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## Promedior

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### Little Promedior aims big in new approach to fibrosis

For a little start-up, Promedior is aiming at a very big therapeutic target.

The two-year-old, Malvern, PA-based biotech company only just completed an extended \$14 million first round a few days ago. Now it's preparing an ambitious early-stage program tackling fibrosis; chronic scarring associated with multiple types of organ failure.

"It's estimated that 45 percent of all deaths are related to fibrotic changes," says Tim Pelura, the CEO of Promedior. "The approach that most folks have been taking is targeting a single cytokine or growth factor and not taking a broader picture."

Which is where Promedior comes in.

Typically, the body responds to wound healing by cleaning the wound, debris and bacteria and then laying down scar tissue to close it. In fibrosis, says Pelura, repeated injury or chronic inflammation triggers a continual healing process with repeated scarring, which in turn can lead to the failure of organs -- including lungs, hearts, livers and kidneys.

"Our approach is targeting multiple cellular phenotypes that show up at the site of injury as opposed to single cytokines," says Pelura. Therapies that currently target those single cytokines, he adds, can be overwhelmed when other cytokines kick in and start doing the same damage.

"Our approach is that we shift the cell types that show up at the site of the wound," he adds. "It's a totally new paradigm in the treatment of disease. We're delivering a protein -- serum amyloid p, or SAP -- that we identified as a switch between scarring and healing."

The scientific basis for this program winds back to the lab work of Richard Gomer and Darrell Pilling at Rice University, who are both on the company's scientific advisory board. They found that when you depleted SAP you caused bone marrow derived cells to show up at the site of injury and produce collagen, "the main component of scarring. This presented a whole new piece of understanding that this protein has a role in the fibrotic process. This protein orchestrates the type of microphage that shows up at the wound. It also is dominant over the traditionally accepted cytokines in the fibrotic process."

Put another way, by introducing the protein into the blood stream, there's preclinical evidence to suggest that it can prevent fibrosis involved in a whole range of diseases like CHF, diabetic nephropathy and pulmonary fibrosis. For Promedior, it means that the company can ramp up programs for a slate of diseases, with a potential licensing deal for each.

Pelura is already engaged in discussions to in-license a related development program, which will give the company a full set of projects to work on for the foreseeable future. He's also already looking to his second round of venture capital, which he expects to close in the summer.

"It will be a significant raise," says Pelura, the former chief technology officer in charge of R&D at Kereos. But he sounds confident that he can get it done. And while he isn't throwing out numbers publicly, he says it will be enough to get his initial program through Phase IIa with a second program ramped up.

"Our investors are big," he says, "and they love the space. We're not in a position to be hurting for money." Polaris Venture Partners, Morgenthaler Ventures, HealthCare Ventures and Easton Capital were all involved in the first round.

"We'd like to come out of 2009 with some really good indicators of activity," says the CEO. "There are so many great tools to follow surface markers on cells and various plasma-borne biomarkers, we're in a position to show drug activity before we even see efficacy."

For now, Pelura is focused on getting a Phase I/II trial wrapped by the end of the year. "We intend to go into a program that not only establishes safety in healthy volunteers but also shows broad activity in various subsets of fibrosis patients."

Pelura wants to complete the in-licensing deal by the summer and get his second round investors signed up for the second stage of development -- much of which will be outsourced. Promedior has a semi-virtual staff of about 15 employees right now, and Pelura doesn't expect it to grow much beyond 25 or 30 during the entire start-up phase through proof of concept. Jay Getsy, a former senior director at Centocor, was recently named vice president of clinical research and development.

Because Promedior's science relates to a variety of ailments, the biotech has the potential to license out several programs while advancing one or two of its own into a late phase. After that, he says, success is likely to lead to a buyout.

Says Pelura: "If you truly have breakthrough technology and you're generating data, the likelihood of an acquisition is pretty high."

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