

Mirabilis Medica Inc.

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Summary: The outstanding success of Novacept, the developer of a device that enabled an office-based procedure for endometrial ablation, demonstrates that Ob-Gyns are eager to offer minimally-invasive, safe, and rapid procedures to their patients as an alternative to the two extremes of surgically removing the uterus or doing nothing. Now Mirabilis Medical, headed up by a Novacept co-founder, hopes to accomplish the same thing for uterine fibroids.

Further Analysis:	Title	Magazine	Issue	Article ID
	New Technologies for Infertility	<i>Start-Up</i>	Jul. 2007	<u>2007900144</u>
	New Technologies for Infertility	<i>Start-Up</i>	Jul. 2007	<u>2007900144</u>

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Mirabilis Medica Inc.

Non-invasive, in-office fibroid removal

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Contact: Mike Connolly, CEO

Industry Segment: Ob-Gyn Devices

Business: Office-based therapy for uterine fibroids

Founded: August 2004

Founders: Michael Lau, MD, Chairman & CMO; Alexander Lebedev; Shahram Vaezy, PhD

Employees: 9

Financing to Date: \$4 million

Investors: vSpring Capital; Charter Life Sciences

Not many years ago, it wasn't unusual to hear various pathologies of the female reproductive system—things like painful and long menstrual cycles or uterine bleeding—referred to as "women's complaints." The way such disorders were treated by the medical community contributed to the notion that these were just unpleasant facts of life for women, and, unless one were willing to undergo the major, invasive, and anatomy-altering hysterectomy procedure, nothing was to be done about it.

Today, though, things are changing. The outstanding success of **Novacept Inc.** demonstrates that Ob-Gyns, once known as slow adopters of new technologies, are eager to offer minimally invasive, safe, and rapid procedures to their patients as an alternative to the two extremes of either surgically removing the entire uterus or doing nothing. Novacept developed a minimally invasive endometrial ablation system known as *NovaSure* to treat menorrhagia (heavy menstrual bleeding) in the Ob-Gyn suite or surgicenter, launching the product in 2000. In 2004, **Cytec Corp.** acquired Novacept for \$325 million, after it posted net sales of more than \$38 million for the year. [W#200410038] This year, *NovaSure* is projected to bring in \$220 million.

Novacept fulfilled an unmet clinical need by developing a minimally invasive device to help patients who wouldn't otherwise have been treated, and it was also blessed with good timing. The company was not the first-to-market with an endometrial ablation system, but it was able to ride a wave of adoption started by frontrunners with a simpler, faster, and more effective tool.

Now **Mirabilis Medica Inc.** hopes to do the same thing for uterine fibroids. It intends to offer a non-invasive office-based procedure that Ob-Gyns can use to remove these benign tumors that form in the uterus wall. Again, it is not the first-to-market, but it believes it is entering a market prepared for such new technologies by first-generation companies such as **InSightec Ltd.** and **Biosphere Inc.** It is perhaps no coincidence that Mirabilis finds itself following in Novacept's footsteps, at least strategically—CEO Mike Connolly was a co-founder of Novacept.

About 25% of women of reproductive age have symptomatic fibroids (*see Exhibit 1*). Symptoms include heavy and prolonged menstrual bleeding, pelvic cramps, urinary frequency and urgency, infertility, and pregnancy loss.

Exhibit 1

Uterine Fibroid Statistics

- By age 50, the cumulative incidence of uterine fibroids is more than 80% for African-American women and 70% for white women.
- An estimated 25% of women of reproductive age have symptomatic fibroids, though not all have been diagnosed. This implies 16 million such women in the US, of whom an estimated 5.5 million will seek treatment each year.
- Between 200,000 and 300,000 hysterectomies are performed annually for symptomatic fibroids.

SOURCE: Office of Research on Women's Health, NIH, 2006

It is still relatively early in the evolution of uterine fibroid treatments. Until fairly recently, most sufferers of uterine fibroids were left untreated. When patients couldn't tolerate them any more, physicians would either remove them in a technically difficult procedure (myomectomy) if trying to restore fertility or if the fibroid was easily accessible, or remove the entire uterus (hysterectomy). Both surgical procedures—hysterectomy and myomectomy—require a 2- to 5-day hospital stay with an average procedure cost of \$8,000, and both require anywhere from 25 to 56 days of recovery before a patient can return to normal activity. Drug treatments are an option, but they come with harsh side effects and aren't a permanent solution: fibroids tend to grow back as soon as drugs are stopped.

Recently, two new therapeutic options entered the field. Biosphere and others have introduced uterine artery embolization procedures in which an interventional radiologist, inserting a catheter into the body through an artery in the groin, injects embolic particles into the uterine artery to block it and thereby asphyxiate fibroids and shrink them. Although this is a less-invasive procedure, it still costs about \$6,000, requires an overnight stay in a hospital for pain management, and an 11-day recuperation period. There has not been a great groundswell of adoption since FDA approval of this procedure 13 years ago. Market leader Biosphere recently estimated 22,000 uterine artery embolization procedures were performed last year, representing a tiny proportion of the estimated 16 million women in the US with symptomatic fibroids.

