

ATRIX LABORATORIES INC

Form 425

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The following is the transcript of the conference call held on October 21, 2004 at 8:30 AM ET regarding QLT's third-quarter earnings results.

### **Additional Information**

In connection with QLT's proposed merger with Atrix Laboratories, Inc., QLT has filed with the SEC a registration statement on Form S-4, a definitive joint proxy statement/prospectus and other relevant materials. INVESTORS AND SECURITY HOLDERS OF QLT AND ATRIX ARE URGED TO READ THE DEFINITIVE JOINT PROXY STATEMENT/PROSPECTUS REGARDING THE TRANSACTION AS WELL AS OTHER RELEVANT MATERIALS BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT QLT, ATRIX AND THE TRANSACTION. The definitive joint proxy statement/prospectus on file with the SEC and any other documents filed by QLT or Atrix with the SEC, may be obtained free of charge at the SEC's web site at [www.sec.gov](http://www.sec.gov). The definitive joint proxy statement/prospectus and other relevant materials have been mailed to stockholders of QLT and Atrix in advance of the special meetings to be held on November 19, 2004 to consider the transaction. In addition, investors and security holders may obtain free copies of the documents (when they are available) filed with the SEC by QLT by directing a request to: QLT Inc., Attn: Investor Relations, 887 Great Northern Way, Vancouver, BC, Canada, V5T 4T5. Investors and security holders may obtain free copies of the documents filed with the SEC by Atrix by contacting Atrix Laboratories, Inc., Attn: Investor Relations, 2579 Midpoint Drive, Fort Collins, CO, 80525.

QLT, Atrix and their respective executive officers and directors may be deemed to be participants in the solicitation of proxies from the stockholders of QLT and Atrix in favor of the transaction. Information about the executive officers and directors of QLT and their ownership of QLT common shares is set forth in the proxy statement for QLT's 2004 Annual Meeting of Shareholders, which was filed with the SEC as Exhibit 99.1 to Form 10-K/A on April 28, 2004. Information about the executive officers and directors of Atrix and their ownership of Atrix common stock is set forth in the proxy statement for Atrix's 2004 Annual Meeting of Stockholders, which was filed with the SEC on April 5, 2004. Investors and security holders may obtain more detailed information regarding the direct and indirect interests of QLT, Atrix and their respective executive officers and directors in the transaction by reading the definitive joint proxy statement/prospectus regarding the transaction on file with the SEC.

### **CONFERENCE CALL TRANSCRIPT**

#### **CORPORATE PARTICIPANTS**

**Therese Hayes**

*QLT, Inc. VP of IR*

**Paul Hastings**

*QLT, Inc. President & CEO*

**Mohammad Azab**

*QLT, Inc. EVP & Chief Medical Officer*



## CONFERENCE CALL PARTICIPANTS

**Dimi Ntantoulis**

*UBS Analyst*

**Douglas Chow**

*Haywood Securities Analyst*

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**David Maris**

*Banc of America Analyst*

**Hari Sambasivam**

*Merrill Lynch Analyst*

## PRESENTATION

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**Operator**

Welcome to the QLT Inc. conference call. I would now like to turn the meeting over to Ms. Therese Hayes. Please go ahead Ms. Hayes.

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**Therese Hayes - QLT, Inc. VP of IR**

Good morning everyone, and welcome to our call. This call is being webcast and will be available on our website for the next seven days at [www.QLTInc.com](http://www.QLTInc.com) where you will also find a press release associated with this call. Today on the call we have Paul Hastings, QLT's President and CEO presenting, Dr. Mohammad Azab, Executive VP of R&D and Chief Medical Officer will be available during the Q&A portion of the call. Before we begin I need to remind you of the following and the warning these are long forward-looking statements. In connection with QLT's proposed merger with Atrix Laboratories QLT has filed with the SEC registration statement on Form S4 containing a joint proxy statement prospective and other relevant material.

Investors and security holders of QLT and Atrix are urged to read the preliminary joint proxy statement prospectus regarding the transaction and the definitive joint proxy statement prospectus when it becomes available as well as other relevant materials because they will contain important information about QLT, Atrix and the transaction. The preliminary joint proxy statement prospectus on file with the SEC and the definitive joint proxy statement prospectus and other relevant materials when they become available and any other documents filed by QLT or Atrix with the SEC may be obtained free of charge at the SEC's website at [www.SEC.gov](http://www.SEC.gov).

The definitive joint proxy statement prospectus and other relevant materials when they become available will be mailed to stockholders of QLT and Atrix in advance of the special meeting to consider the transaction. In addition,

investors and security holders may obtain free copies of the documents when they are available filed with the SEC by QLT by directing a request to QLT Attn: Investor Relations, 87 Great Northern Way, Vancouver BC Canada, V5T 4 T5. Investors and security holders may obtain free copies of the document filed with the SEC by Atrix by contacting Atrix Laboratories Inc., Attn: Investor Relations, 2579 Midpoint Drive, Fort Collins, Colorado 80525.

QLT-Atrix and the respective executive officers and directors may be deemed to be participants in the solicitation of proxies from the stockholders of QLT and Atrix in favor of the transaction. Information about the executive officers and directors of QLT and their ownership of QLT common shares as set forth in the proxy statement for QLT's 2004 annual meeting of shareholders which is filed with the SEC as Exhibit 99.1 to form 10-K A on April 28, 2004. Information on both the executive officers and the directors of Atrix and their ownership of Atrix common stock is set forth in the proxy statement for Atrix's 2004 annual meeting of stockholders which was filed with the SEC on April 5, 2004.

