

Patented IntraSense® technology from leading MEMS pressure sensor manufacturer SMI enables in vivo pressure sensing for medical devices from cardiovascular to urology applications



Omar Abed
President and Chief Executive Officer

Silicon Microstructures, Inc.
www.si-micro.com

Contact:
Anja Carranza
408-473-9747
marcomm@si-micro.com

Interview conducted by:
Lynn Fosse, Senior Editor
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“We are definitely becoming known as a leader in medical pressure sensing, and IntraSense is pushing that to the forefront by showing how innovative SMI can be.”- Omar Abed

CEOCFO: Mr. Abed, would you tell us the vision behind SMI when you became CEO in 2013, and what the focus is today?

Mr. Abed: SMI actually has a long history going back 27 years to the early days of the MEMS (Micro-Electro-Mechanical Systems) industry and especially pressure sensing. Today we are a leading manufacturer of MEMS pressure sensors here in Silicon Valley. We sell our products internationally with about fifty percent of our revenue coming from outside of the US. We focus predominantly on medical, automotive, and industrial markets. The applications for our sensor solutions include for example respiratory devices, transmission management and HVAC controllers.

The focus for SMI has been around building a culture of innovation and reinvigorating the product portfolio and we worked diligently over the past five years to recreate the product portfolio in a way that puts us at the forefront of each of the different segments of the pressure sensor market we play in. I think our culture of speed and innovation is a key driver in our success and our current position and momentum in the market.

CEOCFO: Where did the ideas for innovation come from? How do you know when it is time to make a change and what is doable?

Mr. Abed: When I looked at the market at the time I joined the company, I observed that the market had become complacent with respect to innovation. I saw a lot of products that looked similar and there was a lack of differentiation. The question then became do we focus on stripping down cost and commoditization or are there opportunities for innovation that can disrupt the market and bring across a new wave of innovation in the industry. We determined that there was an opportunity for further innovation, which would both improve performance and cost simultaneously, and as you can see we have driven that innovation.

CEOCFO: *When you are contemplating an innovation, do you talk with potential users? What is the process and the thinking behind starting a particular innovation?*

Mr. Abed: I think you need to look both inside and outside the organization. You look outside because your customers are ultimately the end arbiters of whether your products will be successful, and understanding their needs and challenges are critical to understanding the fundamental problems you are trying to solve. Often the market commoditizes and all products begin to look very similar, leaving cost as the only differentiation factor, then that squeezes out the opportunity for innovation. At that point you are forced to look inside the organization and ask how we can solve these problems in a more fundamental way or that might create more value for the customer. When we understand not what they are asking for directly, but what problems and challenges are that they are facing the space for innovation can emerge. Identifying this space is what is important in innovation, and for SMI it has been an interesting journey.

Over the last five years, we have focused on shrinking the size of our sensors. In each of the classes we address, we have the smallest sensor on the market. This has been the name of the game in the semiconductor business since its inception, that smaller size leads to more computing power as well as lower cost and we have been on the journey as well. By being able to achieve such small products through our process and design innovation, we have been able to introduce a completely new class of sensor, which is the smallest sensor in the world, which we call IntraSense.

CEOCFO: *What is IntraSense and in vivo pressure sensing?*

Mr. Abed: In vivo pressure sensing is the ability to sense pressure real-time at the point-of-use in the human body. IntraSense is a technology that SMI launched at the end of 2017, which is the smallest automated connected pressure sensor that is biocompatible and intended for use in the body. We have taken our extremely small pressure sensors that we have innovated here in our fab, and we created an automated wire attach process that allows us to have a connected pressure sensor to be used for a variety of medical applications. It helps to measure a variety of pressures inside the anatomy, from intracranial and intravascular to intrauterine pressure. The list is quite long and there are more than twenty applications that we have identified so far. Some of these applications are for part of a treatment, for example drug-delivery. Other applications are employed for diagnostic procedures, like monitoring the pressure in the skull (ICP). There are a plenty of applications and use-cases which is exciting. When you look at the human body, it basically consists of electrical and pressure systems, particularly the cardiovascular system, and physicians can utilize localized pressure readings to make a more accurate diagnosis and treatment.

CEOCFO: *Would you explain how the technology works?*

Mr. Abed: We utilize the same MEMS piezoresistive pressure sensing technology that our complete product portfolio uses to convert a pressure reading into an electrical signal. SMI has developed and patented proprietary technology that has allowed us to take this sensor down to the current size, which has enabled us to fit the sensor and attached wires into a 1-French hypotube where the smallest catheters exist today. In some cases, customers wish to use pressure sensing in combination with an endoscopic platform. In this case, a camera with a light source is

inserted into the body. All semiconductor devices are sensitive to light, in order to operate in the presence of light, we have to protect the sensor from this light source so that it continues to provide stable and accurate results. So we have developed a patented light-shielding technology which allows for compatibility with endoscopic applications. Stability of the output is critical in many of the use cases and this enables stable measurements in the presence of light. We worked hard over the last few years to fundamentally understand all the different components of stability both mechanical and electrical and by doing so, we have also built a sensor that is stable for hours or even days inside the body, is biocompatible as it is in contact with fluids such as blood, urine and cerebrospinal fluid, and is compatible with these somewhat harsh environments.

