



**Eric DeRitis**

Communicating presents an image of openness, engendering trust; when you don't communicate, people soon think the worst. Biopharmaceutical companies frequently ignore corporate marketing until too late in the game: Public relations should start at inception to help companies start out correctly.

## Targeted Biomarketing Helping Biotech Businesses Grow

In November 1998, FDA approved Enbrel (etanercept, a monotherapy tumor necrosis factor inhibitor) for treatment of rheumatoid arthritis, a debilitating disease that until then had no effective remedy. In January 2002, the drug was also approved for psoriatic arthritis. Produced by Seattle-based Immunex Corporation, the biopharmaceutical is hailed as a triumph of modern molecular medicine because of its innovative approach to disease modification for many people who use it.

Immunex was already riding high on the results of its clinical trials. With Enbrel's approval, the company hoped to be catapulted into the pharmaceutical elite. Although Immunex was aware that it had less production capacity than it would need, its management team believed that a new Rhode Island production facility coming online over the next several months would ensure that no problems arose.

### The Capacity Crunch

Although the company remains successful — something the pharmaceutical trade press was able to explain in its proper context — you would never know it by reading business press reports.

Enbrel sales in 1999 broke all previous industry records. Yet most news stories in 2000 and 2001 criticized Immunex for not meeting market demand. Because this was about a product related to human health, rather than a consumer product for which unmet demand is often considered good publicity, few success stories were written about the company or the drug. To the contrary, coverage by the business press suggested that Immunex had made a potentially devastating miscalculation.

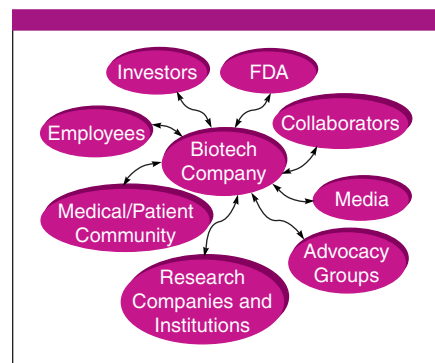
Last year, *Business Week* went so far as to suggest that Immunex “could end up a one-drug wonder” (1). These harsh words were made more painful by their inclusion in one of the world's most widely read business and investment magazines.

Also last year, Reuters Health quoted Daniella Notkin, an analyst with CIBC Oppenheimer, as saying, “Until that manufacturing capacity comes on line . . . patients won't be able to get the drug . . . even if the label is expanded” (2). Even though the article focused on using Enbrel as a treatment for chronic heart failure, reporter Doug Macron felt obliged to talk about the production capacity problems at Immunex.

**Competitors took advantage** of the setback to mount a serious and sustained challenge to Immunex's leadership position. Even though Immunex's business wasn't suffering, the investment community — which regularly reads *Business Week*, *The Wall Street Journal*, Reuters, and other publications — perceived that it was. At the end of the first quarter 2002, Immunex's stock price was about \$28 per share, with a 52-week high of \$31.45 and a 52-week low of \$13.67, down from a high of about \$70 per share in 2000 (see the “Immunex Roller Coaster” box). The company was in a crisis, but not a financial, business, or operational one. This was a crisis in outward communications.

### The Communication Principle

I have been a journalist and professional public relations consultant for many years. I have seen many business triumphs and, sadly, many failures. Immunex's difficulties can be distilled to a simple principle that we



**Figure 1.** Key constituencies in biotech communication

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all have experienced personally: When you communicate, you present the image of openness and you engender trust and calm; when you don't communicate, people soon think the worst.

**The good, the bad, and the ugly.** The Johnson & Johnson handling of the Tylenol scare in the late 1970s is hailed as a great example of the right way to communicate with the press and the public. The company communicated immediately, continuously, and clearly. Conversely, Exxon's handling of the Valdez oil tanker crash in Prince William Sound, AK, is an example frequently cited of how to ruin a company's public image and lose large amounts of money by evading questions, assigning blame, and refusing to accept responsibility.

The need for bioscience companies to communicate is rising. A few years ago, *The Wall Street Journal* seldom mentioned developments in bioscience: Headlines appeared only when the largest corporations in the industry were the subject of news. Now it is rare for a day to pass without bioscience headline coverage in *The Wall Street Journal* and most other papers. Of more importance, industry analysts are

asking bioscience companies to be more vocal. On 5 October 2001, *The Wall Street Journal* relayed this message to Immunex, "Since Enbrel production is constrained at \$750 million for the year [Salomon Smith Barney analyst Elise Wang] would like to hear an update on the renovation of the Rhode Island manufacturing plant, which would boost the supply of the arthritis reliever" and provide some added security for the company's stock (3).

