Chemical Industry's Expectations for the U.S. Business Climate in 2013

Industry Experts Assess the Market Situation Relevant to their Respective Activities in the U.S., Opinions Range from Uncertainty to Optimism

A Look into the Future – Where is the U.S. economy heading in 2013? Industry leaders predict their companies will navigate uncertainty, including changes in pharmaceutical regulations. Many executives expect growth, albeit subdued. CHEManager Europe asked industry experts to share their views on how their U.S. concerns will fare in the coming year. We wanted to know what they expect from the U.S. economy in 2013, whether they are optimistic or pessimistic for the business climate relevant to their respective activities in the U.S., and how they plan to expand their businesses in the U.S. Here's what they have told us.

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D. DeCuir (Albemarle): The economic outlook for growth is somewhat muted for 2013 given recent predictions that the EU zone likely will experience a recession, and growth in Asia, particularly China, is forecast to be below historic levels. This combined with uncertainty about the U.S. growth rates has many economists predicting slow growth worldwide. Albemarle's Custom Services business unit, however, expects to have a good year. While sales will likely slow from the torrid growth rates of 2010–12, I still expect good growth because we have positioned ourselves in multiple markets. Casting this wide net in the marketplace allows us to grow with our customers in the pharmaceutical, agricultural, lubricants and specialty chemicals markets and avoid the cyclicality that many of our single-market competitors face periodically. In addition, Albemarle has a relatively uncommon offering to the North American market where we are primarily located. We are one of the few companies that can perform lab chemistry development, process development and scale-up, as well as commercial manufacturing at commercial volumes from 5 kg/year to 25,000 mt/year. This capability along with Albemarle's expertise, financial security, and excellent safety, environmental and regulatory compliance record draws customers to us for their long-term custom manufacturing needs. We recently completed an expansion at our Tyrone, Pennsylvania, site that doubled capacity for a proprietary product. Other customers' products and new custom projects are also growing at that site, which will necessitate an additional expansion in the near future. Other Albemarle sites that support our Custom Services business are also operating at high rates and may need debottlenecking/expansion to allow for growth in already contracted products. As the economy picks up in 2014, we will be poised for growth and continued success.

Dr. T. W. Büttner (Allessa): In 2013 we expect a quite positive business climate in the U.S. for our activities. At the end of 2012 we formed the new Allessa by combination of the former AllessaChemie and AllessaSyntec. Now we are looking forward confidently to the development of the American economy. Our business in the U.S. is on a robust growth path, driven by the line products, custom manufacturing for the agrochemical industry and innovative oilfield polymers. We see a certain "reshore" tendency to relocate production and products that had been in Asia for many years back to the U.S. and Western Europe, driven by price and reliability issues. Since there is not enough custom manufacturing capacity in the U.S., Allessa as a Western European company does indeed profit from this reshoring movement. The chemical commodity production will be growing again in the U.S., based on affordable energy prices. This will very positively influence our stabilizer business, especially phenothiazine, which is tied into large-scale production of monomers. Our core business, custom and toll manufacturing, is currently driven by a booming agrochemical industry, capacity in high demand and much increased volumes compared with the past two years. Allessa does supply intermediates and actives mostly to the multinational and innovating companies in the agrochemical market. Pharma remains a challenging environment for custom manufacturers, because of the lack of new innovative products, long delays in registration and many products failing in the pipeline. In the past year a certain upswing in the early development stages could be seen. Whether this transfers into real growth in the later stages remains uncertain. We expect that the amount of products introduced in the markets will remain lower than in the past. For the oilfield industry, Allessa has developed a line of proprietary high-performance polymers, which are used in high-temperature drilling and fracking. These products are increasingly needed in these challenging environments. We expect, therefore, a more than average growth rate in these markets. Also, Allessa does act as custom manufacturer for specific polymers in the oilfield industry.

