

Ascenta ascending

Company is a model of efficiency for the drug development industry

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Peer into the biotechnology industry's crystal ball, and the shape you see might look a lot like Ascenta Therapeutics.

The privately held San Diego biotech follows what is rapidly becoming the favored model for fashioning a drug discovery company. A lean and nimble management team. An academic partnership with a university that provides access to potential drugs developed in part on federal grant dollars. And an offshore research unit in a low-cost country.

"Efficient" is a favorite word – almost the mantra – of Ascenta's chief executive officer, Mel Sorensen.

"We've raised about \$35 million in venture capital, and with that we've gotten our lead drug candidate into Phase 2 clinical trials and we have two more drug candidates headed toward the clinic," Sorensen said. "That is a very efficient model compared to anything else we've seen."

Ascenta is different from the sprawling drug discovery and platform technology companies that at one time dominated the industry.

Then, biotechs could raise massive amounts of cash by going public, and then built large research labs teeming with scientists and projects.

But it proved a profligate process, according to the Tufts University Center for the Study of Drug Development. The average cost of delivering a novel new drug rose to \$800 million, and it took more than a dozen years to get a drug from lab bench to pharmacy shelf, according to a Tufts study.



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Executives at Ascenta Therapeutics, a San Diego biotechnology company that is developing cancer drugs, conduct a business videoconference with employees at its Shanghai research unit.

“A lot of investors poured money into these large drug discovery companies, where there was lots and lots of work done but not a lot of medicines came out of it,” Sorensen said. “The \$800 million gorilla is the old way of doing things.”

Wall Street, burned by a number of failed biotechs that went public in 2000 during the frenzy over the mapping of the human genome, has cooled on early-stage drug discovery companies.

Companies such as Ascenta, which is developing cancer drugs, have had to find new ways of getting things done using fewer dollars. That means a new wave of biotechs are keeping molecules in government or academic labs longer, nursing them along in “virtual” startup companies run by small management teams and farming out development work to scientists in cost-efficient countries.

In Ascenta's case, the biotech startup forged a fruitful collaboration with the University of Michigan, which works closely with Ascenta's administrative and research group in San Diego and its research subsidiary in Shanghai, China.

Ascenta was formed in late 2003 with \$5.5 million in venture capital funding and some promising drug candidates licensed from the University of Michigan and the National Cancer Institute.

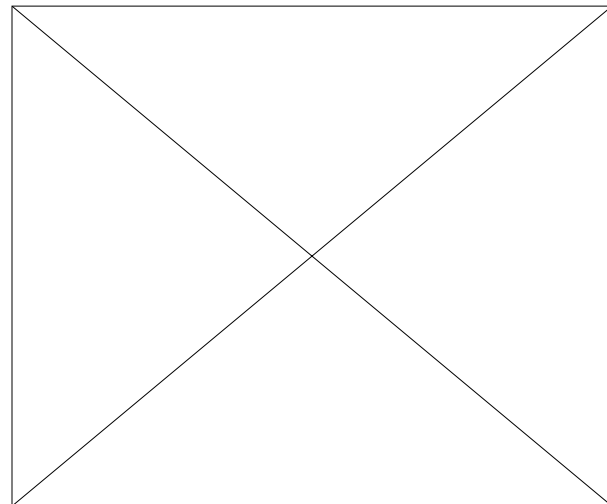


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Ascenta Therapeutics' AT-101 is being developed as a potential treatment for non-Hodgkins lymphoma and other cancers.

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For a time, Ascenta remained in near “virtual” mode, with fewer than five employees and most of the research done at the University of Michigan laboratories of its three scientific founders, Dr. Marc Lippman, Dr. Dajun Yang and Shaomeng Wang.

The Michigan scientists provided Ascenta with several potential compounds designed to trigger apoptosis in cancer cells. Apoptosis is the process of cell death that occurs when a cell develops mutations; in cancer cells, the signaling mechanisms that trigger cell death don't work as they should, allowing cancer cells to grow unchecked.



The academic alliance proved so productive that Ascenta found itself with a problem – how, with tight financial resources, was it going to evaluate and build its growing pipeline of drug candidates while moving its lead drug, AT-101, into the clinic?

Much of the solution came from Ascenta's wholly-owned subsidiary, the Ascenta Shanghai R&D Center, where early-stage chemistry and biology work can be done far more cheaply than in the United States.

In 2004, Ascenta raised \$30 million in additional venture capital, and Yang left his academic post to join Ascenta, using his business and scientific connections in China to help create the Shanghai unit.

Ascenta's Shanghai subsidiary is staffed by 15 scientists educated in the United States or Europe who have returned to China. In most cases, the researchers also have been employed in pharmaceutical or biotech companies in the United States.

Today, the drill for Ascenta goes something like this: Wang's University of Michigan lab produces classes of drug compounds. Those are sent for evaluation to the Ascenta Shanghai subsidiary.

Work is done back and forth between Ascenta's San Diego and China units and the University of Michigan. Once a promising drug candidate is identified, it is handed off to Ascenta's San Diego management and clinical development team.

Among the potential treatments that have emerged from the three-pronged business model is AT-101, which is being tested in Phase 2 trials for the treatment of chronic lymphocytic leukemia, non-Hodgkin's lymphoma and prostate cancer.

The oral drug is designed to trigger programmed cell death of cancer cells by inhibiting the activity of a pool of proteins that are necessary for cancer cell survival.

Sorensen said such novel oral cancer drugs are taking "center stage" in a new era of more targeted therapies for cancer patients. Unlike infused biological drugs, oral agents are more convenient and allow for more effective drug combinations, he said.