

BioMEMS: Mini Medical Devices with Major Market Potential

By Lauren Clark

Imagine:

- a microchip that, when implanted in the retina, restores some vision to blind people;
- a device implanted deep in the body that would allow non-invasive detection of heart failure;
- a miniature human liver on a silicon chip that could help in the development of drugs for hepatitis and other liver diseases.

BioMEMS may be the key to these innovations, and investors in emerging technologies are betting on their potential.

At the Deshpande Center's December 8, 2003 Ignition Forum, a group of about 60 MIT faculty and students from the School of Engineering, the School of Science, and the Sloan School of Management heard about market opportunities in bioMEMS, an emerging field where nanotechnology, computer science, genetic engineering, and drug design intersect.

Three venture capitalists who invest in bioMEMS startups were on hand to give pointers to potential entrepreneurs: Christoph Westphal of Polaris Venture Partners; Seth Rodgers, CTO of BioProcessors Corp.; and Joseph Baron, principal of PureTech Development. Charles Cooney, professor of chemical and biochemical engineering and faculty director of the Deshpande Center, moderated the forum.

"The hope is that after this discussion," said Cooney, "there's an idea or two that works its way across our desks that we might be able to sponsor through the Deshpande Center."

What are bioMEMS?

BioMEMS are, simply put, MEMS (microelectromechanical systems) designed for use in biomedicine and bioengineering. Current applications include DNA analysis tools called microarrays, and the camera pill, a swallowable capsule with a tiny camera that provides diagnostic images of the small intestine.

At present, bioMEMS are based on electronics already in existence, said Joseph Baron. They can be applied to, but are not necessarily dependent on, biology. Future market opportunities exist in bioMEMS that are specifically designed for biological uses, Baron predicted.

The latest applications, such as therapeutic microchips and DNA repair, are moving in that direction. Applications in the more remote future include "therapeutic chips that are actually in the body interacting with macro and micromolecules and that are able to do fantastic things," said Baron.

Market opportunities

Fluid handling, toxicology, sensing, therapeutic intervention (e.g. drug delivery), bio-reactors - all of these are areas of opportunity in the bioMEMS market.

"Pretty much all of what I would consider to be bioMEMS involve fluid handling of some kind, and at least one dimension that is micro-scale," said Seth Rodgers. In the next few years, he added, there will be opportunities in high-throughput and automation, greater precision and uniformity, and access to a confined space (e.g. inside the body).

Christoph Westphal gave examples of products in which his firm, Polaris Venture Partners, invests - products that aim to enter the market in two to six years. One is a retina chip that could restore some vision in the blind; another is a remote sensor that could, for instance, measure right-sided heart failure in a patient non-invasively. "This would be very helpful for doctors," said Westphal.

Michael Cima, materials science and engineering professor and bioMEMS entrepreneur, was among the forum's attendees. "It's a great time to be thinking about how to do therapeutic devices," he commented. "Anything is being considered a drug delivery platform."

A broader area of opportunity raised at the forum was that of "interface." Looking at the bioMEMS market means considering "this very broad interface between biology, electronic systems, mechanical systems, IT ... and bringing that interface to some market opportunity," said Charles Cooney.

"It's difficult to envision an electronic-biological operating system, something that can exchange information back and forth between these two things - whereas in the computer industry, we have devices that start off very large and can get very small, and it all seems to make sense," said Baron.

"Being able to burn a piece of biosilicon on a chip is one challenge. But being able to integrate all these other complex things - controlling navigation within the body, communicating wirelessly with a device, powering implantable devices - is an enormous challenge."

In other words, standards in the bioMEMS field have only just begun to evolve. It will be a while before bioMEMS have the standards and economies of scale that the computer chip industry has. "There is tremendous opportunity" in this process, said Baron.

Market challenges

BioMEMS startups face a few significant challenges, including the regulatory process for medical products, the skepticism of investors toward the high hopes that the completion of the Human Genome Project raised for therapeutic devices, and poorly focused business plans.

"The regulatory barrier is a huge challenge for startups," said Baron. "A lot of the people who have the expertise to manufacture [bioMEMS] have no experience in the rigorous regulatory process. Every iota of the manufacturing process is monitored by the government. It affects the lead time of your products." And the regulatory process becomes more stringent as bioMEMS evolve into devices that act as much like drugs as MEMS.

"The good news," said Westphal, "is that the device environment is easier than the drug environment." There are great opportunities, for instance, in implantables.

Another challenge to succeeding in the bioMEMS market is the pharmaceutical industry's reluctance to "plowing a lot of money into bioMEMS as the next big thing," said Baron.

While Rodgers agreed that pharmaceutical companies are skeptical, he pointed out that "doing nothing is not an option" for them. Under pressure to deliver higher earnings year after year and facing possible price controls, the industry either "has to deliver health benefits much more cheaply or make R&D vastly more productive." If entrepreneurs make products that address those issues, these companies "can be very warm to having a conversation."

A third barrier to entering the bioMEMS market - or any market - comes from the entrepreneurs themselves.

"What a lot of people do wrong is not to focus," said Rodgers. "Startups must think hard about what problem their bioMEMS device will solve." He advised entrepreneurs to "shoot down complexity" at every business-plan meeting and watch the cash closely. "You almost have to have a gas gauge on your desk for cash."

Westphal posed this question to the forum's attendees: "Will bioMEMS have a unique advantage to human disease that will help to speed them through the regulatory process and lead to great margins on the products once they're sold?"

Tips for bioMEMS entrepreneurs

In addition to focusing on a particular problem, tips for developing a bioMEMS business plan included: calculating the cost of manufacturing your product; deciding whether your product should be disposable or robust; and determining what will be required to service your bioMEMS device.

Martin Schmidt, director of MIT's Microsystems Technology Laboratories, offered his input on the issue of manufacturing. He advised entrepreneurs to consider "access to the processing places that make bioMEMS. For computer chips, 80 percent of development and time is in manufacturing, not in the technology itself. Don't just get drawn into the sex appeal." He also added, "Have a rational sense of the cost of making your product. MEMS doesn't have the standards and volume that the chip industry does, so that's a faulty comparison to look at when developing a business plan."

Other fundamental questions to consider when developing a business plan, said Rodgers, are: "How many of these things do I need to make?" and "What is required to service this part?" You may need to think

“cheap and plastic” instead of expensive, robust, and silicon. “Consider the disposable competition to your non-disposable item,” Rodgers advised.

“The razor blade model is a good one,” agreed Westphal. “If you can charge a high price for disposable, that’s good.”

Westphal thinks that “there is enormous hope and promise” in bioMEMS. But that doesn’t mean entrepreneurs should promise the moon to potential investors. “Look for intermediate steps of success,” he advised.

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