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Investors and security holders may obtain more detailed information regarding the direct and indirect interests of QLT-Atrix and the respective executive officers and directors in the transaction by reading the definitive proxy statement prospectus regarding the transaction when it becomes available. Certain statements made during this call constitute forward-looking statements of QLT within the meaning of the private securities litigation reform act of 1995 which involves known and unknown risks, uncertainties, and other factors that may cause our actual results to be materially different from any future results, performance or achievements expressed or implied by such statements.

Forward-looking statements include but are not limited to those with respect to our projections about the interpretation of the recently released anti-VEGF aptamer data or projections as to the safety and efficacy of the anti-VEGF aptamer, our comparisons between the potential anti-VEGF aptamer therapy and Visudyne therapy, and our expectations of Visudyne's competitive position in light of the anti-VEGF aptamer data, our predictions regarding manufacturing risks which Eyetech may face and manufacturing of anti-VEGF aptamer for commercial supply.

Statements with respect to patient and physician demand for Visudyne therapy, and our predictions of the effect of the data now available on Macugen may have on treatment decisions made by physicians. Statements with respect to anticipated level of 2004 sales of Visudyne; estimates of 2004 EPS and the impact of the anti-VEGF aptamer data on future level of sales of Visudyne and earnings. Those with respect to our expectation that the acquisition of Atrix will close and the anticipated timing for completion; estimates of the post integration financial guidance for the combined QLT-Atrix Company anticipated future operating results; anticipated timing for and receipt of further reimbursement approvals for Visudyne therapy.

The anticipated timing for release of data from our Visudyne and occult Phase III trial and QLT's 0074 and BPH and androgenetic alopecia, and receipt of regulatory approvals for expanded use of Visudyne and the six-month formulation of Atrix with Eligard. These statements are only predictions and actual events or results may differ materially. Factors that could cause such actual events or actual results to differ materially from any future results expressed or implied by such forward-looking statements include but are not limited to, the scope and timing of any regulatory and reimbursement approvals of anti-VEGF aptamer therapy, data not available to us concerning anti-VEGF aptamer therapy may lead us to different conclusions or cause our expectations to change.

The competitive position for Visudyne may change in the future; the risk that future sales of Visudyne may be less than expected. That future operating results are uncertain and likely to fluctuate; the risks that the proposed merger with Atrix will not be completed or that the business will not be successfully integrated, the risk that if the merger proceeds risk factors relating to the business or products of Atrix will impact the Company's combined results, the outcome of our application for regulatory approval for expanded use of Visudyne and Atrix's Eligard six-month formulation and Atrisone, our clinical development programs may not be successful as well as the risk factors described in the sections outlined in the Company's most recent annual report on form 10-K under business risk factors, management discussion analysis of financial condition and results of operation. And the notes to consolidated financial statements except as required by law.

We undertake no obligation to update any further forward-looking statements even though our situation or expectations may change in the future. And with that I will pass it over to Paul.

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**Paul Hastings - QLT, Inc. President & CEO**

Okay. Thanks, Therese. So since Friday, last Friday we have received a lot of questions relating to the FDA advisory committee meeting held last Friday to review the clinical data of another potential agent for the treatment of age-related macular degeneration, and its potential effects on Visudyne. We feel it is of the utmost importance to give everyone interested the same message, so were having the call today to do just that. We will answer to the best of our ability; so far the questions that have been posed. It is important to note that we are answering these questions with

what is the best available data that we have, and we encourage people to draw their own conclusions based on their own full review of all available data.

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It is our opinion that the actual users of these therapies, the clinicians, have asked similar questions regarding the data as have been asked by our investors and since retinal specialists are data driven they will draw their conclusions, their own conclusions about any treatment algorithms based on full and transparent data of all of the available therapies. So we're receiving these many questions about our interpretation of the FDA briefing packet for the anti-VEGF aptamer, so during this call we will highlight some of the data presented in those now publicly available FDA briefing documents for these trials. This information, by the way, is available on the FDA website at [www.FDA.gov](http://www.FDA.gov). And you just need to simply click on advisory committees, and then on new documents. Briefing materials for the aptamer were posted on August 26th.

For you, our investors who have been reading countless analyst reports, news articles, briefing documents or perhaps not, it is our responsibility to inform you of our opinion and share with you our response to the multiple questions we are receiving about Visudyne, the potential competition and our view of what might happen in the future. So with the caveats included in all those forward-looking statements that Therese shared with you, I will attempt to do that, and at the end of my remarks you can ask any questions you may have to me or to Mohammed Azab, our Executive Vice President of research and development and chief medical officer who is here with me this morning.

So after thoroughly reviewing this publicly available data and with the caveat that no head-to-head trials have been performed, comparing Visudyne to the anti-VEGF aptamer, and no trial using a well-controlled arm of Visudyne either in combination with or against the anti-VEGF aptamer exists, for example the anti-VEGF trials left the use of Visudyne to the discretion of the investigator and not to a controlled regiment, it continues to be our view that the aptamer does not appear to provide an advantage over standard of care of Visudyne, and we remain confident in the potential for Visudyne in the treatment of age-related macular degeneration.

Until we have data to suggest otherwise, and we have not seen that yet, we will continue to reiterate our guidance for 2004 that we expect to achieve \$430 to \$455 million in Visudyne sales and 81 to 91 cent in earnings on a fully diluted basis. And following the merger with Atrix Laboratories, which is expected to close later this year, we will continue to aim at a combined QLT-Atrix five-year compound annual earnings growth rate of 20 to 25 percent.

Now as to claims being made about, by our potential competitors about Visudyne only serving a small portion of the AMD market, bear in mind that we recently completed an extensive review of Visudyne's multiple clinical trials with the Centers for Medicare Advisory Board or the MCAC panel and subsequently based on that data the CMS expanded reimbursement for Visudyne to include certain patients with occult and minimally classic lesions in addition to the predominantly classic lesions for which we have FDA approval.

