# Actavis to Acquire Allergan for $66 Billion

In a blockbuster deal that will likely thwart a long and aggressive hostile takeover bid by Valeant, Actavis has agreed to acquire Allergan for $66 billion in cash and stock. Actavis will pay $219 per Allergan share. The deal is a combination of $129.22 in cash and 0.3683 Actavis shares for each share of Allergan common stock.

The combination will create one of the top 10 global pharmaceutical companies by sales revenue, with combined annual pro forma revenues of more than $23 billion anticipated in 2015, according to Actavis. The transaction has been unanimously approved by the boards of directors of both companies.

The combined company will be led by Brent Saunders, CEO and president of Actavis, who is the former CEO of Bausch + Lomb. Paul Bisaro will remain executive chairman of the board at Actavis. Two members of Allergan's board of directors will be invited to join Actavis' board of directors after the transaction is complete.

"This acquisition creates the fastest growing and most dynamic growth pharmaceutical company in global health care, making us one of the world's top 10 pharmaceutical companies," Mr. Saunders said in a company news release. "We will establish an unrivaled foundation for long-term growth, anchored by leading, world-class blockbuster franchises and a premier late-stage pipeline that will accelerate our commitment to build an exceptional, sustainable portfolio. The combined company will have a strong balance sheet, growing product portfolios, and broad commercial reach extending across 100 international markets. Our combined experienced management team is dedicated to driving strong organic growth while capturing synergies and maintaining a robust investment in strategically focused R&D."

Actavis projects that the transaction will generate at least $1.8 billion in annual synergies commencing in 2016. Actavis said it plans to maintain annual research and development investment of approximately $1.7 billion between the two companies, which is about $400 million less than what the companies would have spent separately. Mr. Saunders, however, says it is less than the $900 million that Valeant would have cut had it succeeded in its acquisition.

Based in Ireland, Actavis will also realize tax advantages as a result of the deal. Actavis is expected to have a 15% corporate tax rate, saving the combined company hundreds of millions of dollars in taxes that California-based Allergan would have paid at a roughly 26% tax rate.

Mr. Saunders said that the deal would give Actavis the ability to generate organic revenue growth at a compound annual growth rate of at least 10% for the upcoming years. The addition of Allergan's portfolio will double the revenues of Actavis' North American Specialty Brands business. On a pro forma basis for 2015, the combined company will have three franchises with annual revenues in excess of $3 billion: ophthalmology, neurosciences/CNS, and medical aesthetics/dermatology/plastic surgery. The specialty product franchises in gastroenterology, cardiovascular, women's health, urology, and infectious disease treatments will have combined revenues of approximately $4 billion, according to Actavis.

"Today's transaction provides Allergan stockholders with substantial and immediate value as well as the opportunity to participate in the significant upside potential of the combined company," David E. I. Pyott, chairman and CEO of Allergan, said in the news release. "We are combining with a partner that is ideally suited to realize the full potential inherent in our franchise. Together with Actavis, we are poised to extend the Allergan growth story as part of a larger organization with a broad and balanced portfolio, a meaningful commitment to research and development, a strong pipeline, and an unwavering focus on exceeding the expectations of patients and the medical specialists who treat them."

The combined company will have more than 30,000 employees. Its headquarters will remain in Dublin, while US administrative headquarters will operate in Parsippany, New Jersey. Actavis will keep the Allergan operations in Irvine, California.

For Allergan, the deal likely marks the end of a 6-month battle against an aggressive hostile takeover bid from Valeant. Partnered with activist investor Bill Ackman, Valeant has been pursuing Allergan since April and had raised its bid to $53 billion in late May. The Canadian company recently hinted it might increase its offer again, but after the details of the Actavis proposal were released on Monday, Valeant CEO Michael Pearson indicated the price was now too steep for a counteroffer.

