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Live Fitter, Look Better

Device makers are increasingly following the lead of pharmaceutical companies, creating products meant to address lifestyle—rather than life-saving—indications.

by Deborah Erickson

- Aging Baby Boomers with the desire and financial means to do so are taking health care to the next level, seeking fixes for bodily conditions that aren't life-threatening but that do affect comfort and self esteem.
- Lately device makers have begun heading for the sorts of lifestyle markets pioneered by drugmakers. Given the choice, some investors believe consumers will prefer device solutions over daily pill-popping that reminds them they've got health problems.
- Some firms are adopting established technologies to new purposes, while others are identifying perceived market needs first, then seeking out technology that can do the job. Opportunities range from aesthetic procedures to treatments for obesity and depression.
- Lifestyle start-ups face strategic issues that are anything but traditional: How and when to reach out to potential patients and prepare physicians to answer their questions? How to justify reimbursement or convince consumers to pay out of pocket?
- New challenges are sparking new marketing tactics, such as showing physicians in the distribution channel how to distinguish themselves with new devices.

Feeling old, droopy, fat, depressed? Troubled by annoying health problems you didn't have when you were younger? Then fix yourself! Americans are getting the message, through direct-to-consumer advertising, that they can and should seek treatment for all sorts of physical problems they've simply been accepting as unavoidable or unfixable. Don't suffer with allergies and arthritis pain, depression or insomnia. Do something about it. Take *Claritin* and *Vioxx*, *Prozac* and *Ambien* and feel better. Quit smoking. Improve your sex life. Overcome obesity. Take *Wellbutrin*. Try *Viagra*. Get help with *Xenical*.

Major drugmakers have pioneered the practice of exhorting consumers to address common ills with pills, but lately a growing number of device companies are joining ranks, promoting lifestyle medicine. The astonishing rate of growth of *Lasik* vision correction procedures is one testament to the trend: in the first year that **Visx Inc.** made its laser available, 105,000 procedures were done. Five years later, 1.4 million procedures were being done annually, at a recommended price to the patient of approximately \$1,000 per eye. More evidence of consumers' willingness to pay to be fixed is reflected in the dramatic increase in lipoplasty: in 2000, cosmetic surgeons performed 376,633 fat-suctioning procedures—an increase of 113% over the number done in 1997.

For drug companies ever in search of blockbuster products, the attraction of huge consumer audiences is clear: drugs that don't serve enormous populations have to rely on exceptionally high pricing to achieve the multi-billion-dollar sales goals of today's mega-hits. But for device companies, historically accustomed to serving niche markets, the challenges of competing in lifestyle or consumer-oriented medicine markets balance the opportunities. For one thing, devices often seek to address high-acuity, life-threatening conditions for limited patient populations; trying to solve lower-acuity conditions in vast populations represents a fundamental cultural change for the industry.

Related to that, device-company sales and marketing efforts traditionally focus on physicians—and often specialists—and therefore have never tried to achieve the breadth or scale of a true consumer-driven play. That shift from narrow, high-acuity, specialist-oriented markets to broad, low-acuity, consumer markets raises, in turn, reimbursement and payment issues. Is there enough consumer appeal in these device-oriented plays to get consumers to pay out of pocket? And when does a device cross that line from non-covered to covered, from nice-to-have to got-to-have by addressing the real health problems behind a lifestyle condition?

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Finally, the risk of alienating physicians, by making what is perceived as an end-run around them to get to consumers or simply by failing to sufficiently inform or educate them about a new device-oriented therapy, is doubly risky, given that devices are more often tools in the hands of physicians rather than therapeutic agents in their own right. Device firms that, in their embrace of consumer markets, fail to pay adequate attention to their traditional physician base, may find even the most enthusiastic consumer demand thwarted by strong physician resistance.

Still, for a small but growing group of device companies and their backers, the financial pay-off of a truly consumer-driven device opportunity is simply too good to pass up. Says one CEO about such lifestyle plays, "It's our blessing and our curse. The opportunities dwarf the largest device markets, but we've got to create awareness, acceptance and demand for a revolutionary device—and then figure out how to profitably make it as easy to use as physicians perceive drugs to be."

Live Well, Look Better

Drug advertising's effect on consumer psyches is just one factor sparking demand for solutions to health matters that are not life-and-death, but that do affect comfort and self-esteem. The Internet is clearly another. The lay public now regularly uses the web to research all sorts of health matters, and in so doing, people come across sites informing them of new treatment options. Expert forums and chat sites assure consumers that they're not alone, and that they can get help for issues they may never have discussed with anyone face to face.

The expectations of Baby Boomers are probably the most potent drivers of all. "People 55 to 60 years old have never been told no, and they're not going to be told no now," asserts venture capitalist Kurt Wheeler, of MPM Capital's San Francisco office. It is Baby Boomers who are taking health care to the next level, he says, because they've got the desire and the financial means to do so. Since incomes tend to increase as people age, many Boomers are in a position to decide where they want to spend extra money.

Wheeler and other investors are betting that consumers won't have a problem paying out of pocket for procedures and devices that can help them live fitter and look better. Doing so will be a lifestyle choice, like buying a luxury car or traveling to Europe on holiday. But what will they buy? Until now, drug companies have had the edge over devices because of their extensive use of DTC advertising. But given the choice, patients may well choose devices over pharmaceuticals, asserts Thomas Fogarty, MD, a highly regarded physician/entrepreneur who since the 1960s has been involved with some 30 start-ups (see "*Engineering Medicine: Tom Fogarty & Medical Device Start-Ups*," START-UP, November 1996)

"People don't want to pop a pill every day of their lives, because doing so reminds them that they've got a problem," he says. Thus, he figures that implanted devices could prove highly appealing to consumers, particularly if they can be placed less invasively. Fogarty notes that people also know that drugs have side effects—sometimes decidedly bad ones, like the cardiovascular problems caused by *Redux* (phen-fen), the appetite suppressor briefly marketed as a treatment for obesity before being withdrawn from the market. Device makers can argue that products that operate on a physical, rather than a chemical or biological level, are less likely to cause unwanted side effects. Moreover, because devices tend to be used directly by a physician or under his or her supervision, rather than functioning as therapeutic agents in their own right, this theoretically further reduces unanticipated side effects.

New technologies and clever ideas for applying established methods in novel ways are enabling the creation of devices for myriad lifestyle indications. Unlike the traditional device arena—where many firms produce basic products, such as coronary stents or total joint replacements in orthopedics, and differentiate based on countless refinements—there is no standard lifestyle product and no classic business model. Investors are looking closely at the example set by *Visx* for *Lasik*, but mostly they're betting hunches and custom-tailoring strategies and tactics for markets that have never before existed or which are currently dominated by pharmaceuticals. The opportunities on deck include some meant to appeal to consumers concerned about the effects of getting older, such as correcting vision and hearing, improving skin tone and texture, and removing fat for aesthetic purposes. But investors are also betting that novel devices can prove better than drugs at managing chronic disorders such as depression and obesity, gastroesophageal reflux disorder (GERD), benign prostatic hyperplasia (BPH) and back pain.

