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ProNAi raising VC to fund phase-two cancer studies, looks to possible sale

By Tom Henderson

As a result of what it is considers an excellent outcome from a recent phase-one study of its leading cancer drug, **ProNAi Therapeutics Inc.** of Plymouth Township is raising \$5 million in venture capital to fund two phase-two studies and pave the way for a possible sale next year.

Company President and CEO Mina Sooch said if those studies go as expected and produce similar results to those from the phase-one study, the company could be sold in the third or fourth quarter next year to one of the pharmaceutical companies to which she has been talking. ProNAi is a pre-revenue company, and the goal is to sell it to a large pharmaceutical firm.

President and CEO Mina Sooch said potential buyers of ProNAi Therapeutics Inc. are waiting to see study results for the company's leading cancer drug.

"I've met with more than 20 pharmaceutical companies, and they're awaiting results," Sooch said.

The first of the phase-two studies began before Christmas at **St. John Providence Hospital** on the east side of Detroit. The principal investigator on that study of nine-15 patients with non-Hodgkin's lymphoma will be Ayad Al-Katib, M.D.

The second of the phase-two studies, of six to nine patients with a subset of non-Hodgkin's lymphoma, will occur this year at a site or sites to be determined.

The phase-one study, of 22 patients with a variety of solid-tumor cancers, was conducted in Texas, and results were presented in November at the annual Symposium on Molecular Targets and Cancer Therapeutics in Dublin. The symposium was hosted by the **European Organization for Research and Treatment of Cancer**, the **National Cancer Institute** and the **American Association for Cancer Research**.

Phase-one **U.S. Food and Drug Administration** studies are designed to test safety only. ProNAi's drug, with the working name of PNT2258, showed little or no toxicity, which is extremely rare for a cancer drug.

The "NAi" in the company's name comes from the industry term "DNAi," which is short for DNA interference, a way of using single strands of DNA to target specific disease-causing genes, in this case the gene BCL-2, which produces a cancer-causing protein.

The company was founded in 2004, though it traces its history to 2001 and to the work of Reza Sheikhnejad, a scientist at **Wayne State University** and the **Karmanos Cancer Institute**.

WSU and Karmanos declined to pursue patents on Sheikhnejad's work, so he funded a patent himself and assigned it to ProNAi, an early portfolio company of **Apjohn Ventures** in Kalamazoo.

Sooch was a co-founder at Apjohn who closely monitored ProNAi's progress over the years and helped it with fundraising, which has reached about \$20 million, much of it from angel investors and about \$5 million from the state of Michigan.

Sooch, a member of the 2007 class of Crain's 40 Under 40 and chairman of the Ann Arbor-based **Michigan Venture Capital Association** in 2009-10, replaced current board member Charles Bisgaier as president and CEO in July. In May, the company had moved its headquarters from Kalamazoo to the **Michigan Life Science and Innovation Center** in Plymouth Township.

While researchers in the phase-one study were monitoring patients for would-be side effects of PNT2258, they also noticed signs of efficacy in many patients, and dramatic benefits in some patients, said Richard Messmann, ProNAi's chief medical officer and designer of its studies.



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Messmann is a former deputy associate director at the National Cancer Institute, former director of cancer research for the **Great Lakes Cancer Institute** at **Michigan State University** and, most recently, vice president for medical affairs at West Lafayette, Ind.-based **Endocyte Inc.**, which went public in February 2011.

Benefits included decreased white cell counts, a reduction in activity by the protein produced by BCL-2, and either the shrinking of some tumors or a halt in the growth of tumors that would normally be expected to grow, he said.

The results were so good, and so surprising, that they caught the eye of a noted **Harvard University** researcher and professor, Bruce Zetter, who has since joined ProNAi as a scientific adviser. Zetter is the Charles Nowiszewski Professor of Cancer Biology at Harvard University and chief scientific officer and vice president for research at **Children's Hospital Boston**, **Harvard Medical School**'s pediatric teaching hospital.

"I'd heard about the company and knew they were doing novel things, but there are a lot of companies out there doing novel things," said Zetter. He was introduced to ProNAi's work a year ago by its vice president of product development, Wendi Rodrigueza, a former scientist at Ann Arbor-based **Esperion Therapeutics Inc.**, the maker of a successful cholesterol drug that went public in 2000 and was bought by **Pfizer Inc.** in 2003.

Rodrigueza designed the fatty liposome coating for PNT2258 that is at the heart of PNT2258's success in animal and human trials. Most cancer drugs are so toxic they can't be put into the bloodstream for fear of causing systemic damage. They are put directly into tumors, but they then miss other cancer cells that may be circulating in the system.

Messmann said the fatty coating keeps the drug from being attacked by white blood cells in the blood and later helps the drug penetrate the surface of tumors and cancer cells when it finds them.

"When they got their safety data, that's when I really got interested in the company," said Zetter. "Historically, cancer has been attacked with broad-acting poisons with strong side effects, like hair loss, stomach problems and anemia. ProNAi has been able to use small pieces of DNA to bind to genes without side effects.

"And they got efficacy, too, which you don't usually get in phase one. It's a company poised to do really good things. There aren't any competitors in their space, and it's a platform technology that will allow them to target many other genes and, consequently, many other cancers."

Sooch said that if the company isn't sold after the next two small phase-two studies, she plans to raise \$10 million to do a much larger study of 90-120 cancer patients at 20-25 centers here and abroad.

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