Merck’s Tender Offer for Inspire Pharmaceuticals Complete; Inspire CEO Steps Down

Merck & Co., Inc. (Whitehouse Station, NJ), announced that it has successfully completed its $430 million acquisition of Inspire Pharmaceuticals, Inc. (Raleigh, NC). The cash tender offer for all outstanding shares (75.4%) of common stock of Inspire was completed by Monarch Transaction Corp., a wholly owned subsidiary of Merck. The deal, announced in February 2011, allows Merck to expand its ophthalmic business in the United States and acquire AzaSite (azithromycin ophthalmic solution 1%), a treatment for bacterial conjunctivitis. AzaSite’s revenues increased 22% to $42.7 million in 2010, according to Inspire. Following the completion of the deal, it was reported that Inspire President and CEO Adrian Adams, along with a number of senior executives, would be leaving the company. Mr. Adams joined Inspire in 2010 after serving as CEO of Sepracor Inc. (now Sunovian Pharmaceuticals Inc., Marlborough, MA), and prior to that, Kos Pharmaceuticals (Cranbury, NJ), which was later acquired by Abbott Laboratories (Abbott Park, IL).

Merck also confirmed that it would be closing Inspire’s administrative headquarters in Raleigh this year. Merck spokesman Ian McConnell told Cataract & Refractive Surgery Today that the company plans to keep Inspire’s sales team as Merck tries to re-establish its US presence in ophthalmology with the progression of the proposed glaucoma treatment Saflutan (tafluprost), which is under FDA review.

Laser Flap Creation Yielded Better LASIK Outcomes Versus Microkeratome

The flap’s creation with a femtosecond laser (Intralase; Abbott Medical Optics Inc., Santa Ana, CA) yielded better refractive results 3 months after hyperopic LASIK compared with a microkeratome (M2; Moria, Antony, France), according to a study in the American Journal of Ophthalmology. This study analyzes the visual and refractive results 3 months postoperatively of a total of 144 eyes,” lead author Raquel Gil-Cazorla, DOO, of the Universidad Complutense de Madrid in Spain, wrote in an e-mail to
The study compared "72 eyes that had undergone LASIK to correct hyperopia in which the 60-kHz IntraLase femtosecond laser was used [to create the flap] versus 72 eyes, age- and refraction-matched, in which the Moria M2 microkeratome was used."

The mean preoperative sphere was +3.45 ± 1.00 D in the femtosecond laser-flap group and +3.18 ± 1.30 D in the microkeratome-flap group (P = .1). At 3 months postoperatively, mean residual sphere was +0.44 ± 0.60 D in the femtosecond laser group compared with +0.72 ± 0.80 D in the microkeratome group (P = .02). UCVA was 0.89 ± 0.2 (20/22) in the femtosecond laser group and 0.80 ± 0.2 (20/25) in the microkeratome group (P = .04), and BSCVA was 0.96 ± 0.2 (20/21) in the femtosecond laser group and 0.92 ± 0.2 (20/22) in the microkeratome group (P = .2). The safety index in the femtosecond laser group was 0.97 ± 0.1 compared with 0.98 ± 0.1 in the microkeratome group (P = .5), and the efficacy index was 0.89 ± 0.2 versus 0.84 ± 0.2, respectively (P = .3).

“Our results show that the IntraLase femtosecond laser seems to achieve better refractive results 3 months after the surgery compared with the M2 microkeratome, without significant differences in safety between both procedures,” Dr. Gil-Cazorla wrote.

“Factors Linked to Endothelial Cell Loss After PKP Identified”

The donor’s having a larger graft, being younger, and female were factors associated with a higher endothelial cell density following penetrating keratoplasty for endothelial dysfunction, according to a study in the Archives of Ophthalmology.1

Researchers assessed 567 patients enrolled in the Cornea Donor Study. Preoperative and postoperative endothelial cell densities were determined by a central reading center. Multivariate regression analyses were performed to examine which baseline factors correlated with endothelial cell density over time.

Larger grafts (P < .001), a younger age of the donor (P < .001), and a donor’s being female (P = .004) were significantly associated with higher endothelial cell density during follow-up. Median endothelial cell loss at 5 years was 68% for grafts larger than 8 to 9 mm in diameter, 75% for grafts 7 mm to smaller than 8 mm in diameter, and 74% for grafts 8 mm in diameter. Grafts from female donors experienced 67% cell loss compared with 72% cell loss among grafts from male donors. The method of tissue retrieval, the donor’s cause of death, a history of diabetes, and the time from death to preservation or to surgery were not significantly associated with changes in endothelial cell density over time, the investigators concluded.

