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Emerging Surgical Treatments for Presbyopia Square Off at 2005 AAO

It is not surprising that presbyopia-correcting IOLs were a major focus at this year's AAO, given the important CMS ruling and two key product approvals earlier this year. On May 3, a Center for Medicare and Medicaid Services (CMS) ruling allowed Medicare patients to choose these lenses and pay premium product/service charges out-of-pocket. In March, Alcon and AMO received FDA approvals for their ReSTOR and ReZoom multifocal IOLs. Unlike the ASCRS meeting in April, however, at which Alcon's just-approved ReSTOR stole the show, the focus this time around was on the relative merits of the three approved presbyopic IOLs: Alcon's ReSTOR, AMO's ReZoom, and eyeonics' crystalens.

A $200 million market segment by 2006? We estimate that about 90,000 presbyopia-correcting IOLs will be implanted globally in 2005, generating sales of about $75-80 million. Next year, with full-year FDA approvals for both ReSTOR and ReZoom and a full year with these lenses available to Medicare patients, sales could approach $200 million and implants could exceed 200,000.

- **Alcon recently reiterated its 2005 ReSTOR revenue guidance of $45-55 million,** suggesting unit volume of about 55-65,000 lenses. Through September, Alcon had

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Femtosecond Laser: Winning the Clinical Debate and Attracting New Competitors

Evidence and experience are building with respect to the superiority of all-laser LASIK. The scientific and clinical debate as to whether or not the IntraLase femtosecond laser is superior to the microkeratome for the creation of LASIK flaps seems to have subsided, with the femtosecond laser emerging as the clear winner on this front. The debate is now more focused on the magnitude of the superiority, and cost/benefit considerations. We witnessed a similar transition take place after the introduction of custom LASIK to the market: at the AAO meeting in November 2003, shortly after the launch of VISX's CustomVue technology, there was some debate regarding the actual clinical superiority of wavefront-guided LASIK over standard LASIK. By ASCRS in May 2004, after some nomogram refinements and additional clinical data publications, the superiority of custom LASIK had become much more widely accepted.

Attention now turns to continued procedure growth and market penetration, domestically and internationally, and the potential emergence of competitors. The overall domestic LASIK market is no longer providing much of a tailwind: most of the LASIK surgeons with whom we spoke at AAO characterize the current procedure

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trained 3,300 physicians, 2,000 were considered ready to implant, and 1,100 had implanted at least one lens.

- **AMO expects total refractive IOL sales in 2006 of $45-55 million,** including ReZoom and Tecnis multifocals and the Verisyse anterior chamber phakic IOL. 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. ReSTOR has gotten off to a stronger start in the US than ReZoom, driven by Alcon's overall IOL market leadership and more aggressive marketing and training programs, and the fact that AMO's approval for ReZoom came several months earlier than the company had expected.
- **eyeonics has not issued formal guidance for sales of crystalens, but the company just reported $5 million in Q3 sales,** suggesting close to 6,000 lenses implanted in the period. Over 30,000 crystalens units have been implanted in the two years since FDA approval. As of the end of September, 450 ophthalmic surgeons were implanting crystalens, up from about 320 prior to the favorable CMS ruling in May. (See Page 3 for more on eyeonics and crystalens.)

Where was Bausch? It was not lost on many attendees of the conference that Bausch & Lomb was conspicuously absent from the presbyopia discussion, and will have to make significant progress on the product development and/or business development fronts in order to become relevant in this important new category.

The Case for Mixing and Matching Lenses

The case for mixing and matching presbyopic IOLs was made in a number of different venues at this year's AAO, most notably by Richard L. Lindstrom, MD (Minneapolis, MN). It would have been nearly impossible for an attendee with an interest in refractive surgery to have left Chicago without hearing Dr. Lindstrom deliver the message that you can, and probably should, mix and match presbyopic IOLs based on patient needs and feedback. One of his key points was that the concept of combining different lenses in a single patient is not new, and is currently done in patients that receive one multifocal and one monofocal IOL, in patients with monovision, and in the large number of patients that wear two different types of contact lenses. The chart shown on this page, which compares strengths and weaknesses of the three approved presbyopic IOLs, was scribbled on many a notepad at the meeting.