Wang also told *The Wall Street Journal* that she "wouldn't be surprised" if Enbrel sales totaled between \$190 million and \$200 million for the quarter. Unfortunately, she was essentially making an educated guess that this could be the case if all went well. What she clearly wanted was to hear directly from the company (3).

**Good business strategy, but poor PR.** In my conversations and consultations with high-tech, biotechnology, and pharmaceutical companies, I have come to realize a common thread: Whereas high-tech companies implode because too many lack any real technology or business strategy (preferring instead to push marketing and public relations limits to new heights of folly),

biotechnology and pharmaceutical companies frequently possess solid business strategies and develop real-world products that meet stringent government requirements. Yet the industry, more than any other, frequently ignores product or corporate marketing until far too late in the game.

Without marketing, the press and analyst community remain uninformed about how the biotechnology and pharmaceutical industries function and how treatments, therapies, and medical devices are developed. As a result, potential markets and customers never fully understand the context and background from which life-saving products are developed and therefore are unable to help the market develop accordingly.

Although scientific research is clearly the foundation on which bioscience companies are built, executives at those companies are beginning to realize that including a marketing and public relations voice at the table during all stages of a company's development, not just at the time of product launch, is vital to business success. Company founders, who are often discovery scientists or inventors, run their companies with proper dedication to development

### Courting Analysts, Investors, and the Press

**Engage the press early, before your competition does.** That does not mean pushing the boundaries of government advertising regulations. It means not discounting marketing and public relations processes early in your company's development. Reporters who are educated about your company and courted over time will trust you as a source of objective information. They will be in a position to help put any potential bad news in its proper context: They will make your case for you. By working with reporters, you stand a better chance of being quoted in articles; your opinions will be sought. In time, you will be visible enough to be considered a major influence in your specific market.

**Develop a crisis management plan early.** You may never need one, but if the worst should happen, you have a plan ready during tense times when clear thinking might be difficult. Key action items should be covered in the plan. Appoint a crisis manager to oversee emergency press relations, and make sure everyone in the company follows his or her lead. Develop a prepared statement about the issue that contains the facts without opinion or spin. Always tell the truth. Announce bad or questionable news first and fast (before others do). Confront questions or bad news by answering honestly and directly.

**Consider an analyst relations program early in your development.** Reporters rely on financial and market analysts for opinions and commentary about various companies, products, technologies, and markets. Analysts are often the first people reporters turn to

for information. It makes sense, then, to provide analysts with information about your company's products and technology. My teammates and I have arranged and conducted many successful "analyst tours." Do not, however, flout SEC or FDA regulations. Such briefings are usually accepted by analysts, who often feel that they lack specific information about the companies and industries they cover. In the case of Biopure, analysts could have touted the company's powerful safety regime if they had received a detailed briefing earlier from the company. As it was, the analysts presented the BSE concerns.

**Include strategic marketing from the beginning.** Strategic marketing begins at a company's inception, ensuring that it receives sound strategic and marketing input to a business plan geared toward the market as it exists, not as it seems. This will allow you to develop clear, cohesive, and coherent messages that you can roll out through a variety of communications to your relevant constituencies.

**Communicating your business plan.** Public relations, properly defined, is the process of communicating your business plan to relevant or interested constituencies. It is not a substitute for a business plan; it cannot prove that your science is solid or that your trial results are positive. But PR provides you with a mechanism for doing those things in a targeted and meaningful way, and it shows the world how great your company is, even if it is a start-up.

processes, but they often ignore marketing input and fail to regularly communicate their business strategy to their constituencies. They may perceive FDA requirements and payroll as the only major concerns.

### The Market Analyst Angle

In the early 1900s, disregarding communication strategies would have served the average startup adequately. Back then, the business press was in its infancy. Hard news and gossip coexisted (some would say they do again), and the industrial revolution was still a relatively recent event.

**The press begins to change.** As with most social and cultural changes, the metamorphosis of the press began with a small underground movement. In the 1950s, journalists such as Isador Feinstein Stone began to examine tough social issues that the mainstream press was ignoring. Soon news articles and documentaries began to appear about travesties ranging from the mistreatment of coal miners in West Virginia to the plight of poverty-stricken migrant workers in the southern and western United States.