Valid Needs and Vanity

While some lifestyle indications seem decidedly vanity-driven, proponents argue that it's the rare device or procedure that doesn't provide some significant health benefit as well. Cosmetic surgery that improves confidence seems to be correlated with longer life as well as increased happiness and reduced anxiety, according to a study presented on the web site of the American Academy of Cosmetic Surgery. Dental braces, like the nearly invisible type now being promoted to adults on television by **Align Technology Inc.**, do more than make smiles prettier. Improving a person's bite may extend the longevity of their teeth.

But for the most part, lifestyle devices, whatever their ultimate health benefit, aren't designed to

LIFESTYLE DEVICES ADDRESS PROBLEMS OF BODY AND MIND

Exhibit 1

Company	Device and Indication	Competes Against
THE EYES		
Visx	<i>Lasik</i> laser-based method of reshaping the cornea to improve vision and so eliminate need for glasses	Glasses and contact lenses
C&C Vision	Implantable lens for presbyopia	Reading glasses
THE NOSE		
Sleep Solutions	<i>Bedbugg</i> system for diagnosing sleep apnea in patients' own homes	Overnight testing performed in sleep laboratories
Pi Medical	Implantable device for socially disruptive snoring; procedure done in doctor's office	CNS Inc.'s <i>Breathe Right</i> nasal strip for chronic congestion
THE EARS		
Sonic Innovations	Digital hearing aids based on sound-processing software developed at Cal Tech	At \$2,500 per ear, a premium hearing aid option Lower performing hearing aids.
ReSound	Hearing aids with wide dynamic range compression technology developed by AT&T	
THE MOUTH		
Align	<i>Invisiline</i> virtually invisible dental braces for adults; custom-made through rapid-prototyping.	Competes against traditional metal braces. Firm went public in late 2000
THE SKIN		
Thermage	Radiofrequency technology creates microscopic, sub-surface lesions that tighten collagen in skin	Competes against surgical face lifts
Senetek PLC	Anti-aging skin cream, with kinetin, a plant-derived extract. Marketing through major cosmetics manufacturers	Other cosmetic approaches to skin care
THE STOMACH (OBESITY)		
BioEnterics	<i>Lap-Band</i> plastic inflatable belt implanted in patient where stomach attaches to esophagus; can be done laparoscopically	Competes directly against gastric bypass surgery, and against weight-loss drugs like <i>Xenical</i>
Satiety	Endoscopic and laparoscopic approaches to treating obesity, based on technology incubated by The Innovation Factory and The Foundry	Competes directly against gastric bypass surgery, and against weight-loss drugs like <i>Xenical</i>
EXCESS BODY FAT		
Liposonix	Non-invasive ablation of fat for cosmetic purposes, with ultrasound	Diet and exercise
THE URINARY TRACT (INCONTINENCE)		
American Medical Systems	Several devices for male and female incontinence	Other incontinence approaches
THE BACK		
Vertis i.e. painkillers	Spinal pain treatment, based on running electrical current Neuroscience	More aggressive spine therapy, through needles cages or
Oratec Interventions	Spinal pain treatment	More aggressive spine therapy, i.e., cages or painkillers
THE PENIS		
Vivus	Device for delivering pellet into urethra to facilitate erection	Pfizer's blockbuster drug <i>Viagra</i>
EDAP TechnoMed	Transurethral microwave thermotherapy to treat benign prostatic hyperplasia	Merck's drug <i>Proscar</i>
THE MIND (DEPRESSION)		
Cyberonics	<i>NeuroCybernetic Prosthesis</i> , an implantable vagus nerve stimulator that the company calls a "pacemaker for the brain." Device initially approved for epilepsy	For patients who do not respond to drug therapy; competes directly against electroconvulsive (shock) therapy, or ECT
Neuronetics	Non-invasive treatment, based on magnetic energy	ECT

SOURCE: Windhover's Strategic Transactions Database, company web sites

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treat the same kind of life-threatening conditions as start-ups in historically strong device categories, such as cardiovascular. Rather, investors consider some medical conditions lifestyle opportunities if insurers don't cover treatment but patients are motivated enough to pay for it themselves. For instance, devices used to treat incontinence—which have ranged from inserting bulking agents such as mini carbon balls to injections of collagen or chemicals that solidify in place, to extracorporeal devices such as diapers and pads—are not reimbursed by insurers. “There is no good solution to incontinence out there yet, but given the inconvenience and shame involved—boy, is that a lifestyle indication,” observes Lee Wrubel, a managing general partner of Foundation Medical Partners in Rowayton, CT.

Wrubel notes that back pain, like incontinence, is a problem suffered by many people, and its very prevalence is one of the reasons insurers are reluctant to pay for new treatments. Wrubel figures the dynamics make for a good lifestyle device opportunity: that's why he's supporting **Vertis Neuroscience Inc.**, a start-up with an office-based procedure for placing needles in the back and putting electrical current through them. “Whenever I've been in investor presentations, if there's someone there with back pain, he wants it now. People say, ‘I'd pay \$200-300 out of pocket, because my pain is insufferable.’” Vertis is seeking a new reimbursement code from major insurers, but in the meantime is approaching private payers such as auto insurers who've got a lot of patients with back pain making frequent visits to doctors.

Even with such an obvious consumer appeal, however, lifestyle device companies can't forget the importance of physicians in creating successful devices. “These are not orphan spaces, because the devices are not treating life-threatening conditions,” Wrubel declares, “but the bottom line is, you've got to have a strategy to get doctors buying your product. You've got to show not only that something works but that it's going to put money in their pockets.” *START-UP* recently spoke to numerous venture capitalists and companies developing devices for lifestyle indications. Some of the firms got their start in other areas but are now heading for markets arising or expanding as individuals begin taking more charge of their health and appearance. While the range and breadth of lifestyle device opportunities is huge, defying traditional device categorization, because the strategic dynamics differ so markedly from play to play, we've chosen to look closely at four firms that give a sense of the span of activities and the issues involved in pursuing lifestyle device opportunities.

Pursuing the Ideal Body

Becky Robertson, a partner with Bay Area-based Versant Ventures, says her firm has for some time been looking for opportunities that play well to demographic trends, like the aging of Baby Boomers. The firm's investigations spotlighted growing consumer interest in liposuction and patients' willingness to pay out of pocket for the procedure, which is associated with a lot of morbidity and even some mortality. Versant decided that a better device could expand the market, and that it wouldn't take a lot of capital to build such a product. Clinical trials could be done at a relatively modest expense relative to other device categories—because the outcome of the procedure is immediate and the current gold standard device is invasive with high morbidity, a start-up would only have to show its device improves efficacy. If it could do that, the company could tap existing demand and start penetrating the market immediately, without having to wait for reimbursement approval.