The key elements of Dr. Lindstrom's recommended approach are as follows: (1) Staged implantation, with a 2-4 week waiting period after first eye implantation to obtain patient feedback. Dr. Lindstrom is currently starting with the AMO ReZoom lens in most cases, because he feels it provides better distance vision than ReSTOR, better near vision than crystalens, and functional intermediate vision. (2) If the patient is happy with the vision in the first eye, the same lens should be implanted in the second eye; if not, the surgeon should find out why and use a different lens based on patient feedback and product attributes.

	ReZoom	ReSTOR	crystalens
Distance	Excellent	Good	Excellent
Intermediate	Functional	Poor	Good
Near	Very good	Excellent	Good
Effective add power	+2.6	+3.2	+1.25
Strength	Better distance than ReSTOR; Better near than crystalens	Near tasks in bright light	Intermediate tasks
Weakness	Poor near in bright light	Computer use; Poor near in dim light	May need supplemental add power

Source: Richard L. Lindstrom, M.D.
Minnesota Eye Consultants, P.A.

Dr. Lindstrom references the experience of Rick Milne, MD, who initially implanted ReSTOR bilaterally in 55 patients, but has since gone to a "mixed" approach due to some dissatisfaction with intermediate vision. Dr. Milne now implants a ReSTOR IOL in one eye (in the dominant eyes of avid readers) and a ReZoom IOL in the other eye (in the dominant eyes of heavy computer users).

AMO and eyeonics are squarely behind the "mix and match" approach, and Alcon is vocal in its opposition. As the IOL market leader, Alcon doesn't want to concede a single

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ReSTOR implant to either competitor. At Alcon's exhibit booth at AAO, we asked a rep about the mixing of presbyopic implants. The rep's response: that AMO's ReZoom is the same lens as the older AMO Array, with just a different material and small tweaking of optical zones (not true), and that surgeons should not mix and match IOLs due to medical liability concerns (which doesn't make any sense to us).

While we're mixing and matching, how about some LASIK for the road? Dr. Lindstrom expects about 20% of presbyopia-correcting IOL patients to require LASIK enhancement to achieve their best vision. Alcon has discussed enhancement rates for ReSTOR of about 15%. Francesco Carones, MD (Milan, Italy), at the Refractive Surgery Subspecialty Day, said that in his initial group of 60 eyes undergoing RLE with ReSTOR, 27% required fine-tuning using LASIK to achieve satisfactory outcomes. All of this suggests that surgeons performing presbyopic IOL surgery should also have (or have access to) LASIK capability, and should price their services in order to incorporate their anticipated enhancement rate.

Not Ready for Prime Time?

Robert K. Maloney, MD, Los Angeles refractive surgeon and member of ABC-TV's *Extreme Makeover Extreme Team*, made a case for a more measured approach during the Refractive Surgery Subspecialty Day. Some of Dr. Maloney's cautionary points:

- Real accommodation should not be confused with other means of improving near vision (such as multifocality and pinhole effect).
- With multifocality, there's no "free lunch" – some light is inevitably lost, resulting in reduced contrast sensitivity.
- People are paying extra to reduce aberrations in custom LASIK, and are now paying to increase aberrations with multifocal IOLs.
- Some patients don't tolerate multifocality well, but you can't always tell in advance which patients these will be.
- Truly accommodating IOLs are a promising alternative, but are early in their evolution, amplitude of accommodation will likely be patient-dependent, and more objective measures of accommodative amplitude are needed.

A Return to Growth for eyeonics and crystalens

The mood at the eyeonics booth at this year's AAO was much more upbeat than it was at ASCRS in Washington, DC this past April, following a return to growth for the company this summer and fall. Approved by the FDA two years ago this month, crystalens remains the only FDA approved accommodating IOL. At ASCRS in April, Alcon had just launched its ReSTOR IOL (approved in March) with much fanfare, a huge presence in the scientific program, and vocal criticism of crystalens. The company was also facing an unacceptably high rate of posterior capsule opacification (PCO), which has since been corrected

with the introduction of the crystalens SE (Square Edge System), which extends the square edge on the crystalens from 240° to a full 360° around the posterior surface of the lens.

The ReSTOR launch certainly had an impact on crystalens sales during Q2-05, but growth resumed in Q3. Revenues for these two periods totaled $3.3 million and $5 million, respectively, suggesting Crystalens unit sales in Q3 of close to 6,000 (eyeonics reported nearly 2,000 unit sales in August). Over 30,000 crystalens units have been implanted in the two years since FDA approval. With growth back on track and increasing attention being paid to presbyopia-correcting IOLs following the launch of Alcon's ReSTOR and AMO's ReZoom, eyeonics is doubling its manufacturing capacity and plans to triple its field sales and support teams to 100 employees, including 50 new sales territories over the next two years. The company has raised additional capital from insiders to support this expansion. Not much has been said with regard to new product development efforts, but we do know that at least two next-generation products are in development and have been implanted in humans.