The 1960s and 1970s, Vietnam, and Watergate changed the news business. As a result, the business world — the establishment — would no longer get an unscrutinized ride. Reporters began to see themselves as crusaders, and their new thinking evolved over the next 30 years to what it is today. The press and society now conclude that if you are not talking, you are probably up to no good. Ask any American politician alive today — or better yet, ask Biopure Corporation.

**The Biopure example.** When Biopure announced earlier this year that phase 3 trial results of Hemopure (hemoglobin glutamer-250), an oxygen-carrying red blood cell substitute derived from cows and meant only for surgical procedures, were better than what FDA required, the path to greater success seemed assured. But the company was quickly accused of not revealing information that side effects of the therapeutic might cause kidney failure and high blood pressure. Other concerns voiced by some analysts included the potential for the drug to transmit bovine spongiform encephalopathy (BSE) to humans — a point *Business Week* and other publications reported (4).

Reuters health reporter William Langbein wrote, “Even though the final phase 3 data

## The Immunex Roller Coaster Ride — through the Eyes of the Press

For Immunex, the biopharmaceutical development process has been a harrowing roller coaster ride. The company has become a poster-boy for the industry’s shortfall in manufacturing capacity with its introduction of Enbrel. “The problems for biotech companies come when they start to sell their products. That’s when reality sets in,” said J. Eisinger, writer for *TheStreet.com* (1).

Our industry knows better: Problems can strike at any point along the biopharmaceutical development stream, from formulation to packaging, from stability tests and contaminant assays to the product’s reactivity to its container in fill-and-finish operations. Not to mention jumpy or fickle investors who don’t really understand the industry. “Not to be glib, but nobody really had a clue what we were doing,” remembers Steven Gillis, part of what investor’s originally called Immunex’s founding “dream team management.” “In fact, had we known all the hurdles we had to face taking the product from the clinic to the marketplace, we probably wouldn’t have done it. But we were wonderfully naive” (2).

A formidable obstacle challenges such companies as they approach the finish line: It takes four to six years to build and receive approval for a biopharmaceutical manufacturing facility, but early on the company doesn’t know if its drug will receive CBER approval. “Only 50% of therapeutics get out of phase 3 trials, but that’s when the big dollar decisions need to be made — it’s really difficult to decide whether, or how, to spend money on manufacturing at that point,” says Mark Wicker, partner at the Hale and Dorr Life Sciences Group (3). “I cannot tell you how complicated and expensive it is,” says Remi Barbier, chairman, president, and CEO of Pain Therapeutics, Inc. “People can’t figure why, if you can make something in the lab, you can’t just scale up” (3).

Immunex isn’t the only company to hit that wall: Genentech, IDEC, Biogen, Roche, and Schering-Plough all have had recent manufacturing capacity difficulties (3).

### Immunex in the News

**7 June 2000.** “Shares of biopharmaceutical provider Immunex gained 13.1% to 36 1/16 . . . could double the market for its flagship RA drug” (4).



**Figure 1.** Following Immunex’s roller coaster ride through the stock market jungle of bears and bulls can be illustrative for the biopharmaceutical industry at large.

**16 June 2000.** Immunex “saw gains of 19.4% to 44 11/16. Immunex said sales could grow 15% from quarter to quarter” (5).

**19 July 2000.** “Immunex is a biotechnology investor’s dream, but it carries an awfully big price. . . . Sales up 18% from first quarter. . . . Enbrel has quickly become one of the most important new biotechnology drugs. . . . Optimism over Enbrel has led investors to bid up Immunex’s shares to stratospheric levels. The stock is currently trading about 200 times its estimated earnings for 2000. . . . For those who are considering buying in, it makes sense to wait until the current round of biotech mania cools a bit (6).