"We have seen the announcement that Allergan and Actavis have made, and while we will review any such agreement in determining our course of action, Valeant cannot justify to its own shareholders paying a price of $219 or more per share for Allergan," Mr. Pearson stated. "We will remain focused on delivering strong organic results and evaluating acquisition opportunities as we always have: prudently, in a disciplined manner, and in the best interests of our shareholders."

A day after the deal was announced, Mr. Ackman, principal of Pershing Square Capital Management, said he supports the $66 billion deal and will withdraw his request for an Allergan special shareholder meeting, which was scheduled for December 18. Based on Allergan's current share price, Mr. Ackman, who owns nearly 10% of Allergan, has made about $2.3 billion on the deal.

The transaction is subject to the approval of shareholders of both companies as well as regulatory clearances in the United States, Europe, and other jurisdictions. If approved, it is anticipated to close in the second quarter of 2015.

## App Detected Visual Field Loss in an Underserved, High-Risk Population

The results of a study released at the annual meeting of the American Academy of Ophthalmology suggest that a tablet-based test could lead to earlier intervention and improve eye health outcomes in low-resource communities, according to a news release. The investigators used the visualFields easy app (George Kong softwares) on a first-generation iPad (Apple) to screen more than 400 eyes for glaucoma.

"When properly administered, the visualFields easy app performs visual field screening of the central 30° diameter visual field," Chris A. Johnson, PhD, director of the Visual Field Reading Center at the University of Iowa, told *Glaucoma Today*. "The app is properly calibrated to have a background luminance of 31.5 apostilbs (10 candelas per meter squared) and briefly presents a Goldmann size V target at an intensity of 16 dB at 96 locations (24 per visual field quadrant). Testing time is slightly more than 3 minutes per eye."

Pilot testing in Nepal was performed on approximately 210 normal eyes, 180 glaucomatous eyes, and 26 eyes with diabetic retinopathy. The results correlated well with conventional clinical automated perimetry, with agreement between 51% and 79% of the time, the news release said.

"The visualFields easy app accurately detected moderate and advanced visual field loss, but early deficits were more difficult to identify because of a modestly high false positive rate," Dr. Johnson explained. "Refinements are underway for this app to reduce testing time, improve performance, monitor eye and head movements, and optimize testing strategies. These preliminary studies suggest that this type of testing will be useful for telemedicine, accessing at-risk populations, and providing diagnostic screening to individuals who do not have easy access to traditional health care."

*Dr. Johnson acknowledged no financial interest in the product or company he mentioned.*

## Glaucoma Diagnostic Technology for Spectralis Introduced

Heidelberg Engineering presented the Glaucoma Module Premium Edition (GMPE) for Spectralis at the annual meeting of the American Academy of Optometry Professional Press Conference in Denver. According to a company news release, the new glaucoma module, which is pending FDA clearance, combines a proprietary anatomic positioning system (APS) with a series of unique scanning patterns. The APS creates an anatomic map of each eye. The center of the optic nerve head and the fovea are detected via a short pre-scan function. The map is aligned according to these anatomical landmarks, individually for each eye. The company says subsequent scans are oriented to this axis and automatically centered on the optic nerve head, ensuring that relevant structures are precisely examined. The combination of the APS feature and unique scanning patterns for analysis of the optic nerve head, the retinal nerve fiber layer (RNFL), and the ganglion cell layer will reportedly aid clinicians in making correct and early diagnoses of glaucoma.

"Analysis of the eye using optical coherence tomography (OCT) has evolved over the past 10 years," Murray Fingeret, OD, told *Glaucoma Today*. "Initially, OCT was used to evaluate the RNFL. Over the years, other areas of analysis have included the optic nerve (neuroretinal rim) and macula (ganglion cells). Now, with the GMPE for Spectralis, Heidelberg joins other OCT manufacturers that have included optic nerve assessment with their systems. The GMPE provides several new measurements. It determines the size of the optic disc using Bruch membrane opening at 48 locations as the marker for the optic disc margins. This measurement is more repeatable and often differs from the clinical appearance of the disc margin that has been used up to now. At each of these locations, a line is constructed that runs to the internal limiting membrane along the minimal distance. This provides a new metric of rim thickness, minimal rim width, which is compared to a normative database. Using the detection of Bruch membrane opening, the center of the optic disc is deter-