Probably the biggest challenge that eyeonics is facing at present is overcoming criticisms related to mechanism of action. Studies have shown that the amplitude of crystalens movement during accommodation is not enough to fully explain the magnitude of accommodation experienced by patients, calling into question the mechanism of action. In a presentation at the Refractive Surgery Subspecialty Day, Georges D. Baikoff, MD (Marseille, France) argued that the forward movement of today's accommodating IOLs corresponds to only a 0.25D accommodative effect. The company is fully aware of this issue and hopes to have additional clinical information regarding mechanism of action at upcoming conferences.

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Warming Up to Multifocal LASIK

We've been skeptical regarding multifocal LASIK from the start, but clinical experience so far seems to be favorable. Ablating a multifocal "aberration" onto the cornea just doesn't sound like a great idea, given the possibility that some presbyopes may not adapt well to the multifocal optics (see Dr. Maloney's comments above). But visual outcomes reported so far for low-to-moderate hyperopes have been good, as have patient satisfaction statistics, and we have not heard anecdotally that patients have had a difficult time adjusting to the vision. We've heard that some patients have expressed a desire for better near/reading vision, which could be achieved through a nomogram adjustment in a future version if this becomes an issue for many patients. FDA approval is expected in the 2007-08 timeframe.

Preliminary results for the AMO/VISX multifocal LASIK clinical trial were presented at AAO. Colman Kraff, MD of Chicago presented 3-month follow-up on patients with +1.0 to +2.5D of hyperopia. Distance, intermediate, and near visual acuity were all improved in the multifocal eye, and patients were generally more satisfied with post-op uncorrected vision than with pre-op corrected vision.

Refractive Lens Exchange is Already Finding a Niche

The outlook for refractive lens exchange (RLE) appears to be turning more positive, although it remains controversial. The procedure, which is also known as "clear lens extraction," "presbyopic lens exchange (PRELEX)," and "refractive lensectomy," involves the removal of a healthy (pre-cataract) but presbyopic crystalline lens. We've been generally skeptical of the prospects for RLE, assuming that few individuals with healthy natural lenses would choose to undergo elective intraocular surgery, and that few cataract/refractive surgeons would recommend this for their patients. We expect that many surgeons will stay away from RLE for the foreseeable future given the liability concerns. However, now that surgeons and patients are beginning to gain real-world experience with presbyopia-correcting IOLs, the level of interest seems to be increasing.

RLE seems to be finding its initial niche with high hyperopes; risk/benefit is much less favorable for high myopes. Most surgeons that are currently performing RLE procedures are concentrating on presbyopes (at least 40-50 years of age) with high hyperopia (+3D or more, where LASIK is a less effective tool), especially those who cannot wear contact lenses, and preferably with some evidence of early cataract. Some surgeons are willing to treat patients with high levels of myopia, but at this point most are not, given the relatively high risk of retinal detachment (RD) in these patients (probably about 1-3%, based on experience with cataract surgery). Emanuel S. Rosen, M.D. (Manchester, England), at the Refractive Surgery Subspecialty Day, presented a survey of the medical literature regarding the incidence of RD following RLE and cataract/IOL surgery. Dr. Rosen cited 26 references, with incidence of RD ranging from 0% to 8% (overall average of 2%). Although the retina could be reattached in most cases, a repaired retinal detachment would not generally be considered a desirable outcome following an elective refractive procedure.

Insurance industry data provides insight into surgeon interest in RLE. Coverage data provided by the Ophthalmic Mutual Insurance Company (OMIC), published in the June 2005 issue of *EyeNet Magazine* (published by the AAO), showed that 8% of insured ophthalmologists are already covered for RLE, which is a more significant percentage than we would have expected. For reference, this percentage is well below that for LASIK (29.2%), but well above that for conductive keratoplasty/CK (2.3%).

