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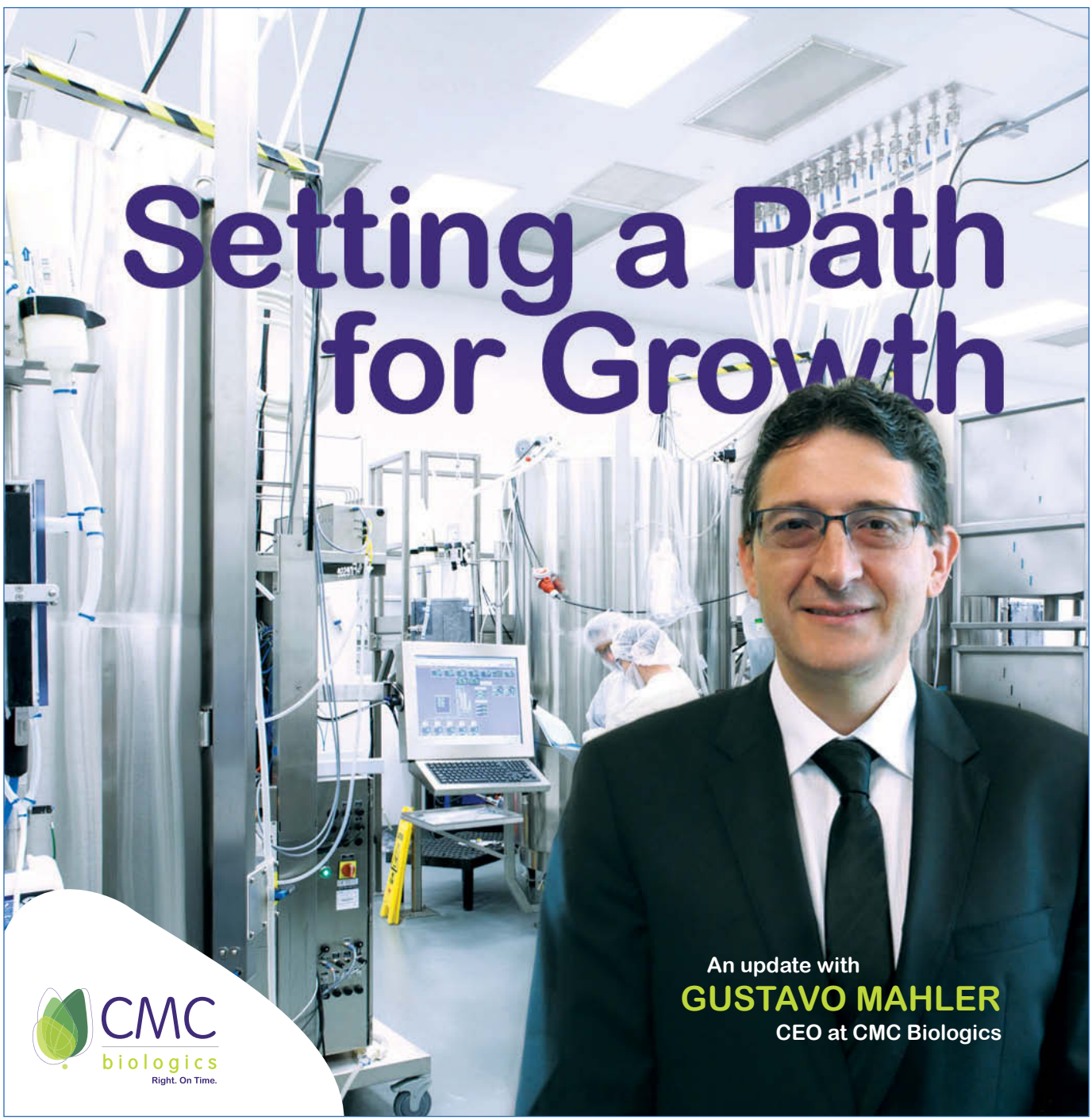

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FOCUS ON pharma

CMC BIOLOGICS – SETTING A PATH FOR GROWTH

The global biopharmaceutical market was valued at nearly US $162 billion in 2014 and is expected to grow at a compound annual growth rate (CAGR) of 9.4% to reach approximately $278 billion by 2020, according to Persistence Market Research. This strong growth is driven in part by the increasing prevalence of chronic diseases and the aging of the global population. Many biologics are effective at treating more widely spread conditions that have not previously responded to small-molecule therapies. Increasing investments in R&D and innovation that are leading to technological advances in biopharmaceutical drugs, including the development of highly targeted treatments, are also contributing to the increasing demand for biotherapeutics.