**17 August 2000.** Immunex “rebounded 10.7% to 44 5/8. It had lost about 15% of its value over the last week after it said it would issue up to another 70 million shares of its stock” (7)

**18 October 2000.** Sales of “Enbrel were \$172.1 million. That’s a 69% increase from the year before, but slightly under many analysts’ forecasts. . . . While we think Immunex has a strong product in Enbrel, we also believe that much of the optimism about the drug is already priced into the stock. . . . Immunex is one of the priciest of the big biotech picks. . . . Given the drug’s dramatic sales growth, it’s conceivable that demand could outstrip supply. Although management offered repeated assurances that it was doing everything possible to avoid a supply crunch, this is one example of how closely Immunex’s fortunes are tied to a single product. Given the current valuation, we think investors would do well to hold off on the stock for now.” (8)

**10 November 2000.** “Immunex priced its public

far exceeded the original primary end point, Biopure stumbled in May and again in August after being accused of 'sitting on safety data' relevant to the Hemopure trial" (5). The company responded only that it would present its data during medical meetings that fall. Consequently, Langbein added "by remaining mum on the safety charge, the stock dropped 11% in May." And so it did. Although Biopure is in a highly competitive segment of the biotechnology market, the stock drop is mostly attributable to investor perception derived from business press coverage.

No doubt the Biopure example sounds familiar. Many founders and executives in the biotechnology and pharmaceutical industries might legitimately characterize their relationship with investors, the medical community, FDA, customers, and the general public as "love-hate." The press, perhaps more than any other institution, has significant influence over those constituencies (Figure 1).

**Courting the press.** Would *Business Week* have written-off Immunex so boldly if the company had courted the magazine over an extended period? No one can say for sure. But what can be said is that a well-planned marketing, public relations, and analyst program, properly executed, would have educated the magazine about the company, its product, and its business model, including its manufacturing limitations, so that low production numbers would not have been a shock to the market.

The strategy of courting the press has worked almost every time it has been used. In the semiconductor industry, several years ago, a small company with a fairly troubled history, Advanced Micro Devices, Inc., used the approach to both promote and condition the market for a new computer chip it developed. The Athlon processor is now almost as well known as the Pentium processors from Intel Corporation and is considered by some analysts and technology experts to be superior.

### The Marketing Strategy

Marketing, which should be in place before beginning a public relations program, provides guidance to management to ensure that the development process is driven strategically and that the product maintains viability in a constantly changing environment. Marketing research helps

## The Immunex Roller Coaster Ride, continued

offering . . . at \$39.75 today . . . will use the proceeds primarily to boost production. . . . For now, Enbrel is Immunex. . . . The company says its capacity can meet demand, but analysts differ. . . . FDA will require an Enbrel labeling warning of increased infection risk. . . . The plant won't be ready to serve up the drug until 2002" (9).

**25 January 2001.** "Immunex seems to be choking on its own success. . . . solid fourth quarter results. . . . facing a serious Enbrel supply crunch that now looks as if it is going to stymie most of the growth that Enbrel would otherwise enjoy in 2001. . . . given Immunex's dependence on Enbrel and its lofty valuation, we believe the stock is best left alone for now" (10).

**8 February 2001.** "Its Enbrel arthritis treatment is a runaway blockbuster. But if it can't keep up with the demand, rivals could take advantage. . . . Immunex always figured Enbrel would become a blockbuster, but after a year on the market, it became clear demand would outstrip supply. . . . It generated \$652 million in sales last year, making it the fastest growing biological drug in history. . . . Yes, Immunex remains a top pick among the biotech analysts . . . . Watch how the company's management team — widely regarded as strong — tackles its Enbrel supply problems. If Immunex succeeds in meeting existing demands and the drug can be used to treat other diseases, this is one hot company. But if it doesn't, Immunex could tumble from its pedestal" (11).

**20 February 2001.** The company "miscalculated the growing demand for Enbrel. . . . Immunex will leave more than \$200 million in sales on the table this year, some of which will be pocketed by Centocor. Immunex pulled its consumer print ads last fall. . . ." (12).

**23 March 2001.** "Immunex delivered a lot of bad news Thursday, issuing a double whammy after the market closed. . . . We had long been concerned about Immunex's lofty valuation and somewhat thin lineup of potential new products, and we'd continue to urge investors to hold off for now" (13).

**26 March 2001.** "The day was a disaster for Immunex, which basically lost their whole pipeline. Bad news about Nuvance, their new asthma drug — it doesn't work (two phase 2 trials bombed) — and then more bad news,

the CHF trial with Enbrel was halted. . . . With all this news the stock dropped to \$11.63. . . . My bet is that the company will recover from these two blows . . . . I personally might consider selling Immunex for a tax loss, but then I would get back into it for the long haul. The production problem with Enbrel will be handled, and there should be a large pent up demand" (14).