C. Stamoran (Catalent Applied Drug Delivery Institute): Health-care delivery in the U.S. continues to evolve in 2013, with implementation of reforms in health insurance mandated by the Patient Protection and Affordable Care Act, passed in 2010, which combines the current private-public hybrid of employer coverage plus government-funded coverage for the elderly and low-income with an individual mandate for those not already covered by these programs. The coverage mandate will be subsidized by the government for lower income individuals. It is expected that 32 million people will be newly insured under this program starting in 2014. Funding for this is to come from insurance provider and pharmaceutical company fees, taxes on medical devices, and other corporate and individual tax changes, once fully implemented. Other recent legislation imposes substantial additional fees and requirements on the pharmaceutical and med tech industries. The FDA Safety and Innovation Act of 2012 imposes new fees on generic drug filers, manufacturers and API (active pharmaceutical ingredients) producers, with the proceeds to be used for added resources to clear up some of the FDA's extensive backlog of generic drug filing reviews, and reduce review times for new filings. At the same time, medical device-related fees were levied on a broader range of companies in the supply chain, and new biosimilar fees were set. These additional fees are further affecting profitability of and investments by the pharmaceutical industry, both in the U.S. and globally. These companies were already dealing with the wave of generic conversions, escalating single-payer market access and pricing pressure around the globe, and increased regulatory expectations for product approval and safety. Companies are likely to push to develop more clinically differentiated products, to increase use of outsourcing for development activities to stretch limited R&D funds, and to focus on less reimbursement constrained areas such as consumer health products. The U.S. market one of the most attractive markets for our business. We do not expect a significant change of the business climate in the USA after the election of the president. However, the political climate in the USA is not as good as it could be. A major challenge is the confrontation between the president and Congress. We hope that both parties will solve their issues finally and will move forward together instead of working against each other. Furthermore, it is foreseeable that the U.S. government must cut spending in the future and this might include spending for the health-care system (Medicaid) and veterans' benefits. Such cuts might have a direct influence on the generic market and at the end on the sales of generic APIs in the USA. A significant input to the costs of APIs and finished dosage forms (FDFs) is the Generic Drug User Fee Act (GDUFA). There is no doubt that the market will be consolidated and the number of registered drug master files (DMFs) will be decreasing, because holding a DMF without sales in the USA will be unattractive in the future. On the other hand, all active producers are under pressure to "digest" these additional costs and it is predictable that the costs for the patients will increase. The positive rationale behind GDUFA is higher safety for patients.

M. Blanc (Novasep Synthesis): We are experiencing strong business growth in the U.S. The ever-increasing complexity of the molecules reaching the market has resulted in a higher demand for the synthesis and purification solutions that Novasep provides. As a result, Novasep has strongly reinforced its U.S. team over the last years, most recently with the appointment of Jean-Baptiste Agnus as head of sales in North America for Novasep's Synthesis Business Unit. Novasep's strategy, based on an offer combining advanced purification with smart synthesis, from development to commercial scale, is paying off. We are seeing an increasing level of interest from our U.S. customers in our core technologies, i.e., chiral separations, hazardous chemistry, large-scale preparative chromatography for the purification of complex mixtures, highly potent active pharmaceutical ingredients (HPAPIs) handling in confined areas; and in many cases more than one of these technologies are required. The need for combinations of these state-of-the-art technologies is best illustrated by the boom of antibody-drug conjugates (ADCs). Because of the mechanism of action of ADCs, targeting malign cells, very powerful toxins can be re-evaluated and ADC toxins often present very low occupational exposure limits as a result. In addition, these molecules have to meet stringent purity criteria, and large-scale preparative high-performance liquid chromatography (HPLC) is almost a must for their complex purification. Within its Safebridge-certified site in Le Mans, France, Novasep combines a strong expertise in HPAPI manufacturing as well as industrial preparative chromatography. This synergy is a token of quality in this domain, and the trust our customers have put in our capabilities has recently led us to invest $4 million to increase our ADC toxin production capacities. The need for high purity APIs has also triggered the decision to invest at the Mourenx, France, site in a $40 million facility Novasep will design for the world's largest chromatography system ever built for the pharmaceutical industry. This is a sign that our offer perfectly responds to the market needs: advanced synthesis combined with state-of-the art purification. Based on these successes, we definitely expect the business growth to carry on through 2013.