So in the USA clinicians have access not only to all of our data but also to reimbursement for certain patients with all three forms of wet AMD. In Europe Visudyne is approved for both predominantly classic and occult and in Japan it's approved for all three lesion sub types. Those of you who went through that process with the CMS with us know how rigorous the review from the CMS MCAC panel was, as well as the thorough discussion of the data at that meeting. We will discuss some of that data later at this call, some of the data related to Visudyne.

So knowing firsthand how much hard work goes into completing clinical trials, we first want to say and ultimately receiving approval for therapy for the treatment of wet AMD, that we applaud anyone willing to go through this process and make available other therapies for the treatment of patients with this multi-factorial disease who will benefit from having alternative and potentially additive therapies. We believe there is room for many agents in the treatment of this disease and it is our hope and belief that Visudyne will always be part of that armamentarium of therapy available to clinicians.

It is however fair to say that we were somewhat surprised that the panel review of the proposed new product did not focus on certain issues. We will get into those specific issues in a bit, but let me first say that it is our belief that in



light of those certain issues, clinicians, some of whom have now had access to this publicly available data will consider those issues when making treatment decisions for their patients with AMD once these products are all available, and it is in the end the clinicians who will decide how all of these current and potential new therapies will be used once they reach the market.

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We also noted from the panel that the FDA has not completed yet its full review of the potential new product and we will not know what the label will look like obviously until that product is approved, so some of the issues that we have been getting questions on the past couple of days may be answered by ultimately the label for the product and the subsequent publication of the data from all these trials. But for now, all we have is what is available in these briefing documents as well as the published data that we have for Visudyne.

So when the discussion at the recent FDA panel, interesting lesion size and subtype data that are presented in the bar charts provided in the FDA briefing packet, particularly given our historical experience with the FDA's review of Visudyne in 1999 and 2000, were just not highlighted. We are getting a lot of questions about our interpretation of that and there are numerous reports by analysts that also refer to that. We encourage our investors to read all those reports and come to their own conclusions based on the available data.

These briefing documents posted the day before the panel led us and several sell side analysts notably both QLT and Eyetech and Pfizer analysts to conclude that several key issues would likely be raised at the panel meeting including the perceived inconsistency in the two independent trials to demonstrate efficacy across all subtypes given the data in those tables. The minimal and inconsistent response in occults and predominantly classic large lesions and the graphical conclusion that the combined statistical significance in the .3 mg dose was driven primarily from the difference in the minimally classic subgroup.

In the occult subgroup it appeared that the difference in one trial drove the combined occult treatment versus sham difference and at both trials it appeared that there was not a noticeable difference between treatment and sham in the predominantly classic subset. Large lesions appeared to respond in treatment in one trial and not the other. All we can do is refer you to those charts in the FDA briefing document, and you can come to your own conclusion about those perceived inconsistencies and in the end of course, if treating physicians have access to this data and some of them already have, as well as published data on products like Visudyne and others they will certainly draw their own conclusions and decide when both products are available for use, how again they will use these therapies.

So it may be that all these issues may not even be required for approval of the product, however we do think that they may have an impact on the potential use of compounds when they are on the market, and therefore their potential impact on Visudyne. So let's go a little bit to the efficacy analyses. As outlined in the briefing documents, only the .3 mg dose achieved statistical significance at the predefined adjusted level in both studies. The 1 mg dose is only significant in study numbers 1003 but not in study 1004, and the 3 mg dose is not significant in either study. So there's no dose response curve.

The difference between the 0.3 mg dose of the aptamer and sham in each study was 13 percent difference in study 1003 and 14 percent difference in study 1004. Now not to make a direct comparison since no head-to-head trials have been done but in our TAP trial, the trial that was used to obtain Visudyne approval for those with AMD patients with a predominantly classic form of the disease had an overall 15 percent difference in favor of Visudyne and a 28 percent difference in favor of Visudyne in a predominantly classic analysis. So therefore similar comparative data. Visudyne has been used in over 350,000 patients, and has a proven long-term efficacy and safety profile that retinal specialists are very familiar with.

Moving onto other issues discussed at that panel meeting and questions that have arisen from it, safety issues were broadly discussed with a particular focus on endophthalmitis and duration of treatment. Again, Visudyne has well-established long-term efficacy and safety which has been known for up to five years from the extended TAP trials. Long-term efficacy and safety for the patients in the trials beyond one year with the aptamer may not be available soon for the new agent and specifically the trial has been redesigned or rerandomized, or the patients have been rerandomized at one year.

Stabilization of vision loss at two years and effect when treatment is stopped was also discussed related to the anti-VEGF aptamer. And we were questioned about that. Our market research tells us that Visudyne treatment frequently gradually declined and eventually stops because of the cessation of leakage and the drying out of lesions in many patients. Since the anti-VEGF intravitreal injections are done every six weeks regardless of leakage or any other parameters that is not clear yet when the aptamer treatment should be stopped, and what happens to lesion and vision with treatment cessation; longer-term data, of course, will determine that.

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The average number of aptamer intravitreal injection treatments in the first year was 8.5 treatments compared to approximately 3 treatments in the first year in the Visudyne trials. Patients have to come in every six weeks as compared to every 12 weeks in the Visudyne trials. It was also highlighted that in preparation for intravitreal injections several procedures must be undertaken including the application of a lid speculum, the installation of a topical anti-infective and the injection of a subconjunctival anesthetic. In addition, in the clinical protocol the patient must remain lying down for at least 30 minutes after the injection.

