therapeutics are changing the game. These drugs have large effect sizes and are leading to smaller clinical trials as well as to new thinking about biomarkers and surrogate endpoints.

One example of a new targeted orphan drug is ivacaftor for cystic fibrosis. The drug targets one mutation with 1300 patients. It took only 5 years to develop the drug and only 3 months to review at the FDA. The therapeutic effect was demonstrable in as few as 90 patients. The drug was approved with a very specific label – cystic fibrosis with the g155d mutation. This drug changes the trajectory of the disease and has a long term effect. This has raised expectations in the community very high for other orphan diseases.

There are a number of challenges with orphan drugs. The efficacy is so large that trials can often include under 200 patients pre-label. What will this mean for safety? Post-market safety will become the rule, not the exception. One solution is for industry to partner with patient advocacy groups which often provide a built-in registry.

In addition, common diseases are becoming orphan diseases based on mechanism, target and pathogenesis. One issue is resistance, which we are likely to see in cancer treatment. This will require combinations and sponsors collaborating. Every review division is different, but the oncology division, for one, is very open to science and is looking to the future.

What if every disease were an orphan disease? We don't know. We must think about what diagnosis will be and what reimbursement will be for diagnosis. We need to discuss the economic model – everybody is talking about price/value. There is a limit to the ability to pay for orphan drugs as more drugs like ivacaftor become available. Another issue is that eventually these orphan drugs will become generic. Who will manufacture these orphan drugs and at what price? We need to start discussing these issues.

The Pharmaceutical Market: Trends, Issues and Outlook

DOUGLAS M. LONG
VICE PRESIDENT, INDUSTRY RELATIONS
IMS HEALTH, INC.

Double digit U.S. pharmaceutical growth is back since the hepatitis C drug Sovaldi was launched at the end of 2013. Year-to-date pharmaceutical spending growth is 12.5% in 2015 and industry sales are now $400 billion. Hepatitis, diabetes and oncology are the primary drivers of spending growth, and they will soon be followed by the PD1s and PCSK9s. New brand spending increased by nearly $20 billion in the last 12 months, and over 75% of new brand spending is on specialty medicines. Large patent expiries in 2015 include Namenda, Nexium, Abilify and Copaxone and these will likely dampen growth somewhat in the second half of 2015. Prescription drug growth will finish the year at about 1.3%. Prescription growth is likely to continue at 1-2% for the next several years.

There have been a number of notable factors in the pharmaceutical industry in 2015. We have seen changes at the CMS and FDA and the Supreme Court upheld Obamacare. We have seen price wars and exclusive launches in hepatitis C. As a result, the cost to treat for hepatitis C has dropped from $90,000 to $50,000 while Express Scripts is exclusive with AbbVie and CVS is exclusive with Gilead. The first US biosimilar, Zarxio, was launched and more will follow. The hydrocodone/APAPs were rescheduled. OTC switches continued and Viagra and Cialis may be switched to OTC by 2017. Merger mania has hit the generics companies, the major drug companies, the PBMs, the payors and the retailers. Everyone is focused on orphan drugs and tax inversions.

I want to focus on the specialty drug market now totals $109 billion in sales and has a 23% growth rate. Specialty drugs now account for about 1% of prescriptions dispensed, but over 35% of all drug spending. Viral hepatitis, diabetes, oncology and autoimmune are the fastest growing specialty segments. Specialty medicine growth is fueled by new brands, especially orphan drugs. Of the 78 new active substances launched in 2013 and 2014, 35 of them were orphan drugs. The expectation is that 37-43 new active substances will be launched each year from 2015-2019. The crowded specialty space is getting more crowded with new entrants in Hep C, PD1s, PCSK9s and orphan drugs.

In traditional medicines, diabetes and anti-coagulants are seeing the most innovation. The flu season last winter saw the most prescriptions in the past 6 years. Offsetting this growth, lipid regulators have declined from $25 billion before Lipitor's patent expired to $13.5 billion and will soon be below $10 billion when Crestor goes off patent. It remains to be seen what the effect of the PCSK9s will be. Anti-ulcerant sales declined by 13.8% following the patent expiration of Nexium. Prescriptions of Nexium have remained strong because a 90 day supply of the generic is cheaper than a 30 day supply of OTC Nexium. Hydrocodone/APAP fell significantly after the DEA rescheduled the drugs.