Refractec Looks to Get CK Back on Track in 2006

For Refractec, 2005 has clearly been a transition year. After two years of solid procedure growth following the initial FDA approval of conductive keratoplasty (CK) for hyperopia in April 2002 (which preceded the approval for presbyopia in March 2004), procedure growth slowed significantly in 2005. CK procedure volumes totaled 5,500 in 2002, 22,500 in 2003, and nearly 48,000 in 2004. For 2005, procedure volume will likely come in close to 50,000, representing only modest growth over 2004. The most likely reason that procedure volumes flattened in 2005 was that CK was essentially "re-launched" with a refinement in technique ("NearVision CK with LightTouch"), and users have had to learn to incorporate this new technique.

The LightTouch technique seems to offer a real improvement. The technique, developed by H.L. "Rick" Milne, MD (Columbia, SC), involves the delivery of RF energy to the periphery of the cornea with only a minimal amount of pressure exerted on the instrument tip. It has been found that this lighter touch results in a more robust refractive effect, enabling the surgeon to apply fewer spots (8 instead of 16-24) in a larger single ring that is further outside the visual axis (7-8mm instead of 6-7mm). The resulting procedure is faster and thus more comfortable for the patient, produces a greater and more predictable refractive effect, and results in significantly less induced cylinder.

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Clinical studies are underway to move some off-label treatments onto the label. The LightTouch technique described above is currently being performed off-label by surgeons. An efficacy-focused IDE study of LightTouch is currently underway, aimed at obtaining a supplemental pre-market approval. Initial data may be available in time for ASCRS next spring. Another clinical trial is enrolling 150 post-LASIK patients that suffer from presbyopia. Enrollment began this past summer and is expected to be completed by mid-2006. Preliminary results of the first 23 patients, one month post-surgery, were reported at AAO.

Visual outcomes and patient satisfaction were very good, and importantly, there have been no flap complications or other adverse events. This should be an attractive market niche for Refractec, given that post-LASIK patients are generally emmetropic (ideal for CK), should be very motivated to stay out of glasses, have already made the decision to undergo refractive surgery at least once before, and should find a minimally invasive procedure attractive.

CK has been an evolving and somewhat controversial treatment since it was launched over three years ago. A physician survey reported by Shareef Mahdavi in *Cataract & Refractive Surgery Today* (September 2005) showed that surgeon sentiment regarding CK is higher today than it was one year ago. Among current CK users surveyed, 40% said that CK would remain a niche player and another 40% said that CK would become a big player over the next 3-5 years. The survey also indicated that 20% of current CK users believe that CK will become obsolete over the next 3-5 years – we weren't surprised to see this, because we've spoken to surgeons that share this view.

CK should continue to find a niche within presbyopic treatment, and we expect Refractec to see renewed growth over the next two years. Our relative optimism is based on the following: (1) The rising presbyopia tide should lift most (if not all) ships: CK is differentiated from and less invasive than other surgical approaches, and should benefit from increased surgeon and patient interest in surgical presbyopia treatment. (2) It has been estimated that roughly 20% of presbyopic IOL patients will require a "touch-up" following implantation; most of these will likely be done using LASIK, but CK could also be used to enhance near vision in patients with ReZoom and crystalens. (3) The LightTouch technique should result in better outcomes once it has been disseminated and clinical trial results are available. (4) The post-LASIK presbyopic population should be an attractive pool of patients for CK, once safety and efficacy have been demonstrated and reflected in the label.

On Deck for Presbyopia: Corneal Inlays

We expect to hear more about corneal inlays for presbyopia in the coming years as clinical data and international experience build. Corneal inlays represent a potentially less invasive and less risky alternative to RLE for pre-cataract presbyopes, and a removable and potentially reversible/adjustable alternative to multifocal LASIK. These devices take advantage of femtosecond laser technology that allows the creation of precisely shaped and centered pockets or flaps within the cornea. By the time these inlays are approved in the US (likely around 2010), availability of femtosecond laser technology will not be a barrier to adoption. Two of the leading products in development:

- **The PresbyLens from ReVision Optics** is a multifocal lens made from a proprietary micro-porous, biocompatible hydrogel. For presbyopes that do well with multifocal contact lenses, PresbyLens could offer a similar visual experience with perfect centration and the comfort/convenience benefits of surgical vision correction.
- **The AcuFocus Corneal Inlay** is an opaque, ultra-thin ring-shaped device that blocks light and effectively creates a smaller pupil diameter in a patient's non-dominant eye. Depth of field is increased using a "pinhole effect." Because it blocks light entering the eye, this inlay could reduce contrast sensitivity and create an imbalance between the eyes, although anecdotal feedback regarding initial human implants has been favorable. **Q**

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market as flat, and have similar expectations for 2006. A slight competitive headwind also comes from the gradual re-emergence of surface laser procedures (PRK, Epi-LASIK, and LASEK). These surface approaches make up less than 10% of laser vision correction procedures today; the percentage is likely to grow modestly, but the lack of rapid healing and visual recovery will prevent them from realizing a surge in popularity.