Additionally in an attempt to reduce age-related blindness additional procedures were added to the clinical protocol including the use of a sterile preparation and drape similar to that used in intraocular surgery, use of either a preinjection topical ophthalmic antibiotic drop for three days prior to the injection or 10 ml Ovidine iodine flush which is a flush with a local antiseptic immediately prior to injection. So the Visudyne procedure requires about 20 minutes. There are over 750 lasers placed in the United States at many treatment centers, and the retinal specialists again are familiar with this procedure.

Each different procedure and intravitreal injection or an IV administration followed by a ray of light will provide different challenges for clinicians treating this disease, and in the end again the choice of which procedure and which drug to use in which ways will be in the hands of the clinicians. We are not of the opinion that it is easier to give intravitreal injections with all the preparation and follow-up needed than to give a simple 10-minute infusion followed by a ray of light.

The way in which the FDA will deal with the risk of endophthalmitis with intravitreal injections of new agents will remain unclear; suggestions from the panel members included a combination of educational materials and training for physicians and patients and a requirement for follow-up through either additional office visits or patient phone calls. None of this will be determined of course until the product is labeled.

On the safety and/or efficacy synergy of combining the aptamer with Visudyne based on the limited data available to them, the panel didn't see any safety concerns with the combined use of the two agents in the clinical trials for the aptamer. We already know that in addition to the combination investigations conducted by the Companies that are examining new anti angiogenics numerous retinal specialists have already used the combination approach with Visudyne by combining Visudyne plus Triamcinolone, although the cumulative number of intravitreal Triamcinolone injections is averaging in practice to be about two to three injections, not eight. And it is our belief that like many of the multi-factorial diseases like age-related macular degeneration, therapies may be combined at the discretion of the treating clinician.

It would be our intention to support combination controlled trials using agents once available on the market like we've done with Triamcinolone. So in summary we've always maintained AMD is a severe and complex disease which like other severe and serious diseases will likely be best treated with a cocktail of drugs. Visudyne is an important first therapy to build from, and it is our intention to continue to maximize Visudyne both as a single agent and in clinical trials and combination to best serve the patients. We believe that even in a competitive environment Visudyne will continue to grow due to the transparency of all our published data supporting the treating clinician society's treatment algorithms, increased penetration into the AMD market with our recently expanded CMS reimbursement coverage for certain patients with occult and minimally classic lesions in the United States. Awareness among retinal specialists of Visudyne's efficacy in all subtypes based on publications and a treatment procedure that does not require direct intravitreal injections. Visudyne has its own side effect profile that is well understood by clinicians and carefully and easily monitored and managed.

Broad approval in the U.S., including three subtypes in Japan, occult and predominantly classic in Europe, New Zealand and Australia and many other countries. And finally the widespread use of Visudyne in combinations with other agents led by the clinicians own combination use of Triamcinolone leading to many publications of

investigator-sponsored trials with the two agents; and we are also providing grants for many controlled investigator-sponsored trials used in combination therapy of Visudyne and Triamcinolone.

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So what we hope is that investors will focus on the long-term growth of Visudyne and understand that Visudyne will probably remain a growing product for the treatment of certain patients with wet AMD for quite some time. We hope you will also focus on our milestones and those of our merger partner Atrix Labs for the remainder of this year. That is the Phase III occult data that will come from our VIO trial to be presented at AAO in October. The imminent filing of the Atrixone NDA for mild to moderate acne in Q3 by Atrix, 074 benign prostatic hyperplasia and androgenic alopecia Phase II data by year end, Atrix's anticipated Eligard six-month approval product in Q1 '05. And with the merger of QLT and Atrix Labs we are positioned to be a fully integrated, profitable biopharmaceuticals company with multiple drugs on the market as well as many promising pipeline products and a proprietary drug delivery platform.

So with that I'd like to go to questions.

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**Therese Hayes - QLT, Inc. VP of IR**

Thank you, we will now take questions from the telephone lines.

## QUESTION AND ANSWER

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### Operator

(OPERATOR INSTRUCTIONS) Dimi Ntantoulis from UBS Securities.

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**Dimi Ntantoulis - UBS Analyst**

Good morning, just a couple of questions. It looks like Macugen is going to get approved, now whether it gets used or not is clearly another issue. But with Macugen and with Lucentis and Retain et cetera coming on board, there's obviously going to be a lot more crowded space and all the marketing companies of these products will be spending marketing dollars. What do Novartis and QLT where do you plan both on a strategy basis to combat this sort of noise in the marketplace for your competitors? And what are the financial implications is the first question.

Secondly are you surprised that Macugen got such an easy go at the panel and why do you think that might be? And just finally an update on Atrix and sort of what the outstanding issues are for the proxies to be submitted. Thanks.

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**Paul Hastings - QLT, Inc. President & CEO**

I am writing down the questions you asked me. So I hope I get them all. The first question which relates to approval or potential approval of multiple agents, first of all we now know what the full dataset or most of the full dataset are for the anti-VEGF aptamer and we expect as most people do that the product will be approved. We don't know exactly when but our expectation is probably Q1 '05. And yes, it's true that many companies and particularly the ones who will have products approved next year will be out there promoting these products to the retinal specialists, there are only 1400 retinal specialists, you can't inundate them with thousands and thousands of sales reps and expect that they will be listening and paying attention to all those promotional messages when most of these retinal specialists are 100 percent driven by data, not promotion.

