

## Noven Pharmaceuticals, Inc.

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Noven Pharmaceuticals, Inc.

11960 Southwest 144 Street

[Miami \(/places/united-states-and-canada/us-political-geography/miami\)](#), [Florida \(/places/united-states-and-canada/us-political-geography/florida\)](#) 33186

U.S.A.

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Web site: <http://www.noven.com> (<http://www.noven.com>)

*Public Company*

*Incorporated:* 1987

*Employees:* 252

*Sales:* \$55.4 million (2002)

*Stock Exchanges:* NASDAQ

*Ticker Symbol:* NOVN

*NAIC:* 325410 Pharmaceutical and Medicine Manufacturing



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Noven Pharmaceuticals, Inc. is a Miami-based company devoted to the development of transdermal drug delivery products. The company uses a small adhesive patch worn on a patient's skin to provide controlled delivery of a drug for a defined period of time, thereby improving patient compliance. Concentrating on the delivery of existing drugs, Noven has been able to focus its research and development efforts on improving transdermal technology, making Noven an industry leader and resulting in the development of much smaller patches that in addition to improving patient comfort allow for patch versions of drugs that would have previously been too large to wear. Noven's advanced technology also allows two drugs to be delivered on one small patch, such as its CombiPatch product that offers both estrogen and progestin to menopausal and post-menopausal women in the [United States \(/places/united-states-and-canada/us-political-geography/united-states\)](#). Other Noven products, sold through its licensees, include Estalis, the European version of CombiPatch; Vivelle, an estrogen patch for the U.S. market;

Menorest, an estrogen patch for the European market; Vivelle-Dot, the U.S. version of a later generation estrogen patch, the world's smallest; and Estradot, the European version of Vivelle-Dot. In addition, Noven directly markets DentiPatch, a product used by dentists as a preliminary anesthetic.

### **Development of Transdermal Technology: 1980s**

From the beginning researchers faced three problems in developing a skin patch appropriate for the delivery of drugs: comfortable size, proper adhesion, and possible skin irritation. The first transdermals, produced in the 1980s, relied on a reservoir system that contained the drug in an alcohol solution. Although these patches effectively delivered a proper dosage of a prescribed drug, the alcohol caused skin irritation. The next generation of transdermals opted to solubilize the drug in an acrylic adhesive, resolving the problem of skin irritation, but leading to other complications. To make a patch small required more drugs and less adhesive, resulting in a product that did not stick very well to the skin. To maintain adhesion and still keep the patch to a reasonable size, researchers turned to a skin permeation enhancer, which once again resulted in problems with skin irritation. Despite the difficulties in working with transdermals, the technology offered great promise. One of the early researchers was Noven's cofounder, Steven Sablotsky, a University of Florida graduate with a degree in chemical engineering. While working with start-up Key Pharmaceuticals, he served as director of product and process development and was instrumental in the creation of a nitroglycerin transdermal patch, the Nitro-Dur II. As the result of its success with the product, Key was acquired by Schering-Plough in 1986. Noven's other cofounder was Sablotsky's cousin, Mitchell Goldberg, a New York City securities dealer. The two had grown up together, drifted apart because of their careers, but became reacquainted in 1986 when Sablotsky attended Goldberg's wedding. During this exciting period for Key, Sablotsky and Goldberg began to discuss the possibility of starting their own company to take advantage of the Nitro-Dur II by offering a second generation transdermal estrogen delivery product that relied on the adhesive method rather than a reservoir system. They founded their company in January 1987 and incorporated it in December 1987, with Sablotsky serving as president and chairman of the board and Goldberg as executive vice-president and director. Goldberg was responsible for business development, licensing, and corporate communications. The company name was a combination of letters from the first names of Steven Sablotsky and his wife, Noreen. Together the parties raised \$250,000 in seed money from family and friends. Initially the company was little more than Sablotsky working at the kitchen table in his East Kendall, Florida, home, but as the business began to take shape, Noven leased 20,000 square feet of space near the local Tamiami Airport.

### **Going Public: 1987**

Operating with limited funds, Sablotsky and Goldberg looked to raise \$1 million to fund Noven's research and development of transdermal, as well as transmucosal, drug delivery systems. They decided to take the company public, scheduling the offering for October 1987. Noven's investment banker advised the partners to hold off and to take a wait-and-see attitude. Then the stock market crashed. According to Sablotsky, his banker told him, "Steve, you're on your own. I hope you didn't burn any bridges." The offering was postponed, not taking place until six months later. With so few companies now opting to go public, Noven was able to gain swift approval from the Securities and Exchange Commission. The company's research and development phase lasted until 1994, the initial focus on transdermal patches to deliver estrogen to menopausal and postmenopausal women, a potentially massive market as women of the baby boom generation began to enter menopause. Estrogen replacement offered a number of benefits for older women: lowering the risk of heart attack, preventing osteoporosis, and lessening palpitations and "hot flashes." As a result, estrogen replacement therapy was expected to grow steadily over the ensuing years and transdermal delivery systems hoped to control a third of that market. Noven made quick strides in developing an estrogen patch and as early as 1989 the company was able to sign a worldwide licensing agreement