In 2004, InSightec received FDA approval for a new procedure for non-invasive ablation of fibroids on an outpatient basis via high-intensity focused ultrasound (HIFU). It has demonstrated clinical success in relief of symptoms, but it experienced slow uptake. A March 2007 press release by InSightec reported that 2,500

women worldwide had received treatment with its *ExAblate* system to date. Among InSightec's challenges is the large investment required to offer the therapy. *ExAblate*'s capital equipment works in tandem with the *Signa* magnetic resonance imaging scanner of **General Electric Co.'s GE Healthcare**, which provides guidance during ablation procedures. Institutions that would like to provide InSightec's therapy are thus required to shell out more than \$2 million. Initial adoption has been by the radiology community, which makes sense given the high cost of the system, and because GE Healthcare is InSightec's exclusive worldwide distribution partner. But referral patterns make it difficult to grow procedure volume. [W#200520498] InSightec is attempting to work with the Ob-Gyn community, which controls the patients, via lease-back arrangements and other kinds of financing models. Mirabilis, on the other hand, has from the outset been determined to give Ob-Gyns a tool that fits their practices, however it isn't excluding the radiology community.

Mirabilis was forming just around the time that InSightec was entering the market. When the company was founded in 2004, its scientific founder—Shahram Vaezy, associate professor of Bioengineering at **University of Washington, Seattle**—had been working for seven years on a high-intensity focused ultrasound system to ablate fibroid tumors, and he had conducted a number of studies in animals. Just about the time he had reached a limit to funding from NIH and other grantors, Alexander Lebedev approached the tech transfer office at the university, in search of interesting technology around which to form a company. Lebedev, a young MBA with a science background, developed the business plan for Mirabilis and led negotiations with the university for the license to the HIFU intellectual property platform. He brought in Michael Lau, a gynecological surgeon specializing in endoscopic surgery, to spearhead the company as chairman and CEO. The company raised \$4 million in July 2006 in an institutional round co-led by Charter Life Sciences and vSpring Capital, and Mike Connolly joined the fledgling company as CEO in October 2006. [W#200630480] Lau remains chairman and CMO of the company.

Connolly says that, thanks to InSightec, HIFU has been demonstrated to be safe and effective for treating uterine fibroids. His company's challenge is to get the cost down, and to make a device that is simple and user-friendly enough for Ob-Gyns to use in their own offices. Mirabilis has thus been developing a non-invasive transvaginal device—it doesn't require dilation of the cervix because the probe itself doesn't need to enter the uterine cavity. "We are able to shoot through intervening tissue to treat the fibroids," says Connolly. He believes Mirabilis' approach to HIFU has not only cost, but clinical advantages. InSightec, in using a transabdominal approach, shoots HIFU through abdominal skin, fat, muscle, and the peritoneal cavity before reaching the uterus. And sensitive areas like the spine and bowel, which lie behind the uterus, are also in the line of fire. Connolly says, "We tend to shoot upward into the patient, rather than at the back." And because Mirabilis has a short focal distance, Connolly believes the company may have more flexibility with parameters such as ultrasound frequency or power levels.

The Mirabilis IP covers, among other things, probe designs for transvaginal application of HIFU, methods to use real-time ultrasound image guidance with minimal on-screen interference from HIFU, novel methods of coupling HIFU energy from transducer to tissue, an ablation method that may substantially speed up the procedure, and technology related to other novel gynecological applications of HIFU.

It's too early for Mirabilis to disclose its pricing model, but Connolly suggests that Mirabilis will sell its system for tens of thousands of dollars (compared with the multimillion-dollar investment required by InSightec). "We would not look for a high mark-up on the system, but we would expect to make most of our money from disposables or per-use fees," Connolly says.

In the next quarter, Mirabilis will embark on its first human studies to demonstrate safety and feasibility. The company will be doing a peri-hysterectomy study, in which it will target and ablate small amounts of tissue. After the uterus is removed in the hysterectomy procedure, pathologists will check to see that targeted tissue was necrosed without causing unintended damage elsewhere.

Connolly believes that Mirabilis—like Novacept—has the potential to change the practice of medicine. Today when a woman is diagnosed with fibroids, the physician has a tough decision to make—if the woman is interested in getting pregnant, which option will have the most positive impact on fertility? And just how large should fibroids get before they're removed, considering the cost and invasiveness of some of the current treatments? Connolly foresees that once the Mirabilis device becomes available, the physician may be able to diagnose fibroids with standard diagnostic ultrasound and say to the patient, "Look, you have a 5-cm fibroid that is causing your cramps and bleeding. I could see you Thursday next week for a half hour, and we could take care of that for you. You'll be back to work the next day."

Connolly makes a good case that if his company's technology is successful, it could become the treatment of first resort. "The procedure is non-invasive and can likely be done without anesthesia, so that gynecologists can do it in the office. Insurance companies should like it because it saves money over hysterectomy or other invasive procedures. Physicians will be happy because, in the length of time it takes to go to the hospital and do a hysterectomy, they could do two or three of our procedures and probably even make more money per procedure, since most of the fee for surgery goes to the hospital and anesthesiologist. Meanwhile the true beneficiary, the patient, enjoys minimal pain and recovery time."—*Mary Stuart*