CEOCFO: *Would you give us a couple of examples of how IntraSense can make a difference?*

Mr. Abed: Generally speaking to be able to monitor the pressure at the site of the procedure provides physicians with critical information to ensure procedures are done quickly and accurately while minimizing the risk for damage. One example is endoscopic applications, which I mentioned before. When a physician needs to get a visual of a particular area in the anatomy, whether it is the colon, kidney, or any organ area that they want to examine more closely, they have to inflate that area with either saline or a gas. The risk arises if it is over-inflated, you can potentially damage those sensitive tissues and organs, while if it is underinflated the physician does not get the image or the view that they need to make the procedure go as quickly and as smoothly as they would like. By having localized pressure sensing, they can control that inflation pressure very precisely.

Another interesting application is drug-delivery. As you can imagine certain drugs are very expensive and can be as expensive as thousands of dollars to even tens or hundreds of thousands of dollars. Additionally, if the drugs are delivered to the wrong site they could harm healthy tissue. In these cases the precise administration of the medication to the targeted area is critical. IntraSense can help by measuring localized pressure. Every tissue in the anatomy has a particular pressure environment, so that with the aid of IntraSense the different tissues can be detected and the drug is administered at the correct site, without creating leakage into the rest of the body. This can actually harm the body as well as minimizes the efficacy of the drug-delivered. Also, IntraSense can monitor the pressure of the drug-supplying device, to ensure the medication is not delivered too quickly.

Lastly, one of the big areas in the space of cardiology are procedures like stent placement or angioplasty where you have a build-up of plaque in the arteries. In this case, pressure sensing will allow you to navigate through the artery to find the precise location and to measure the blockages in the artery. By having the power of localized pressure sensing, the physician is able to correctly diagnose whether a stent for example is needed or not, and then also determine the precise location where that stent should be placed.

CEOCFO: *What has been the response from the medical community?*

Mr. Abed: It is interesting, this is our third generation of in vivo sensors, but it is the first where we actually provide the wire attach, so it is the

complete sub-assembly. The reception from customers has been extremely positive. I think offering this more complete solution has allowed us to garner a lot more interest than we had in the first two generations of the product. The small size allows for easy integration into existing products, or new products that will go into the market. Its small size allows those products to be quite cost-effective but also ease the integration for customers. We work closely with our customers and that includes tackling challenges like calibration or different attachments for example, or on the electrical side, we might include connectors or flex as an intermediary to their final system.

On the sensor side, we facilitate the mounting process by offering a shuttle which will be easier to mount than having to mount the sensor directly to the housing. While we have greatly simplified the process of integration, we definitely work very closely with customers to ensure that a solution meets their exact needs for their exact product. We recognize that in each application, there are a vast array of challenges in meeting the customer's needs.

CEOCFO: *What might be different from the doctor's end; is there training involved?*

Mr. Abed: I think the great thing here is, we are giving more information to physicians, allowing them to make more accurate diagnosis or more precise treatment. No extensive training is required since the sensor is integrated into medical invasive devices by our customers. For devices which already facilitated pressure sensing in previous generations through an external pressure transducer, the transition for the physician to in vivo pressure sensing will be easy. If pressure measurements are incorporated as an additional function to a device it might require some training for the physician to learn how to interpret the pressure read-outs. There would be ideally a range of pressures for a given procedure where the physician would know they are in the sweet spot and operating according to plan versus determining something has gone wrong. We have seen cases where fewer physicians were needed for a given procedure and manpower for the hospitals as a result of procedure times going down. Perhaps the more important thing is we have seen less risk for infection or for damage to the patient, which requires re-hospitalization, post-op. For physicians, we believe information is power and IntraSense attempts to give the physician the information they need to do the right thing.

CEOCFO: *Where are you today with IntraSense?*

Mr. Abed: We are actually in talks with tens of customers, and the first customers will go in production with devices incorporating IntraSense later this year. We are still in the initial wave of education and awareness, and awareness is generating a lot more interest, applications, and new-use cases. We literally get inquiries weekly about completely new applications. On our end we are also in the learning process about how in vivo pressure sensing can be utilized to benefit the medical industry. It is a really exciting time. On the one hand we have the challenges of ramping and satisfying our early customers, but also the educational opportunity of learning about different use-cases in the body. It is a dynamic and exciting time within SMI.

CEOCFO: *Do you find it easy or easier to attract talent, as SMI is so innovative and exciting?*

Mr. Abed: I definitely think this gets people excited. When you look at Silicon Valley, on the one hand it is full of intellectuals and talented individuals. You have top universities, top companies, a lot of research being done. On the other hand, the competition for that talent is fierce. When you have products like IntraSense, and you are focused on innovation that benefits society like SMI is, then you really draw people who are motivated to change the world. Here at SMI, we avoid jumping into commodity businesses where we only offer interchangeable products, we really want to change the world by bringing new solutions and new approaches.

CEOCFO: *Does the world recognize SMI yet? Why is SMI so important and why should you stand out from the crowd?*

Mr. Abed: Yes, that is an ongoing journey and we are right in the middle of it. The awareness is growing rapidly. If you look at our core markets, we have automotive, and in that space I think we are definitely recognized as a leader in pressure sensing. Also industrial, we have launched several new products including a new low-pressure product, which is the lowest in the world and is disrupting the industrial market. That being said, we are a predominantly medical company. We are definitely becoming known as a leader in medical pressure sensing, and IntraSense is pushing that to the forefront by showing how innovative SMI can be. It is an exciting time and I think our brand awareness is growing exponentially.

CEOCFO: *Final thoughts?*

Mr. Abed: Our mission is to enable customer's success through innovative pressure sensing solutions, so that our customers can improve health, safety and the environment. We are very proud of our latest generation of products because they have been successful in doing exactly that.