So we have an ample sales force at Novartis to promote Visudyne. There is plenty of data that is available for Visudyne that is transparent and fully published and available to retinal specialists, and we think that is what's going to drive the use of these agents not necessarily how many reps are promoting the product. In terms of whether we are surprised by the easy go of the Macugen product with the anti-VEGF aptamer at the panel, no I do not think we were surprised by anything. I think what happens at a panel happens at a panel. And it is just the way it went. So the day before the panel a lot of notes came up from a lot of people highlighting what some of the potential issues may be,

some of those issues were brought up some of them were not. But we are pretty confident that as time goes on all of those issues will become available and out in front for full data disclosure with people who will actually be using the product.

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And then you want to know about Atrix. Yes, we are hoping for approval of the merger with Atrix by year end. We would like that to happen as soon as possible and we would like to begin to complete our integration of the two companies and start maximizing the value that both companies will synergistically bring together.

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**Dimi Ntantoulis - UBS Analyst**

Just on the Atrix merger is there some sort of regulatory or governmental holdup currently? I would have thought proxy documents would have been out by now.

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**Paul Hastings - QLT, Inc. President & CEO**

I think we will be filing those very, very shortly and so far there are no there's nothing that would surprise us in terms of any comments we are getting or anything that would make us think that the transaction wouldn't be able to be voted on by the end of the year.

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**Dimi Ntantoulis - UBS Analyst**

Great. Thank you.

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**Operator**

Douglas Chow from Haywood Securities.

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**Douglas Chow - Haywood Securities Analyst**

I just have two questions. Just wondering if I am not sure if you can answer this, but if you were just looking at the data that has been presented on Macugen so far, do you think they have enough for approval in the predominantly classic and occult? And the second question is if you could just give us general guidance of what you think is the breakdown of minimally classic occult and predominantly classic treatments in the current quarter or early in the previous quarter.

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**Paul Hastings - QLT, Inc. President & CEO**

So we can't speak to how the FDA interprets data that is presented to them or whether they are going to approve or not approve the product in those certain indications. We've highlighting what we've seen in the individual subtypes in the data. And that will probably drive the use of the product and that is probably what is most important to us. In terms of guidance for minimally classic predominantly classic and occult, most of the new patients were in the last quarter were occult patients and minimally classic patients. And that's about as much as we give out for guidance but it seems to be going very well. The ramp up of product has been going well since April when we actually had the implementation of the CMS decision and we expect that to continue.

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**Operator**

Michael Lachman from ThinkEquity Partners.

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**Michael Lachman - ThinkEquity Partners Analyst**

Good morning. Just a few questions. When do you plan to provide formal 2005 guidance compared to Visudyne revenue and in advance of that, are you willing to make any broad comments at all with regard to the kind of sales trend you expect to see next year?

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**Paul Hastings - QLT, Inc. President & CEO**

Yes, I think the best thing we can do is what I have already done, Michael, and say that we are shooting for a compound annual growth rate of our combined Company of 20 to 25 percent in earnings. We won't give formal 2005 guidance until we've completed our budget negotiations and other negotiations that we have every year when Novartis and that usually will conclude sometime in the January timeframe, after a full review of the budget. So we will be looking at a number of different factors, including whether or not the competitive products get approved or when we anticipate those products being approved, how much money we will need to spend to be able to counter when those products are approved. And so we will give the guidance at the same period of time we've given every year, and I do apologize for that. I'd like to give it to you before if I could, but it is a matter of going through the processes with the partner of getting their budgets in order. So that's about as much as we can do at the moment.

In terms of sales trend for 2005, again, in our models of our merger with Atrix, we planned in those models to have a product approved in 2005. Another product for the treatment of AMD. So nothing has really changed in our forecast going forward in terms of our growth, which is again our compound annual growth rate over five years of 20 to 25 percent.

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**Michael Lachman - ThinkEquity Partners Analyst**

With regard to the Atrix merger have you provided or if you have any update any thoughts with regard to dilution or accretion over the next couple of years?

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**Paul Hastings - QLT, Inc. President & CEO**

We what we've given guidance about is that we would have some moderate dilution in 2005 with accretion in 2006. And we are still aiming for that sort of goal, and we expect that that will happen.

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**Michael Lachman - ThinkEquity Partners Analyst**

Turning back to the Macugen trial in the sham groups of the Macugen trial there was a relatively high level of Visudyne use on study in patients with either minimally classic or occult disease, I think it was just over 30 percent in the international study and just over 40 percent in the North American study by our account of the data. Do you think this is at all reflective of how Visudyne is being used today in the real world, and if not, what was different about the way the trial was conducted?

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**Paul Hastings - QLT, Inc. President & CEO**

I am going to let Mohammad answer that question but I just want to make a pretty broad statement again about this.

The use of Visudyne in the clinical trials was totally at the discretion of the physicians who were testing another investigational agent for the treatment of AMD. The usage did not appear to be similar necessarily to the protocol used to Visudyne that we did in our clinical trial. So it is kind of hard to compare apples-to-apples when one of the treatments was well controlled and the other was at the discretion of the physician. But with that I will let Mohammad give you some comments on where he sees how these therapies were used together.

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**Mohammad Azab - QLT, Inc. EVP & Chief Medical Officer**

I think the general difference between the trial 03 and trial 04 was that 03 is an international trial in so many countries and the approval and reimbursement of Visudyne at the time for many of these countries had not been established yet, so that drove the lower use at that time. But mind you the trials were conducted like in terms of old statutes and the one-year data over a year ago. Or over the past two years. So that reflects sort of the reimbursement and approval in these international trials. In Visudyne in the North American trial as you noticed that there is a large use of Visudyne in the predominantly classic up to about 60 percent of the patients or more and in the occult and minimally classic there is about 10 percent choose (ph) in the occult and minimally classic population in this trial, which once again reflects a couple of things. Could reflect some off-label use, but I think more importantly what you need to remember that is that could reflect conversion of those lesions to predominantly classic during the trial. So at any one point a patient who enters a trial as an occult or minimally classic could also have conversion and therefore become eligible for Visudyne use. So it is a combination of the two factors. That the actual use in the market and probably some conversion of the lesions, as well. Whether that will reflect the actual clinical practice, I think it depends really on how widely that trial is representative of the North American market. And that is really a difficult question to answer.

