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Article Reprint • Page 1 of 2

Emerging Company Profile

JHL: Biomanufacturing solar system

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Senior Writer

JHL Biotech Inc. aims to build a network of R&D and manufacturing facilities across Asia to develop, manufacture and commercialize affordable, high-quality biologics that meet international standards. The company is developing an internal pipeline of biosimilars. It also is working with collaborators to develop both novel biologics and biosimilars, as well as offering a broad portfolio of GMP-compliant contract manufacturing and process development services.

Most biologics manufacturing facilities in China do not comply with international GMP standards and produce versions of existing biologics that are less pure than the original products and unlikely to meet international standards as biosimilars (see *BioCentury*, March 18, 2013).

By contrast, President and CEO Racho Jordanov said the biologics manufactured by JHL will meet the international quality standards set by EMA, FDA, the **World Health Organization** and other agencies.

JHL already has research and GMP-compliant manufacturing facilities in Taiwan to support preclinical and early clinical development of biologics, and is building a facility in China to do commercial-scale GMP-compliant manufac-

turing, which it expects to complete in 2015.

“Our goal in Asia is to create a solar system of biopharmaceutical facilities to

supply clinical materials around the world,” said Jordanov.

To make biomanufacturing more efficient, JHL is developing its own technologies to integrate with off-the-shelf components.

The company has adopted the FlexFactory biomanufacturing platform from the GE Healthcare unit of **General Electric Co.** FlexFactory comprises self-contained single-use technologies, such as systems that use disposable bioreactors, and computer-controlled algorithms to automate various manufacturing steps.

JHL itself is developing proprietary technologies that include cell lines and gene expression systems, as well as tools to determine the structure of a molecule and how feasible it would be for the company to manufacture it.

JHL said it will use patents and trade secrets to protect its proprietary technologies.

At least five other Asian companies are focused on GMP-compliant biologics manufacturing. These include **Celltrion Inc.** and **Samsung Group's** Samsung BioLogics unit in South Korea, and **Innovent Biologics Inc.**, **Henlius Biotech Co. Ltd.** and **WuXi PharmaTech Inc.** in China.

See next page

JHL Biotech Inc.

Zhubei, Taiwan

Technology: Biologics manufacturing with single-use technologies and proprietary cell lines, expression systems and analysis tools

Disease focus: Biomanufacturing, biosimilars

Clinical status: Preclinical

Founded: 2012 by Racho Jordanov and Rose Lin

University collaborators: Academia Sinica; University of Toronto

Corporate partners: BioLineRx Ltd.; General Electric Co.; Selexis S.A.

Number of employees: Under 60

Funds raised: Undisclosed

Investors: Burrill & Co.; China Development Investment Bank; Kleiner Perkins Caufield & Byers; Sequoia Capital

CEO: Racho Jordanov

Patents: None issued

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Emerging Company Profile,
from previous page

According to Jordanov, JHL's key employees set it apart from its competitors. The company has just under 60 employees, with more than a dozen having worked at large biopharmas such as **Amgen Inc.** and **Genentech Inc.**

The management team has extensive experience working not only in key Asian markets such as China, Taiwan and Singapore, but also in Europe and North America.

Prior to JHL, Jordanov was senior director of Singapore operations at Genentech. He had been with the company for over two decades.

JHL has five in-house biosimilars in preclinical development but is not disclosing the innovator comparators. The two most advanced are JHL1101 for cancer and autoimmune diseases and JHL1921 for cystic fibrosis (CF). The company expects to file INDs for both candidates in 1H15.

JHL also has JHL1147 and JHL1188 for cancer and JHL1227 for autoimmune diseases.

The company has not yet selected the regulatory agency where it will file its INDs. While JHL initially will focus on marketing its biosimilars in China and other key Asian countries, Jordanov said the company intends to expand to markets around the globe.

JHL also is busy on the partnering side. Over the next 24 months, the company expects to manufacture the first biosimilar under its collaboration with **Selexis S.A.** and to complete preclinical studies on diabetes candidate BL-9020 with partner **BioLineRx Ltd.**

BL-9020 is a mAb inhibitor of natural cytotoxicity triggering receptor 1 (NCR1; NKP46; CD335).

JHL raised an undisclosed sum in a series A round and has received grant funding from the Chinese government. It has also secured an undisclosed amount in loans from several European banks.

Jordanov said JHL's aggregate funds should carry the company until it is cash flow-positive, which it expects to achieve in 2016. He noted the company plans to raise additional funds before then, but declined to give details.

COMPANIES AND INSTITUTIONS MENTIONED

Amgen Inc. (NASDAQ:AMGN), Thousand Oaks, Calif.

BioLineRx Ltd. (Tel Aviv:BLRX; NASDAQ:BLRX), Jerusalem, Israel

Celltrion Inc. (KOSDAQ:068270), Incheon, South Korea

Genentech Inc., South San Francisco, Calif.

General Electric Co. (NYSE:GE), Fairfield, Conn.

Henlius Biotech Co. Ltd., Shanghai, China

Innovent Biologics Inc., Suzhou, China

JHL Biotech Inc., Zhubei, Taiwan

Samsung Group, Seoul, South Korea

Selexis S.A., Geneva, Switzerland

World Health Organization (WHO), Geneva, Switzerland

WuXi PharmaTech Inc. (NYSE:WX), Shanghai, China