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Now Available: OIS@AAO Executive Summary - "Eye on Innovation"

International Business Forum (IBF) has published our in-depth report on the Fourth Annual Ophthalmology Innovation Summit (OIS), which was held in Chicago on November 8, 2012, just prior to the American Academy of Ophthalmology (AAO) Annual Joint Meeting. The report covers all 29 presenting companies from the fields of ophthalmic devices, bio-pharma, and healthcare information technology, with a focus on important recent developments. The report also reviews the key takeaways from the panel discussions and keynote speeches.

Click here for a link to the report on the IBF/OIS web site.

Click here for the PDF document.

The one-day conference brought together over 800 ophthalmic industry leaders, physicians, and investment professionals. The purpose of OIS is to create an ecosystem of clinical, technology and business -- to unite a diverse group of key players in the ophthalmic field to foster innovation and facilitate business transactions. The conference, which has been held prior to the last four AAO annual meetings and last year's American Society of Cataract and Refractive Surgery (ASCRS) annual meeting, provides a forum for addressing key issues impacting the ophthalmic field and a platform to showcase the most promising private ophthalmic companies.

Presenting companies included 25 ophthalmic device and bio-pharma innovators at all stages of development, from early clinical to commercial. This year OIS added a session highlighting four companies in the rapidly evolving field of Health IT.

Panel discussions covered topics such as the latest FDA legislation and its impacts, emerging drug delivery technologies, the premium IOL market, pharmaceutical pipeline management and corporate leadership. Additional presentations addressed trends in ophthalmic venture capital and public market performance, the challenges facing corporate innovators and the impacts of the recent election on the industry.

The Second Annual OIS@ASCRS will be held on April 18, 2013 in San Francisco, CA, prior to the start of the ASCRS Symposium and Congress. Later this year, the Fifth Annual OIS@AAO will be held in New Orleans, LA, on November 14, 2013. **Q**

Femtosecond Laser Cataract Surgery: Developments Since AAO

The LENSAR Laser System received FDA clearance for corneal incisions in cataract surgery. With this 510(k) clearance from the FDA, which was announced on December 10, the LENSAR system became the third femtosecond laser in the US that is cleared for all critical components of laser cataract surgery, including lens fragmentation, anterior capsulotomy, and corneal incisions. The other two femtosecond lasers that are cleared for the full range of cataract surgery incisions are the LenSx Laser from Alcon and the Catalys Precision Laser System from OptiMedica Corp. On November 16, OptiMedica announced that it had raised an additional $35 million of capital to support its commercial rollout and development of new products.

Bausch + Lomb is still awaiting FDA clearance for corneal incisions and lens fragmentation for its VICTUS Femtosecond Laser Platform. The system is currently cleared in the US for anterior capsulotomy during cataract surgery and for creation of corneal flaps during LASIK and other procedures. On January 28, Bausch + Lomb announced that it had

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Laser Cataract Surgery [*from page 1*]

completed its acquisition of Technolas Perfect Vision GmbH, the developer of the VICTUS laser. The two companies have been co-promoting the VICTUS laser since December 2011.

The Centers for Medicare and Medicaid Services (CMS) published guidance that addresses when physicians and facilities may charge Medicare beneficiaries for the use of a femtosecond laser when performing cataract surgery with the implantation of premium IOLs. The CMS guidance document, entitled "Laser-Assisted Cataract Surgery and CMS Rulings 05-01 and 1536-R," was published on November 16. (Click here for a link to the CMS policy statement.)

On December 17, the American-European Congress of Ophthalmic Surgery (ACOS) sponsored a webinar to review the CMS guidance, featuring Allison Shuren, Alan Reider, and Tom Gustafson of the law firm Arnold & Porter LLP. (Click here for a link to the webinar archive on Eyetube.net.) Our review of the CMS guidance is based largely upon the analysis provided by Arnold & Porter LLP, and we provide the same disclaimer: that this should not be considered legal advice.

The guidance document built upon, but did not amend or replace, the two CMS rulings issued in 2005 and 2007 related to implantation of premium IOLs following cataract surgery. Under these previous rulings, Medicare allows beneficiaries to pay additional non-covered charges associated with insertion of a premium IOL -- a presbyopia correcting intraocular lens (PC-IOL) or an astigmatism correcting intraocular lens (AC-IOL) -- following cataract surgery. Two specific categories of additional charges for non-covered services are allowed: charges related to the premium IOL itself, and charges for resources required for fitting and vision acuity testing of a premium IOL.

Prior to the recent guidance publication, there was a wide range of views regarding whether Medicare cataract patients could be charged for use of the laser. On the one extreme, the laser could be viewed as a "golden scalpel," replacing conventional tools used for covered steps of the procedure, and therefore not chargeable to the patient under any circumstances. On the other extreme, the laser could be viewed as enhancing the function of premium IOLs or the refractive results of cataract surgery in general, and therefore chargeable to the patient in all cases. CMS wrote the new guidance for laser-assisted cataract surgery partly in reaction to press stories about practices apparently charging patients for use of the laser for all types of lens surgery.