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**Michael Lachman - ThinkEquity Partners Analyst**

If I could just ask one more thing regarding the average number of treatments per patient that you are currently seeing with Visudyne during the first and second year of therapy, where do you think that metric currently stands in the U.S.? And as combination therapy with Triamcinolone has picked up over the last year or so, have you seen any change in that average number of treatments per patient? And do you have any thoughts with respect to what the frequency of treatment may be when Visudyne is used in combination with Macugen?

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**Paul Hastings - QLT, Inc. President & CEO**

Actually what we saw with the limited data that is available in the aptamer trials and what we see in clinical practice with Visudyne and Triamcinolone is people are given about two to three treatments of Visudyne, two to three treatments of TA. In the aptamer trials what you saw again was about two to three treatments of Visudyne but again totally at the physician's discretion. So who knows how Visudyne might be used with other agents, but we know that with Triamcinolone for example, in clinical practice again they are giving two to three intravitreal injections of Triamcinolone and they give it probably every three months the same way they use Visudyne every three months and they give about two to three treatments of that.

In the beginning they were a lot of the clinicians were trying to and they will always do this by the way they were trying to minimize the number of re-treatments they needed to give by adding an additional agent, Triamcinolone. And as the practice became more commonplace, people actually began to not just stop when they got the same results with the combination of Triamcinolone and Visudyne or their perceived same results as they got with Visudyne alone, they actually did another treatment to see if they could get further improvements. So there's a lot of that going on.

There are a number of investigator-sponsored trials that are going on, as well as company-sponsored investigator trials in a controlled fashion with Visudyne plus TA and it would be our intention that when new drugs are available on the market that these kinds of trials will continue with whatever new agents are also available.

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**Operator**

David Martin from Dundee Securities.

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**David Martin - Dundee Securities Analyst**

I got a couple of questions. When you published the top data you published the combined data of the two trials that you ran. I'm wondering if you can take us back to that data and tell us in predominantly classic whether one of those trials worked better than the other or whether they both worked equally as well. Also when the label is published for Macugen, do you expect that they will publish the combined data or will they break it out, and in your experience would you expect the physicians to go back to the briefing documents or would they go just based on whatever data is in the label to drive their decision?

The second question is QLT stock has come off a bit since the Atrix merger was announced or the Atrix acquisition. I'm wondering if that is addressed in any terms and conditions of the deal.

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**Paul Hastings - QLT, Inc. President & CEO**

So we're expecting the deal will continue to be able to be put in front of our investors and voted on by year end. And there are no terms and conditions which would necessarily affect what is happening today. Now on whether physicians will go by what is on the label or what is in data or what is available for data, we don't know what data will be available we don't know what data will be published. We do know that the briefing documents are publicly available data today. We know that a number of people have been asked for their opinions of those briefing documents by many of the analysts, so those opinion leaders already have had access to that data.

In our point of view there is no way that the opinion leaders will simply use the therapy based on what is in this label. They will want to know what different subtypes or what the effects are in different subtypes and they will want to see that data. Whether those data are available or not that is not up to us. But hopefully they will be in full disclosure and with peer review publications and they'll have access to that. People make their decisions based on data, David, and I'm sure they will be digging into that as best as they can.

In terms of whether or not we know when their label is published, whether it will be the combined data or break it out. We do not know and that will be up to the regulatory authorities. And on what our data said and (indiscernible) will let Mohammad answer that question.

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**Mohammad Azab - QLT, Inc. EVP & Chief Medical Officer**

Just as an addition to Paul, usually of course we will not know the label until it is approved but it is very common that in the sort of description of the clinical trials in the FDA labels that they do describe the two individual trials that contributed to the decision. Because that is part of the mandate of the FDA to ensure that there are two adequate and well controlled trials and usually there are descriptions of the two trials individually in the label. And that is actually what is in our Visudyne label when you review it.

In terms of our publication, although that we publish on the combined data, we did present the individual sort of data subgroup analysis as part of the combined data publication. We also did present the sub group analysis in terms of the actual difference between the different subgroups and also the actual P value of the difference between those subgroups. In addition to that, which we believe is required, is when you do know that there is a possibility for interaction between important variables and the treatment and as you have seen from the presentation of the FDA, they expect patients to be stratified by lesion type and by baseline vision. So we expect that there would be in the

submission or in the review an interaction test between lesion subtypes and baseline vision and treatment.

So we have presented the interaction tests and their P values also in our publication, so all of these are information that we hope will be available in the publication or ultimately in the label that we already have from Visudyne.

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**David Martin - Dundee Securities Analyst**

So (technical difficulty) your (indiscernible) trials showed consistently a positive benefit in predominantly classic?

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**Mohammad Azab - QLT, Inc. EVP & Chief Medical Officer**

Yes, as I mentioned the two trials were consistent in the high benefits predominantly classic subgroup, and that benefit to us, 28 percent and was consistent between the two trials I believe, between the two individual trials each one was in the order of the 24, 25 percent or higher and combined between 25 and 30 percent and combined we had a 28 percent (indiscernible) between Visudyne and sham in the predominantly classic.

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**Operator**

Christine Charette from BMO Nesbitt Burns.

