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Back from the brink

After a few rocky years Francois Nader found winning strategy for NPS

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Francois Nader, president and chief executive of NPS Pharmaceuticals in Bedminster, helped revive the company in 2006.

When Francois Nader arrived at NPS Pharmaceuticals in 2006, the company was reeling from a major drug development setback, a shortage of money and serious questions about its future.

Nader, who filled dual roles as chief medical officer and chief commercial officer, helped to stop the cash burn and then provided management and the board of directors with a plan to repair the business.

"The company was in a state of shock," Nader said recently, "and it became clear it had to do surgery quickly."

If the bet NPS is making on its two drugs pays off, it will be the culmination of a calculating turnaround strategy set in motion nearly five years ago by Nader, who applied his experience in investment banking and an understanding of science from years of managing drug research to revive the company's drug-making ambitions.

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High hopes for the company's medicines, which could become the only available treatments for two rare diseases, have pushed its shares up more than 100 percent during the past year.

That isn't to say there aren't still potential pitfalls. In the pharmaceutical business, even a prospective drug that advances to late-stage development — as the pharmaceutical giant Merck found out earlier this month — is susceptible to disappointing setbacks.

For NPS, a costly stumble sent the company on a new course.

In 2006, three months before Nader arrived, the Bedminster-based drugmaker was anticipating regulatory approval for Preos, a new treatment for the bone-deteriorating condition osteoporosis. Instead of approving the drug, federal regulators said they wanted more information to explain why patients were developing hypercalcemia — too much calcium in the blood — at certain doses.

To produce more data, NPS would have to complete another expensive, time-consuming study and submit the results to the Food and Drug Administration. "The company did not have the cash to do additional studies," said Nader, 54. who became CEO in 2008. "Most of its resources were tied up with Preos."

KEEPING COMPANY TOGETHER

NPS quickly generated $275 million by divesting other products in its pipeline. It slashed employees, reducing a work force that had ballooned to 400 to just 19 people before increasing it, gradually, to its present 65. It also closed facilities, including research laboratories and its original headquarters in Salt Lake City.

"The immediate concern was how to keep the company financially solvent," said Michael Bonney, a pharmaceutical executive who sits on the NPS board of directors, "and then how do we craft a business."

Nader, whose experience in the pharmaceutical business was spent largely in research and development, went through the company's entire pipeline — one product at a time — to determine its best prospects.

"It became clear to me, very quickly, that we had interesting assets," he said.

He set about proposing a strategy focused on developing medicines for rare diseases — in the industry, they're called orphan drugs — and outsourcing such things as research and regulatory affairs in order to reduce operating costs.

IMPORTANCE OF TWO PRODUCTS

The company bet its future on two drug candidates that fit Nader's strategy. The ambitious osteoporosis medicine NPS had tried to push out in 2006 was repurposed as a treatment for the rare hormone deficiency disorder called hypoparathyroidism. The disorder, which usually results from injury to the parathyroid gland during surgery, leaves patients unable to regulate the calcium and phosphates in their blood. The drug is referred to now as NPSP558.

The company also pulled its proposed treatment for short bowel syndrome, a drug named Gattex, off the back burner so it could accelerate its development.

One of the company's saving graces — a cushion to help stabilize the business — is a stream of royalty revenue from products it has licensed out to other drugmakers.

One of the largest of the agreements was forged with biotech powerhouse Amgen around Sensipar, a drug for secondary hyperparathyroidism. Patients with the condition produce extra parathyroid hormone because their calcium levels are too low. In 2009, the licensing agreement with Amgen generated $64.5 million in royalties for NPS, according to regulatory documents filed with the Securities and Exchange Commission.

Two years after his arrival, with CEO Tony Coles leaving for another drug company, the board named Nader to take the corner office. "We had no reservations," said Peter Tombros, the company's non-executive chairman and a longtime director. " He had won our confidence."

"He is the architect of what we have today," Tombros said. "He was the one who had to lead the way for all of the deliberations we went through."

ROAD TO RECOVERY

Since 2006, NPS Pharmaceuticals has:

- Whittled payroll from 400 to 19; it now stands at 65
- Raised $275 million by divesting products and properties
- Outsourced parts of business, including research and development
- Narrowed product focus to two promising drugs for rare diseases

PROJECTED SALES

Data from the late-stage clinical trials of Gattex are due out next month, and if the results are positive, the company expects to file for marketing approval from the FDA later this year.

Late-stage study results on NPSP558, the proposed treatment for hypoparathyroidism, are expected to be out by the end of 2011.

If everything goes according to plan, the company expects to file for regulatory approval next year.

By 2013, NPS could have two products on the market. Wall Street projects annual sales of Gattex to reach $300 million. The second drug, NPSP558, is expected to have annual sales of at least $100 million, according to analysts.

Nader's strategy isn't so difficult to grasp. While the patient populations for orphan drugs are smaller — NPS estimates there are only about 15,000 patients in the United States with short bowel syndrome, for instance — there will be immediate and high demand for a new medicine.

"What's attractive are the higher margins," said Alan Carr, an analyst with Needham & Co. "You need a limited sales force because there aren't as many physicians to see and the development track is more quick."

Wall Street is eagerly awaiting results of the late-stage study data on Gattex, which will provide the clearest signal yet about whether the company has made a good bet.

In anticipation of those results, Wall Street pushed the company's stock up to $7.39 a share from $3.28 a share, a 125 percent jump.

"The biggest hurdle will be whether they get good data from the phase three trial," Carr said. "It's a key event for the company."

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