The new guidance remains silent on, and therefore does not appear to change, Medicare policy regarding refractive keratoplasty, or correction of astigmatism. Cataract patients may be billed for use of the laser to create astigmatism-correcting incisions, just as they have been allowed to be billed in the past for creation of such incisions using a blade. For Medicare cataract cases involving implantation of a conventional (i.e., non-premium) IOL, this is the only functionality of the laser that may be billed to the patient.

In this guidance, CMS distinguishes between two separate functions of the femtosecond laser systems: imaging and cutting. The cutting capabilities of the laser may not be billed to Medicare beneficiaries under any circumstances. In cases involving premium IOLs, the imaging capabilities of the femtosecond laser systems that are necessary to implant the premium IOL may be billed to patients as a non-covered service. This is subject to the limitation that these additional services are not performed when a conventional IOL is implanted.

This limitation comes with an important exception: that performance of such additional services by a physician on a limited and non-routine basis in conventional IOL cataract surgery (such as cases with laser incisions for astigmatism-correction) would not disqualify such services as non-covered services. This is interpreted to mean that as long as a surgeon does not use the laser in a majority of conventional IOL cases (such as to correct astigmatism), then the surgeon may bill the laser imaging functionality to premium IOL patients.

The CMS guidance would appear to allow for "tiered" fee structures for premium IOL patients. Prior to this guidance, it was not clear whether or not surgeons would not be allowed to charge their premium IOL patients different fees depending upon the use of the laser system (i.e., one price without the use of the laser system and a higher price with the laser system). Based on the new guidance, it would appear that such differentiated or "tiered" pricing would be permissible, as long as the additional fee is based upon the use of the laser system for imaging and not for cutting. **Q**

Full Year Financial Results Reported for Alcon and AMO

On January 23, Novartis reported 2012 financial results. Full year 2012 revenues for Alcon totaled $10.225 billion, an increase of 5% constant currency (cc) over 2011 sales. US sales expanded 5% to $4.016 billion, and international sales grew 5% (cc) to $6.209 billion. Surgical sales grew 8% (cc) to $3.752 billion, Ophthalmic Pharmaceuticals grew 5% (cc) to $4.019 billion, and Vision Care (contact lenses and lens care) grew 4% (cc) to $2.454 billion.

Within Alcon's Surgical segment, growth was broad based. Cataract IOLs expanded 4% (cc) to $1.281 billion in 2012. Advanced technology IOLs performed well, growing 15% (cc) in Q4, led by toric IOLs, which grew 21% (cc) in the quarter. Sales of other cataract products grew about 7% (cc) to $1.651 billion in 2012. Vitreoretinal products expanded 12% (cc) to $578 million, and the refractive/ other segment grew 24% (cc) to $242 million.

Abbott also reported 2012 results on January 23. Full-year 2012 revenues for Abbott Medical Optics (AMO) totaled $1.097 billion, an increase of 0.8% (cc) over 2011 sales. AMO's US sales were $399 million (+0.7%) and international sales were $698 million (+0.8% cc).

This is the first time that Abbott has reported results for AMO since it acquired the business in February 2009. The last reported results for AMO as an independent company were for 2008. In that year, US revenues were $438 million and OUS revenues were $747 million, with 81% of revenues coming from cataract and refractive surgery and 19% from contact lens solutions. In 2008, Alcon's Surgical revenues totaled $2.881 billion, including $1.073 billion in IOLs, $1.692 billion in cataract/ vitreoretinal products, and $116 million in refractive surgery. **Q**

Upcoming Meetings and Events

ASCRS/ASOA Winter Update 2013. February 14-18, 2013, Aventura (Miami), FL

17th ESCRS Winter Meeting. February 15-17, 2013. Warsaw, Poland

Aspen ACOS-Dulaney Winter Meeting. February 24-27, Aspen, CO

American Glaucoma Society Annual Meeting. February 28-March 3, 2013, San Francisco, CA

AAO 2013 Mid-Year Forum and Congressional Advocacy Day. April 10-13, 2013, Washington, DC

Second Annual OIS@ASCRS. April 18, 2013, San Francisco, CA

ASCRS Cornea Day and **ASCRS Glaucoma Day.** April 19, 2013, San Francisco, CA

ASCRS/ASOA Annual Symposium and Congress. April 19-23, 2013, San Francisco, CA

ARVO Foundation Vision Innovation and Venture Forum. May 3, 2013, Seattle, WA

ARVO Annual Meeting. May 5-9, 2013, Seattle, WA

5th World Glaucoma Congress. July 17-20, Vancouver, BC, Canada

ACOS Summer Symposium. August 1-4, 2013, Deer Valley, UT

ASRS Annual Meeting. August 24-28, 2013, Toronto, Ontario, Canada