**27 March 2001.** "Investors are accustomed to watching biotechnology stocks rise and fall dramatically on news about drug development. But the body blow delivered to Immunex last week by investors was a stunner, signaling a new era in biotech stock valuations. Immunex lost half its \$10 billion market value [after Enbrel failed trials as a CHF treatment]. Immunex shares have clawed back some since then, but the company is still down almost 40% since the announcement, just above its 52-week low" (15).

"The recent Immunex collapse is a reminder — or if you're an Immunex shareholder, an expensive lesson — that while a stock's price may seem to disregard fundamentals for a time, realistic valuation will come along to spoil the fun at least once in a while. . . . Immunex stock is down 38.41%" (16).

**15 August 2001.** "Immunex acts to increase Enbrel output; second RI production facility will cost company \$500 million. . . . hopes to eventually sell \$3 billion to \$4 billion worth of Enbrel a year. . . . Although Wall Street analysts viewed the announcement positively, they also said it would have little short-term significance. 'It's great,' said Rachel Leheny, an analyst at Lehman Brothers. 'But I think most of us are more concerned about when the first facility is going to come online.' 'The mosaic that they are painting is very positive,' [Mark] Augustine [of U.S. Bancorp Piper Jaffray] said. . . . 'It's a sign of building for the long term. . . . By the near term, needs are still quite a bit of a consideration'. . . . Shares rose 20 cents in after-hours trading to \$17.05, up 1.2%" (17).

"It's time for investors to let Immunex out of the biotech penalty box. Shares of the Seattle-based biotech firm have been dogged since March on the very real fears that Immunex has a serious inventory problem. . . . [Enbrel shortfall and pipeline setbacks] dropped Immunex's shares from

identify product attributes (supported by scientific and clinical studies) that differentiate your product and company from the competition.

From its inception, a biopharmaceutical company is at the center of a dynamic constellation of constituencies critical to its success. Those groups need to be kept informed and educated about the company, its products and technology, and its management capability. That communication provides a supportive environment for the company's growth and viability, in the form of physicians and patients available for clinical trials, additional rounds of financing, a helpful and responsive FDA, and an informed and receptive media.

Immunex, Biopure, and AMD can serve as valuable lessons. Other positive and negative examples exist, but they all point to specific steps (listed in the "Courting Analysts" sidebar) that bioscience companies should consider.

Even if you work in a small start-up company, you have compelling reasons to implement a small and focused marketing and public relations program that concentrates on one or two specific and useful initiatives. As a former reporter, I can tell you that the press will remember you when it counts if you talk to them over the long term. But if you stay silent, the press will follow suit. After all, they haven't heard of you before.

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### The Immunex Roller Coaster Ride, continued

\$32 a share in early March to just less than \$11 a share by the end of the month. The stock has started to recover only in the five months since, and now trades at \$18 a share. . . . But Immunex has solved its Enbrel problem. . . . bullish 2002 sales forecast. . . . If this isn't enough to get your attention, just take a step back and consider that Immunex is a real biotech company. We're talking real products and — drumroll, please — real profits. This is not a company that tries to seduce investors with blue-sky scientific hype and promises of considerable red ink for years to come. . . . Immunex trades at about 58 times 2002 earnings, which may seem expensive but is actually well within the biotech-sector ballpark. . . . the company is forecast to grow 40% during the next five years. . . . Is the Immunex story without warts? Of course not. . . . But Immunex has cash — \$1.7 billion at the end of the second quarter" (18).

"Shares of Immunex were up as much as \$1.37, about 8.4% Tuesday, on Monday's news that . . . Enbrel showed 'positive preliminary results' in phase 2 clinical study testing the drug for treatment of psoriasis" (19).

**23 January 2002.** "For the twelve months ended 31 December 2001, the company reported record net income of \$170.0 million, or 30 cents per share on record revenues of \$986.8 million. . . . an increase of 16% over 2000. . . . 'One of our operational goals is for Enbrel to hit the \$1 billion mark in 2002' . . . . The company also announced on 17 December 2001 that Immunex has agreed to be acquired by Amgen Inc. The deal will merge Immunex, one of the fastest growing biotechnology companies in the industry, with Amgen, the largest biotechnology company" (20).

**22 April 2002.** "Immunex net profit falls, extra Enbrel uncertain" (21).

*And so the roller coaster ride continues.*

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