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Summary of Speaker Presentations
Young & Partners Pharmaceutical Senior Executive Summit
Co-Sponsored by
Pharmaceutical Executive Magazine and Young & Partners
"Emerging Pharma Strategic and Financial Issues"
November 19, 2008
The Harvard Club
27 West 44th Street - New York City

12:00 P.M.	Lunch and Speaker **"The Current and Future State of the Pharmaceutical Industry"** Pat Clinton, Editor-in-Chief, Pharmaceutical Executive Peter Young, President, Young & Partners
1:30 P.M.	Keynote Speaker **"The Driving Forces Behind the Specialty Pharma Business Model"** Jonah Shacknai, Chairman and CEO, Medicis Pharmaceutical Corporation
2:30 P.M.	**"The Pharmaceutical Market: Trends and Forecasts"** Doug Long, Vice President, IMS Health Inc.
3:15 P.M.	**"Pharma M&A: Driving Factors in the Market"** Peter Young, President, Young & Partners

Summaries of the Speaker Presentations
(These summaries were prepared by Young & Partners and were not reviewed by the speakers.)

CONFERENCE SPEAKERS

The Current and Future State of the Pharmaceutical Industry

Pat Clinton, Editor-in-Chief, Pharmaceutical Executive

There many who express concern that the industry is facing a cliff. We've been worrying about patent cliff and loss of revenue. I think we need to worry about how we get out of the other side. We are facing many challenges along many fronts. There is a crisis in Medicare. Pharma companies are facing unprecedented competition for compounds, defending pricing, with generics competitors, and with upcoming government policies changes.

On the positive side, there is a remarkable crop of drugs coming, but it is not clear where financing will come to bring them to market and the challenge of getting through the process is getting larger. The scarcity of patients for trials, the changing rules, and the increasing financial cost of Phase 3 trials are all slowing the engine of innovation of the industry.

The old model was sell to lots of drugs that did some good at enormous gross margins, whether they made economic sense for the payers or not and whether patients actually took them properly or not. The new model seems to be to sell smaller quantities of drugs at astronomical prices even though in some cases they provide little real-world benefit--such as CA drugs that offer weeks or months of survival--, while shifting as much risk as possible onto biotech companies. It will work for some, but it's not the simple solution to everything that many have thought. Specialty requires new skills, new techniques. Will this highly targeted model work?

On top of all of this is the upcoming health care reform legislation. I sincerely believe that the pharma industry needs to have a seat at the table, but it comes at a cost. The industry needs to focus not on just create products, but yo help develop solutions. We have to be involved in the discussion as a partner whose input is not discounted because of commercial interests. If insurance companies and for profit hospitals can be there, why not the pharma industry? Other costs will be transparency, openness about profits and their role and finding a more effective way to deal with bad clinical news.

The Current and Future State of the Pharmaceutical Industry

Peter Young, President, Young & Partners

For many years pharmaceutical companies used their internal research and development capabilities to develop and commercialize drugs in a 6 to 10 year timeframe. A multitude of changes have occurred and have disrupted the old pharma business model. Despite advances in drug development technologies (RNAi, ion channels, humanized MAbs, glycosylation, genomic screening, etc.), the cost of drug development has soared for numerous reasons and the time to commercialization has increased to over 12 years. Coupled with the increase in costly advertising, the threats to patents and pricing by governments, the cost structure and business model is failing. Big pharma companies have shifted their strategies and are following very diverse paths to achieve success. They include expansion into vaccines, aggressive pursuit of biotech companies and their products, diversification coupled with internal development and expansion of generic activities, pursuit of regional consolidation, and geographic diversification.

Clear failing strategies include the narrow pursuit of the old Big pharma business model, mega mergers, and the creation of larger, but still weak regional players through regional mergers. Clear winning strategies include heavy use of biotech methods and alliances and acquisitions of biotech companies, restructuring research to be more nimble and collaborative, willingness to stop research projects earlier, and focusing on singles and doubles rather than just home runs. On one end is the possible, but highly unlikely scenario that the big pharma companies will be able to invent, license or acquire commercial drugs at a rate sufficient to offset the loss of revenues from patent expirations, competitive actions and pricing pressures. On the other end is the distinct possibility that many big pharma companies will have to dramatically resize themselves, drastically reduce their R&D activities, and retreat into a marketing and distribution focus. Pharma tends to avoid early stage companies, engage in some partnerships and alliances, and buy late stage biotech companies. This leaves biotech companies with serious funding gaps as the venture capitalists and the public markets fall in and out of love with the biotech industry, often at the wrong times. One suggestion is that the pharma and biotech companies form investing consortiums with pharma companies contributing funding, and lowering their risk through equity investments in a pool of biotech companies. The pharma companies would also have pre-negotiated rights to market certain products that come out of the biotech companies.

The Driving Forces Behind the Specialty Pharma Business Model

Jonah Shacknai, Chairman and CEO, Medicis Pharmaceutical Corporation

Medicis was founded in 1988 and has maintained its focus as a dermatology company. Medicis Pharmaceutical Corporation is the leading independent specialty pharmaceutical company in the United States focusing primarily on the treatment of dermatological and aesthetic conditions. Medicis is dedicated to helping patients attain a healthy and youthful appearance and self-image. Since our inception in 1988, we have introduced more than 25 new products and formulations, making us a prolific source of new products in the specialties we serve. Today, we have leading branded prescription products in a number of dermatological and aesthetic categories. Medicis products have earned wide acceptance by both physicians and patients due to their clinical effectiveness, high quality and cosmetic elegance.
Medicis provides award-winning support to our physician-customers as they care for their patients and build their practices. We do this through new product development, growth of existing brands, strategic acquisitions, and collaborative relationships. Our goal is to maintain a strong leadership position in customer focus, both in dermatology and aesthetics, and other specialty fields we may enter.