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**Christine Charette - BMO Nesbitt Burns Analyst**

I've got several questions. I'll take them one at a time. First one is for Mohammed basically because you're the only person who was there back then, but when the TAP results came out Visudyne reached physical significance for the trial overall, but there was a decision that was made to seek approval for predominantly classic AMD only. Was that decision based on internal decision at QLT or was it based on FDA guidance that they were giving you, and would you given the Powell (ph) meeting on Friday in retrospect do you think that was the correct decision to make?

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**Mohammad Azab - QLT, Inc. EVP & Chief Medical Officer**

Christine I have to answer your question from a historical perspective that was an internal decision; that decision was made prior of any interaction with the FDA regarding that submission.

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**Christine Charette - BMO Nesbitt Burns Analyst**

And was it given what happened on Friday, was that decision the correct decision to make?

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**Mohammad Azab - QLT, Inc. EVP & Chief Medical Officer**

I think that is in retrospect one can make different assumptions. The facts or the reality is that we have submitted for the predominantly classic and the main reason driving that decision was really to provide the therapy for the patient who would most benefit because there seems as we've seen, that there is a large benefit in the predominant classic subgroup, which closer to 30 percent difference. That's much higher than any of the differences we've seen in any of the trials with new agents. Of course, with the caveat there is still no head-to-head trials. But it is of course, you can look at the different subgroups can have different interpretations. So the interpretation at the time from our subgroup analysis and the interaction tests that this is the patient that most benefits and that was the decision made at that time.

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**Christine Charette - BMO Nesbitt Burns Analyst**

And given what happened on Friday, is it possible for you to refile TAP and just ask approval for the entire patient population, or is that not feasible?



**Paul Hastings - QLT, Inc. President & CEO**

We are not going to speculate on that at the moment. But we certainly are looking we are going to be in front of the FDA soon with our VIO data and looking at all the different lesion subtypes. Certainly we have statistical significance back then at that level. I have to tell you that I personally after I joined the Company had a meeting with Dr. Chambers and asked him specifically would he have approved Visudyne for the different subtypes based on the data that was available? And he told me that he would have simply looked for the data subtype that was driving the most result, and that is where he would have gone. So yes, we're a bit surprised when similar data was presented with the newer agent, and the reaction to it was more broad.

So it is what it is, and we will continue to go for as many different FDA approved indications as possible for Visudyne, but what is probably most important right now is that we are available and reimbursed for all 3 forms of this disease. The data is fully transparent for people to follow the treatment algorithms that are put together by the retinal community and their society organizations, and that is really what's going to drive the use.

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**Christine Charette - BMO Nesbitt Burns Analyst**

Were you able to call any information on retreatment rates from the data in the package sorry, for the next therapy retreatment rates with and without Macugen; were you able to call any data from that?

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**Mohammad Azab - QLT, Inc. EVP & Chief Medical Officer**

Christine, throw that one at us again. We didn't quite get it.

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**Christine Charette - BMO Nesbitt Burns Analyst**

Were you able to come to or call any data on retreatment rates, the impact of Macugen on Visudyne retreatment rates if you compare sham to Macugen treatment? If you compare the 2 groups, the patients that did get photodynamic therapy, is there an impact on retreatment rates if they received Macugen as well?

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**Paul Hastings - QLT, Inc. President & CEO**

You know what, first of all, when you looked at the different ways that these patients were given Visudyne, whether it was before the trial began or after the trial was up and running, it is very difficult given the limited number of patients to draw any conclusions about the retreatment rates of Visudyne. The trial wasn't designed to look at retreatment rates for Visudyne. It was designed to assess the safety and efficacy of Macugen given 9 intravitreal injections per year, so it is difficult to come to that conclusion or to figure out what happens to retreatment rates.

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**Christine Charette - BMO Nesbitt Burns Analyst**

My last question is Visudyne versus Macugen positioning. Eyetech makes a lot of noise about intravitreal injections being more profitable for physicians, being easier for them to do than photodynamic therapy. What is your view on that, and how would you position the one procedure versus the other to the physicians to convince them that photodynamic therapy is still the one that is the one to do preferably?

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**Paul Hastings - QLT, Inc. President & CEO**

Right, so it is our position that Visudyne has been used in over 350,000 patients. There are over 750 lasers placed in the retinal specialist's office in the USA alone. People are very used to the procedure. It's about a 20-minute procedure, and that procedure is very, very commonplace in their practices today, and it's a procedure that is done every 3 months. Now, regarding your comment that some folks are suggesting that intravitreal injections are easier, it is not our opinion or the opinion of people involved in these clinical trials that have had to go through the protocol to use the agents that there is any less time involved in giving an intravitreal injection, given the preparation before and the follow-up after. So it is just a simple matter of what's going to be their preference.

Regarding whether a person will make more money with one procedure than the next, we would certainly hope that that is not what is going to drive the use by a particular retinal specialist, that they are going to look at the data and make that decision based on safety and efficacy, and make their safety assessment based on their use. So it is going to take a while for them to get used to giving that many repeated intravitreal injections, just like it took them a while to get used to using the laser and the intravenous infusion of Visudyne. And that's going to be borne out in the marketplace.

Now that's different than what their experience is right now with intravitreal injections because they are not giving them as frequently in general practice as every 6 weeks for 8 times a year. But all of these things will be again, I think the people who you want to ask those questions to, by the way, because we'll do our best to get people's opinions widely known; but the people to ask that question are the retinal specialists who review these data sets. They are the ones you need to ask, you know; will you use something 8 times a year with an intravitreal injection right off the bat and simply replace what you've been using for years, or will you begin to look at how you're going to treat the whole patient with the algorithm of using these agents either alone or potentially with your own clinical judgment in combination.

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**Operator**

(OPERATOR INSTRUCTIONS) David Maris from B of A.