Versant found the investment opportunity it was looking for at The Innovation Factory (TIF), an Atlanta-based technology incubator incorporated at the start of 2000, with initial funding of \$30 million given by a consortium of Versant, Schroder and The Carlyle Group. It was founded by Tom Weldon, who had previously founded brachytherapy company **Novoste Corp.** (See “*The Innovation Factory: Re-tooling Device Start-Ups*,” *IN VIVO*, January 2000.)

It was during a brainstorming session that The Innovation Factory came up with the idea to create a device capable of non-invasively ablating fat, says president Steve Waite. The group then went out and found the intellectual property that most closely represented the ideas they'd come up with, and wrapped a business plan around it. Thus was born **Liposonix Inc.** The firm, founded in January 2001, aims to use a high-intensity focused ultrasound device to image and ablate subcutaneous fat, non-invasively. Waite says that initial animal studies of technology generated by two inventors in Mountain View, CA and the early prototype device they created have been very encouraging. The firm expects to receive its first full (post-seed) round of funding soon to carry the work further.

Waite perceives some key analogies between the way *Lasik* surgery for vision correction was popularized, and the way Liposonix will commercialize its device. Like Visx before it, Liposonix is developing technology to serve a perceived need in the market, rather than beginning with a technology and then finding an application for it, the way many devices are created. The fat-ablating company will likely set a price point similar to that for *Lasik*, Waite says: he reckons a procedure could cost the patient \$2,000-5,000. The Liposonix business model may mimic that of Visx as well in that the cosmetic surgeons that his start-up will target have practices similar to those of ophthalmologists, he notes. Quite a bit of the revenue generated by ophthalmology practices derives from what Waite calls “retail medicine,” because payment is made without benefit of reimbursement. So too with most cosmetic surgery practices, which perform mostly elective procedures, in addition to a small base of procedures in reconstructive surgery.

Initially the firm intends to position its device for aesthetic contouring of specific body areas, such as

hips, thighs, abdomen and buttocks. The Liposonix procedure on these “pockets of resistance” will be a far finer one than liposuction, which removes a larger volume of fat from overweight or obese patients. The start-up will focus on body sculpting at first, but “If it’s safe and effective we could move to obesity,” Waite declares.

Liposonix also wants to simplify the task of educating physicians in use of its machine and to improve outcomes by creating defined matrices to ablate fat in specific patterns. “We feel the designs we’ll come out with will help the average physician be able to contour more efficiently, effectively, consistently. This device is not going to be just for centers of excellence,” Waite declares. He says the firm intends to use the Internet to assist the physician and educate the consumer, but as yet, the company’s web site is just a page with a name holding the space. That assist will likely entail Liposonix providing explanatory brochures and suggested marketing plans.

Liposonix plans to design a clinical study to show the safety and efficacy of its device, and Waite figures data will be well-received by physicians and patients alike. “They’ve not had a lot of clinical trials in this particular market,” he says, noting that devices currently used to perform liposuction aren’t labeled for that procedure—they’re just normal canulas and suction devices used in many sorts of surgery. Liposonix has got initial specs for its device, but its founders are as yet uncertain whether they’ll eventually seek to register it as a PMA or predicate device.

Clinical trials will probably start in 2003. In the meantime, Liposonix will be working to develop the product and address questions such as where fat goes when it’s ablated. Waite says that animal studies show the fat dissipates over a relatively short period of time, “and it’s our speculation that it’s resorbed by the body, goes through the circulatory system and ends up in the liver. We think adjoining fat cells move into the space once occupied by those the procedure removes.”

The start-up has assembled a medical advisory group that includes dermatopathologists and cardiologists, to help shed light on the biology and science of the device. This firm and others working in the area will have to assess how the body deals with removal of fat cells, and what happens if a patient regains weight. Some patients who’ve undergone lipoplasty and subsequently gained weight have experienced a “French poodle effect” of fat bulging out in odd places.

What sorts of consumers comprise the target market for Liposonix? Becky Robertson says they’re the same people that are interested in undergoing laser procedures to diminish wrinkles and taking *Botox* injections to reduce frown lines to look better as they age. “There’s all sorts of psychology involved in these decisions,” she notes, adding, “you either buy into the whole notion of appearance medicine or you don’t, as an individual. Over time, that view may change. It’s like when you’re 20, dyeing your hair may seem like something you’d never do—but when you’re forty and going gray, the option may seem more reasonable.” As the population ages, Robertson says the line moves on the things considered to be socially acceptable by the average person: “It’s a moving target that’s moving in the direction of cosmetic procedures,” she says.

Snoring Is Serious

No one is trying to make the case that cosmetic surgery—as differentiated from reconstructive surgery—is anything but a highly personal lifestyle issue, whatever the psychological benefits from feeling better about one’s appearance. But at least one lifestyle device firm that is facing just that kind of positioning challenge argues that what some might dismiss as a minor lifestyle annoyance is really a major health problem.

The backers and management of **Sleep Solutions Inc.** believe that inability to get restful sleep is in fact a public health issue. Tom Fogarty, one of the firm’s founders, points out that sleep deprivation is a major cause of vehicular accidents and industrial accidents, not to mention lost productivity. And the problem doesn’t necessarily track to people partying or working all night, he explains.

Some people—perhaps as many as 20 million Americans—suffer from obstructive sleep apnea (OSA). Because a person with OSA snores horribly while sleeping, and does so in a characteristic way, it’s generally a bed partner that recognizes there is some sort of breathing problem. People with OSA go to sleep and stop breathing for lengthy periods, up to 40 or 50 times an hour for 20 or 30 seconds at a time. The reduced oxygen flow to the brain serves as a wake-up call to the body, so the people struggle and gasp for air continually while they’re sleeping. They never get the deep, restful REM sleep vital to health.

Sleep apnea is a serious problem, with ramifications far beyond disturbing partners’ sleep, asserts Dan Dugan, former president of **Acuson Corp.** and current CEO of Sleep Solutions. He’s not alone in making the point. Dugan says that lately, more presentations are being made at medical conferences about the health risks of apnea, and news of this research is making its way from specialized journals into the general media. “There is a life-threatening correlation with hypertension, as recently reported in a study in the *New England Journal of Medicine*. Apnea is associated with irregular heartbeat, and people that suffer OSA are at greater risk of heart attack and stroke,” Dugan asserts. He says this sort of information is being communicated in magazines and newspapers, so that consumers and physicians are increasingly aware. The firm posts such articles on its web site along with frequently asked questions; it also sponsors a chat room through the site.