Dr. M. Grehl (Umicore Precious Metals Chemistry): The economic climate in the U.S. shows signs of recovery since the peak of the downturn in 2008 but there is still room for more improvement. With that said, we see different kinds of opportunities for our catalysts in different sectors. For example, the industrial chemical sector in the U.S. is expected to grow around 2-3% in 2013, but we see increased opportunities for petrochemical and agrochemical companies. We expect that energy sector will continue to be a growth market in the U.S., so chemical companies in the downstream markets will benefit. Drug companies are also experiencing a modest improvement from recent years. Large pharma companies have undergone significant restructuring and cost reduction in the U.S., including a reduced domestic manufacturing footprint. Small pharma companies with solid pipelines have been able to secure funding either from private investors or through partnerships. This has helped the specialty chemical companies in the U.S. attract new projects, but competition for these projects is intense. All of these types of companies are potential users for our products. We are quite optimistic about our potential for growth in the U.S., so much so that we have decided to invest a significant sum of money to construct a new and larger manufacturing facility on the our campus in Tulsa, Oklahoma. This plant will give us the opportunity to manufacture the entire Umicore product portfolio including our newest and most advanced catalysts. As chemical manufacturing becomes even more global in nature, it is critical to have exceptional manufacturing facilities throughout the world, whether in the U.S., Europe, Asia, and now South America. For example, our customer's project may start in the U.S. for early development and may then transition to Europe or Asia for later stage manufacturing. Alternatively, a process may be developed in one location and then implemented in a variety of our customer's manufacturing plants around the world to service their local market. At Umicore, we are fortunate to have the necessary infrastructure in place to support our customer's projects wherever they start and to wherever they may migrate to.

The Umicore PMC catalyst business had one of its best years in 2012 and we expect that 2013 will be even better. This increase has been driven by steady growth in one of our key existing business segments but also by new opportunities identified for our advanced catalysts. One of our primary strategies is to transition our business from products that support the commodity chemical sectors to value-added catalysts used in new applications and technologies. We have an experienced business team in the U.S. that is identifying the right opportunities for us and the new manufacturing plant will allow us to supply product to our customers efficiently and cost-effectively.

Dr. A. M. Cano Sierra (Rockwood Lithium): Since the mid-1980s Rockwood Lithium has a long term experience in research and development, production and sales of tailor-made organometallic compounds mainly for the organic synthesis in the pharmaceutical industry. We have been collaborating with our customers to develop unique premium solutions: customized products and services combined with integrated process solutions are the foundation of our success and that of our customers. During the last five years we saw that these kinds of compounds experienced an increased demand from the polymer industry too. Rockwood Lithium has used its large experience to respond this demand offering standard and tailor-made customized products, sustainable solutions that help our customers to enhance product quality, increase process and cost efficiency, and improve health and environmental protection. Rockwood Lithium is proud to be the first address for our customers to develop tailor-made customized solutions and be recognized as a reliable source of supply. We have invested in new capacities and cost-effective technologies. Besides the development of new products we are aware that a comprehensive customer service is required and will be provided by our company too. Rockwood Lithium is the world's leading supplier of Lithium compounds like Butyl lithium, Lithium hydrides, alkoxides, and amides. With our expertise in this field of chemistry we also supply other organometallic compounds such as Magnesium reagents. Our product portfolio is based on continuous research and development of leading edge technologies. Headquartered in Germany, Rockwood Lithium serves its customers with a worldwide network of sales offices as well as with production sites in Germany, both South and North America, India and Taiwan. With laboratories and research centers in different regions of the world, we can respond quickly and flexibly to the needs of customers, developing and testing custom-made solution close to their locations.

J. Robinson (Manchester Organics): At Manchester Organics, around 50% of our sales are to the USA, so the health of the U.S. economy is extremely important if our growth targets for the business are to be achieved. After several years of sporadic growth, we do expect to see more consistent expansion from the U.S. economy in 2013 and, with the threat of recession from the "fiscal cliff" now apparently receding, we expect to see solid, if unspectacular, growth in 2013. We do, however, expect to see stronger growth in the U.S. biotech and virtual pharmaceuticals sector and we will be working hard to expand our growing presence in this sector in 2013. The overall economic outlook has significant bearing on this sector, principally because it is so dependent upon venture capital, and similar forms of high-risk investment, for its funding. A stronger outlook for the economy overall is essential if the levels of investment of the past few years are to be maintained and, we hope, increased. It has been widely reported that many venture capitalists have been looking to shift their investments to later-stage, and thereby lower-risk, projects as a result of the financial uncertainties of recent years, but this can be very difficult to do in the drug discovery space, due to the inherent risks and uncertainties of bringing a new drug candidate to market. With the "patent cliff" replacing the "fiscal cliff" as the primary concern for analysts in the pharma industry, increased investment in the biotech/virtual pharma sector is crucial if the U.S. is to maintain its position as the key innovator in new drug development. We are optimistic that economic conditions will allow increased investment in this sector in 2013 and we are also optimistic that Manchester Organics is well placed to take advantage of any opportunities that arise as a result.

