Orleans Record

Huge Opportunity For Gene Therapy Research At AnC Bio, Scientists Say

JAY — AnC Bio Vermont is poised to take advantage of a huge global demand for gene therapy manufacturing facilities.

Scientists from across the globe met this week at Jay Peak Resort to talk about the opportunity at AnC Bio Vermont, expected to be built and operational in 2017, to add gene therapy to its current business plans to manufacture adult stem cells for medical uses.

There's plenty of science about gene therapy, but finding enough manufacturing space is very hard, said Professor Chris Mason of The Advanced Centre for **Biochemical Engineering at University** College London, a globally recognized authority of gene and cell therapy. "That's where Jay Peak's facility is very important," Mason said Friday morning. "There's a huge global shortage" at a time when there is "massive" demand, he added. "The opportunity here is phenomenal." "That capacity doesn't currently exist," said Gregory Bonfiglio, a managing partner of Proteus Regenerative Medicine in Portola Valley, Calif.

Bonfiglio and Mason were at Jay Peak with a team gathered to help AnC Bio Vermont design a gene therapy manufacturing operation. They and others spoke with The Record Friday morning.

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Greg Bonfiglio, CCRM Chair, Board of Directors

Bonfiglio wants AnC Bio Vermont to help fill a "significant market need." He is chairman of the board of the Centre for Commercialization of Regenerative Medicine in Toronto, which works with researchers from around the globe. They are doing the first and second phases of clinical trials in regenerative medicine or gene therapy in Toronto.

But the center does not have a location to do the next phase and manufacturing, Bonfiglio said. "AnC Bio represents a wonderful opportunity to manufacture it," he said. "There is no capacity in Montreal or Toronto." AnC Bio Vermont is a major development for Bill Stenger, President and CEO of Jay Peak Resort, fueled through the EB-5 foreign investment program. It's rural location near a growing airport and the U.S.-Canadian border is considered a plus.

Construction of the four-story AnC Bio Vermont facility began last year, with ground preparation and underground utilities in place. Then construction stopped at the former Bogner plant site while AnC Bio Vermont updated its business plan with the changing global biotech field. The company will also rent clean rooms to scientists for research, manufacture adult stem cells and make artificial organs.

And that slow-down in construction has allowed AnC Bio Vermont to include gene therapy manufacturing, said AnC Bio Vermont partner Bill Stenger, CEO of Jay Peak Resort, and AnC Bio counsel Bill Kelly said. "The timing is incredible," Mason said. Bonfiglio agreed. The research trials underway at the Toronto center will be ready for the next phase in two years, just as AnC Bio Vermont opens, he noted. "It works well for our timing," he said.

Vincent Narbut with Biologics Consulting Group will help AnC Bio Vermont seek FDA approval for the adaptation of the company's plans. AnC Bio Vermont when built will be at the forefront for decades and decades, Mason said. Mason and Bonfiglio waxed poetic about the potential for gene therapy to tackle gene-driven cancers like leukemia and some single-gene diseases like hemophilia and cystic fibrosis. "We are in a period of great transition," Mason said. "I wouldn't be here if I didn't passionately believe in this."

Patients with some cancers and diseases today die or manage to live while

dependent on taking very costly drugs every day with side-effects. In the future they could receive a one-time therapy treatment that could either cure the disease or allow a patient to live a very long life in a durable remission, Mason said. Adult stem cell therapy involves replacing some of the cells in a human's body, he said. Gene therapy is like changing the program in cells, he said.

While AnC Bio Vermont developers finetune the business plan and prepare to renew construction in April or as soon as weather will allow, Stenger said the push will begin to attract future employees from Vermont's career centers, colleges and University of Vermont. Now is the time, Stenger said, to help these institutions build their programs so graduates will have a career at AnC Bio Vermont.