mined, and three circles with diameters of 3.5, 4.1, and 4.7 mm are scanned and compared to the normative database. A unique presentation is included for both the RNFL and the minimal rim width measurements, which are provided showing the percentage that the measurement falls within the normative data range. This is significant, because the printout presents this using figures that are compressed and difficult to detect if subtle loss is occurring. When areas are within the green zone using the temporal–superior–nasal–inferior-temporal presentation or with a sector analysis and thought to be perfectly normal, they may be further analyzed to see how close the measurements are to tipping to the next significance level."

*Dr. Fingeret is a consultant to and speaker for Heidelberg Engineering.*

## Glaucoma Foundation Holds Third Scientific Think Tank on Exfoliation Syndrome

The Glaucoma Research Foundation (GRF) recently held the 2014 International Scientific Think Tank in New York. The event was the organization's third consecutive annual gathering to focus on exfoliation syndrome (XFS). According to a news release, GRF decided 3 years ago to devote its efforts to curing XFS.

"As a result of this new focus, we have significantly increased the number of people who are working in this disease and areas relating to this disease," said Robert Ritch, MD, the GRF's medical director and Think Tank organizer, in a news release. "We have gained more professional awareness and, in the last 3 years, have probably tripled the number of people doing research in this field."

Several working groups have reportedly continued the conversations begun at the Think Tank annual meetings. One of the groups focuses on genetics, genomics, gene environment, and gene interactions. A second group is working on biomarkers. More specifically, this group is looking for characteristic molecules, determining which molecules or compounds are increased or decreased in eyes with XFS, and identifying systemic molecules or systemic markers that can be detected, possibly for a blood test for XFS. A third group is using animal models in an effort to find ways to create better models. A fourth group is exploring the production of exfoliation material by the cells in the eye and growing cells in a three-dimensional tissue culture to harvest exfoliation material.

The GRF said its research grants program is now solely funding projects aimed at furthering XFS research. Since 2013, the GRF has raised more than $2 million to support this initiative.

## Transcend Medical and Volk Optical Launch the Transcend Vold Goniolens


The Transcend Vold Goniolens (TVG), developed by Transcend Medical in collaboration with Steven D. Vold, MD, will now use Volk lens technology, according to a news release. The TVG will also be manufactured and sold exclusively through Volk Optical and its worldwide network of distributors. Intended specifically for microinvasive glaucoma surgery, the TVG is the only goniolens to feature a movable stabilization ring and floating lens, which are designed to provide optimal visualization and precision during ab interno procedures.

## Hydrus 2 Glaucoma Study Met Primary Endpoint

Ivantis, developer of the Hydrus Microstent, announced that the international Hydrus 2 trial met its primary endpoint. According to a company news release, the randomized, controlled study showed that, 24 months postoperatively, the device significantly reduced IOP and medication use in patients with open-angle glaucoma undergoing cataract surgery.

"Hydrus 2 is the first randomized, controlled, multicenter trial to demonstrate the ability of a [microinvasive glaucoma surgical] device to lower IOP (> 20% without medications) compared to cataract surgery alone at 2 years [postoperatively]," Thomas W. Samuelson, MD, the medical monitor of the Hydrus 2 study, said in the news release. "It was the first trial to employ a 'terminal washout,' designed to eliminate the confounding effects of topical medications in the assessment of IOP, which is vital to truly understanding the efficacy of a therapy. As a glaucoma surgeon, I am very encouraged by the 2-year data demonstrating excellent efficacy along with the safety that we have come to expect from the [microinvasive glaucoma surgery] sector."

