

# EyeQ Report

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## Ophthalmology Q3-05: IOLs Strong, Refractive Mixed, and AMD in Transition

This issue features a recap of third quarter reports from nine publicly traded ophthalmology companies, spanning the fields of refractive surgery, cataract surgery, contact lenses and lens care, and AMD. Our approach is to focus on the most important items in each company's quarterly release and conference call, with an emphasis on key products and pipeline developments. Whenever possible, we provide some historical context to quarterly results and connect the dots between companies.

## Refractive Surgery: Winners and Losers in an Overall Flat Market

The US LASIK procedure market in Q3 was relatively flat versus prior year, and the current outlook for 2006 indicates more of the same. The international market is tougher to gauge, as there is less available data. There are mixed signals from the excimer laser manufacturers regarding the health of international LASIK markets. AMO/VISX has been placing a lot of hardware internationally, but Bausch & Lomb, which has a strong LASIK presence outside the US, stated on its Q3 conference call that it is seeing declining procedure trends in many parts of Europe.

AMO/VISX turned in solid refractive results, driven by international laser placements, continued conversion to CustomVue, and a favorable technology/upgrade cycle. Alcon and Bausch & Lomb (B&L) are clearly struggling in refractive.

IntraLase continues to gain share in the US LASIK market, which is visibly impacting B&L's microkeratome blade business, although growth is being driven largely by the international business.

Among the large corporate LASIK service providers, LCA-Vision continues to gain market share, executing on its value pricing, DTC marketing model and generating growth that is far outpacing the overall market. TLCVision underperformed overall US procedure trends in Q3, but is about to launch an expansion strategy aimed at the value pricing segment.

## Cataract Surgery: IOL Franchises Strong Across-the-Board

All three major IOL suppliers turned in solid results in Q3-05. Alcon reported an 18% increase in IOL sales, and about 8% "core IOL growth" excluding the favorable impact of the ReSTOR multifocal launch. AMO grew IOL sales 6%, and B&L turned in "double digit" IOL growth. B&L's strong performance is somewhat surprising given the lack of a multifocal or accommodating IOL offering for presbyopia, and declining sales of phaco products. In the phaco segment, B&L appears to have lost market share to both AMO (phaco revenues up 15%) and Alcon (non-IOL cataract/vitreoretinal revenues up 9%).

#### Specialty Lenses Continue to Lead Contact Lens Growth

Bausch & Lomb reported solid contact lens growth of 10%, or 12% excluding the disposal of a European subsidiary. Growth was led by specialty lenses (multifocal and toric) and PureVision silicon hydrogel lenses.

Both AMO and Alcon reported declines in lens care solution sales in Q3, as growth in

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multipurpose solutions failed to overcome declines in older technology products. B&L was the only major supplier that eked out a small amount of positive growth.

AMD: Visudyne Down, Macugen Up, Lucentis (and RHEO) Coming

Treatment regimens for wet age-related macular degeneration (AMD) are about one year into what will be a period of transition lasting three years or more. With Eyetech and Pfizer's Macugen about ten months into its US launch, sales have risen steadily and have had a meaningful impact on domestic Visudyne sales. Visudyne is holding up well internationally, where Macugen is generally not yet

available. Off-label use of Genentech's Avastin is also having an impact on both Macugen and Visudyne sales in the US. Meanwhile, Genentech just released impressive clinical results for Lucentis from the pivotal ANCHOR trial, to go along with the previously released impressive results from the pivotal MARINA trial. Genentech plans to file its BLA next month and request priority review. Once Lucentis is approved, as early as H2-06, the impact on both Visudyne and Macugen will be immediate and significant.

On the dry AMD front, OccuLogix has achieved key milestones recently on the path toward PMA submission and FDA approval of RHEO Therapy. Yesterday, the company announced that all final 12-month follow-up visits have been completed for the pivotal MIRA-1 Trial, and the final PMA module is expected to be filed in late Q1-06. Q

## AMO Accelerates Product Rationalization and Delivers Strong Cataract and Refractive Growth

On November 2, Advanced Medical Optics (AMO) reported global sales of \$248.2 million, a 25% increase over Q3-04 resulting primarily from the addition of the acquired VISX business, which accounted for all but 1% of the revenue growth. The effects of foreign currency translation on reported revenues were minimal in the quarter. Current revenue guidance is as follows: for 2005, \$920-930 million (implying O4-05 revenues of \$252-262 million); for 2006, \$1.02-1.04 billion; for 2007, \$1.10-1.12 billion (representing 7-8% growth over a 2006 sales forecast that include a full year of product rationalization and VISX sales). Long-term annual revenue growth is targeted in the 6-8% range in the cataract business, 7-9% in laser vision correction, and 1-3% in eye care. In Q3, adjusted (non-GAAP) EPS came in at \$0.35, up 21%. Given full year guidance of \$1.45-1.50, O4 EPS guidance is \$0.38-0.43 (down 22-31% versus O4-04).