“Quality of Vision Improved 3 Months After LASEK”

In patients undergoing LASEK, the quality of vision worsened in the early postoperative period but returned to preoperative levels by 1 month. According to a study in the Journal of Cataract & Refractive Surgery, the quality of vision was better than that of preoperative levels by 3 months after surgery.1

The study included 100 patients (68 myopic, 32 hyperopic) having bilateral LASEK with the Amaris laser (Schwind eye-tech-solutions, Kleinostheim, Germany; not available in the United States). Participants completed a quality-of-vision questionnaire preoperatively and 5 days,
2 weeks, 1 month, and 3 months postoperatively. The outcome measures were the quality-of-vision scores for the frequency of symptoms, severity, and bothersome nature. The scores ranged from 0 to 100, with higher scores indicating a poorer quality of vision.

For the frequency of symptoms, the mean preoperative quality-of-vision score was 6.78 ±11.45 (standard deviation). Postoperatively, the mean scores at 5 days, 2 weeks, 1 month, and 3 months were 70.71 ±11.26, 50.55 ±14.63, 7.15 ±12.49, and 2.45 ±6.01, respectively. For the severity of symptoms, the mean preoperative score was 6.22 ±10.52, and the mean postoperative scores were 54.85 ±12.19 at 5 days, 38.95 ±11.42 at 2 weeks, 4.38 ±7.80 at 1 month, and 1.94 ±4.64 at 3 months. For the bothersome nature of symptoms, the mean preoperative score was 4.91 ±9.48, and the mean postoperative scores at 5 days, 2 weeks, 1 month, and 3 months were 38.97 ±24.18, 21.90 ±16.50, 3.61 ±7.01, and 1.44 ±4.91, respectively. There were statistically significant differences for all comparisons except between preoperatively and 1 month postoperatively. There was no statistically significant difference between the two groups at any time interval.


**Corneal Inlay Inserted Into Corneal Pocket for Presbyopic Correction**

Using a femtosecond laser, the surgeon can create a corneal pocket beneath a previous LASIK flap and can safely insert a small-aperture corneal inlay to correct presbyopia, according to research presented at the annual ARVO meeting in Fort Lauderdale, Florida.1

The study examined seven patients (five male, two female) aged 45 to 60 years who had prior LASIK. Participants were required to have an uncorrected distance visual acuity of 20/20 or better in the untreated eye and 20/50 or better in the treated eye with uncorrected near visual acuity of J4 or worse. Other inclusion criteria were a spherical equivalent of between -0.75 and 0 D with 0.75 D or less of cylinder, a prior flap thickness of 160 µm or less with a corneal thickness greater than 480 µm, and normal corneal topography.

In all patients, the Kamra corneal inlay (AcuFocus, Irvine, CA; not available in the United States) was inserted into a corneal pocket that was created in the non-dominant eye using a femtosecond laser (Femto LDV Crystal Line; Ziemer Group, Port, Switzerland). The pockets, which were 6.5 mm wide, opened temporarily and were positioned to leave 250 µm of residual posterior stroma. The investigators measured corneal thickness using ultrasound pachymetry (Sonogage, Inc., Cleveland, OH) and Fourier-domain optical coherence tomography (FD-OCT; Optovue, Inc., Fremont, CA), and they evaluated flap thickness using FD-OCT.

Mean central corneal thickness showed good agreement between pachymetry (524.7 ±33.2 µm) and FD-OCT (526.6 ±17.3 µm). During the original LASIK procedure, the flap’s thickness was targeted for 90 µm for one patient and 160 µm for the other six patients (mean = 150 µm). Before the pocket procedure, the FD-OCT–measured LASIK flap’s mean thickness was 138.4 µm, which exemplifies the importance of accurate corneal measures before attempting the pocket procedure in post-LASIK patients, the researchers noted. The mean distance between the flap and pocket was 138.1 µm. FD-OCT showed a mean of 256 µm (attempted 250 µm) for the depth achieved for the corneal inlay. No damage was observed in the corneal or flap structures.

At 3 months postoperatively, mean uncorrected near visual acuity improved by four lines, from J6 to J2. Mean uncorrected distance visual acuity was 20/30 versus 20/20 preoperatively, due to a slight myopic shift, the investigators reported. Additionally, one patient experienced an epithelial abrasion with residual stromal edema 1 day postoperatively. With this patient removed from the analysis, the mean uncorrected near visual acuity improved to J1, and mean uncorrected distance visual acuity improved to 20/25. No additional complications were noted during follow-up.