Hydrus 2 enrolled 100 patients with open-angle glaucoma at seven European eye hospitals. One-half of the patients received the device and underwent cataract surgery (treatment group), and one-half received cataract surgery alone (control group). A total of 93 patients were available for follow-up 2 years postoperatatively. The primary endpoint of the trial was the proportion of

## Online Survey Results September/October 2014

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|---|---|
| **Would you diagnose and treat blood flow abnormalities in the optic nerve to decrease the risk of glaucomatous progression in eyes with an acceptable IOP?** | |
| Yes | 60.87% |
| No | 21.74% |
| Unsure | 17.39% |
| **Do you currently use topical brimonidine, topical unoprostone, and/or trabeculectomy to treat blood flow abnormalities in the optic nerve?** | |
| Yes | 33.33% |
| No | 66.67% |
| **Do you currently use anterior segment imaging in your practice?** | |
| Yes | 39.13% |
| No | 60.87% |
| **Are you considering purchasing a device to image the anterior segment?** | |
| Yes | 40.91% |
| No | 59.09% |

patients per group who achieved at least a 20% reduction in IOP at 2 years compared with their IOP before surgery.

Prior to entering the study, patients had, on average, an IOP of 19 mm Hg and were instilling two eye drops daily. They were asked to stop using their medications roughly 30 days prior to surgery to establish an unmedicated IOP. At the time of surgery, all patients had a mean IOP of 26 mm Hg. Patients were then randomized to either the treatment group or the control group, and medications were withheld after surgery. The study protocol recommended the IOP level at which medications should be re-administered during the 2-year follow-up period. At the end of 2 years, IOP medications were stopped for approximately 30 days to establish another unmedicated IOP and to isolate the effect of the Hydrus device.

According to the news release, 2 years postoperatively, 73% of the treatment group was medication free compared with 38% of the control group ($P = .0008$), an improvement of 92%. After medications were discontinued, 80% of the treatment group achieved a 20% or greater reduction in IOP compared with 46% of the control group ($P = .0008$). A 20% drop is clinically meaningful, according to the American Academy of Ophthalmology. The rate of side effects was reportedly comparable in both groups, and vision was not affected by the addition of the Hydrus to the cataract surgery. Additionally, in a site-by-site analysis, the results across all seven centers were consistent with one another, which supports the reproducibility of the surgical technique and the validity of the overall results, according to Ivantis.

## Carl Zeiss Expands Glaucoma Offerings With New Cirrus Model

Carl Zeiss Meditec introduced the Cirrus HD-OCT 5000 with unique scans and clinical assessment tools for glaucoma at the annual meeting of the American Academy of Ophthalmology in Chicago. According to a news release, ChamberView improves clinicians' ability to assess patients' risk of angle-closure glaucoma, and HD Angle scan offers greater tissue penetration and unprecedented levels of resolution of key angle anatomical landmarks. The company says that new wide-field visualizations with the Cirrus PanoMap help facilitate the assessment of patients for glaucoma. This feature displays structural data for the entire posterior pole in a single report.

## InnFocus MicroShunt Reduced IOP and Glaucoma Medications

At the 2014 Ophthalmology Innovation Summit in Chicago, InnFocus reported the results of 59 glaucoma patients treated outside the United States for up to 3 years with the InnFocus MicroShunt. According to a company news release, the patients implanted with the device experienced a significant and stable reduction in mean IOP to below 14 mm Hg. Between 70% and 80% of patients reportedly either require fewer medications or are off medication completely.

The InnFocus MicroShunt consists of a microtube that is about twice the size of an eyelash. The company's goal is to provide a safe, effective, stable, and easy treatment for early- to late-stage glaucoma. According to InnFocus, the patented microshunt is made from the innovative SIBS Material to control flow. The glaucoma drainage implant is currently in phase 1 FDA trials at 11 centers in the United States and has been implanted alone or in combination with cataract surgery in clinical trials outside the United States. The company said it expects to have treated approximately 150 glaucoma patients in six countries by early 2015. ■