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ASIA EDITION

â€œChina will continue to rise as a key base for global pharmaceutical manufacturingâ€•

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It is undoubtedly an interesting time for the contract development and manufacturing organisation (CDMO) sector, and particularly, for companies like STA, with facilities that span China and the US. For those who don't know, we are a WuXi AppTec subsidiary that specialises in contract services for small molecule process development and manufacturing. Development costs in the US are comparatively high and are driving the main bulk of our business for patented API development work, but also, we are seeing pharma in Europe and increasingly Chinese biotechs emerging, that are bringing drug candidates to STA for development and commercialisation.

More broadly in the CDMO space, in the last few years we have seen the rise of biologic drugs (which has led to rapid expansion at our sister company, WuXi Biologics) and a number of acquisitions as the industry consolidates and we move towards more strategic partnerships. However, what remains without doubt is that outsourcing of pharmaceutical and small molecule API drug development will continue apace. The market forces, and the need for outside skills that are often the crucial difference in speeding a drug to market, are simply too hard to ignore. Perhaps more significant is that we are also seeing a change in the relationship for CMOs and CDMOs with their pharma customers. It is no longer a transactional relationship, pharma and biotech customers are instead seeking the best skills sets to help them develop a drug or meet technical process challenges. So, what you are now seeing in the CDMO sector is companies striving to invest in new technologies with specialised development teams that can help expedite the drug development process. Small CMO

companies who are well managed, especially the ones with leading technology, are high-priority acquisition targets.

Another major trend is overseas investment driving life sciences innovation in the West. Chinese investors are looking beyond China, ahead to Western biotechs, as promising local biotechs are valued high due to supply and demand. Yet, at the same time, we see much of this biotech development work then turning to our R&D centres in China, which is really showing the globalisation of the industry. We have seen some US biotechs prefer to keep the very early stages of the development process closer to home, which is why last year we opened a San Diego site. This means we can offer the very early R&D stages out of the US close to the client, before transferring to China for later stage production to gain the cost benefits.

For bigger pharma customers, we have a different relationship. As we are often working on many projects simultaneously, we offer them dedicated R&D teams in China that can work flexibly with their teams - it is a special sort of strategic relationship we envisage increasing as the industry moves toward a more virtual R&D model.

I touched upon it earlier, but clearly the industry is also gearing up for new technologies and capacity through acquisition or conversion. Our approach has been a little different, in that we have invested heavily in our own facilities so we can deliver new capacity with the latest technology, rather than trying to adopt older sites from others. At the new 39-acre Changzhou facility, which became operational last February, we have a fully integrated site with both R&D and manufacturing. Once completed it will have over 500 scientists and well over 1000m3 total reactor volume. Unlike some of the other CDMOs, who sometimes try to pick up work at a later stage, our unique strategy is to maintain huge pipeline of early clinical stage clients with commercial potential. So rather than trying to back integrate, we are helping our customers from the inception of their product through to launch.

At the integrated Changzhou site, we have both pilot and commercial plants as well as R&D. We plan to eventually run nine large plants at this site. The plants will fulfil our customer's R&D pipeline needs, with many of the programmes now entering process validation stage, requiring us to add production capacity. In fact, since the Changzhou site opened less than a year ago, we already have over 40 active pharma customers running programmes at this site - 90 per cent from the United States and Europe - with 60 APIs and/or intermediates under development, and one New Chemical Entity API already in commercial production.

Globally, the market is becoming more stringent on data integrity issues, after a high number of warning letters issued to drug manufactures by the US FDA in recent years. Companies like ours that have no issues are seeing a natural upturn in work as pharma and even the biotech sector becomes increasingly cautious about which partners to invest in.

Another major advantage for STA has been recent regulatory changes in China that opened up new opportunities. China's State Council announced a detailed pilot plan for the Marketing Authorisation Holder System ("MAH") for drugs in 10 provinces in China ("Plan") in May 2016. The three-year pilot programme is an important reform measure to encourage drug innovation. According to the Plan, China-based drug research and development ("R&D") institutions and individuals in the piloted regions are eligible to apply for and hold drug product licences. Eligible parties can now commercialise their drug assets without having to become drug manufacturers themselves as long as the drug is manufactured in China. This new policy added incentives for drug development companies to work with reputable China-based CDMOs with a global quality system and regulatory approval track record. The beneficiaries of the MAH pilot programme are not only multinationals but also China-based biotech start-ups. In addition, innovative drug development companies located outside China also have a stronger desire to work with China-based CDMOs, so that they can be well positioned to launch their products in China sooner down the road.

In short, I expect China will continue to rise as a key base for global pharmaceutical manufacturing in the next 2-5 years. Several factors are the key drivers of China's biomedical innovation: the Chinese government's pro-innovation policies and investment, the strengths and scale of the country's scientific talent pool, including rapidly growing number of western trained professionals, and "mass entrepreneurship and innovation" as first proposed by Chinese Premier Li Keqiang in 2014.

A number of emerging China-based biotech companies such as Hutchison Medi Pharma, Hua Medicine and Nasdaq-listed BeiGene, just to name a few, will start to commercialise their innovations in China and in global markets over the next 2-5 years. Within five years, I anticipate an increasingly harmonised international regulatory environment, with regulations and guidelines from China FDA aligned with those from the USA and EU.

In terms of challenges, CDMOs must adapt to the new paradigms in the market - speed and flexibility will be a major factor in those that fail or succeed. Today new drug molecules are becoming more and more complex, while simultaneously, shorter development timelines are required. Emerging biotechs, who heavily focus on addressing a specific therapeutic area and

outsource special skills, are rising in every corner of the world. One must assume therefore, that the production schedule with the CDMO can be modified, shifted, decreased or increased with ease whereas the reality of the experience could be the total opposite. As a result, partnering with a CDMO who can provide both "upstream" development services and "downstream" manufacturing services are becoming more and more essential.

Additionally, the appearance of new product classes such as ADCs, oligonucleotides and other complex combination products post new challenges and opportunities to the CDMO industry. It's not good enough to be an expert in small molecule or large molecule alone any more, global leading CDMO players need to be equipped with an integrated technology platform and talent pool to master more and more complex pharmaceutical products.

From an STA perspective, we see our unique R&D capacity - we have more process and analytical chemists than any other CDMO - continuing to drive an expanding stream of NCEs into later stage development as well as commercialisation. What is most exciting is that this is naturally opening up more opportunities, and with the new sites we have such flexibility in how to run a client's programme.