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AAIPHARMA® | CAMBRIDGE MAJOR LABORATORIES

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FOCUS ON pharma

AAIPHARMA SERVICES/ CAMBRIDGE MAJOR LABORATORIES – SETTING THE COURSE FOR SUCCESS

By Stephan Kutzer, Chief Executive Officer

Valued at almost US$162 billion in 2014, the global pharmaceutical market is anticipated to have a compound annual growth rate (CAGR) of 9.4% reaching nearly $278 billion by 2020, according to Persistence Market Research[1]. Driven in part by the increasing prevalence of chronic diseases and the ageing of the global population, this strong growth has brought numerous biologics effective at treating more widely spread conditions to a development and manufacturing peak. While increased R&D is leading to advances in biopharmaceutical drugs, including the development of highly targeted treatments, formulation and drug delivery advances are creating a resurgence in API production and various solid dose forms.

The healthy growth predicted by market research firms for the pharmaceutical contract development and manufacturing markets seem to have been realised in 2015. The factors driving that growth continue to influence the pharmaceutical market in 2016, leading to further expectations of increasing

AAIPharma/Cambridge Major Laboratories operates two cGMP manufacturing facilities: one in Charleston, South Carolina, for parenteral products and one in Wilmington, North Carolina, for oral solid dose. Each is approved by the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) and is fully integrated with a packaging and distribution centre. cGMP laboratories for Small and Large Molecule Development Services are located in Durham and Wilmington, North Carolina as well as in St. Louis, Missouri and Edison, New Jersey for Analytical Testing. These facilities and scientific staff have supported development and testing for clinical trial supply and commercial programmes for decades.

demand. In fact, the latest survey from Nice Insight - the new 2016 Nice Insight CDMO Outsourcing survey, with input from over 500 outsourcing-facing pharmaceutical and biotechnology executives, suggest that the depth and breadth of outsourcing by pharmaceutical/biopharmaceutical companies will indeed continue to expand significantly in 2016. According to Nice Insight, the percentage of survey participants whose companies spent more than $50 million annually on outsourcing remained consistent at 23 to 24% from 2012-2014[2], that number nearly tripled to 71% for CDMOs in the 2016 survey; while the percentages of respondents whose companies spent less than $10 million and $10 to $50 million on outsourcing decreased.

Looking at drug substance and drug product demand, Frost & Sullivan shows that sterile parenteral contract services make up about 82.8% of the total sterile CMO/CDMO market; including small-volume parenterals for vial, ampoule or syringes, making up the majority of sterile contract services with 88.9% of market share, and large-volume parenterals for bag or bottle. The sterile parenteral manufacturing subsegment is expected to reach a market size of $6.5 billion by the end of 2016.[3] For oral solid dose forms in the contract manufacturing industry, this market is experiencing expansion, with demand for fixed-dose combinations, controlled-release dosage forms and similar lifecycle management strategies.[4]

Meeting customer needs as a CDMO

As the markets undergo these significant changes, companies are relying more heavily on CDMOs to provide the services, expertise, and technologies required to help them favorably compete in a challenging marketplace. Contract service providers, in turn, are strengthening their capabilities to meet this demand by building high performance organisations geared to optimal customer collaboration. An example is the combining of AAIPharma and Cambridge Major Laboratories, to form a full-service global CDMO supplying drug substance and drug product development, manufacturing, testing, and packaging services to customers seeking more integrated support. AAIPharma/Cambridge Major Laboratories (AAI/CML) is a solution oriented organisation built on the fundamentals of customer service, creativity and flexibility.

AAI/CML has added new capabilities and expanded capacity for oral solid dose manufacturing

AAI/CML also added additional capabilities and capacity for oral solid dose manufacturing and sterile/parenteral manufacturing; expanded laboratories and enlarged their headquarters space in Wilmington, North Carolina (USA). These capabilities complement dosage-form specialties, including minitabs, paediatric sprinkles, chewable products, sublingual tablets, orally disintegrating tablets, extrusion granules, and extrusion spheronisation.

AAI/CML can also handle drug product manufacturing for potent drugs, controlled substances, and moisture/oxygen-sensitive drugs.

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About AAIPharma/Cambridge Major Laboratories

AAIPharma and Cambridge Major Laboratories have joined to form a world-class supplier of comprehensive pharmaceutical development and manufacturing services. With seven sites across the globe, combined capabilities include API development and manufacturing, solid state chemistry, formulation development, analytical development and testing services, clinical and commercial finished dosage form manufacturing (solid dose and parenteral), packaging, and stability services.

Stephan Kutzer, Chief Executive Officer

Dr Kutzer most recently served as Chief Operating Officer of Lonza, Inc., part of the Lonza Group, the Swiss chemicals and biotechnology company. He has also served as Chief Operating Officer and/or President of several divisions, including Lonza Pharma Biotech Division, Lonza Custom Manufacturing, Lonza Biopharmaceuticals and Lonza Performance Chemicals. Dr. Kutzer holds a Master's Degree in Chemical and Process Engineering and a Ph.D. in Engineering Sciences (Chemical Engineering) from the Technical University of Munich, Germany.

CLINICAL PACKAGING, LABELLING & DISTRIBUTION

AAIPharma/Cambridge Major Laboratories provides custom packaging, labelling, study kit assembly, storage, distribution and QP services for worldwide research studies. In addition, we can accommodate scale-up through commercial supply. Our flexibility allows client to fulfil their supply chain needs, from stand-alone packaging services to full development programmes with integrated manufacturing, stability storage and analytical support all guided by our expert project managers, quality and regulatory affairs teams.

LEADERSHIP FOR THE FUTURE

Looking ahead, pharmaceutical and biotech companies will continue outsourcing solid-dose and parenteral development and manufacturing, while the complexity of active ingredients and production processes continue to develop. Highly competent, experienced CDMOs that have the expertise to meet these new industry demands and are willing to evolve their organisations to do so, will meet with success in strengthening the global pharmaceutical supply chain.