In October, AMO announced that it was accelerating its plans to rationalize its cataract and eye care product lines, and intent to increase investment in its refractive surgery franchise, particularly in support of refractive IOLs and international expansion. AMO began to phase out certain non-core cataract and eye care products last year, and had originally expected the process to conclude by the end of 2006. The company has decided to accelerate this timeline and discontinue many of these products by the end of 2005; AMO estimates that these discontinued products would have accounted for \$30-40 million in 2006 sales (mostly in eye care), to be offset by incremental sales of promoted products. This process will result in a number of organizational changes, write-offs and other charges in the range of \$70-80 million,

and a 6% global workforce reduction.

At the same time, AMO reset its adjusted EPS guidance for 2005 at \$1.45-1.50. This was \$0.20 lower than the previous guidance range, with \$0.12 of the reduction resulting from operating costs associated with the accelerated rationalization and repositioning, about \$0.03-0.04 attributed to slower-than-expected capture of VISX cost synergies in Q3, and \$0.04-0.05 resulting from weakness in the eye care business. EPS guidance for 2006 is \$2.20-2.30 (up about 52%); EPS guidance for 2007 is \$2.65+ (up 15-20% or more).

#### **Surgical Products**

Ophthalmic surgical sales grew 50% to \$170.6 million; excluding \$47.7 million of sales related to the VISX acquisition, surgical sales increased 8.4%. Sales of IOLs grew 6.1% to \$62.3 million, and sales of viscoelastics increased 2.0% to \$28.9 million. Growth rates for both IOLs and viscoelastics include the Pfizer products that were acquired in June 2004, and represent a blend of higher growth rates for branded/promoted products and declines for products that are being actively discontinued and phased out. Sales of phacoemulsification products were \$19.5 million, a strong 15% increase over Q3-04. Sales of "promoted" surgical products, representing 84% of non-VISX surgical revenues, grew 17.5%.

AMO nearly doubled sales of the acquired Tecnis monofocal IOL, and sales of refractive IOLs (Verisyse, ReZoom, and Tecnis Multifocal) increased nearly four-fold. AMO expects total refractive IOL sales in 2006 of \$45-55 million. ReZoom is expected to account for most of this, given that the Tecnis Multifocal is not expected to be approved in the US until late 2007. A majority of 2006 refractive IOL revenues are expected to come from the US, driven by stronger pricing and promotion. About 800 US surgeons and about 800 international surgeons have been trained on ReZoom.

Laser vision correction (LVC) sales of \$50.4 million consisted of \$47.7 million of VISX revenue (up 23%) plus about \$2.6 million for Amadeus microkeratomes (up 7%). LVC system sales of \$11.1 million, up 71%, reached the highest level since Q3-03 (also \$11.1 million), when VISX was aggressively placing WaveScan diagnostic systems. This time around, the increase resulted from international laser sales, with global placements up 56% to about 47 lasers (about three-quarters of placements were outside the US). Hardware sales were also boosted by the beginning of the iris registration rollout; AMO projects that about half of active US VISX lasers will be upgraded with iris registration by the end of 2005, with the remainder upgraded by next spring. LVC licensing revenue increased 15% to \$31.2 million. With US

procedure volume basically flat on a rolling 12-month basis, licensing revenue growth was driven by CustomVue conversion, both domestically and internationally. The domestic CustomVue penetration rate has reached the mid-40%'s. LVC service/parts sales were \$5.4 million, up 7%.

#### Eye Care

Eye care sales declined 9% to \$77.6 million. Declines were driven primarily by the Japanese market, where contact lens wearers are aggressively moving away from hydrogen peroxide solutions (where AMO has a strong presence), and the shift toward daily disposable contact lenses is impacting multipurpose solution sales as well. The transition away from hydrogen peroxide is also taking place in parts of Europe. Globally, hydrogen peroxide sales declined 28%. Outside of Japan, AMO's eye care sales increased 6.5%. Sales of "promoted" eye care products declined nearly 11% due to the inclusion of the company's largest hydrogen peroxide brand.