These technological advancements and the rapid expansion of the biologic drug market are in turn driving the growth of the contract biopharmaceutical manufacturing market, which is predicted by Roots Analysis, to increase at an annualized rate of 8.3%. Biologic drug companies are turning to contract manufacturing organizations (CMOs), and more frequently contract development and manufacturing organizations (CDMOs) to reduce costs and gain access to state-of-the-art technologies. Competition between service providers is quite fierce, however, as drug manufacturers seek more collaborative, long-term and cost-effective relationships with a limited number of strategic partners.

In recognition of these key market trends, CMC Biologics has made significant investments in both innovative and flexible facility designs and capacity expansions that has enabled its customers to meet increasingly aggressive production and regulatory timelines and thereby help speed their products to clinic and market. The company has also focused on building holistic relationships with clients in order to understand and enhance their early development efforts, and to be able to implement long-term strategies that ensure success over the full lifecycle of a drug candidate, from cell line and process development, through the clinic to commercial production. The company also places a strong emphasis on customer satisfaction and surveys its clients regularly in order to solicit their feedback.

Building on a strong track record

During its 13 years of operations, CMC Biologics has developed over 80 mammalian, bacteria and yeast-based processes for pre-clinical studies through commercial production. Several have involved continuous production via perfusion; an advanced technology that provides numerous efficiencies and other advantages over conventional fed-batch production. Through these efforts the company has gained experience in identifying the optimum conditions for upstream and downstream processes, as well as the transfer and scale-up of both.

The company is continuously building on this foundation. Five agreements signed in 2015 highlight the range of capabilities offered by CMC Biologics that are sought by a diverse array of customers. In January, the company agreed to exclusively develop, manufacture and supply Factor VIIa bulk drug substance to Serendex Pharmaceuticals A/S for pre clinical and clinical studies and commercialization. CMC Biologics announced in May that it will supply the bulk drug substance [coagulation factor IX (recombinant)] for Emergent BioSolutions' recently FDA-approved product IXINITY®. The company provided the clinical supplies of the coagulation factor IX (recombinant) drug substance. CMC Biologics will also undertake the process transfer and cGMP production of RV001 (Teprotumumab), a recombinant monoclonal antibody targeting insulin-like growth factor 1 being developed by River Vision Development Corporation for the treatment of Grave's Orbitopathy and other indications (announced in July). In addition, the company announced in August that it has entered into an agreement with the PATH Malaria Vaccine Initiative (MVI) for the process development and manufacture of specific monoclonal antibodies with the potential to protect humans from malaria infection using its CHEF1® expression technology. Most recently, CMC Biologics announced an agreement with Immunocore Ltd for the process transfer and cGMP production of IMCgp100, Immunocore's lead product, at it's microbial facility in Copenhagen, Denmark, to support Immunocore's pivotal clinical trials globally.

CONTINUED INVESTMENT IN PROPRIETARY TECHNOLOGY

The CHEF1® expression technology is a proprietary mammalian expression system developed by CMC Biologics that accelerates the development of cell lines for cGMP production. Production cell lines are rapidly identified using using robust screening and cell cloning procedures. The combination of reliable raw materials, including chemically defined media and feeds, suspension adapted serum-free CHO DG44 cells, and CHEF1® expression plasmids are used to produce high levels of recombinant protein in rapid timeframes. Most notably, CHEF1 vectors do not require gene amplification to achieve high-level expression, decreasing development timelines by many months in comparison to the industry standard CHO expression systems. In addition, because methotrexate is not used, quality and regulatory concerns are reduced. The combined result is increased speed to

initiation of early clinical trials.

