

## Local ties assist new Pfizer drug

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**Pfizer Inc.** is getting ready to launch what it hopes will be its next blockbuster: a new insulin product for diabetics that can be inhaled rather than injected.

Behind the scenes, two local companies played key roles in the development of Exubera, which just secured Food and Drug Administration approval.

**Plexus Ventures** in Maple Glen brokered the partnership of **Nektar Therapeutics**, which initially developed the drug, and Pfizer, which had the deep pockets needed to get the product through the regulatory approval process.

Meanwhile, a subsidiary of **West Pharmaceutical Services** in Lionville helped create, and will continue to make, the delivery system that will be used by patients taking the drug.

Exubera is a rapid-acting, dry-powder insulin designed to be inhaled into the lungs prior to each meal.

With more than 18 million people suffering from diabetes in the United States alone, many of whom have difficulty adhering to insulin shot regimens, industry analysts believe Exubera could quickly become a multibillion-dollar product for Pfizer.

In 1993, Plexus Ventures was retained by Nektar, then known as Inhale Therapeutic Systems, to assist the San Carlos, Calif., company's efforts to find a development and commercialization partner for its experimental inhaled insulin.

Plexus, founded in 1990 by a former SmithKline Beecham executive, is a life sciences consulting firm that specializes in helping pharmaceutical and biotechnology companies license drug candidates. Plexus was acquired by two other former SmithKline Beecham (now GlaxoSmithKline) executives, Robert P. Moran and Michael O'Sullivan, in 1993.

"It took a long time to get Exubera to market," said Moran, the firm's president. "Where the company had difficulty is its management, and I don't blame them for thinking this way, assumed the insulin companies would flock to the idea of an inhaled insulin product."

As it turned out, the three companies -- Eli Lilly, Novo Nordisk and Hoechst -- with the top selling insulin drugs in the market were all skeptical of an insulin formulation that required inhaling a powder into the lungs.

"We came up with the strategy of going after a respiratory treatment company since they already had knowledge about inhalation through their asthma medicines," Moran said.

Plexus also targeted pharmaceutical companies marketing orally administered anti-diabetic drugs other than insulin.

About 20 companies were identified as potential partners including Pfizer, which markets the oral anti-diabetic drug, Glucotrol, and was interested in extending its diabetes franchise into insulin.

After conducting thorough due diligence of Inhale's technologies, Pfizer -- best known for Lipitor and Viagra -- emerged as the top contender to license Nektar's insulin technologies. New York-based Pfizer signed a deal securing development and commercialization rights to the product in 1996.

Moran declined to disclose specific financial components of the deal, but he did say Pfizer has spent "hundreds of millions of dollars" getting the drug tested and approved.

"I give Pfizer a lot of credit," Moran said. "They were committed to this product and they stuck with it. Both companies showed a lot of commitment to each other. I think this is going to be an important product for Pfizer, whose pipeline is not as robust as it was a few years ago."

West Pharmaceutical also stands to benefit financially from Exubera through its subsidiary, The Tech Group, which it acquired last year for \$140 million.

The Tech Group and West's device group merged into a single entity. It operates out of engineering and manufacturing facilities in Pennsylvania, Arizona, Indiana, Michigan, Puerto Rico, Ireland and Mexico.

The subsidiary specializes in injection molding components and devices.

Mike Treadaway, general manager of drug-delivery devices at Tech Group, said the company has been working with Nektar on an Exubera delivery device for seven years.

Treadaway said the device they created is about the size of a sunglasses case, weighs 4 ounces and is made primarily of plastic injection molding components.

Exubera will be sold in a blister pack. After a dose is loaded into the device the medicine is released. It appears as a cloud of insulin powder, resembling smoke, Treadaway explained, that is suspended in a chamber until inhaled by the patient.

"There is an enormous benefit to this delivery technique over the injection of insulin, which can be cumbersome," he said. "A lot of diabetic patients don't adhere to their treatment regimen. We are really hopeful the market will embrace this and it will revolutionize how people take insulin."

As one of two contract manufacturers of the delivery device, along with Bepak in England, West stands to benefit financially as well.

Treadaway said it's too early to estimate the potential revenue from the product for West, which last year generated sales of about \$700 million. Last month the company said it expects revenue to grow by about 17.5 percent to between \$810 million and \$839 million.

"This [Exubera contract] does have an enormous potential for us," he said.

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