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Scoping Out Gastroenterology Start-Ups

Gastroenterology offers several large device markets, particularly in endoscopy, and it's a growth sector for big companies looking to create new franchises.

When it comes to technological innovation, the field of gastroenterology lags other clinical spaces. Gastroenterologists are said to be slow adopters of new technologies, and disruptive innovation seems to come along only every 30 years or so. The last major advance, say some, happened back in 1983 at DDW (Digestive Disease Week), the annual gastroenterology conference, when **Olympus Corp.** introduced the first CCD sensing camera on the end of an endoscope, enabling the electronic capture of images. Before that, the last major advance was the advent of fiberoptics in 1956. Those technologies advanced image quality, but the basic endoscopy procedure itself—which relies on snaking a semi-rigid hose at the end of which is a visualization tool through five to six feet of twists and turns in a soft organ—has not changed in 50 years. Start-ups are fond of pointing this out, because, with some rare exceptions, it's been difficult for all but the largest companies—Olympus, **Pentax Corp.**, **Fuji Photo Film Co. Ltd.**— to succeed at capturing any part of the market with new technologies, and indeed, there are many start-up and product failures along the way.

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The field is tantalizing because it offers one of the rare screening paradigms in medicine, and therefore, enormous markets. In the US, it's recommended that everyone over the age of 50 be screened for colorectal cancer by a colonoscopy procedure, at various intervals depending upon a person's disease risk. In 2008, almost 150,000 new cases of colorectal cancer were diagnosed in the US, and more than 50,000 people die each year from the disease. Perhaps 75% of these deaths could be prevented if the disease were caught early. It can lurk, symptomless in people with no additional risk factors other than their advancing age. That's a compelling case for screening, and in 2009, some 27 million colonoscopies will be performed.

Nevertheless, even at these high volumes, compliance with colorectal screening recommendations is low, less than 50% for colonoscopy, the gold standard for detecting precancerous polyps. On one hand, as a nation, the US needs to boost its overall rate of colorectal screening. New colorectal cancers cost the health care system $8.3 billion in 2007, with Medicare paying at least $2.4 billion. On the other hand, if compliance were what it should be, there wouldn't be enough capacity in the gastroenterology specialty to meet demand, considering the complexity of current screening procedures. The strain on capacity will only get worse in light of a coming shortage of gastroenterologists, of which there will only be 1,050 by the year 2020, according to a recent study performed by The Lewin Group (and commissioned by GI endoscopy market dominator Olympus).

GI endoscopy is unusual among screening paradigms in its degree of invasiveness and cost. It takes, on average, 30-40 minutes for physicians to do each procedure, plus additional time to manage the sedation or anesthesia component of the procedure, and patients recovering from sedation. That's the reason why new non-invasive technologies like capsule endoscopy—the swallowable pill camera developed by **Given Imaging Ltd.**—are gaining such traction, as evidenced by Given's revenues of $125 million in 2008. Olympus is also in the capsule endoscopy game, although it had to enter into a cross-license agreement with Given as a result of the settlement of patent litigation, as is IBM Healthcare, which has its focus on China, in partnership with local capsule endoscopy manufacturer Chongqing Jinshan Science & Technology. (*See "IBM Kicks Off Smart Healthcare System with Capsule Endoscope,"* PharmAsia News, *May 2009.*) Venture capital-backed start-up **SmartPill Diagnostics Inc.** is also working on capsule endoscopy, although its initial indication is GI motility disorders, not colonoscopy.

CT Colonography or "virtual colonoscopy," which is colonoscopy performed by CT scanning, is another new non-invasive screening modality. Small companies seeking to advance this space include **iCAD Inc.**, which gained 510(k) approval in May 2009 for its *VeraLook* computer-aided detection for CT Colonography. Still, none of these non-invasive technologies can do what standard endoscopes can—allow a physician, in the course of screening, to snare polyps and take other tissue samples. That's why start-ups continue to try to improve upon GI endoscopes.