IntraLase has become an increasingly international growth story. IntraLase has steadily grown its share of the US LASIK flap market, and is approaching a 20% share of US procedures. As overall LASIK procedure growth has slowed in the US and IntraLase has begun to move beyond the highest volume early adopters, domestic results have fallen short of expectations. The international business, however, has filled the gap. 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.

IntraLase management now estimates that more than half of its laser placements over the next 1-2 years 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.

It would be a gross overstatement to say that competition is heating up in the femtosecond laser market, but potential competitors are beginning to appear on the horizon. Three companies: Ziemer (Switzerland), WaveLight (Germany), and 20/10 PERFECT VISION (Germany) either showed or talked about competitive femtosecond lasers at this year's AAO (see details on next page). With a worldwide installed base of 327 lasers in 24 countries, and cumulative procedures of over 500,000, facing potential competitors that have treated few if any human eyes, IntraLase's continued market leadership position is not in question. But all three of these European companies have developed successful products for the LASIK market before and can't be completely dismissed. Any competitive threat posed by these three companies would likely be more significant outside the US, given IntraLase's stronger blocking patent position and greater market penetration in the US. In addition, we've seen in the past that European laser manufacturers have enjoyed much more success outside the US, where they have some "home field advantage" (think WaveLight and pre-Bausch Technolas).

Annual US Customer Survey Results

The third annual IntraLase US customer survey once again showed positive business trends among users. Some of the key findings, reported by Shareef Mahdavi of SM^2 Consulting:

- The average fee increase to patients is $394 since acquiring IntraLase technology, separate from price increases associated with custom LASIK; IntraLase users have raised prices 22% against an industry backdrop of 14%.
- Among IntraLase users, the femtosecond laser is used to create flaps in 88% of cases; by comparison, the same surgeons perform custom LASIK 50-60% of the time.
- Average annual procedure growth among IntraLase users was 15%, slightly higher than the industry average 13%.
- IntraLase users report patient conversion rates (consultation to surgery) of 76%, versus only 69% pre-IntraLase, with the increase attributed largely to reduced patient fear.

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Roundup of Papers, Posters, and Presentations

A number of scientific papers, posters, and Subspecialty Day presentations at AAO outlined the benefits of the femtosecond laser. Some highlights:

- **Edward E. Manche, MD** compared IntraLase with Bausch & Lomb's Hansatome in a contra-lateral eye study using VISX CustomVue to treat myopia. This study mirrored an earlier study led by Daniel Durrie, MD, using Alcon's LADARVision platform for vision correction. In Dr. Manche's study, the IntraLase eyes demonstrated superior visual performance, including visual acuity, higher order aberrations, and patient preference.
- **Jonathan H. Talamo, MD** presented a retrospective analysis comparing two mechanical microkeratomes with IntraLase. IntraLase was associated with significantly lower rate and severity of epithelial irregularities, no significant difference in diffuse lamellar keratitis (DLK), and avoidance of potentially severe complications such as free-cap and buttonhole (0.3% versus 0.0%).
- **Dan B. Tran, MD** looked at stromal bed quality on eyebank eyes using scanning electron microscopy. There was no difference noted between mechanical microkeratomes and the 15 kHz IntraLase; the newer IntraLase FS30 30 kHz system produced smoother stromal bed surfaces.
- **David J. Tanzer, MD** noted faster visual recovery, better visual acuity, and better low contrast acuity with IntraLase versus both the Hansatome and AMO's Amadeus microkeratome.
- **Ella G. Faktorovich, MD** reported results comparing IntraLase versus the Hansatome. More IntraLase eyes achieved 20/15 post-op acuity at three months (77% versus 67%) and at six months (76% versus 72%). Transient light sensitivity (TLS) was noted in 3.8% of IntraLase eyes, which can be minimized through surgical technique and laser settings.
- **Karl G. Stonecipher, MD** also discussed TLS syndrome, with onset 2-6 weeks post-op and resolution in 1-3 months. Incidence of TLS decreased to 1% or lower after adjusting laser energy settings.
- **Gonzalo Bernabeu Arias, MD** described the superior biomechanical response of the cornea to IntraLase versus the Moria M2 microkeratome, attributed to a lower change in corneal curvature.