With the June 2005 expiration of AMO's non-compete agreement with Allergan in the dry eye field, the company is gearing up to enter this market. Current plans call for a full commercial launch of an internally developed over-the-counter product in early 2007. Q

## Alcon Generates Huge Profit Growth with Favorable Product Mix and Operating Leverage

On October 19, Alcon reported global sales of \$1.071 billion for Q3-05, representing constant currency revenue growth of 10.5% over Q3-04. Full year revenue guidance remained unchanged at \$4.35-4.40 billion, implying Q4 sales of about \$1.06 billion.

Diluted net EPS grew an outrageous 52% to \$0.95, driven by (1) gross margin expansion from 74.1% to 77.0%, from improved manufacturing efficiencies, product mix, and reduced royalty expense; (2) operating margin expansion from to 28.9% to 34.3% driven by the higher gross margin and lower R&D and SG&A expense as a percentage of sales; and (3) tax rate reduction from 30.0% to 21.1%. Full year EPS guidance was raised by about \$0.16 to a new range of \$3.58-3.60, implying Q4 EPS of \$0.79-0.81. Alcon has left its initial 2005 EPS guidance of \$3.08-3.14 in the dust. Alcon management used to characterize its long-term growth goals as 8-10% on the top line, with 1.5-2x that growth rate (implying

12-20%) on the bottom line. Through nine months of 2005, Alcon has delivered 9.7% constant currency top line growth and 39% EPS growth (on an adjusted basis).

#### **Pharmaceutical Products**

Pharmaceutical sales grew 15% globally (constant currency) to \$438 million (41% of sales), including about 12% growth in the infection/inflammation and glaucoma categories. Alcon believes that Travatan (prostaglandin for glaucoma) has gained 3.0 share points in the US through August 2005 versus the same period last year, and that Vigamox (fourth generation fluoroquinolone anti-infective) has claimed a YTD US share through August of 44.9%. Patanol has accounted for 67% of ocular allergy



prescriptions in 2005, losing only about one share point in the face of competitive launches, but allergy sales growth was only 3.4% due to wholesaler inventory reductions. The otic franchise grew 38% and picked up 3.7 share points in the US to 31.4%.

RETAANE update: Alcon has enrolled more than 2,100 patients in the two risk reduction trials, and expects full enrollment of 2,500 patients by the end of 2005. Once fully enrolled, these studies are expected to last four years. In October, Alcon presented 24 month data confirming the safety of RETAANE after two years of administration, which was the purpose of the 24 month analysis (no surprise here, we already knew that the drug is safe, the issue now is efficacy). The company is continuing its discussions with the FDA and international regulatory bodies regarding the path to approval of RETAANE. Alcon also plans to start clinical trials to evaluate the efficacy of RETAANE in combination with Genentech's Avastin, with further details expected in the coming weeks.

#### Other pharmaceutical pipeline updates:

- Alcon launched Nevanac ophthalmic suspension during Q3, for the treatment of pain and inflammation associated with cataract surgery.
- On November 7, Alcon announced that Patanase (nasal spray for allergy) provided faster and overall better allergy symptom relief than Nasonex in a 425 patient onset-of-action study. The FDA is requiring that one of the inactive ingredients be removed before Patanase can be approved, and Alcon believes it will have to provide additional information to the FDA on the modified formulation prior to approval.
- Alcon has identified a lead compound from its dry AMD research program, although no details have been provided.

#### **Surgical Products**

Surgical product sales grew 9.3% globally (constant currency) to \$484 million (45% of sales). IOL sales increased 18.2% to \$165 million. Net of ReSTOR sales (see below), IOL revenue growth in Q3 was about 6%, or about 8% if ReSTOR units had been priced in-line with traditional IOLs (probably a more fair comparison). This is close to where Alcon pegs its own "core" IOL growth, at about 8.5%. Cataract/vitrectomy product sales rose 8.9%. Once again, Alcon's refractive business brought down the overall surgical growth rate, declining 29.1% due to a decrease in global laser sales and procedures.

IOL sales included \$17.5 million for the AcrySof ReSTOR multifocal. YTD sales of ReSTOR through Q3 were \$27.9 million. Full year ReSTOR sales guidance remains unchanged at \$45-55 million, implying Q4 sales of \$17-27 million. Given the current growth trajectory, the upper end of that range appears achievable. Full year guidance suggests unit volume of about 55-65,000 ReSTOR lenses. Through September, Alcon had trained 3,300 physicians, 2,000 were considered ready to implant, and 1,100 had implanted at least one lens. During Q3, Alcon received FDA approval for the AcrySof ReSTOR Natural (a yellow, blue-light absorbing version), and Alcon is aggressively transitioning its ReSTOR customers to this product. Planned future enhancements to ReSTOR include an aspheric design (employing an optic like the one in AcrySof IQ) and a toric version to treat astigmatic patients.