Invendo medical GMBH, profiled in this issue, intends to do a major overhaul of GI endoscopy, addressing what it sees as all three shortcomings of conventional devices: the patient discomfort that requires sedation, the challenge of passing scopes through complicated anatomy, and finally, the infection risk of reusable scopes. The latter is the subject of a horrific investigation by the Veterans Administration after colonoscope reprocessing errors at two Veterans Affairs hospitals put more than 10,000 patients at risk of developing a viral infection such as HIV, hepatitis B, or hepatitis C. Some of those patients were actually infected. Invendo has a new type of endoscope that avoids "push endoscopy" and addresses all three of these issues.

One of the problems with endoscopy today is that while 70% of the cases are routine and go according to plan, some 30% are not. The extreme tortuosity of a patient's anatomy can extend procedure times or prevent clinicians from navigating the scope all the way to the cecum at the end of the colon. NeoGuide Systems Inc. was founded in 2000 to develop an endoscope that could drive itself, avoid looping, make all cases easier, and in the process, enable sedationless endoscopy. Unfortunately, NeoGuide is a good example of why it is so difficult for new companies to succeed in this space. The company went under, selling its assets to **Intuitive Surgical Inc.** in May 2009. (*See "NeoGuide Systems Inc.", START-UP, September 2004 and "Intuitive Surgical Acquires New Technologies,"* IN VIVO, June 2009.) NeoGuide's technology was overly complex; the device was a serpentine endoscope with a series of articulations held together by wires, and the cost of goods was high. Furthermore, the company's goal of sedationless endoscopy is still questionable, in this country at least. Today the majority of patients undergo sedation (conscious or deep), and many in the gastroenterology community believe that's a good thing. A presentation at the June 2009 DDW meeting, for example, argued that success rates—in terms of completing the procedure and diagnostic yields—are higher when patients are sedated, perhaps because that eliminates certain aspects of patient management during the procedure.

> Non-invasive screening technologies can't do what colonoscopes can: allow a physician to take a tissue sample during a screening procedure.

The problem with NeoGuide underscores one major hurdle for start-ups aiming to develop improved endoscopes: the might of incumbents like Olympus, which holds more than 70% of the GI endoscopy market. Olympus has the resources to vigorously defend its turf against all newcomers in the market and in the courts. The installed base of expensive capital equipment with years of life left in it also presents a difficult point of entry, as do the habits of gastroenterologists comfortable with the look and feel of the tools they use every day. For that reason, **Softscope Medical Technologies Inc.**, also profiled here, offers an adjunctive technology that slips onto the tip of most endoscopes on the market today, a propulsive assist device to help eliminate the difficult cases and smooth out workflow. Softscope is targeting both the colonoscopy market, where its technology will enhance productivity, and the small bowel market, where it will enable therapeutic and diagnostic procedures not possible with existing enteroscopes. The small bowel indication has resulted in an installed base of 3,200 Given Imaging consoles in the US market, and while Given has succeeded in providing diagnostic information that was never before available, there is still a gap in therapeutic follow-up that Softscope hopes to fill.

Mauna Kea Technologies SAS, profiled in this issue, will also ride on the existing platform of endoscopes with which physicians are comfortable, where it will provide an adjunctive device that adds new kinds of information at the microscopic level that will help physicians better target biopsies and decide on the best course of patient treatment. Its *Cellvizio in vivo* confocal laser microscope serves as a new kind of optical biopsy that will potentially advance the state-of-the-art in difficult diseases like Barrett's Esophagus, ulcerative colitis, and biliary strictures.

Start-ups need not necessarily rely on the large incumbents in gastroenterology to provide exit opportunities. Large diversified medical device companies have always acquired new clinical franchises to jump-start their growth strategies, and this trend has been accelerating since the market downturn has begun to provide reasonably priced opportunities—in the past six months, we've witnessed **Johnson & Johnson** getting into aesthetics through its purchase of Mentor Corp.; **Abbott Laboratories Inc.** buy Advanced Medical Optics and a new ophthalmology franchise and **Covidien Ltd.** buy its way into vascular disease. (*See "Coviden Set to Compete in Vascular Business,"* IN VIVO, *May 2009.*) In a GI market that is large and growing, and which hasn't seen a lot of innovation, companies selling single-use surgical instruments—**Boston Scientific Corp.**, and Johnson & Johnson for example, might well take advantage of the opportunity to couple them with new, improved endoscopes to disrupt the *status quo*.

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—Mary Stuart

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