As Dugan sees it, the trouble—and the market opportunity—lies in the fact that only about five percent of the people with OSA have been diagnosed with it. Treatment is available. The

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primary method involves having the patient wear a mask at bedtime, which puts a tube blowing air into the nostrils. The tactic gives additional pressure on expiration, pressurizing the airway so it won't collapse and cut off air-flow. Patient compliance with this treatment is less than stellar, though Dugan says several companies are working on improved masks. The second-line approach is surgery. (See "Resmed: Waking Up to Sleep Disorders, IN VIVO, May 2000.)

Sleep Solutions is positioning itself as a company that can make a diagnosis of sleep apnea more efficiently and cost effectively than is now possible. The current procedure for diagnosis requires a person to go into a sleep center, which may or may not be in a hospital. It usually takes three nights, and the cost of testing can range from \$1,100 up to \$3,000, depending on the region of the country. The methods are sophisticated and complex, Dugan says. Sleep Solutions wanted to come up with a fundamentally different way.

The goal was to make the diagnosis process user-friendly enough for a person to use at home, unattended. "If somebody has to go into the home to administer the test, you haven't really improved the model much because that assistance would be expensive," Dugan observes. Part of Sleep Solution's challenge, therefore, was to develop not only diagnostic technology, but also a service to get the test into the home and make the diagnostic report accessible to patient and physician. Dugan thinks the firm has achieved most of what it needs to succeed. Its slogan: "Real answers. At home. At last."

The device Sleep Solutions came up with, trade-named *BedBugg*, comprises several sensors: a basal sensor listens to air flow to tell whether the person is breathing only partially or normally. A pulse oximeter placed on the finger measures blood oxygen saturation, while a chest sensor detects whether the chest is moving up and down as it should with normal breathing. Another sensor listens to snoring at a decibel level.

The device relies on software that cancels out ambient noises in the patient's bedroom, including his or her own snoring and gasping. Company engineers came up with the device in a somewhat roundabout way, having begun working in the early 1990s to solve the annoyance factor of snoring. They were trying to create a sound barrier or bubble around the snorer, something akin to Bose headphones that cancel sound for people flying on airplanes. "They found they were trying to break the laws of physics

and couldn't do it," Dugan says. But the software worked well enough to permit listening to a patient's airflow. Since apnea is characterized by the repeated narrowing or collapse of the upper airway, the engineers devised the sensors to take advantage of their ability to listen. Together, the package of technologies gets the job done with a very simple user interface.

Dugan says that a clinical study the firm did with **University of California, San Francisco**, testing results achievable in various settings, correlated 96% with diagnoses made within a laboratory setting. Today in sleep labs, he explains, technicians collect four to eight hours of information. Patients are

CYBERONICS MARKS DEPRESSION DEVICE MILESTONES

Exhibit 2

2001

June 13	The US FDA approves an expansion of the depression pivotal study (D-02) from 210 patients to include an additional 30 patients.
June 11	The 210th patient receives the vagus nerve stimulation (VNS) implant as part of the D-02 trial, approximately three months ahead of schedule.
May 10	Results of a neuroimaging study of nine patients enrolled in the VNS depression pilotstudy (D-01) demonstrate that VNS increases activity in the regions of the brain that regulate mood.
May 1	Results released from the pilot study (D-01) of the 60 total enrolled patients show that 31 percent of patients had a 50% or greater reduction in depression symptoms, and many patients experienced a statistically significant improvement in quality of life.
April 30	Long-term results released from the pilot study (D-01) of the first 30 patients reveal that response rates were sustained and remission rates were significantly increased at 12 months post VNS implantation.
April 11	VNS receives Canadian approval for the treatment of depression.
March 13	VNS receives European approval for the treatment of depression.

2000

Dec. 18	European clinical study of VNS for depression (D-03) begins.
August 2	Randomized, controlled study of VNS for depression (D-02) begins.

1999

Dec.16	Results from an open pilot study (D-01) show positive results of VNS therapy in patients with treatment-resistant depression.
June 28	Results from a Cornell University study demonstrate VNS improves mood in epilepsy patients, independent of its effect on reducing seizure frequency.

SOURCE: Cyberonics

often videotaped, and trained personnel look at graphed evidence of breathing obstructions and manually score them. Patients using the Sleep Solutions system aren't visually monitored and they don't see graphs; they just put a small device next to the bed and hook up the sensors over three nights. Then they return the device to the company in a pre-addressed FedEx box. Sleep Solutions uploads the data into a central computer that analyzes it with software algorithms written by the firm's engineers. Not even the referring physician has to look at wave forms on paper. Sleep Solutions generates a report summary of the analysis, which is posted to the company's web site or faxed to the doctor.

Dugan believes his firm's Internet-enabled infrastructure will be key to its success. "It's a new paradigm for getting diagnostic services directly to the patient. We call it *Meditrack* Internet-enabled logistics. It's a database and system architecture for direct patient residential delivery of testing and products," he says. Because the service can be provided to any patient anywhere, Dugan believes, "it eliminates geographic and socioeconomic factors that might otherwise reduce access to groundbreaking technology."

Sleep Solutions can diagnose obstructive sleep apnea for about \$500, but the firm doesn't plan on positioning its method for private pay by patients. It hopes instead that insurers will reimburse doctors that prescribe the at-home test, since most already do pay for the far more expensive testing performed in sleep labs. The company is negotiating with major insurers now, and has just begun putting its distribution organization in place. "Patients need to feel comfortable that they'll be reimbursed if they take our approach," says Dugan. Meanwhile insurers have to review the technology to make sure it's clinically validated.

While management negotiates with major insurers like Blue Cross/Blue Shield and United Health Care, the firm is also seeking contracts with government institutions, like the Veteran's Administration, which has over 400 hospitals in North America. The typical patient profile at the VA suggests that a large proportion of patients have undiagnosed OSA, Dugan asserts. The need to diagnose these patients is not unrecognized, he says, but there are only 2,500 sleep labs across the country, and many have just two or three beds in them. "That low capacity means there's a large backlog of patients waiting to get a sleep study," he notes. The VA in Palo Alto, CA, for instance, had 700 patients waiting when the company began working with it for a clinical trial. Dugan believes that HMOs—indeed any capitated provider—would benefit from the immediate cost savings of his company's technology.

As with most device companies, however, physicians will be key to Sleep Solutions' success. "As we get payer relationships in place, we'll target and educate physicians in a number of different areas," Dugan declares. But for Sleep Solutions, targeting physicians isn't a simple marketing issue, because people with sleep disturbances can find their way to medical attention through different routes. Many are seen by internists, who could refer directly, but who now generally know little about OSA and will need to be educated about it. It's also typical for patients to go to pulmonologists or ENT specialists to discuss breathing problems. Dugan says Sleep Solutions will attend major ENT meetings, and seek to publish scientific papers. The firm recently did have results of its clinical trial with the VA accepted in the *Journal of Otolaryngology: Head and Neck Surgery*. Dugan's happy about that, noting that, "In order to have new technology accepted, you have to have it published in a peer-reviewed journal that's respected."