Medicaid was the leading driver of retail prescription growth in the first year of expanded coverage under the Affordable Care Act. Medicare Part D also grew, while commercial insurance will continue to shrink. Many of the co-ops are failing. The ACA will likely have to be reopened in 2017 regardless of who is the next President.

Integration has been increasing in the health care system over time. We are now operating in the Advanced Integrated Delivery Network Model. CMS is increasingly paying based on value. In the future, outcomes will be key and no (demonstrable) outcomes will mean no income.

Despite the merger mania, the pharmaceutical industry is not heavily concentrated. The top 10 companies have about 48% market share. Gilead is #1 with a 6.1% share. Pfizer used to have a 13% market share. Even combined with Allergan (and assuming Actavis is sold to Teva), Pfizer would have a 7.4% market share.

I want to turn now to the generic drug industry. Generics account for 17% of spending and 83% of prescriptions. This will go to 85-86% by 2017-18. The great sweet spot of the generics industry was 2000 to today. Patent expirations will slow over the next several years. This is driving consolidation in the generics industry, which is already very concentrated. The top 10 companies have 58% market share before the recent mergers. Teva and Actavis will have a 21% market share before

any required divestitures. More mergers are expected. Generic price inflation has been prevalent recently and has been driven by increasing FDA scrutiny of manufacturers which has caused more quality and supply issues. Biosimilars are here now and will be increasingly important over the next few years.

Five thoughts to leave you with include: (1) the Hep C drugs, PD1s, PCSK9s and orphan drugs will grow the pharmaceutical market, (2) the first biosimilar launch is an important event, (3) market access and more price negotiations are on the horizon, (4) merger mania will continue, and (5) we will see more regulation and reimbursement issues in the future.

Strategy Case Studies: Building a Specialty Pharmaceutical Company

RICHARD HOYT
VICE PRESIDENT OF BUSINESS DEVELOPMENT AND LICENSING
MALLINCKRODT PHARMACEUTICALS

Mallinckrodt is quite an old company by heritage that has had a variety of owners over the years. The company was spun out from the former Tyco Healthcare (n.k.a. Covidien) in 2013. Through a series of rapid acquisitions and divestitures, the company has become a recognized specialty pharmaceutical company.

Mallinckrodt was founded in St. Louis, MO in 1867. The company started importing botanicals and opium for the controlled substances business. The imaging business goes back to the 1920's and a partnership with Washington University. The nuclear medicine business traces back to Mallinckrodt's involvement with the Manhattan Project. The third time Mallinckrodt started a pharmaceutical business was in the mid 90's with a forward integration of their Active Pharmaceutical Ingredients business into generic and branded drugs. This is the third time Mallinckrodt has traded as a public company.

At spin, the company had bifurcated revenues from a slow-growing imaging business and a pharmaceutical business oriented toward pain management. The company was able to leverage core strengths to expand the Specialty Pharmaceuticals segment. These strengths included skills in acquiring and managing highly regulated raw materials, deep regulatory knowledge, distinctive manufacturing/logistics skills in vertical integration, expertise in specialized chemistry development and a global commercial reach.

The primary focus of the portfolio strategy centered on expanding branded pharmaceutical capabilities in attractive adjacencies domestically and priority markets internationally. Mallinckrodt leveraged this simple portfolio strategy, its motivated management team, and its supportive board of directors to transform.

The company acquired Cadence Pharmaceuticals in the winter of 2014. The acquisition stood on its own financially but was evaluated as a platform for the MNK hospital business. The company had already been interested in auto-immune disease for some time when it acquired Questcor Pharmaceuticals. The favorable market reaction that Mallinckrodt enjoyed from investors after the Cadence deal allowed the company to do a combination cash and equity deal for Questcor. Those two acquisitions shifted Mallinckrodt from its business mix at spin in 2013, a mix of a generic chemical business with some imaging products, to a business firmly rooted in specialty pharmaceutical products.

The company then further expanded its hospital franchise with the acquisition of Ikaria, a provider of nitric oxide and rare disease therapeutics. These were areas that Mallinckrodt was already developing capabilities in. That deal was followed by the acquisition of Therakos which provided even more emphasis and capabilities in the hospital platform. The company recently announced the divestiture of the Contrast Media business which is expected to close in the first quarter of 2016.