year later, Noven reacquired the rights to the United States and [Canada \(/places/united-states-and-canada/canadian-political-geography/canada\)](/places/united-states-and-canada/canadian-political-geography/canada). During this initial stage, Noven posted revenues of \$656,169 in 1989 and \$1.1 million in 1990, with net losses of \$87,904 and \$186,863, respectively. In 1991 revenue dipped below \$200,000 while losses topped \$3 million. In need of a cash infusion, Noven attempted in September 1991 to sell itself for \$47 million in stock to another south Florida pharmaceutical, Ivax Corporation. A month later, however, Ivax backed away from the deal due to the valuation of Noven's "goodwill," the difference between the company's tangible assets and its potential. To this point Noven had no products on the market and had yet to file its first application with the Food and Drug Administration, although it had at least two products for which it was preparing paperwork. According to the *South Florida Business Journal*, "under existing accounting principals and tax laws, Ivax would have been required to charge the 'goodwill' against revenue without having the benefits of corresponding tax deductions. Noven had so much 'goodwill' that Ivax could afford to buy the company using stock worth about \$47 million then, but it could not risk the cost of paying taxes on the amortized 'goodwill' for 40 years in the future, as accounting rules required." As a result, Ivax reluctantly decided not to proceed with the acquisition.

In the months after the failed merger with Ivax, Noven was able to secure much needed cash by signing licensing deals for its estrogen patch with two giant pharmaceuticals while retaining its freedom. Obtaining rights to the United States and Canada was Ciba-Geigy, which had been selling its own patch before concluding that Noven's product, named Vivelle for the North American market, was superior. Ciba decided to market Noven's patch as its own, acquiring warrants that would allow it to purchase a 7.6 percent stake in Noven. The French firm of Rhone-Poulenc Rorer (RPR) obtained rights to the rest of the world for the 10-day estrogen patch. To raise further cash, Noven held a secondary stock offering that netted \$17.7 million. Because its licensees would require an overabundance of available product before marketing the estrogen patch, Noven had to expand its production capacity. Management considered moving the company to [Pennsylvania \(/places/united-states-and-canada/us-political-geography/pennsylvania\)](/places/united-states-and-canada/us-political-geography/pennsylvania), close to RPR's U.S. headquarters in Philadelphia, but officials in Dade County, Florida, were eager to keep Noven and offered a number of incentives to stay. Not only did Noven receive economic aid in labor recruitment and training, the county smoothed the way on zoning waivers and provided quick approval on water and sewage permits. As a consequence, Noven was able to purchase and lease a total of 100,000 square feet in three buildings located on 15 acres of land in South Dade County.

Noven was still an unprofitable business in June 1994, when it again tapped the equity market, raising \$30.3 million by selling 2.25 million shares of stock at \$13.50 per share, an amount that was \$2 less than what the company had hoped for. Much of the funds went to purchase necessary equipment for a new manufacturing, distribution, and research facility. By now Noven had a number of other transdermal products in the pipeline, including patches for hormone replacement, cardiovascular disease, antifungal therapy, dental pain management, and asthma. In 1993 the company generated \$4 million in revenues, posting a net loss of \$3.3 million, and a year later had sales of \$6 million and a net loss of nearly \$5 million. In the fall of 1994 the company received [FDA \(/social-sciences-and-law/political-science-and-government/us-government/food-and-drug-administration\)](/social-sciences-and-law/political-science-and-government/us-government/food-and-drug-administration) approval on its estrogen patch, and with the product finally able to enter the marketplace it appeared that Noven was on the verge of finally turning a profit, but a number of factors intervened to jeopardize the future of the company. In January 1995 another estrogen patch, produced by Berlex Laboratories, received FDA approval and it appeared that it would become available in the United States and Canada in the next three or four months.

