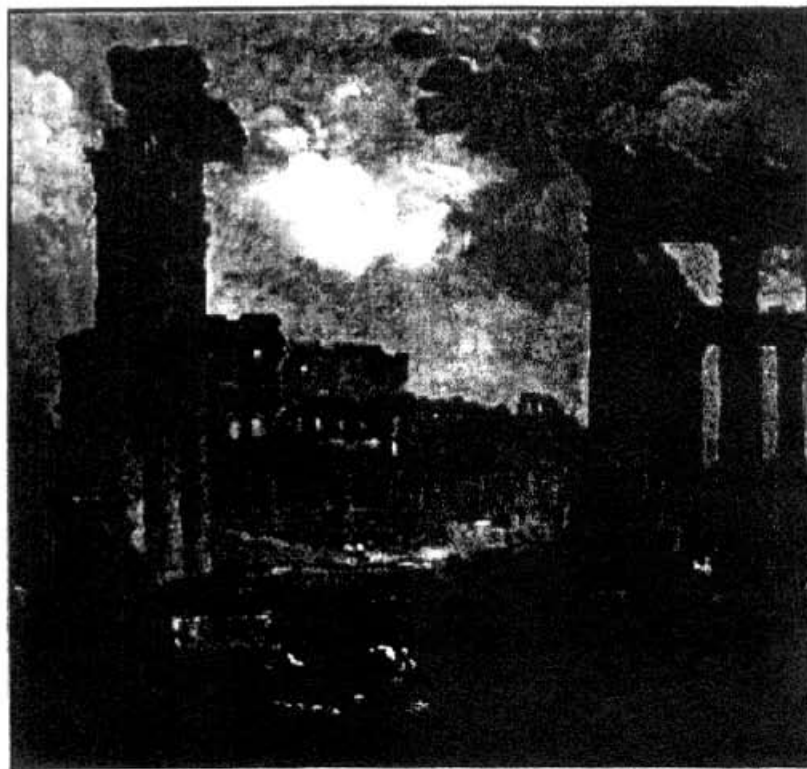


# IN VIVO

## THE BUSINESS & MEDICINE REPORT

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### **PSS Redux: The Fall and Rise of a Physician Supply Company**

After a meteoric climb through the mid 1990s, PSS's fall was almost as precipitous. Now, the company is trying to put things right again. The first of a two-part series.

### **The Foundations of High-Value Discovery Deals**

Big discovery deals are rare but possible: deep biology, tech transfer and barter underlie today's top deal values.

### **Given Imaging: A Capsule View of GI Diagnostics' Future**

Newly public Given's ingestible video capsule for the first time enables direct small bowel imaging. Having obtained a fast product approval, will physicians take the leap and adopt this radical new diagnostic tool?

### **Launching Zevalin**

Having secured the first FDA approval for a therapeutic radioimmunoconjugate, methodical Idec appears to have positioned itself as a truly integrated pharma company? But the complexity of delivering *Zevalin* to patients makes success even harder to predict than for most new oncology products.

### **Preparing Molecular Imaging's Future**

To protect their existing businesses and leverage into new markets, makers of diagnostic imaging equipment are combining imaging modalities and championing the use of new molecular probes.

### **Successful Product Launches in Japan**

Japan presents huge opportunities for new product launches, but Western companies often squander them, failing to understand the unique aspects and requirements of the market.

**The FTC Boosts Generics • GPOs Cry Foul**

## Medinol's Coming Out Party

There are a lot of reasons why small companies, whose expertise lies in developing innovative technology, turn to larger rivals for distribution alliances, chief among them that the small companies are then free to do what they do best, without the diversion of creating their own sales and marketing effort, while still realizing a revenue stream from their technology.

But there are also a lot of reasons why those same small companies often resist granting full, worldwide distribution rights, chief among them that the company, with an eye to its future, likes to save for itself the potential of a major market such as the US. And some companies discover, sometimes too late, another reason to withhold worldwide rights: relinquishing such rights leave them too dependent on their bigger rival. Should disagreements about strategies or direction arise, the small company has little recourse or leverage to gain the upper hand. At that point, they face a tough choice: accept a situation they don't like or walk away.

That's the choice Israeli stent developer Medinol Ltd. faced, and it chose to walk away—in Medinol's case from an extremely successful collaboration with device giant Boston Scientific Corp. (BSX) [W#199620088]. This year's PCR (Paris Course on Revascularization) meeting held in May represented a coming out of sorts for Medinol: the beginning of its efforts to market and sell its products on its own.

Founded in late 1992, Medinol was, from the beginning, concedes CEO Judith Richter, "not oriented to business, but to technology." "The idea was just to start a good company developing valuable technology," she says. Medinol's original goal was to develop a wide range of medical devices, in clinical areas ranging from cardiovascular to ophthalmologic, orthopedics to urology. In November of 1995, however, BSC and Medinol, which had, by that time, developed the *NIR* stent, signed a ten-year agreement that, in effect, made Medinol BSC's in-house stent development program, and Medinol's focus became cardiovascular devices. The company later dropped or spun off its development efforts in the other clinical areas—one, Optinol, is still operating and markets a device to relieve the pressure in the eye caused by glaucoma.