#### **Consumer Eye Care**

Consumer product sales increased 2.2% (constant currency) to \$149 million (14% of sales). Sales of artificial tears increased 15.6% driven by Systane, but this was offset by a 1.5% decline in contact lens solution sales. Q

## Bausch & Lomb Revenue Growth Led by IOLs and Specialty Contact Lenses

On October 26, Bausch & Lomb reported Q3-05 sales of \$589 million, an increase of 7% over Q3-04.

Foreign currency translation had minimal impact on reported revenues. Management projects 7% revenue growth for the full year 2005 (6% excluding the acquisition of CT Freda), which is below previous revenue guidance due to weakness in refractive surgery and a slower-than-expected launch of the

Retisert implant for uveitis. B&L projects 9% revenue growth for 2006 (also including CT Freda). Adjusted (non-GAAP) EPS was \$1.02, up 29% over prior year. Management is guiding to adjusted EPS in Q4 of \$1.20 (+28%), and 2006 EPS of \$4.20-4.30 (+15-17%).



**B&L** had to characterize its reported Q3 results as "preliminary" due to an ongoing investigation involving allegations of improper management conduct at the company's Brazilian subsidiary. We do not expect this to become a material issue for the company, as this unit accounts for less than 1% of total sales and management appears to be taking the appropriate actions to resolve these issues.

**B&L** continues to make progress on its ongoing IT redeployment. With the US vision care and OTC pharmaceuticals businesses having recently "gone live" on the new ERP system, just over half the company is now running on the new platform. Although the project is about one year behind original expectations, the company still projects annual savings of about \$25 million, most of which will be realized by 2006.

The company will hold an investor update meeting on Thursday, December 1, 2005 in New York City. The event will be webcast, beginning at 8:30am ET and concluding by about 1:00pm ET.

#### **Product Line Results**

Contact lens revenues increased 10% to \$188 million, or about 12% excluding the impact of the disposal of the Woehlk subsidiary in Europe. Growth was led by specialty products, including SofLens and PureVision Torics (mid-teens growth), PureVision SVS in the US, and SofLens Multifocal. PureVision Toric was launched in the US in October. Contact lens sales increased 17% in the Americas (nearly 20% in the US), 2% in Europe (7% excluding the disposal of Woehlk), and 11% in Asia. Supply constraints have impacted the growth of PureVision SVS to some extent – the company expects all single-vision and toric production lines to be up and running by Q2-06. PureVision Multifocal should be launched in the first half of 2006. The one-day lens launch in Japan has been a disappointment; the company plans to launch a new material and new package during Q4.

Lens Care revenues increased 3% (in constant currency) to \$135 million. Although revenue growth was modest, B&L avoided the declines reported by Alcon and AMO. Revenue growth was well-balanced geographically, with 2% growth in the Americas, 9% in Europe, and 3% in Asia.

Pharmaceutical revenues increased 12% (in constant currency) to \$145 million. Positive contributors included anti-inflammatories (particularly Lotemax), dry eye and glaucoma products, nutritionals, and OTC general eye care products. In the Americas, generics continued to decline due to new competitors, and nutritional sales declined despite good end-user demand due to tablet inventory reduction in the trade as accounts transition to soft-gels, as well as prior year comps that included stocking orders for soft-gels. The Retisert implant for posterior uveitis began to ship during Q3; the sales ramp has been below company expectations due to reimbursement and formulary negotiations, coupled with the high cost of the device. As of October 1, CMS made the Retisert device eligible for pass-through status at 106% of wholesale cost -- this could be important if private payers follow the lead of CMS, because there are few Medicare patients with posterior uveitis.

Cataract and Vitreoretinal revenues increased 4% to \$89 million. B&L reported double digit gains in both IOLs and viscoelastics, offset by modest declines in phaco products. Incorporation of aspheric optics led to nearly 20% growth in SofPort silicone IOLs in the Americas and over 15% growth of acrylic Akreos IOLs in Europe. Solid sales growth in IOLs is somewhat surprising given the lack of a multifocal or accommodating IOL offering for presbyopia, and declines in phaco products. Overall, cataract sales were up 2% in the Americas, 3% in Europe, and 12% in Asia. A US launch of the Akreos IOL is slated for 2007.