But one key group of physicians, sleep specialists, present an unlikely challenge for the company. Indeed, Sleep Solutions has begun talking to physicians currently involved in sleep medicine and Dugan acknowledges that some feel threatened that the firm's technology could put them out of business. To help gain their acceptance and crack the market, Sleep Solutions is pitching *BedBugg* to these specialists as an alternative diagnostic method for patients not geographically close to the labs. "They could get more patients this way," and use the technology to distinguish themselves from competing facilities, Dugan declares. The firm plans to prepare information that doctors can send to patients.

Once insurers and physicians are acquainted with *BedBugg*, Sleep Solutions will then turn to building consumer awareness. "It won't do any good getting consumers interested in this if their doctors don't know about it and insurers won't pay for it," Dugan reasons. But when and if the product passes muster with insurers, and especially if it wins the endorsement of sleep specialists, Dugan figures he can tap novel ways of getting consumer attention for it. He's got some experience with clever marketing tactics: As president of Acuson, Dugan worked with *Scientific American* magazine and the Smithsonian Institution to get national exposure for the ultrasound diagnostic system it pioneered. "Eventually we'll be looking at all sorts of avenues to introduce our system to consumers, but for now we're concentrating on what we can do to validate it," he says.

Addressing Obesity

Most consumer-focused device plays appeal to a person's desire to look or feel better independent of any real health benefit, aside from that stemming from the psychological boost that comes with feeling better about oneself. Sleep Solutions bridges a cultural divide for most device companies by linking presumably lifestyle issues to more basic health issues and higher-acuity illnesses—an approach pursued, as well, by Tom Fogarty's latest start-up, called **Satiety Inc.**, which targets obesity. It's

a marketplace and pathology that Fogarty Engineering has been looking at for ten years. In that time, the outfit has moved various device concepts for the indication between front and back burners. Now, it's ready to get cooking.

The key driver of treatment in the obesity market is the growing understanding within the medical community and among individuals that excess weight is unhealthy, not just unsightly. Insurance companies are also beginning to recognize the problem and the merits of treating it, Fogarty says: "If you convert someone from hypertensive to non-hypertensive, from diabetic to not diabetic by weight reduction and dietary control, that person is healthier and less likely to require medical treatments that raise costs." Obese people are also at far greater risk of complication if they need to undergo surgery.

Satiety aims to develop two technology platforms, one of which comes out of Fogarty Research and another that hails from The Foundry, based in the Bay Area and founded by Alan Will and Hanson Gifford. The company is so young that the founders are not yet willing to say much about the devices or their application—only that the Foundry brings an endoscopic approach to treatment that involves using a balloon to reduce stomach volume. Fogarty Research brings a laparoscopic approach that involves 1-centimeter incisions.

Already it's clear that the three-month old company is looking beyond treating morbidly obese people weighing, say, 600 pounds, to the huge market populated by moderately obese people weighing in at 300 pounds or so. "If you go state by state, there is not a state in the union where 20% of the population isn't moderately obese," Fogarty declares. Because obesity runs a spectrum of disease states, from moderate to morbidly obese, the technology appropriate for treating the different types of patients is not necessarily the same, Fogarty declares. Hence, the two platforms. "What you use depends on the patient's degree of obesity," Fogarty says, though he concedes that it is possible

that a device to treat a morbidly obese person "might also be harnessed to help someone with a less severe a problem who is looking for an assist with weight loss."

The regulatory routes could also be different for Satiety's two platforms, Fogarty notes, though he can't say for sure. The firm has not yet talked to the FDA about its reasoning. "But if you had somebody 30% over normal body weight who required a semi-elective surgical procedure, and if you had a method—possibly a temporary one—by which you could effect weight reduction and so reduce that person's risk of complications... that might be very beneficial." Fogarty says that Satiety is doing animal studies now, and will certainly

consult with the FDA on a clinical trial design. Demonstrating safety shouldn't be too onerous a task, he figures: less invasive devices are, almost by definition, safer than what's gone before.

People have tried device approaches to treating obesity previously—putting objects in the stomach to take up space—but complications arose with migration of the device. Fogarty says Satiety has figured out a way to avoid the problem, by suturing or stapling a volume-displacement device in place. Satiety's approach is also less invasive, he notes, and that too should increase the safety of the procedure.

Satiety will be coming into the obesity market against gastric bypass surgery, which surgically sections off part of the stomach to reduce its holding capacity. Fogarty notes that patients need to have a certain percentage of body mass over the norm in order to get approval to undergo that very invasive surgical procedure and be reimbursed for it through insurance. There are a few centers that can do it laparoscopically, "but only a very few, because it's very technologically challenging," Fogarty explains. He says Satiety intends to make stomach volume-reduction easier for physicians and safer for patients. Those factors promise to make the procedure a viable option for more people than ever before—as do Satiety's plans to put its tool into new hands. Currently, only surgeons perform gastric bypass surgery, but general internists who presently use endoscopy in a

DRUGS DOMINATE LIFESTYLE MARKETS

Exhibit 3

Product	Manufacturer	Launch Date	Indication
<i>Vaniqa</i> (eflornithine topical)	Bristol-Myers Squibb	Sept. 2000	Unwanted facial hair
<i>Sarafem</i> (fluoxetine)	Eli Lilly	July 2000	Extreme PMS
<i>Lamisil</i> (terbinafine)	Novartis	May 1999	Toenail fungus
<i>Caverject</i> (alprostadil)	Pharmacia	Jan. 1999	Erectile dysfunction
<i>Sonata</i> (zaleplan)	Wyeth-Ayerst	Sept. 1998	Insomnia
<i>Xenical</i> (orlistat)	Roche	April 1998	Obesity
<i>Viagra</i> (sildenafil)	Pfizer	April 1998	Erectile dysfunction
<i>Detrol</i> (tolterodine)	Pharmacia	March 1998	Overactive bladder
<i>Meridia</i> (sibutramine)	Knoll	Feb. 1998	Obesity
<i>Propecia</i> (finasteride)	Merck	Jan. 1998	Male pattern baldness
<i>Ditropan</i> (oxybutynin)	Alza	Dec. 1997	Overactive bladder
<i>Zyban</i> (bupropion)	Glaxo Wellcome	July 1997	Smoking cessation

SOURCE: Industry sources and company reports

variety of different procedures could deploy the start-up's endoscopic approach.

Fogarty thinks Satiety's methods will ultimately replace gastric bypass surgery altogether—in much the way that laparoscopic cholecystectomy (gall bladder removal) has all but obviated open surgical methods. “Globally, demand for less-invasive procedures has been patient-driven,” Fogarty asserts, arguing that patients learned about the methods not from physicians but from word-of-mouth and the consumer press, through reports of case studies and feature stories on new ways of doing certain procedures. “Companies didn't overtly advertise—word got out,” he says.

