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## **TWO MINUTES WITH** Robert Hamas Ideal Implant Inc.

When you can't find Dr. Robert Hamas meeting with patients at his plastic surgery practice, you can find him tooling about the offices of Ideal Implant Inc., a Dallas-based breast implant development and manufacturing company he started in 2006. Hamas created an implant that aims to mimic the design of silicone implants but through a more-natural design with edges that conform better to the chest wall. The implant is filled with the environmentally safer saline solution. The product is currently undergoing clinical trials for FDA approval, which are being conducted by 46 surgeons in 36 private practices throughout seven regions of the country: Los Angeles, Sacramento, Dallas, Houston, Atlanta, Jacksonville and Miami. The clinical trials will last for 10 years, although the implants could receive approval and be available to the general market in spring 2012. Hamas was interviewed by staff writer Shashana Pearson-Hormillosa.

### **Q. Why did you start Ideal Implant Inc.?**

**A.** I had the technology for years and could not get the two breast implant companies interested in it because they had been doing silicone until it was stopped (in 1992 by FDA regulations; regulations were lifted in 2007). The company is totally privately funded and majority-owned by plastic surgeons. I started out by showing prototypes to surgeons and asking if they would invest in a company that would make the product to see how interested they were. I had a lot of reinforcement from the surgeons as well as female patients, and that's what inspired me to start the company.

### **Q. What's been the hardest part of getting started?**

**A.** It's been different things at different times: learning the regulatory system for the FDA approval — I had to get up to speed right away; learning manufacturing requirements for quality; and learning about the trial in terms of investigators and getting stuff done. Now, we're limited to how much promotion or marketing we can do at this time because of the restriction on the clinical trials being limited to only 500 women.

### **Q. Describe the incentive plan to get long-term participation in the clinical trials.**

**A.** The cosmetic surgery patient is unique in that she doesn't usually return to the doctor unless there is something wrong. So, we developed a trust fund in which we deposit \$3,500 per patient. Women will get a substantial amount of payout if they return for every required follow-up visit. In previous breast implant trials, follow-up has been low — about 60 to 80%. We're hoping for 95%. They have a strong incentive; it's something that makes the patient want to come in.