### Company Perspectives:

*Already a leader in the development of advanced drug delivery technologies, Noven Pharmaceutical's mission is to become the world's premier developer, manufacturer and marketer of transdermal drug delivery systems.*

Noven, on the other hand, was still nine to 12 months from being able to manufacture its patch in one of the company's new South Dade facilities, which was experiencing difficulty in gaining FDA approval. Ciba was reluctant to introduce the product unless it was certain of a steady supply, forcing Noven to start producing the patch at an existing facility for the European market and to build up sufficient inventory for eventual sales in [North America \(/places/oceans-continents-and-polar-regions/oceans-and-continents/north-america\)](#). Noven officials were confident that their estrogen patch, designed to be used twice each week, was superior to the one developed by Berlex, which was to be worn for an entire week, resulting in problems with adhesion and skin irritation. Nevertheless, experience held that the product that launched first gained a significant market share. Essentially, Noven was forfeiting the advantage it had with Ciba, whose first-generation transdermal product had a monopoly on the estrogen patch market, generating \$125 million in North American sales. Moreover, other companies were coming out with second-generation transdermal patches, so that Noven would have an even more difficult time entering the market. As a result investors lost confidence in the prospects of the company and Noven's stock languished in the \$8 range, after hitting a high of \$19.25 the previous year. Because of sales to Europe Noven was able to double its revenues over the previous year, logging sales of \$12.1 million, but the company's net loss also grew to nearly \$6.6 million.

Although Noven's new manufacturing plant had still not received FDA approval, Ciba (soon to become part of Novartis AG) decided in the spring of 1996 to finally start marketing Vivelle, after experiencing a 7 percent drop-off in sales of its older patch. This turn of events resulted in an surge of investor confidence, which would more than double the price of Noven stock. Such volatility in the price of the company's stock would be commonplace over the next few years. By the spring of 1997 the stock was again trading at the \$8 level, due to lower levels of reorders as the company worked through its stockpile of estrogen patches. Noven hoped to improve its fortunes, and move closer to its elusive goal of profitability, when it introduced its second product, DentiPatch, in 1997. The adhesive strip filled with lidocain was designed to numb the mouth within two minutes and remain effective for 45 minutes, allowing a dentist to painlessly introduce a needle to the area. Although a positive step, Noven lost close to \$9.6 million in 1997.

### **New CEO and Move to Profitability: Late 1990s, Early 2000s**

In December 1997 Noven hired a seasoned executive, Robert C. Strauss, who was named president and chief executive officer as part of a transition to new management in early 1998. Not only did Sablotsky step down from these posts, he promised to ultimately resign as chairman of the company. Prior to joining Noven, Strauss served briefly as president and chief operating officer at Ivax, following 14 years of holding various executive positions with Cordis Corporation. Under his guidance Noven began to take significant strides toward profitability, due in large part to the introduction of new products that Sablotsky had been instrumental in developing. The company received FDA approval on the world's first combination patch, one that joined estrogen with progestin for menopausal women. In the late 1990s Noven also introduced Vivelle-dot and Estradot, much smaller estrogen patches that used the company's revolutionary Dot Matrix technology that ushered in a third generation of transdermal patches. Dot Matrix patches were able to achieve higher drug concentrations on the acrylic portion, resulting in smaller patches, because a silicone layer was added to provide adhesion. Because the silicone and acrylic did not compromise each other's functions, the patch offered drug delivery efficiency and was able to stick to the skin in spite of rigorous activities such as exercise and swimming.

Noven became profitable in 1999, earning \$10.46 million on revenues of \$31.6 million. The following year sales grew to nearly \$43 million while the company posted a net profit of \$19.6 million. One of the more exciting products Noven looked to market at the start of a new decade was a patch to treat Attention Deficit Hyperactivity Disorder (ADHD) with a 24-hour dose of methylphenidate, the chemical name of the drugs Ritalin, Concerta, and Aderall. The company's position in the emerging

nearly \$1 billion market. Investors bid up Noven's stock in anticipation of the company establishing a franchise in this area but when officials announced that the launch of the patch would be delayed by as much as a year while one more study was conducted, there was a general selloff—a continuation of the roller-coaster ride Noven's stock had experienced for the past decade.

In July 2001 Sablotsky fulfilled his pledge and resigned from Noven's board, and Strauss was elevated to the position of chairman in addition to maintaining his role as president and CEO. The business that Sablotsky had started from his kitchen table 15 years earlier was now very much established and profitable, a leader in transdermal technology. Noven continued to experience growing pains, especially abroad, but there was little doubt that the company was well-positioned for strong and sustained growth.

### Principal Subsidiaries

Vivelle Ventures L.L.C.

### Principal Competitors

ALZA Corporation; Amarin Corporation plc; Elan Corporation; Novavax, Inc.; Schering-Plough Corporation.

### Key Dates:

**1987:**

Company is founded by cousins Steven Sablotsky and Mitchell Goldberg.

**1988:**

Initial public offering is completed.

**1994:**

First product gains FDA approval.

**1999:**

Noven posts first net profit.

**2001:**

Steven Sablotsky resigns from the board.

### Further Reading

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—Ed Dinger

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