Mallinckrodt's portfolio is now founded on highly durable specialty brands and generics. These include Acthar Gel, Uvadex, INOmax, OFIRMEV and specialty generics products. This has created a company with auto-immune/rare disease, hospital-based, and generic drug platforms. The company continues to think about how to transform the business within those platforms and potentially bolting on a fourth, if opportunity allows.

These acquisitions have added $1.1 billion in revenue but have tripled margins to ~30%. The underlying business has gone from a -5% decline to a 5% growth. The company has begun to think about developmental opportunities in addition to commercial assets. The company will continue to reshape the portfolio toward high-value-creating businesses in specialty pharmaceuticals where they are a natural owner.

The transformation has happened so rapidly because the management team is focused, organized and incentivized around creating value for patients, physicians and shareholders. Secondly, there is a certain lack of bureaucracy which allows for open, informal discussion about ideas. Finally, the board and management have a terrific relationship and are well-aligned.

Mallinckrodt sees bond yields rising, market response becoming more circumspect and valuations declining. The company will adapt its tactics to accommodate the changing landscape and environment both today and in the future.

Mallinckrodt can attribute its deal-sourcing success to the senior industry expertise characteristic of both its board and management. Interestingly, only one of the four companies acquired was running a process. Most of the successful M&A work has been identified internally and approached aggressively. An affirmative decision was made upfront not to dedicate the time or resources to approach deals with any hostility. The transactions moved rapidly (4-6 weeks) because the company knew what they wanted and engaged in diligence in a very risk-conscious manner. The company would move at a similarly rapid pace for any deals of similar size.

Strategy Case Studies: Building Multiple Strategic Platforms

AMIT HASIJA
VICE PRESIDENT & HEAD OF NORTH AMERICA BUSINESS DEVELOPMENT
SANOFI

Sanofi is probably one of the most diversified large pharma companies. R&D is core to our strategy and is a significant percentage of allocated capital. Sanofi has historically been organized geographically. The new organizational model will consist of five global business units. This step is necessary to drive focus and simplification.

R&D plays a major role in the successful execution of Sanofi's strategy. The question that presents itself is, "Once innovative products are brought to market, how must their structure be adapted for future challenges and opportunities?" In 2007-2009, Sanofi experienced very low R&D productivity. They faced multiple setbacks and low returns despite increased spending. 2010-2013 saw a transformation as the portfolio shifted from small molecules to biologics. This has led to the launch of new products in 2014 and an expansion of the open innovation model. Today, 72% of Sanofi's R&D projects are biologics.

Sanofi's innovation model takes into account the changing environment. Pricing and market access are under increasing pressure. Payers and providers want new therapies that are clinically and economically better than the existing alternative, together with hard, real-world outcomes data to back any claims about a medicine's superiority. As a result, Sanofi expects to launch high potential new medicines and vaccines at an accelerated pace.

Sanofi realizes that there is a need for an improved insulin experience to get more patients to control. Hypoglycemia contributes to poor compliance and affects treatment efficacy. As a result, they have broadened their diabetes portfolio to address this need and sustain their market leading position.

Sanofi Genzyme has become the Specialty Care Global Business unit of Sanofi. Since acquiring Genzyme in 2011, the platform has launched a multiple sclerosis franchise and three new products (Cerdelga, Lemtrada and Aubagio), acquired a 12% stake in Alnylam Pharmaceuticals (landmark alliance for global advancement of RNAi therapeutics as genetic medicines) and licensed Voyager Therapeutics products (novel gene therapies for severe CNS disorders).

In creating multiple strategic platforms, Sanofi has noted that innovation is an important part of the strategic view, organization is an ongoing effort with multiple platforms and different platforms have different requirements.

The Sanofi story is driven by R&D development. Strategic decisions are made based on where there has been clinical success. Regeneron has been a big part of Sanofi's success in terms of the R&D pipeline. Sanofi does more development than many people realize. For large pharma, certain discovery platforms need to have ecosystems created around them. Do you have a presence in the regional hotbeds of R&D i.e. Cambridge, San Francisco, Raleigh-Durham? Do you know the academics who are working on things that you are going to care about in the future?