Refractive surgery revenues declined 11% (in constant currency) to \$31 million. Although Zyoptix procedure fees were up 9%, growth was offset by lower sales of lasers and microkeratome blades. In the Americas, procedure card fees increased 6% but overall refractive sales were down 5%, as the Hansatome blade business is feeling the effects of a flat procedure market and competition from IntraLase (and to a lesser extent other microkeratomes, such as AMO's Amadeus). B&L hopes that the introduction of the new Zyoptix XP microkeratome will reverse recent share losses. Refractive revenues declined by more than 20% in Europe and by 7% in Asia. While B&L management does not currently view the refractive business as a key growth driver for the company, the business is viewed as a necessary part of the business mix and not as a candidate for divestiture. Ω

## Eyetech Delivers Strong Macugen Sales, but Lucentis Clinical Data Keeps Stealing the Headlines

On October 31, in its last quarterly financial release as an independent company, Eyetech Pharmaceuticals reported net product revenue for Macugen of \$55.5 million, an 18% sequential increase over Q2-05. Total revenue reached \$67.4 million. Eyetech achieved operating profitability for the first time, excluding certain charges, with adjusted (non-GAAP) EPS of \$0.06. Eyetech management maintained its guidance for net Macugen product revenue in a range of \$175-190 million (implying Q4 net product revenue of about \$50-65 million), along with a continued trend toward profitability in Q4. The acquisition of Eyetech by OSI Pharmaceuticals closed earlier this week.

More than 50,000 patients have been treated since Macugen was launched in January 2005. According to market data referenced by the company, twice as many patients were treated with Macugen than with Visudyne photodynamic therapy (PDT) during July. This, however, does not seem like a fair comparison, given the fact that Visudyne patients receive about 2-3 treatments during their first year, versus 8-9 Macugen injections. According to the company, through July 2005, more than 138,000 patients were treated for wet AMD, a 44% increase over the January-July period of 2004.

Clinical developments: (1) Eyetech and Pfizer have completed enrollment of a Phase II study of Macugen for the treatment of retinal vein occlusion (RVO). (2) Last month, Eyetech and Pfizer enrolled the first patient in a 900 patient Phase III study of Macugen for the treatment of DME and diabetic retinopathy; full enrollment is expected by February 2007, and injections will be at six week intervals for three years. (3) During Q3, Eyetech and Pfizer also announced that they expect the European Medicines Evaluation Agency (EMEA) to approve Macugen for the treatment of neovascular

AMD, based on a positive opinion from an advisory committee.

On November 7, Genentech released the latest round of impressive Lucentis data. Lucentis will represent a significant competitive threat to Macugen once it receives FDA approval, as early as H2-06. In August, Genentech announced positive preliminary one-year data on Lucentis from the Phase III MARINA Trial, a two-year study of 716 patients with minimally classic or occult wet AMD. Nearly 95 percent of patients treated with Lucentis maintained or improved vision at 12 months in MARINA. The second Phase III study, ANCHOR, was supposed to be more challenging because it was a head-to-head study versus Visudyne/PDT instead of a sham-controlled trial. However, ANCHOR also met its primary efficacy endpoint of maintaining vision in patients with wet AMD.

In ANCHOR, approximately 95% of patients treated with 0.3 or 0.5 mg of Lucentis maintained or improved vision (defined as a loss of less than 15 letters in visual acuity) compared to approximately 64% of those treated with Visudyne/PDT [p<0.0001] during the first year of the two-year study. The Lucentis treatment groups further demonstrated a statistically significant difference from the control arm in the secondary endpoint of mean change in visual acuity during the first year. On average, patients treated with Lucentis improved, while patients treated with PDT declined. Preliminary safety findings were consistent with those observed in MARINA.

Data from both the ANCHOR and MARINA studies will be submitted to the FDA as part of a Biologics License Application (BLA) that Genentech plans to file in December 2005. Lucentis has not yet been granted Priority Review, but Genentech will request this designation at the time of submission. Q

## IntraLase Approaches 20% US Procedure Share, but International Growth is the Big Story

On October 25, IntraLase reported Q3 revenues of \$22.9 million, a 48% increase over Q3-04. Gross margin has expanded from 45% to 54% over the past year, driven by a higher mix of per procedure revenues, manufacturing cost reductions, and improved margins on maintenance revenues. In the third straight profitable quarter for IntraLase, net income was \$2.4 million, or \$0.08 per diluted share, versus a net loss of

\$3.1 million in Q3-04. IntraLase reiterated its guidance for 2005: revenue growth of at least 58% to greater than \$95 million, and EPS of \$0.33-0.37; management appears comfortable with the high end of this range. The company expects that about half of 2005 net income will come in Q4, driven by seasonally high laser demand, a large number of 30



kHz upgrades, and increasing per-procedure sales as a percentage of total revenue.