General press coverage will likely raise awareness of Satiety's platforms as they're developed, but the company's founders won't leave their chances to that. Like the would-be fat-ablating start-up Liposonix, Satiety is looking at the example set by *Lasik* vision-correction surgery. The firm plans to identify physicians who have good reputations in a given area, and advertise through them. “You've got to develop relationships with top practitioners. They have to believe that a technology is really good for patients. If they do, it's to their benefit to make the public aware of it,” Fogarty declares. He says that most often a company pays for advertising through the specialist, but that cost-sharing arrangements are a possibility.

Satiety isn't the only firm betting it can popularize a device-based approach to stomach reduction. California-based **BioEnterics Corp.**, a unit of **InaMed Corp.**, continues to try to win FDA approval for its *Lap-Band*, an inflatable plastic belt that is surgically implanted in the patient where the stomach meets the esophagus. Once inserted, the device is inflated with silicon or air through a port beneath the skin. The therapeutic goal is the same as that for gastric bypass surgery or Satiety's approaches—to help the patient feel full quickly and cause physical discomfort if he or she continues to eat.

Lap-Band has been used by European doctors since 1993 as an alternative to gastric bypass surgery, but it ran into trouble at the FDA. An advisory committee asked BioEnterics in June 2000 to provide more evidence that the product is safe and effective. Reportedly four of the US centers involved in testing the device stopped their trials of it, and sometimes even removed the device from implanted patients, because of complications such as infection, leakage and esophageal difficulties.

BioEnterics' experience demonstrates how the Internet can work for and against medical device companies. A rudimentary web search for “medical devices obesity” turns up several articles about *Lap-Band*, including an announcement that Brookhaven Memorial Hospital Medical Center, on Long Island, NY had been selected to participate in a clinical trial; a CNN.com story entitled “FDA panel refuses to endorse obesity *Lap-Band*,” and a highly negatively charged article from YourLawyer.com, emphasizing the device's downsides. The article quoted a source who'd been involved in clinical testing of the device, saying, this patient “population has been repeatedly victimized by unsuccessful weight loss schemes with great economic and health costs in the past....[*Lap-Band*] will provide another chapter in this sad tale.”

Fogarty doesn't expect that his firm will suffer any negative associations as a result of *Lap-Band*'s difficulties because the technologies are different, even if both reduce stomach volume. But neither can Satiety expect a competitive boost by being contrasted to *Lap-Band* or other device-based methods of treating obesity, for instance by electrically stimulating the nerves and stomach directly. “They're all emerging technologies,” Fogarty says. “Success in the market will depend on who gets there first, what proves effective, and what's acceptable to patients and doctors.”

Zapping Depression

As investors seek to tap into the potential of the Internet or ride along with the consumer markets being created by drug firms' DTC campaigns, they're reversing the historic device-development paradigm by beginning with a perceived market need and trying to develop technology that addresses it. But other device companies well past the start-up stage, with technology already on the market, are also finding their way to lifestyle applications—moving to create markets the way device companies have always done it: by adapting a proven technology to new opportunities. One such example is **Cyberonics Inc.**, a public company that successfully developed an implantable stimulator of the vagus nerve as a treatment for epilepsy, a condition that historically has been treated with drugs. Now, as it seeks to expand the applications of its nerve-stimulation method, Cyberonics is once again gearing up to compete in a market dominated by pharmaceuticals. This time, it's taking its technology and going after depression.

The idea to develop the *NeuroCybernetic Prosthesis* as a treatment for depression came about through observations that epilepsy patients who'd been implanted with the device were experiencing improvement in mood, independent of changes in seizure frequency. Other evidence suggested that vagus nerve stimulation (VNS) would be effective in depression, notes CEO Skip Cummins: the preclinical and clinical work in epilepsy demonstrated that the vagus nerve had widespread and bilateral projections into various regions of brain. As it turned out, MRI and PET scans showed that VNS modulated the amount of blood flow to areas of brain believed to be responsible for mood disorders. Animal and human studies showed that depression-associated neurotransmitters, neurepinephrine and serotonin were favorably modulated by VNS as well.

“Our study program in depression looks like no other device study program you've ever seen,” Cummins declares. “It's double-blinded, randomized, as rigorous as any drug study protocol.” The way he sees it, Cyberonics has little choice but to be rigorous, because the markets it's after are

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drug markets. “That’s our blessing and our curse. The opportunities dwarf the largest device markets, but we’ve got to create awareness, acceptance and demand for a revolutionary device—and then figure out how to profitably make it as easy to use as physicians perceive drugs to be.” (See “Cyberonics on Its Own,” IN VIVO, October 2000.)

The stopwatch-sized device that Cyberonics sometimes describes as a “pacemaker for the brain” is implanted in the left chest area just under the skin. An electrode connects it to the left vagus nerve in the neck, so that mild electrical stimulation can be delivered 24 hours a day—generally for 30 seconds at a time at five-minute intervals. The frequency, intensity, and duration of the dosing are adjusted externally by a physician. Side effects include voice alteration, shortness of breath, neck discomfort and coughing, all of which are reported less frequently over time.

The device, which costs about \$12,000, was approved in spring of 2001 for treatment of depression in all member countries of the European Union and in Canada. At the start of October 2001, Cyberonics had just finished collecting data from the 235th and final patient in a Phase III study it will make the basis of its appeal for US marketing approval. The firm expects to announce trial results by the end of March 2002 and to submit its pre-market approval (PMA) application to the FDA by June 2002.

Data that Cyberonics announced in July 2001 at the World Congress of Biological Psychiatry showed that just under one out of three patients responded to VNS treatment of depression. The patients selected for the 60-person trial had to have been in a major depressive episode for at least two years or have had at least four such episodes in their life. And they had to have not responded satisfactorily to at least two and as many as five previous drug therapies representing different classes of medication. The study showed that nine out of 10 patients who had an initial response to VNS maintained that benefit after 12 months of treatment. Several people who did not respond initially did so over the longer term.

Is an implantable device that has so far been shown to work in just a third of patients good enough to compete against a battery of pharmaceuticals? Cummins is adamant that the answer is yes, because when the therapy works—in patients whom nothing else has helped—it not only improved the primary disorder, but did so with what Cyberonics believes is an acceptably low side-effect burden. “The goal is to help people lead as normal a life as possible,” Cummins says. “And you don’t get people to that goal if you reduce their depression scores but give them sedation, cognitive impairment, weight gain, and so on—as so many pharmaceuticals do.”

But Cyberonics’ study raises a question not just for its depression application, but for other device companies aiming to address lifestyle opportunities with existing and new technologies: can devices find acceptance among physicians and patients for conditions that are life-impairing, but not life-threatening? Can companies accustomed to selling products for high-acuity conditions affecting narrow patient populations compete in far broader consumer markets against entrenched pharmaceutical firms and their mammoth marketing efforts? Tom Fogarty, as noted, believes device companies not only can compete against drugs, but may actually have an edge: he argues that some patients will prefer a one-time procedure to a lifetime of pill-popping that reminds them of their problem.