Unfortunately, as a country we are going through a significant downturn that is affecting everyone. Although we are a very strong competitor and a leader in our market, we cannot escape the macro trends entirely. My perception from speaking monthly to several hundred physicians in the cosmetics category is there is a definite downturn nationwide. Previously the downward effect was felt more in the West, Southeast and a bit in the Midwest, but the phenomenon has now become national. The physicians that I speak to are sharing with me economic data suggesting flatness or declines in the10 percent range. Certainly we see that reflected in our own business.

On the other hand, this has also been a year of strong developments such as the acquisition of LipoSonix, Inc. and a number of positive product development and approval milestones. By staying focused, maintaining our leadership position and strong salesforce, and continuing to develop the right products, Medicis will continue to be a highly successful specialty pharma company.

The Global Pharmaceutical Market: New Realities and New Opportunities

Doug Long, Vice President, IMS Health Inc.

The new reality of the pharmaceutical market has been defined. Growth opportunities exist but in new places. Near term pressures are intense, and rapid adaptation is essential. There are longer term potential upsides for 2009. The new reality is low growth in developed markets which is a result of less growth from innovation. In addition, generics volume penetration is increasing, payers exercise greater control, and regulators know more and have access to more information. While patent events drag down some categories, other ones such as Oncology, Respiratory, and HIV are able to grow above the market. The economic environment brings uncertainty for 2009. Innovation is at historically low levels, providing minimal growth in 2009.Safety issues, including "black box" warnings are having a significant effect. Patents on $24bn of products are due to expire in 2009 and an additional $33 billion of products in 2010.

New opportunities in the pharmaceutical industry include robust growth in "pharmerging" markets, large unmet needs in oncology and specialty, underserved primary care, and untapped potential for mature brands. To refocus the business, there is a need to redefine growth drivers and reallocate investments. To adjust the cost base, there is a need to adapt to the future portfolio, and outsource non-strategic functions. To strengthen the value of medicines, the industry has to frame benefits and risks, adopt payer mindset to define value, and communicate to all stakeholders. To implement new commercial models, pharma has to revise the nature of selling, move to regional/local structures, and align to changes in decision-makers. The impact on pharma will be an increase in evidence based culture, a shift of investment to growth areas, optimized R&D and manufacturing productivity, exploration of new distribution channels, re-evaluation of sales & promo models, and engagement strategy. Growth opportunities for pharma exist but in new places, near term pressures are intense, and rapid adaptation is essential. Longer-term upsides to pharma growth are possible because of growing share of healthcare budget for pharmacotherapy, accelerated uptake of healthcare information technology, increased diagnosis of asymptomatic conditions, improved compliance and persistency rates, expanded patient access to healthcare, greater clinical evidence of drug efficacy, emergence of new therapeutic platforms, and aging population and economic development.

Pharmaceutical M&A: Driving Factors in the Market

Peter Young, President, Young & Partners

Merger and acquisition activity was very low for many years, but a rash of periodic large scale acquisitions and mergers created surges in the number and value of transactions starting in 1999. Dollar volume surged to a record $230 billion in 2000 when many large scale mergers occurred. The rationale given for these transactions was the potential for cost savings, more potent sales force offerings, and increased research scale. Unfortunately, a number of the mergers happened from weakness, not strength, and often did not improve either R&D product pipelines or costs beyond short-term cost savings. Since 2000 there have only been two mega deals, Pfizer/Pharmacia and Sanofi/Aventis. Most of the deal activity has been regional consolidation efforts, large and medium sized bolt-on and additions, expanding specialty pharma companies, and consolidations and expansions in generics. Much of the recent M&A activity has been by acquirers who spent significant sums to acquire various product portfolios or drug pipelines. The pressure to consolidate on a global basis will continue, except for selected niche and specialty companies.

In the first three quarters of 2008 dollar volume has slowed considerably. Volume in terms of numbers of deals in the first three quarters of 2008 slowed significantly relative to the pace last year. Acquisitions by Japanese pharmaceutical companies have been significant this year, but US and European acquirers have been cautious. In recent years, pharma companies are intelligently turning to acquisitions of products, smaller pharmaceutical companies, biotech companies, licensing, and marketing/development partnerships to achieve their business goals. On a different front, there has been significant consolidation of the generic pharmaceutical industry as its moves through a different stage of development. Young & Partners sees a continuation of the more recent M&A trends for the next five years. Selected regional mergers, bolt on acquisitions of pharma products and businesses coupled with biotech acquisitions, and strategic alliances and licensing will dominate the headlines. The intriguing question is whether these activities will be sufficient, coupled with internal development activities, to save the large pharma companies. Some geographic M&A moves will also arise as the center of gravity for the ethical pharma industry continues to be dominated by the U.S., and the center of gravity for generic pharmaceuticals will shift gradually to certain parts of Asia.