Laser revenues increased 29% to \$11.1 million, and laser unit sales grew 26% to 34 lasers for the period. Excluding FS30 upgrades, laser revenues increased 17%. The worldwide installed base stood at 327 at the end of O3. Half of US laser placements in Q3 took the form of operating leases, which typically convert to sales within 12-18 months. Contributing \$1.1 million, or about 10% of total laser revenues, were 45 FS30 (30 kHz) upgrades that were shipped in the quarter, at an ASP of about \$24,000. IntraLase expects to ship 70-75 upgrades in O4; the roughly 120 upgrades expected for 2005 would exceed the company's previous goal of 40 by a factor of three. IntraLase has received more than 175 upgrade orders to date, suggesting a backlog of demand for Q1-06 of at least 55 units. The FS30 cuts flap creation time in half, to just under 30 seconds, and enables tighter laser spot placement, which facilitates lifting of the corneal flap.

Per-procedure revenues, consisting of sales of disposable patient interface kits, grew 70% to \$9.7 million. Per-procedure unit sales increased 65% to about 83,000, which was down by about 3% sequentially from Q2 due to seasonality. In the US, per procedure unit sales increased 18% over prior year but were down 20% sequentially, as a weaker than expected September magnified normal seasonality (management believes that the months of July, August, and October showed normal seasonality in the US). International markets did not demonstrate the same seasonality, with sequential per-procedure unit growth of 35%. IntraLase reached a US procedure share of about 19-20% in Q3, compared to an estimated 18% at mid-year, 17% in Q1-05, and 15% a year ago. Per procedure revenue reached 43% of total sales in O3-05, compared with 37% in O3-04.

Maintenance revenues increased 74% to \$2.1 million in Q3, representing 14% sequential growth over Q2.

During the quarter, IntraLase received 510(k) clearance for the therapeutic applications of lamellar keratoplasty and penetrating keratoplasty. Therapeutic applications help drive laser sales in academic institutions in the US, and in Europe, were LASIK surgeons tend to have broader practices that go beyond refractive surgery.

**IntraLase has become an increasingly international growth story.** Despite steady share gains in the US, domestic results

have fallen short of expectations, as overall LASIK procedure growth has slowed in the US and IntraLase has begun to move beyond the highest volume early adopters. The overall domestic LASIK market is no longer providing much of a tailwind: on its Q3 conference call, market leader AMO/VISX characterized US procedure volumes as flat on a rolling 12-month basis. Most of the LASIK surgeons with whom we have spoken recently share this view, and have similar expectations for 2006.

The international business, however, has filled the gap. Approximately 60% of the lasers sold in Q3, or about 20 units, were placed internationally. With initial laser sales in China and Poland in Q3, IntraLase systems are now available in 24 countries. The company plans to begin selling in the larger Latin American markets in 2006. IntraLase management now estimates that more than half of its laser placements over the next year or so will be outside the US. When the company went public about a year ago, analyst forecasts for 2006-2008 assumed that only about 35% of laser hardware revenues and only about 25% of procedures would come from international markets. Over the past year, while total procedure and revenue forecasts have remained flat or even decreased slightly, the percentage of business that is forecast to come from outside the US over the next three years has increased: forecasts for international laser hardware revenue (as a percentage of total laser revenue) have increased from 35% to 50%-plus, and international procedure volume forecasts have increased from about 25% to about 40% of total worldwide procedures.

International success has come as something of a surprise, as refractive surgery markets outside the US have never supported per-procedure fees and custom LASIK has been slow to catch on. The fact that IntraLase sells an actual disposable patient interface kit, rather than just a key card, is an important differentiator, as are the patient appeal and clinical benefits of bladeless LASIK. Although the international LASIK opportunity is more open-ended than the domestic opportunity (larger, less-penetrated procedure base), it is more difficult to quantify given the lack of good market data outside the US. There are mixed signals from the excimer laser manufacturers regarding the health of international LASIK markets. AMO/VISX has been placing an increasing number of lasers internationally, but Bausch & Lomb, which has a strong LASIK presence internationally, stated on its Q3 conference call that it is seeing declining procedure trends in many parts of Europe. Q

### LCA-Vision Continues to Gain Share and Outpace the Market with its Value Pricing Model

On October 25, LCA-Vision reported revenues of \$47 million, an increase of 51% over prior year. Operating margins also increased significantly, from 17.7% in Q3-04 to 25.6% in Q3-05. Diluted EPS increased 118% to \$0.37. The company once again increased its full year 2005 EPS guidance, this time by \$0.15 to a new range of \$1.40-1.45. Revenue growth for 2006 is targeted in the range of 30-40%.