P. C. Michels (AMRI): Contract research organizations (CROs) are evolving from tactical providers into strategic partners as the pharmaceutical and biotechnology industries continue to seek solutions aimed at improving both R&D innovation and productivity. The challenges faced by these industries are creating a paradigm shift, with greater value coming from outsourcing strategies that provide more comprehensive, adaptable and tightly integrated solutions that are tailored to drug discovery and development challenges. Adopting a collaborative and integrated approach to drug discovery and development from an early phase can reduce overall time, effort, risks and costs. This is imperative for patent life and value, considering increased drug approval requirements. The most effective integration strategies coordinate the best experts from multiple disciplines and global locations within an organization to strive toward and adapt better ways to solve problems or accelerate projects for customers. AMRI has long coordinated cross-site, cross-discipline expertise for customers in order to tackle tough synthesis and production problems, and generate unique outcomes within a simple and confidential framework. Moreover, AMRI Smartsourcing offers a versatile and strategic way of partnering that includes full access to all our resources, including leading technologies, global facilities and a record of accountability. Integrated solutions need to utilize the strongest component parts; this includes knowing when to seek mutually beneficial partnerships and alliances, or introduction of new business models, like insourcing. Insourcing is a collaborative model that is designed to foster improved decision-making, cycle times, problem solving, communication, and the quality of products and reporting. Increasingly, research alliances include collaborations with government entities and universities — typically to turn leading-edge research ideas into tangible, practical health treatments, as rapidly and cost-effectively as possible. Ultimately, this refocusing on collaboration, co-creation and value, rather than simply cost in outsourcing, is starting to have a real effect on products to the clinic and market.

Dr. T. Iliopoulos (Euticals Group): The world merchant active pharmaceutical ingredient (API) market is expected to grow at an average 6.5%-7% per annum over the next five years, with generic APIs outpacing the overall growth. Integration among pharmaceutical companies and consolidation is going to continue and will create free capacities and fewer and fewer API manufacturing players. Biologics and generics are the fastest growing segments. The highly potent API (HPAPI) market in North America has been highly developed with 44.8% share in the overall market for HPAPI in the world. In 2013 demand for generic APIs in the BRIC countries will reach 37% to 38% of the world generic APIs demand, with China at the top, while the U.S. will remain the largest world APIs market and second as a generic APIs consumer after China. North America has the most advanced and highly developed health-care system with the largest spending. This factor alone attracts API manufacturers, including development and manufacture of HPAPIs. Italy ranks second after China as an API manufacturer. Its market share on world API sales has been decreasing over the years, however Italian manufacturers have seen an increase in their sales to the U.S. with a market share of approximately 29%. The main challenge for the Italian industry remains the competition from India and China although only a few hundred API manufacturers in these countries have had inspections from international authorities, including USFDA. The challenges and rising costs of doing business in the East (India and China), compounded by the new EU laws, which will come into effect on July 2, and by which APIs imported into the EU must comply with EU good manufacturing practice (GMP) standards as stipulated by the ICH Q7 guideline, will dramatically affect API sourcing decisions. Euticals' business model is revolving around manufacturing in the mature Western markets such as Italy, France, Germany, U.K. and U.S. where it has an established manufacturing footprint. As an increasing number of products losing patent protection over the next decade will be highly specialized, Euticals believes that focusing on innovative and cost effective processes and in niche technologies is the winning card for sustainable sales growth in North America and "pharmerging markets" regardless of the economic crisis in Europe.

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