Cyberonics officials are gearing up as well for a bigger play that directly challenges pharmaceutical hegemony in treatment. Applying the lessons learned in the course of developing the prosthesis for epilepsy, Cyberonics thinks it can make the case for treatment of depression to the different constituencies that need to be won over. Demonstrating clinical efficacy is just the first challenge. Assuming that’s good enough, Cummins figures, “the only way to fully satisfy patients is to ensure that payers will see the value in the treatment and reimburse for it.” It’s not just the hospitals that order the device, but the physicians who put it in, who need to be reimbursed. For their part, payers need demonstration that the treatment is cost-effective and will save money over time.

To better support its appeal for insurance reimbursement when and if the device is approved in the US for depression, Cyberonics has made a point of thoroughly examining the health economics of the disorder. Cummins explains that his firm worked with **The MedStat Group** and the **Massachusetts Institute of Technology**, looking at MedStat’s 35,000 patients drawn from the top 50 US companies, to examine the cost of treatment for employees with depression. The study set a reference date in 1995 and sorted patients into three groups: regular depressed patients; patients who prior to ‘95 had failed three treatments; and lastly severely treatment-resistant patients—those who’d failed at least two drug regimens but also had either been hospitalized or attempted suicide.

The annual average health care costs of treating depressed patients from 1995 to 2000 showed just how costly caring for treatment-resistant patients can be. Whereas ordinary depressed patients engendered total health care costs of about \$5,000 per year and the second group of treatment-resistant patients ran up costs of about \$10,000, the severely treatment-resist patients had health bills that averaged \$41,000 a year.

Cummins reckons that some 1.2 million people in the US currently suffer from treatment-resistant depression. If all of them got a *NeuroCyberonic Prosthesis* at the company’s price of \$12,000, the Houston, TX-based firm would be looking at a \$14 billion market—a market larger than the entire cardiac pacemaker market. If the device is deemed equivalent only to electrocon-

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vulsive or shock therapy (ECT)—the current recourse for severely treatment-resistant patients—the market size would be far smaller: \$1.1 billion if Cyberonics could treat all of the 80,000 Americans who become first-time ECT patients each year.

Cummins intends to pursue the larger market, by targeting psychiatrists treating patients with *Effexor* (venlafaxine), *Wellbutrin* (bupropion) and lithium. These drugs are most commonly used as third or fourth-line choices because they're more difficult to manage and titrate, and they come with higher side effects than other classes of drugs. In 2000, just 5,400 psychiatrists wrote 10 million prescriptions for those three drugs. Cummins points out that by targeting this group of physicians, Cyberonics is focusing on a niche that equals 10% of the total market for anti-depression therapy. About 30% of those 10 million prescriptions were new ones written for treatment-resistant depression, and he means for Cyberonics to get its fair share of them.

"When we talk to psychiatrists for our pre-launch and launch efforts, we don't talk about who this device is for. We ask, "Which percentage of your patients need a more effective, tolerable, long term or maintenance therapy?" Cummins explains. The answer is always lots, he says—but Cummins also acknowledges that physicians accustomed only to writing prescriptions for drugs do tend to view devices as risky. "Their perception is our reality," he declares.

To crack the epilepsy market, which was a drug market, Cyberonics introduced different kinds of services, attempting to make it as easy for physicians to prescribe the firm's device as to write a prescription for a pharmaceutical. Cummins says the firm is going to leverage not only what it learned, but the infrastructure it has already established for epilepsy, as it moves into the depression market in the US.

Doctors and their staff don't have time to explain VNS to potential patients, so Cyberonics gives its own nurse educators that task. "They've got to spend two hours. It's new," Cummins says. Cyberonics also has its own people do insurance verification, and pre-authorization of reimbursement, again because docs don't have time and staff to do that. The firm also maintains a registry to track how patients are doing, so physicians wondering how patients just like the ones they're seeing have responded to treatment with the device over time, and which settings proved best. Cyberonics started its registry in epilepsy a year after approval, but plans to start one for depression a year before it anticipates approval. The firm expects this resource will help it train physicians on how to do dosing. "We know that we'll have to do all the extra work associated with using this new device therapy if we want it to be accepted," Cummins declares.

Now that the company has done the development work once for epilepsy, Cummins says it won't be nearly so hard to get the ball rolling in depression. "The only thing different is the prescriber—instead of neurologists, we'll detail psychologists and add them to our registry," he says. Cyberonics already identified the network of surgeons to whom neurologists treating epilepsy patients could make referrals. The structure of the sales and marketing organization built for epilepsy will be the same, just expanded, geographically. The relationships with hospitals and the methods for verifying insurance and running the patient registry are all in place.

Cummins believes Cyberonics' infrastructure and the understanding it embodies, is every bit as valuable as the firm's method patent, which he says basically covers the delivery of a pulsed electrical signal, anyway, anywhere to the vagus, hypoglossal and trigeminal nerves for treatment of anything. "This know-how is key to profitably developing drug markets with device-based therapies. If you look at any other device maker attacking established medical markets, they are light years behind us," Cummins boasts, adding, "The only thing we do that's device-like is the product we make." Cyberonics is already looking beyond epilepsy and obesity, and testing VNS as treatment for obesity, Alzheimer's disease and three anxiety conditions—post-traumatic stress disorder, obsessive compulsive disorder and panic disorders, as well as migraine headaches.

But, ironically, the more effectively Cyberonics taps into drug- rather than device-sized markets like depression, the more company officials will feel the pressure of realizing the full potential of lifestyle opportunities: they'll have to face the huge disparity in scale between the kinds of marketing efforts device companies traditionally bring to their businesses and those employed by drug companies. Indeed, for all of his enthusiasm about the applicability of VNS to many different disease states, Cummins believes there is no way that Cyberonics can, as a stand-alone device company, realize its full potential.

"We'll never have a sales and marketing capacity large enough to get adequate share of voice with psychiatrists, payers, or patients and their families," Cummins says. So he's looking for a pharmaceutical partner to co-promote the device. The ideal partners are firms already interested in treatment-resistant depression—those currently marketing serotonin reuptake inhibitors, anxiolytics, mood stabilizers and antipsychotics. He points out that none of the companies now in that space, with the exception of **Pfizer Inc.**, has a play in all those markets. He figures the others should be interested in leveraging the position they've got, and in getting a significant share of the profits to be had in another segment.

Cyberonics is not alone in developing a device-based approach to depression. Steve Waite of The Innovation Factory says that just 60 days ago, his group acquired technology from Neotonus, a privately owned Atlanta-based company, intended for non-invasive treatment for depression. The work will roll into a brand-new start-up called **Neuronetics Inc.** At this early stage, he'll say no more than that the technology is a form of TMS—transcranial magnetic stimulation. It

generates a magnetic field that penetrates the brain and excites cortical neurons, causing them to release a number of neurotransmitters and positively impacting blood flow in the regions stimulated. "Numerous trials have shown this technique to have anti-depressant effects." Waite declares.

