Translational triumvirate

By Michael J. Haas, Senior Writer

Although the **Southern Research Institute** and **The University of Alabama at Birmingham** have worked together on discovery research and preclinical development projects for the past decade, the collaborators—like most research institutions—lacked the financial resources to take promising candidates into the clinic by themselves. The two Alabama-based organizations are looking to change that situation by forming a joint venture with the Indian research and manufacturing services company **Jubilant Organosys Ltd.**

The partners think the JV will develop potential therapies further and faster than any of the entities could do alone.

The JV will be tasked with taking therapeutics for cancer, infectious disease and metabolic disorders from discovery through Phase II testing, at which point it will seek out-licensing agreements, John Secrist III, president and CEO of Southern Research, told *SciBX*.

In 1999, UAB and Southern Research partnered to combine the university's target discovery research with the institute's preclinical discovery and development capabilities, according to Richard Marchase, VP for research and economic development at UAB. "Our investigators have discovered potential targets for drug therapies, and Southern Research has the preclinical development expertise that we lack," he said.

"Southern Research is strong in chemistry, and our approved drugs all arose from ideas and discovery initiatives started by our chemists," said Secrist. He said the preclinical team can address activity and selectivity of compounds, including both *in vitro* and *in vivo* evaluations, as well as mechanism-of-action studies.

Indeed, Southern Research has discovered or co-discovered seven approved cancer therapies, including clofarabine, a second-generation purine nucleoside analog that inhibits DNA polymerase and ribonucleotide reductase to treat relapsed or refractory acute lymphoblastic leukemia (ALL) in pediatric patients, and Folutyn pralatrexate (PDX), a small molecule that inhibits dihydrofolate reductase (DHFR) to treat peripheral T-cell lymphoma (PTCL).

Although Southern Research has provided seed capital to help the university move its discoveries along the drug development path, Secrist and Marchase said neither organization has had sufficient funds to take compounds into the clinic. Thus they began seeking a third party in the private sector.

The two institutions were introduced to Jubilant in 2007 when a former U.S. government liaison to India, whose father was a UAB faculty member, recognized the potential for a collaboration. Southern

Research and UAB concluded that Jubilant had the capital and the capabilities—including medicinal chemistry—they were looking for, according to Marchase.

"We have a large group of medicinal chemists—about 450—that allows us to do chemistry on a scale not available at UAB or Southern Research," said Sri Mosur, president and CEO of global drug discovery and development at Jubilant.

Secrist said the JV would involve 6–8 of the 30 chemists at Southern Research.

"We will assist in the oversight of chemistry that occurs both at Southern Research and at Jubilant in India," he said. "One of Jubilant's strengths is that it has a lot of laboratory chemists. We can take a drug compound that we've identified at Southern Research or UAB with high throughput screens, chemical synthesis and maybe even preclinical studies, and Jubilant can do the lead optimization" more cheaply than it could be done in the U.S.

Jubilant's drug discovery partnerships include **Amgen Inc.**, **AstraZeneca plc**, **Eli Lilly and Co.** and **Endo Pharmaceuticals Holdings Inc.** In those deals, the Indian company is turning discovery-stage compounds from the pharmas into preclinical candidates. Under the Lilly and Endo deals, Jubilant also will co-develop any clinical candidates.

Jubilant will own 50% of the JV, with Southern Research holding a 25% stake and the remaining 25% owned by the **UAB Research Foundation**, said Marchase. Ownership of any new IP generated by the JV would be split along those lines in most cases, he said.

Secrist said the partners are in the process of selecting specific indications, disease targets and therapeutics to pursue. "We will select maybe two projects per year to push forward," he said. "In a few years we expect to reach an equilibrium of four to five active projects."

Within three years, Secrist said the JV hopes to have two compounds in clinical testing.

Genzyme Corp. has rights to clofarabine from Southern Research and markets the drug as Clolar in the U.S. and Canada and as Evoltara in the EU, Australia and New Zealand.

Allos Therapeutics Inc. has rights to Folutyn from a partnership between Southern Research, **SRI International** and **Memorial Sloan-Kettering Cancer Center**.

Haas, M.J. *SciBX* 2(47); doi:10.1038/scibx.2009.1718
Published online Dec. 10, 2009

COMPANIES AND INSTITUTIONS MENTIONED

Allos Therapeutics Inc. (NASDAQ:ALTH), Westminster, Colo.
Amgen Inc. (NASDAQ:AMGN), Thousand Oaks, Calif.
AstraZeneca plc (LSE:AZN; NYSE:AZN), London, U.K.
Eli Lilly and Co. (NYSE:LLY), Indianapolis, Ind.
EndoPharmaceuticals Holdings Inc. (NASDAQ:ENDP), Chadds Ford, Pa.
Genzyme Corp. (NASDAQ:GENZ), Cambridge, Mass.
Jubilant Organosys Ltd., Noida, India
Memorial Sloan-Kettering Cancer Center, New York, N.Y.
Southern Research Institute, Birmingham, Ala.
SRI International, Menlo Park, Calif.
UAB Research Foundation, Birmingham, Ala.
The University of Alabama at Birmingham, Birmingham, Ala.