Same-store procedure growth and the opening of new LasikPlus vision centers contributed to growth in the quarter. Overall procedure volume increased 47% to 34,187, representing roughly 10% of US LASIK procedures. At centers open at least 12 months, same-store revenues increased 48%. Revenue per procedure increased only 3% to \$1,376, indicating that revenue growth was driven almost entirely by procedure volume growth, and not by price increases or adoption of custom/wavefront-guided LASIK. It is worth noting that the prior-year comparative quarter, Q3-04, also represented strong growth over Q3-03: revenues +53%, procedures +46%, and same-store revenues +38%. As procedure volumes and geographic coverage have grown, the percentage of patients that finance their LASIK purchase has remained relatively constant: about half the patients finance through GE, roughly 10% finance their purchase directly through LCA-Vision, and the rest pay by cash or credit card.

During the quarter, LCA-Vision opened three new LasikPlus vision centers in Milwaukee, Phoenix, and Austin. In October, the company opened a center in Portland, bringing the total number of new centers in 2005 to seven. Overall, the company operates centers in 34 markets in 23 states, reaching approximately 37% of the US population. Earlier this week, the company announced the opening of a new center in Pittsburgh, and additional openings in Birmingham and Albuquerque are planned by the end of 2005. While the company has not yet indicated a specific number of new centers planned for 2006, something close to the 10 new centers opened in 2005 is expected. LCA-Vision has generally been able to get new centers profitable within six months or less after opening. At this time, management has no interest in acquiring mature LASIK centers.

Execution of the company's value pricing/direct-to-consumer marketing model has led to consistent market share gains in the fragmented LASIK service market, and procedure growth that has outpaced overall industry growth rates. LCA-Vision has clearly found an audience of price conscious consumers; adoption of custom LASIK has been well below industry averages, and the company has no plans at present to purchase IntraLase lasers for its centers. Q

### OccuLogix Achieves Milestones on Path toward FDA Approval for RHEO Procedure to Treat Dry AMD

On November 7, OccuLogix reported its Q3 financial results. Because OccuLogix is a development stage company working toward FDA approval, with only minimal commercial activity in Canada, financial results take a backseat to regulatory milestones at this time. In Q3, the company generated revenues of \$0.6 million and a net loss of \$2.9 million, or \$0.07 per share. As of September 30, the company had accumulated \$6 million in inventory of OctoNova pumps and Rheofilters, on the way to the year-end goal of \$10 million, in preparation for a US launch targeted for late 2006 or early 2007.

Yesterday, the company announced that all final 12-month follow-up visits have been completed for the pivotal (phase III) MIRA-1 Trial ("Multicenter Investigation of Rheopheresis for AMD"). MIRA-1 is a multi-center, randomized, double-masked and placebo-controlled trial to evaluate the safety and efficacy of the RHEO procedure in patients with intermediate-to-late stage dry AMD. OccuLogix completed enrollment of the trial in December 2004. A total of 169 patients in this study have completed 12-month follow-up exams, surpassing the company's

goal of at least 150 complete data sets.

OccuLogix plans to file the final pre-market approval (PMA) modules with the FDA in late Q1-06. At that time, the company will likely disseminate top line study results, with additional detail to follow at the appropriate medical conferences. In October, the company announced that it had reached agreement with the FDA regarding statistical analysis and filing plans. The PMA filing process began in Q4-04 with the submission of the first three of four required PMA modules, containing non-clinical bench test results, quality assurance data, and manufacturing documentation. Along with safety and efficacy data from MIRA-1, OccuLogix will submit supporting safety data from the large RheoNet registry, which contains a database from commercial RHEO procedures performed in Germany and Canada. An FDA panel meeting could take place in Q3-06, and discussions with CMS regarding Medicare reimbursement could begin as early as Q2-06, once the pivotal MIRA-1 clinical data are available. Q

## QLT's Visudyne Holds Up Well Internationally but Feels the Impact of Competition in the US

On October 27, QLT announced Visudyne worldwide sales of \$123.7 million in Q3, an increase of 8.6% over prior year. Full year Visudyne revenue guidance remains \$500-530 million, representing growth of 12-18%. Total product sales were \$150 million, up 7%. Total company revenues were \$64 million, up 6% on a pro forma basis. Adjusted (non-GAAP) EPS was \$0.17. Management maintained adjusted EPS guidance of \$0.63-0.77, with results likely in the bottom half of this range.