Judith Richter says that Medinol's relationship with BSC was much more than that of an OEM supplier, and more like "a partnership" built around its innovative stent technology. "The idea was that we would develop and manufacture the stent, and they'd have the rights to distribute it worldwide," she says. "In the beginning, they'd get the stent from us and package it and send it to customers." Later, when customers began to ask for stents mounted on balloons, BSC would get the stent from Medinol and mount it on a BSC balloon before shipping it out. "But we would be responsible for developing all of the stents," says Richter. For its part, Medinol's stent would be the only one BSC markets—if it tried to market a stent of its own, under the agreement, it'd have to compensate Medinol for the lost business.

"The idea was that we'd be their stent developer," Richter goes on. "That's why they came to us in the first place, they weren't having luck developing their own stent." The final relationship thus became exclusive for both parties. "In order to get worldwide rights, we'd be their exclusive developer," she notes. "If they later developed their own stent, they'd have to pay us royalties."

The BSC/Medinol pact worked well for a number of years and then tensions and pressures began to build. There was a public falling out last year, prompted when BSC informed Medinol that it had, in secret, set up its own manufacturing facility in 1997 and was taking over the manufacture of the *NIR* stent. (BSC reportedly decided to inform Medinol of the facility last year on its own, when it became clear that a grand jury investigating other practices at the company discovered the operations, rather than have Medinol find out through the legal proceedings.)

Over the years, BSC tried several times to acquire Medinol, first, in 1997, when given its success, Medinol was considering an IPO. Notes Richter. "We were doing very well and everyone wanted us to go public. Boston Scientific asked us not to and suggested, instead, that they would buy us. But then they backed off for

some reason." BSC approached Medinol again in 2000. "But I can't tell you how serious they were," Richter says.

The construction of a separate manufacturing facility would have been grounds enough to end the distribution agreement, but Medinol officials also believed that, as time went by, BSC dragged its feet in introducing the company's follow-on products. "We knew our [new] stents worked because there were patients walking around, doing beautifully with them, but [BSC was] slow in developing delivery systems," says Richter. "That was one of the things that affected our relationship: Medinol was very fast in developing new products, while our partners were not."

Richter deflects questions about the reasons for the break-up, noting only "We declared [the agreement] over at the end of February of this year." But Medinol has filed suit against BSC for breach of contract, charging that BSC, in effect, stole Medinol's design and manufacturing processes, including those for the most recent stent design, the *NIRflex*, and refused to pay any royalties.

With BSC gone, Medinol could either look for a new partner or go it alone. Richter insists that the reputation the company has built up made the decision to market its product on its own an easy one. "Our stents and products are very well-received all over the world," she says. "We have a substantial market share, and over the years, we've shown [physicians] that we're a very innovative company" through repeated iterations of its *NIR* stent, including the *NIRSIDE*, *NIRinol*, and new *NIRConforma* devices.

In many ways, Medinol's strengths remain those upon which the company was founded. "Medinol is a company that is built on the highest understanding of science and technology," says Richter. One-third of Medinol's workforce is in R&D. And while virtually all of its product development is done in-house, the company recently acquired a balloon technology to provide the delivery systems that, in the past, BSC provided. It received a CE mark on its delivery system last winter and got approval from the FDA to begin its clinical trial.

For Medinol officials, their success as a stand-alone company clearly rests on their ability to continue to develop innovative new technology. "We're convinced that our stents are superior to all of the other stents [on the market]," says Richter. "The *NIR* was revolutionary—it was the first stent with a flexible closed cell, which has tremendous clinical value." Moreover, she says that Medinol's technology is supported by very strong IP protection and notes that the company recently won a patent infringement case in Germany against Cordis Corp., a Johnson & Johnson (JNJ) operating company.

Key to Medinol's technology: a patented manufacturing process that is, says Richter, different than any other stent company's in the world. "We're the only ones who manufacture our stents from flat panels," she goes on, based on principles borrowed from the micro-electronics industry. "Most stent manufacturers take metal tubes and do laser cuttings. We're the only ones that do photo-etching on flat panels." The benefit, says Richter: the process enables Medinol to inspect both the inside and the outside of the stent before implantation. In addition, with laser cutting, there's often some melting of the metal that doesn't occur with etching.

Richter argues that Medinol's technological focus enables the company to develop new designs or change existing designs very rapidly, and the combination of fast product development and a unique manufacturing process are key to the company's success going forward. But creating new technology and getting customers to buy it don't always go hand-in-hand. The question for Medinol is, having proven themselves as technology developers, can they become effective marketers as well—particularly in the crowded stent marketplace today? On the market just a couple of months, it may be too early to tell. But Richter says that she's been encouraged by the enthusiasm of customers she's spoken to.

Having just freed itself from one partner, Medinol isn't looking for a new one. But Richter argues that the flexibility and conformability of Medinol's stents make them excellent carriers of pharmaceutical agents, and the company isn't about to let the drug-eluting stent opportunity pass it by. "We think our design is an ideal bedding for drugs," she says. "One of the key issues with drugs is how well they're distributed in the vessel, and our closed cell design ensures that once you put the drug on, it spreads evenly, so there isn't too much concentration of the drug in one place and not enough somewhere else."

Medinol itself isn't interested in launching its own line of drug-eluting stents, says Richter, though she hints, without being more specific, that Medinol will soon announce the development of a new technology that combines stents and drugs in some way. With "a stent that is most friendly to drugs," she says, Medinol is open to licensing opportunities with any company that has the right therapeutic agent and needs the right stent to deliver it. But isn't Medinol shy about doing other development deals just now? Not at all, says Richter: "I know a lot of people whose second marriage worked better than their first."