DA VINCI Femtosecond Surgical Laser

The most interesting new potential entrant in this field is the DA VINCI Femtosecond Surgical Laser, unveiled at AAO by Ziemer Ophthalmic Systems of Switzerland. Zeimer's Amadeus II microkeratome is successfully marketed today by AMO/VISX. Of course, there's a long way to go before this product can really compete with IntraLase: regulatory clearances have yet to be received in either the US or Europe, clinical studies have to be conducted (we're not aware if any human eyes have been treated yet), and the product has to steer clear of IntraLase's intellectual property. Company management claims that the DA VINCI system will not be blocked from entering the market either in the US or internationally; we have not done enough analysis to weigh in on this issue.

Source: Ziemer Ophthalmic Systems

The key differentiating feature of the DA VINCI system, based on what we know today, is its compact size, portability, and articulating arm that will allow it to fit underneath or alongside current excimer lasers and be used in an integrated fashion with them. This could facilitate patient flow within a refractive practice by allowing patients

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to "stay put" during flap creation and excimer ablation. This may prove to be an important feature, given the fact that some surgeons express dissatisfaction with patient flow using IntraLase.

The company also claims to deliver a much smaller spot size than IntraLase, ability to create flaps in a similar amount of time as IntraLase's new 30kHz system, a closed-loop adjustable suction system for fixation on the eye (similar to Amadeus II), and no need for special environmental controls. Like the IntraLase system, the DA VINCI interfaces with the eye using an applanation surface. Pricing is expected to be similar to that for IntraLase.

Ziemer plans to submit to the FDA for a 510(k) marketing clearance this month, and hopes for approval by February 2006. The company plans to begin a clinical study in the US next year after receiving its 510(k). Ziemer hopes to receive a CE Mark in Europe this month, and begin a clinical study in Switzerland shortly thereafter. The company is gearing up manufacturing in Switzerland, and plans to begin shipping units next April. Nomograms for the laser need to be perfected prior to launch. According to Ziemer, development has been ongoing for four years, involving nearly 60 engineers in Germany and Switzerland.

At AAO, Ziemer had a mock-up of the DA VINCI laser in its exhibit booth and a working prototype in a nearby hotel for presentations to surgeons. The company also held meetings with a number of potential marketing partners. In our view, the most interesting potential marketing partner would be AMO/VISX, which already markets Ziemer's Amadeus II microkeratome. If the product pans out from a clinical standpoint and is not blocked in important geographies by IntraLase patents, the DA VINCI system could do well in the hands of the LASIK market leader.

20/10 PERFECT VISION and WaveLight

20/10 PERFECT VISION of Germany once again showed its FEMTEC femtosecond laser at this year's AAO; it has been showing its laser at ophthalmology conferences for over three years now. The company received FDA 510(k) clearance in February 2004 and CE Mark in April 2004, but to our knowledge has made little or no progress in commercializing its laser and has only recently begun treating human eyes. 20/10 says that it is ramping production and is planning to focus its marketing efforts in Europe and Asia. We do not believe that the company has near-term plans to commercialize the FEMTEC laser in the US despite its 510(k) clearance. 20/10 appears to be focusing its efforts on applications other than the creation of LASIK flaps, including penetrating keratoplasty, tunnel cuts for intracorneal ring segments, and cuts for astigmatic keratotomy. The company's most successful development has been the WaveScan diagnostic system, which it sold to VISX in 2003.

WaveLight Laser Technologie AG of Germany is also developing a femtosecond laser, but appears to be at an earlier stage of development than either Ziemer or 20/10. The company is saying that it plans to show its product at conferences next year, and introduce the product to the market by the end of 2006, although this sounds aggressive. Like Ziemer, WaveLight is a real company that has a track record of developing successful products for the LASIK market, and as such cannot be dismissed as a potential competitor. WaveLight has placed 100 of its highly regarded ALLEGRETTO WAVE "wavefront optimized" excimer lasers into a crowded US market since it received FDA approval just over two years ago. Almost 600 WaveLight excimer lasers are installed worldwide. **Q**

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