1. Leon FS, Ramírez E, Booker ET. Creating a femtosecond pocket under previous LASIK flap for correction of presbyopia with a corneal inlay. Poster presented at: The ARVO Annual Meeting; May 1-5, 2011; Fort Lauderdale, FL. Poster #5767.

**Visian ICL Safe, Effective for Myopic Correction**

Implantation of the Visian ICL (STAAR Surgical Company, Monrovia, CA) for moderate-to-high myopia was safe and effective and provided long-term predictable and stable refractive results, according to a study in the Journal of Cataract & Refractive Surgery.1

In the retrospective, observational study, researchers evaluated the medical records of 111 patients (188 eyes) who were implanted with the Visian ICL for myopic correction. The included patients received the implant between 2001 and 2007 and regularly returned for postoperative evaluations for at least 3 years. Uncorrected and
corrected distance visual acuities, refraction, phakic IOL vault, endothelial cell loss, and adverse events were evaluated for 5 years after the ICL's implantation.

The mean spherical equivalent decreased from -11.17 D ±3.40 (standard deviation) preoperatively to -0.88 ±0.72 D at 5 years postoperatively. The mean change in the refraction from 1 month to 5 years was -0.65 ±0.65 D. The mean uncorrected and corrected distance visual acuities were 0.69 ±0.26 (20/29) and 0.83 ±0.15 (20/24), respectively. The mean safety and efficacy indices were 1.27 ±0.33 and 0.89 ±0.35, respectively. No eye lost more than two lines of visual acuity, and 70% achieved 0.80 (20/25) or better corrected distance visual acuity. The total amount of endothelial cell loss was 7.7%. There was a tendency toward a decreased phakic IOL vault over time, and no vision-threatening complications occurred.

"In summary, our long-term results suggest that Visian Implantable Collamer Lens [phakic] IOL implantation to correct moderate to high myopia is a safe and effective procedure that provides predictable and stable refractive results over the long term; in this case, over 5 years," the authors concluded. "Future studies with a longer follow-up are necessary to assess late-onset complications, specifically in the development of anterior lens opacities and the change in vault over time."


WaveTec Vision Raises $15.9 Million for Wavefront-Guided Custom Cataract Technology

WaveTec Vision (Aliso Viejo, CA) announced that it has raised $15.9 million from investors to expand the commercialization and adoption of its ORange intraoperative wavefront aberrometer. The financing will also allow WaveTec to grow its infrastructure and further demonstrate the clinical efficacy of ORange, according to a news release.

During a presentation at the 2011 ASCRS meeting in San Diego, postrefractive IOL power calculations were shown to be more precise with the use of wavefront aberrometry.1 Allon Barsam, MD, presented the results of 141 consecutive cataract surgery cases in patients who had previously undergone myopic LASIK or PRK. Using version 2.5 of ORange software, Dr. Barsam and colleagues found that nearly 50% of patients were within ±0.50 D of the intended correction and approximately 80% were within ±1.00 D. These results are significant, because IOL power calculation is more difficult in postrefractive eyes due to the varying axial lengths, Dr. Barsam explained. He added that the results with ORange "compare very favorably with the methods based on the preoperative K readings with manifest refraction and similar to the other formulas."

The series D financing was led by existing investor Versant Ventures (Menlo Park, CA), with participation from existing investors Accuitive Medical Ventures (Palo Alto, CA) and De Novo Ventures (Menlo Park, CA). New investor Gund Investment Corp. (Princeton, NJ) also participated in the funding.

Avedro Completes US Phase 3 Corneal Cross-Linking Trials

Avedro, Inc. (Waltham, MA), announced the completion of all of the 1-year follow-up visits for patients enrolled in its two multicenter phase 3 studies. The clinical trials are evaluating the safety and efficacy of corneal collagen cross-linking for the treatment of progressive keratoconus and ectasia after refractive surgery.

This degenerative disease is the leading cause of corneal transplants in the United States. Ectasia following refractive surgery is a complication associated with LASIK. Outside the United States, cross-linking has been deemed safe and effective and is approved for the treatment of keratoconus and ectasia after refractive surgery, according to Avedro.

Peter Hersh, MD, is the director of the Cornea and Laser Eye Institute at Hackensack University Medical Center in New Jersey and medical monitor for Avedro’s clinical trial. He stated in a news release, “Avedro’s efforts to make this clinically important treatment available to US patients is applauded by all US ophthalmologists who today lack any approved therapeutic treatment to halt the progression of these sight-threatening conditions.”

News is compiled by Callan Navitsky, Stephen Daily, and Jennifer Kreasoulas, PhD.