The Innovation Factory has provided initial funding internally, but is now looking for additional investors so that Neuronetics can begin clinical trials within six months Waite believes the magnetic therapy will compete with other methods of managing treatment-resistant depressives, whether that's pharmaceuticals, ECT, or Cyberonics' device.

Where's the Exit?

The four companies profiled above give some sense of the diversity of lifestyle-focused medical devices, diversity evident both in terms of technologies and markets served and in the challenges the firms will face. Yet, as a group, they also illustrate some common issues and themes facing device companies that seek to tap this potentially explosive opportunity.

For one thing, even when it's clear consumers will drive demand for a product or procedure, most investors like the device companies they back to approach their market through a physician. That way, a responsible person can be trained to do a technique, either using a new tool or leaving behind a new device, and up go the odds of reproducible results. Selling through the physician also improves the pricing potential for a product—certainly raising it above what could be charged for, say, a product sold directly to consumers through a pharmacy.

Moreover, while the potential size of consumer-driven markets is much greater than the kinds of narrow specialty niches typically targeted by device start-ups, companies that seek reimbursement for a lifestyle product may have a more difficult time making their case than firms working in more traditional areas like cardiovascular or orthopedic devices. Sleep Solutions, for instance, has to educate consumers and physicians and payers about what sleep apnea is—convincing them that it's more than dreadful snoring and that the health ramifications are severe enough to warrant diagnosing more broadly throughout the population. Cyberonics, too, has to justify the high cost of its device for depression relative to pharmaceuticals. That's why the firm has aggressively tracked health economic data the way it has—to demonstrate the cost of *not* using its product. Reimbursement remains a wild card for companies and investors who must place their bets years before products are ready to come to market.

Lifestyle firms that expect patients to pay for their own treatment face particular issues as well. Educating physicians before consumers catch wind of a product or procedure and come storming in asking for it is critical—failure to do so runs the risk that the doctor will be uninformed and will seek to switch the patient to a different therapy. There's no surer way of irritating a clinician, and missteps or poor timing there can kill a market before it starts. The developers of *Lasik* did it well: they spent enough time with doctors that by the time patients showed up asking for the procedures, physicians said, "Yes, you're a candidate," rather than "I don't know what you're talking about." That task extends the time and increases the cost of pre-marketing, in part by raising the hurdle for clinical proof. But there doesn't seem any way around it. Doctors need clinical data.

One of the challenges all of these firms face is convincing physicians not only that a product works, but that they will make money by using it. Selling to specialist clinicians therefore requires a company to get a good handle on the issues—in some sense, the ergonomics—of the way office and surgical practices work in a given field. Investor Lee Wrubel notes that ophthalmologists, for instance, are paid largely by Medicare and their patients are elderly. "You've got to look at their demographics...it's quite different from, say, orthopedists whose patients are, on average, in their 40s," he says.

And then there are the special marketing or consumer outreach issues raised for device companies by lifestyle-oriented technologies. The four companies profiled above already are using or plan to use the Internet to boost business. By presenting information in the form of articles, frequently-asked question lists, and expert forums the firms can to some extent guide consumers through issues and demonstrate the value of their offerings. The channel also provides a means to extract information from site visitors that the companies can later apply to marketing materials. Sleep Solutions, for instance, asks consumers to type in a key word—and that exercise shows how people think about the issues and what's uppermost on their minds.

When it comes to the matter of physician compensation, companies developing lifestyle products are increasingly adopting a tactic that has served well the developers of *Lasik* vision-correction surgery—namely, showing the distribution channel how to distinguish itself with the technology and benefiting from that association. The founders of Satiety, for instance, say they'll aim to convince well-regarded surgeons or medical practices of the value of their technologies and then they'll follow through on that connection by providing the experts with material they can

Can lifestyle device start-ups, with their huge potential markets, overcome public-market skepticism that has thwarted traditional device IPOs?

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forward to patients to explain the process. Brochures and explanatory language can drive marketing efforts that the company pays for, or shares costs on, but that appear under the auspices of locally known medical practices. Liposonix plans to apply similar tactics to help physicians market themselves as well as the new ultrasound device for fat ablation. Still, the size and scope of consumer-oriented marketing are unlike anything that traditional device firms experience.

One question that device start-ups in this sector are mulling, but are as yet too young to address, is that of exit strategy. For traditional start-ups, the preferred exit strategy of a public offering has in recent years been all but shut off, due to the forbidding public markets for device IPOs. As a result, many device start-ups now see acquisition by a larger device company as their most likely exit strategy.

In lifestyle devices, acquisition is still an option for some firms—though not as obvious a path, given that lifestyle devices tend to be one-offs that don't fit neatly with existing device businesses. Many venture capitalists name **Johnson & Johnson**, broadly speaking, as a likely acquirer of lifestyle companies because it has long had a consumer division and is apparently showing interest in the doings of small lifestyle-oriented companies. Whether expertise at selling baby powder and shampoo proves applicable to selling devices remains to be seen. But MPM Capital's Kurt Wheeler observes: "They have critical mass; they can figure it out." **Medtronic Inc.**, **United States Surgical**, a division of **Tyco International Ltd.**, and **Ethicon Inc.**, a J&J operating company, are among the other big firms investors are eyeing as potential acquirers of lifestyle device firms with surgical orientation. **Coherent Inc.** and **Mentor Corp.** are, along with J&J, others that might want to reach into aesthetic medicine.

The more intriguing question is whether lifestyle start-ups, with their huge potential markets, can overcome public-market skepticism about device IPOs. Even as acquisition remains the most likely exit, lifestyle investors like Versant's Becky Robertson say that "there is a chance to create the big brand and grow up a stand-alone company, because nothing else exists yet." Robertson began her career at **Lifescan**, developers of the first patient-administered glucose monitoring device. In the years before the firm was acquired by J&J, it taught the industry that companies can build relationships with consumers, not just physicians. The firm did market directly to consumers, within the constraints of the time, and it also worked effectively with nurse practitioners to educate people with diabetes, and help them feel supported.

"You can bond with the consumer," Robertson says, and companies in position to do so should consider it. The size of certain lifestyle markets will justify a fair amount of investment in building a brand, she believes, even if the margins are far slimmer than those for pharmaceuticals. Devices may address the same or different indications as drugs, but what patients want is similar—a more convenient way of dealing with a problem. Investors and inventors like Tom Fogarty believe the trend towards lifestyle devices will grow as people seek not only to achieve the image of being healthy, but as they come to realize that "if you're not healthy, you have an impaired lifestyle."



Comments? Send an e-mail message to the author at derickson@windhover.com

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