Boca biotech firm Nabi primes for shot as vaccine player

By Stephen Pounds
Palm Beach Post Staff Writer

Monday, February 14, 2005

BOCA RATON — Nabi Biopharmaceuticals is the little pharma that could.

Palm Beach County's largest biotechnology firm is tiny compared with Merck or Pfizer, but in a state where life-science companies are more like poor dot-coms Nabi is an example of what's possible even in a modest biotech outpost like Florida.

"They're kind of like an anchor tenant at the mall," said Caroline Popper, a Sarasota-based biotech consultant. "They're a flagship biotechnology company for the state."

With four drugs on the market and $177 million in sales in 2003, Boca Raton-based Nabi is one of Florida's few biotech firms with name recognition outside the state. Now it faces a crucial year as it completes a conversion to drug maker from blood plasma supplier.

"Nabi is really a company in transformation," Chief Executive Officer Tom McLain said recently.

During the next 12 months, Nabi hopes to:

• Complete clinical tests on patients to prove that its StaphVAX is a safe vaccine against common staph infections. With those results, Nabi will be armed for fast-track review by the U.S. Food and Drug and Administration.

• Gain approval from Europe's equivalent of the FDA to market StaphVAX overseas. With approval, Nabi can launch marketing campaigns in the 25 member-countries of the European Union.

• Finish a $20 million project to add 11,500 square feet of production space in its Boca plant. Then, Nabi can hire more workers here for drug production.

• Show positive test results that its drug to quit smoking, NicVAX, is effective in higher doses. Initial tests have found it superior to other smoking-cessation treatments.

"It's a stretch goal," McLain said of the firm's ambitious plans. "It's a very aggressive stretch goal."

Nabi, with 700 employees, is working hard to become a player in the vaccine business. While it markets four drugs, it developed only one of them, and that's an improved version of a drug it acquired. Now it's developing StaphVAX and NicVAX vaccines and two other drugs on its own.

It's a bold move for a company that from its 1969 start until 1998 was a plasma collector. And it can take 10 to 15 years to bring a new drug to market. However, if successful, the new vaccines have the potential to be a windfall. StaphVAX alone could yield the company $1 billion a year in new sales.

Last year, the FDA decided StaphVAX would solve an unmet medical need and designated it for fast-track review. If granted FDA approval, StaphVAX would be the first vaccine against staph infections that have grown resistant to other medicines.
"StaphVAX is the primary driver of this company," said analyst Dallas Webb of the Stanford Group in Boca Raton.

Anti-smoking drug promising

To develop NicVAX, Nabi received a $4 million research grant from the National Institutes of Health in 2000. The vaccine causes the immune system to produce antibodies that soak up nicotine and deaden the craving to smoke.

Nabi's most recent study showed one-third of patients who took NicVAX quit smoking, compared with 9 percent of patients who quit after receiving a placebo. When the latest study results were released, on Sept. 28, investors took notice. Nabi's stock price jumped $1.79 a share to $13.48 and traded at 10 times normal volume. On Friday, the stock (Nasdaq: NABI) closed at $13.09.

The company is testing the anti-smoking drug at a higher dose, and that study will be finished in the second half of this year.

If NicVAX works, Nabi is likely to take on a partner to sell it. The target market would be family practitioners — a group that's typically the territory of pharmaceutical giants and too large for Nabi.

"You'd need a sales force of 3,000, and Nabi's not going to build a sales force of 3,000," said analyst Thomas Shrader of Harris Nesbitt Girard.

Both new vaccines could be produced at Nabi's Boca plant. Its drug production now is done by outside manufacturers except for Nabi-HB, its treatment to neutralize the hepatitis B virus, which it makes in Boca Raton.

Nabi has other drugs in the pipeline at early stages. Right now, the company does most of the research and development at its laboratory in Maryland. But with the planned expansion of The Scripps Research Institute to Palm Beach County, the company will shift more of that work to Boca.

"Without Scripps, we wouldn't fracture our emphasis," CEO McLain said. "Now, there's a local collaboration opportunity that didn't exist before."

It's too early to tell what Scripps and Nabi might work on together, but it's likely to be immunology — the branch of medicine dealing with immunizing against diseases.

"That's our sweet spot," McLain said.

1995 brought big change

Though only a small part of Nabi's business today, blood plasma collection was the mainstay of its predecessor, North American Biologicals Inc., when the company was formed in Miami more than 35 years ago.

The company changed owners and went through ups and downs until 1984, when an executive from Abbott Laboratories, David Gury, was named CEO. Gury wanted to get out of the plasma business. So in 1995, he took the company in a different direction.

That same year, Nabi moved to Boca and bought Univax Corp., a Rockville, Md.-company with a promising drug pipeline. It had one drug on the market and held distribution rights for WinRho, a treatment for a blood disorder that disrupts clotting.

By that time, the company was known by the acronym NABI.

"In Hebrew and Arabic, it means prophet or foreteller, someone who looks to the future," Gury said. "I thought it fit well."

By the late 1990s, plasma firms like Nabi were feeling pressure from government regulators to do better at detecting AIDS and hepatitis C. Two large plasma refineries went out of business, and suppliers found fewer buyers. It created a glut of raw plasma and pushed Nabi closer to making pharmaceuticals.

In 2001, Nabi sold 47 plasma collection centers for $153 million. It used the proceeds to reduce debt but left some cash in reserve. The company still maintains a strong cash position but it has lost money from operations in the past two years as it plowed profits back into its vaccine development.

"You have to give the management team credit for moving away from low-margin plasma and into biotech," said Mel Rothberg, executive vice president of Viragen in Plantation. "They have a (drug) pipeline that seems to be on track."

PhosLo gains in importance

After Nabi dumped much of its plasma business, McLain succeeded Gury as president in 2002. A year later, he became CEO, and last year when Gury retired added board chairman to his responsibilities. Seven years ago, McLain came from the eye care firm, Bausch &
Lomb in New York, where he was in charge of finance and had cleaned up major accounting problems.

Together, Gury and McLain brought three drugs to market: WinRho; PhosLo, a capsule that reduces dangerously high phosphate levels in the blood; and Aloprim, a drug to counter the buildup of uric acid that can lead to kidney failure in leukemia and lymphoma patients.

Last year, Nabi learned that WinRho would revert to its owner, Cangene Corp., next month. Instead of Nabi, Cangene gave the rights to sell WinRho in the U.S. to its European distributor. It was an unexpected blow because Nabi used WinRho to finance the company's drug pipeline.

"They were confident they weren't going to lose the contract, but they were wrong on this one," Harris Nesbitt Girard's Shrader said.

The loss of WinRho makes PhosLo that much more important. Nabi is marketing it to kidney dialysis centers in the U.S. and has applied to sell it in Europe. The company has made PhosLo a precursor to selling StaphVAX.

"The acquisition of PhosLo was a real great move. It gets their sales force into renal dialysis centers, where they'll be marketing StaphVAX," said Oren Levy, a biotech consultant with White Mountain Capital in Nanuet, N.Y.

While Wall Street and industry observers credit Gury for Nabi's transformation strategy, they give McLain high marks for moving it forward and reminding Wall Street when milestones are reached.

"He's an execution guy and Nabi is an execution story," analyst Shrader said.

To be sure, McLain will have his hands full this year getting StaphVAX and NicVAX vaccines through critical patient trials and finishing revamping the Boca plant, Stanford Group stock analyst Webb said.

"I'd characterize (Nabi) as one of the most exciting biotech companies in the country," Webb said. "We think 2005 is going to be a pivotal year."