Speaker Roundtable – A Selection of Questions and Answers

MODERATOR: PETER YOUNG, PRESIDENT AND MANAGING DIRECTOR, YOUNG & PARTNERS
PARTICIPANTS: CONFERENCE SPEAKERS

Peter Young (Young & Partners): What do we think about the impact and results of the Affordable Care Act (ACA)? How has it impacted the pharmaceutical community? Is it working?

Rick Hoyt (Mallinckrodt): When we thought about the ACA we came up with the view that more patients were going to have access to healthcare. We evaluated the potential impact that would have on the hospitals and their ability to provide services. The jury is still out on whether we have actually seen that impact manifest. The ACA is still a work-in-progress.

Amit Hasija (Sanofi): The ACA has created a large incentive for big pharma to focus on integrated care solutions. We are probably having more of our products purchased by the government than ever before.

Dr. Stephen Spielberg (Therapeutic Innovation and Regulatory Science): Like all such social experiments, the ACA will go through a great deal of evolution. If you think about what Medicare looked like in 1965, it does not look anything like it does today.

Doug Long (IMS Health): The ACA is a work-in-progress. There are parts of the system that are under stress. As a result, we are seeing massive increases in price and a lot of consolidation. I have never been an advocate of "bigger is better." We needed health-care reform. In my opinion, ACA was not necessarily the best way to do it and needs to be fixed. We are relying on the 50% of the population that does not consume significant healthcare dollars to support the 5% who consume 50% of the healthcare dollars. In addition, they really made a mistake with essential benefits. The ACA was meant to bend the cost curve and it has not accomplished this goal. I think paying for outcomes is the way we have to go. We have the further challenge with the ACC in that it depends heavily on the primary care doctor and many doctors are leaving the practice and primary care capacity is plunging.

Randy Guggenheimer (Young & Partners): Unfortunately there is a dynamic in Washington D.C. that makes it very difficult to get reasonable things done. I think the ACA has covered more people, but it has come as a cost.

Dr. Stephen Spielberg (Therapeutic Innovation and Regulatory Science): Just to be contrarian, 90% of primary care could be provided by nurses. We waste a huge amount of money over-training people to do things that could be managed by a workforce that would do a much better job in terms of counseling and providing on-going care. There are also other system and behavior problems. For example, 1/3 of the prescriptions in the USA go unfilled. Half of the remainder is not taken as written because either patients can't afford them or they don't trust their doctor. This leaves 1/3 of the prescriptions for life-saving medicines produced by pharmaceutical companies not being taken as written. There are significant opportunities to save costs. Lastly, the error rates in the U.S. are too high. In the Canadian insurance system is 3%. Comparatively, the error rate in the U.S. private insurance systems is 30%. There is so much waste in the system that could be applied to taking care of patients.

Peter Young (Young & Partners): Where do you think the recent ruckus about pricing is headed?

Doug Long (IMS Health): It will sustain itself through the next election. This was straight out of previous presidential elections when they talked about healthcare costs and pharmaceutical pricing. It is my hope that people are going to be a lot smarter about this issue this time around. This current uproar about pricing started with Turing and then shifted to Valeant. Although Valeant and Turing were the initial targets of the press about pricing, politicians and others are now trying to indict the drug industry as a whole.

Amit Hasija (Sanofi): There are some products that were mispriced at the outset. In some cases it does make sense to take a price increase, but the issue became egregious price increases. Sanofi has taken price increases, as has our competitor Novo Nordisk, in the insulin category.

Peter Young (Young & Partners): The unfortunate aspect is that no one is telling the story about the positive impact that drugs have had on healthcare costs. The statistics are very much in favor of drugs as a way to keep patients out of the

expensive hospitals, from being subject to other expensive procedures, or to cure them of their ailment. I think the drug industry is doing a poor job of communicating that message.

Rick Hoyt (Mallinckrodt): There is no question that the message about the intrinsic health-economic benefit is being diluted by negative publicity around the Turings and the Valeants. There was a drug store in St. Louis that was giving away 10 of the most commonly prescribed drugs for free. These are drugs that can drastically improve quality of life and they were just given away. Stories that demonstrate the societal benefit drugs provide are not being told enough.