In the US, Visudyne sales totaled \$51 million, down

9.7% versus Q3-04, clearly reflecting the impact of the January 2005 launch of Macugen. Excluding a \$3.8 million distributor inventory build during Q3, US Visudyne sales declined by about 16%. QLT management believes that offlabel use of Genentech's Avastin also impacted domestic sales in Q3, and management does not believe that Visudyne is being commonly used in combination with Macugen. Outside the US, where Macugen is generally not available, Visudyne fared better: international sales totaled \$72.8 million, an increase of 26.6% over prior year. Q

## TLCVision Expands into Value-Priced Service Segment to Re-Ignite Procedure Growth

On November 7, TLCVision reported net revenues from the Operating Business (which excludes the impact of the company's investment in OccuLogix) of \$61 million, up 6% over Q3-04. Diluted EPS attributable to the Operating Business was \$0.04, down from \$0.06 in Q3-04.

Overall refractive procedures totaled 42,500, down 7% versus prior year, and overall refractive revenues totaled **\$42.8 million, down 3%.** TLCVision performed about 13-14% of all US LASIK procedures in Q3. Revenues from the 77 TLC Laser Eye Centers were up 9% to \$35 million, driven by a 4% increase in price per procedure to \$1,521. On a same-store basis, North American procedure volume in centers was down by 5%, but additional volume from recent acquisitions brought overall center procedure volume for Q3 back up to last year's level (27,300 procedures in O3-05). Increased penetration of IntraLase contributed to revenue growth in the centers, and the 61% rate of custom LASIK adoption exceeds industry averages. In the centers, lower volume and increased IntraLase adoption (TLC is passing along the cost of IntraLase to the patient but not marking it up significantly) combined to reduce gross margin, from 27.5% to 25.2%. Access business revenue declined 16% to \$7.8 million on an 18% decline in procedure volume to 15,200. Within the Access business, the transportable-laser segment is outperforming the fixed-laser segment.

Revenues from other healthcare services increased 13% to \$18.2 million. Other healthcare revenues from ongoing operations increased 20%, with Midwest Surgical (mobile cataract) revenues up 17% and Vision Source (optometric

network) revenues up 21% versus Q3-04. The company also announced the acquisition of 20/20 Medical, a Chicago-based mobile diagnostics company that provides in-office diagnostic services to ophthalmologists and optometrists, with 200 customers in eight states.

In order to address the unfavorable LASIK procedure growth trends in the business, TLCVision has launched a new expansion strategy aimed at the value-priced consumer **segment.** With this move, TLCVision is clearly taking a page from the LCA-Vision playbook, which is an especially big step considering the rivalry and differences in operating philosophy between these two service providers. TLCVision plans to open a number of value-priced "LASIK Select" branded vision centers over the next 12 months, and generate procedure volume through direct-to-consumer marketing. The company also acquired TruVision, a managed-care contractor for elective healthcare services that is intended to serve as a patient generation channel for these new centers as well as existing TLC centers. TruVision is expected to refer over 23,000 LASIK procedures to its network of providers in 2005 and 28,000 in 2006. Based in Salt Lake City, TruVision represents over 85 million members across 37 contracted health plans in 44 states. TLCVision is paying \$17.5 million in cash and stock, coupled with a three-year earn out. Management expects this growth strategy and acquisition to increase 2006 revenues by over \$25 million and EPS by \$0.03.



TLCVision plans to open 15 value priced "LASIK Select" branded vision centers by the end of 2006. Five LASIK Select centers that TruVision was about to open will be operational by the end of 2005, with five new centers planned for Q1-06 and another five planned for H2-06. TLCVision will initially steer clear of markets that are currently served by its own premium TLC Laser Eye Centers and other value priced competitors. The company is making a notable departure from the LCA-Vision approach by planning to install IntraLase lasers in all 15 LASIK

Select centers. Whereas LCA-Vision management maintains that the value-oriented customer is not interested in premium services such as custom and IntraLase, TLCVision believes that these consumers respond to a low entry point, but that some are interested in paying-up for such services. The upside of this approach for TLC is added revenues and profits; the risk is increased capital investment, and a marketing message and technology decision that could be distracting to some value-oriented consumers. **Q** 

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