The 2.012 Accelerated Monoclonal Antibody Development Platform from CMC Biologics utilizes the CHEF1® expression technology and well-developed antibody production platform for rapid and seamless process development and transfer to cGMP manufacturing. With this system, 500g of a monoclonal antibody can be produced under cGMP in just 12 months from the start of CHEF1® cell line development.

As the industry migrates away from blockbuster drugs to more niche, targeted therapies, manufacturers are looking for service providers that are nimble, flexible and capable of responding rapidly to changing market demands. Recent capacity expansions at CMC Biologics' Seattle, Washington and Copenhagen, Denmark facilities totaling more than 30,000 liters are designed to meet these specific needs. The company's Bioreactor 6Pack™ manufacturing facility in Seattle was officially opened on October 1, 2015, and is currently being prepared for cGMP production of commercial supply in support of a leading customer's BLA filing and initial product launch in the United States.

A Bioreactor 6Pack™ system is also being installed at the company's Copenhagen facility. This system, which is scheduled for initial GMP production late 2015, will initially consist of a Bioreactor 3Pack™ configuration with three 2,000L single-use production bioreactors and a seed train. Three additional 2,000L single-use production bioreactors will be added at a later date to complete the Bioreactor 6Pack™ line, thereby establishing identical Bioreactor 6PackTM facilities in the US and Europe.

The Bioreactor 6Pack™ configuration consists of six 2000L single-use production bioreactors and a 2000L seed train, allowing for flexible production with scales from 2000L to 12000L in a single production suite. The bioreactors can be run in single unit operations or in groups, simultaneously, sequentially or in staggered fashion to achieve our customers' desired production needs. This innovative and flexible manufacturing approach will enable customers to meet accelerated timelines and rapidly respond to other changes in the marketplace. Furthermore, having the same unique facility design in both the US and Europe will enable CMC Biologics to optimize its process transfer capabilities and synergies between the sites, proving its clients the production scale and flexibility required to gain competitive advantage today.

"CMC Biologics remains vigilant in addressing growing market demand in Europe and the US for increasingly scalable biologics production. Combining capacity with our proprietary technologies allows us to best serve customer needs for meeting market demand for critically needed medicines. Likewise, our company maintains a healthy corporate stability and profitable growth ensuring our continued ability to invest and grow with the market," states Gustavo Mahler (pictured below)

DEVELOPMENTAL OPPORTUNITIES

Along with growing demand for clinical-stage production and commercial manufacturing services, there is a trend toward increased use of CDMOs at every earlier project stages. In line with this trend, CMC Biologics has experienced significant growth in demand for its early-stage services. The company's Berkeley, California facility is specifically designed to support Phase I/II customer projects, and an expansion is underway at the site to ensure that the future needs of its clients can be met. In addition, many current customers prefer to work under umbrella, or platform, agreements that cover multiple projects and/or pipelines.

The need to accelerate development timeline has been another focus for CMC Biologics. The company's CMC QbD (quality-by-design) Development Program allows for the definition of a Design Space earlier in the development program that considers the eventual commercial-scale process requirements. Strategies are then developed to address these critical product quality and process issues early on. While this approach requires more upfront effort, the result is a seamless transition to commercial scale.

LEADERSHIP FOR THE FUTURE

With these significant investments in innovative proprietary technologies, facility designs and capacity expansions, CMC Biologics is positioning itself to remain a leading CDMO supporting the development and commercial manufacturing of therapeutic proteins and other biopharmaceutical drug substances. Beginning in January 2016, Gustavo Mahler, currently COO for global operations, will take the helm as CEO in a long-planned transition, replacing Claes Glassell, who will remain on the board of directors. This transition is a natural development for the company and Gustavo, who will be leading the CMC Biologics Executive Team through an anticpated period of significant growth and expansion as it reaffimrs its leadership position as a biologics CDMO.