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**David Maris - Banc of America Analyst**

B of A. I have a multipart one question but multipart.

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**Paul Hastings - QLT, Inc. President & CEO**

That's okay, we'll let you get away with it.

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**David Maris - Banc of America Analyst**

A couple years out, what do you suppose will be the use of Visudyne in combination with other agents, and what will be monotherapy? And do you think that some of the monotherapy, the combination patients will go from using Visudyne 2 or 3 times a year to using it fewer times a year, because that's I think one of the biggest questions that some investors have. The second is some of the FDA's comments seem to indicate that they were still pretty early in the review of the drug. Do you think that the FDA will wait for the 2-year data, and what do you think the possibility is that it is beyond the first-quarter approval?

And then lastly, there are some people out there with estimates of \$2 billion or more for Macugen. I guess that would be 8 times as large as your product, 9, 10 times. How do you assess that algebra for one? And second, some folks that

follow Eyetech say, well, look, the 8-time a year dosing or 9-time a year dosing is a benefit because doctors will get paid more, so they will like to do that and maybe they will look at other agents that are dosed less frequently as not as lucrative for them?

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**Paul Hastings - QLT, Inc. President & CEO**

Thanks, David. I think on your last point to make a statement about that, about people using it because they're going to make more money on it by giving it more frequently is an insult to the retinal specialists. I don't think they would make their decisions based on that. And I think you need to ask—and people need to ask them. Certainly in meetings that I've attended and large meetings like AAO meetings and ARVO meetings where retinal specialists have had a chance to ask questions relative to the number of repeated injections, they've made points about the inconvenience of, for their practice, of bringing patients back as frequently as that. So that is going to become an issue for them.

And also, the reimbursement of procedures is under constant scrutiny of the centers for Medicare services and will continue to be. So when we came out with Visudyne, the procedure fee for the use of Visudyne was much higher than it was subsequent to the drug being used in the marketplace, and that may end up happening—it already has with intravitreal injections, and it may continue to happen, and that will be regulated over time as therapies get used. So that is something that we are not really taking that seriously. That is, that people say that people will use it more because they will get paid more for it and more frequent injections.

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**David Maris - Banc of America Analyst**

Just to follow up with that, is it fair to say that physicians would be paid more if they used Visudyne more often, and you're actually not seeing that happen as well?

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**Paul Hastings - QLT, Inc. President & CEO**

Exactly. They're just not driven that way in clinical practice. And so what you actually see, and it speaks to your first question, what clinicians are trying to do is to get the best possible outcome for their patients with the least number of treatments. They want to get these patients in and out, treated for the disease, stabilized and in some cases hopefully improved, and they want to do it with as less frequent treatments as possible. There are so many patients with AMD out there that once the treatment algorithms that they want to use are optimal, that what we saw with Visudyne and Triamcinolone, for example, was even though by adding Triamcinolone it seemed to reduce the overall number of retreatments for Visudyne, we seemed to be treating more patients with the combination because people had the perception that it was working better in their patients, and they got better results either near or mid or long-term. So that's going to continue. So we don't expect that clinicians will be all that welcoming to therapies which will go on for 2, 3 or 5 years, whether it is Visudyne or other agents. So we are not expecting that.

In terms of what we expect the future like you mentioned the 2 to 3 times that we see Visudyne being used today, will that reduce over time? It may. We don't know. And again, most of that will be borne out in the marketplace. But that seems to be the number of treatments, whether it is alone or in combination with other agents, that will stabilize or begin to improve in very—in some patients in combination with other drugs, some of these patients' situations. So who knows what's going to happen to it, but I think we are going to continue to project that the product is going to continue to grow, and that's what we've been seeing in the market research we've been doing.

In the part of your one question that asked about the still very early in the review process and do we think they'll wait for 2-year data, given how close they are, the FDA is to getting the 2-year data, they probably will look at that. A couple of comments were made both by Dr. Chambers as well as Dr. John Kabole (ph) that that data was still being assessed, that is the 2-year data, and they wanted to see that. So we expect that will happen. We can't really speak to when the product may be approved. We are planning that the product may be approved in Q1 of next year, and that's where we're going.

Now, in terms of the \$2 billion or more for expectations for drugs, there are all kinds if you go back to 1999, we're having deja vu here. So go back to that when Visudyne was anticipated to be approved and all kinds of numbers were flying around out there. Again, what's going to happen in the marketplace could be the same or could be very different than the numbers people are throwing out there today. Given that Visudyne has been on the market for four years now, we certainly don't expect any product, Visudyne or others to ramp up to \$2 billion in the course of a couple years. It will take time. But certainly it is not out of the realm of possibility that this is a \$2 billion market. It doesn't mean that \$2 billion of drugs will be sold in this market. It means that certain paces we put in these therapies and will continue to put in these therapies, and the market will grow.

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That particular amount is not that much larger at all than amounts being spent on many, multi-factorial diseases in this elderly population. So from a reimbursement point of view we think there is still a long way to go. In terms of the radar screen for reimbursing these drugs for multi-factorial disease. And I think, David, I got all your questions. Did I?

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**David Maris - Banc of America Analyst**

Yes, you did, and thank you.

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**Paul Hastings - QLT, Inc. President & CEO**

Mohammad, did you want to add anything?

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**Mohammad Azab - QLT, Inc. EVP & Chief Medical Officer**

No, I think just on the retreatment rate we are not seeing anything different in the trials actually from what is happening on the market, David, as from our trials that is about the average treatment in our trials were about in the first year about 3 to 3.5. What we have seen in the marketplace actually the average treatment is lower already now with the use of Triamcinolone and that, but still the product is growing, and the average (indiscernible) is about two treatments per year or 2.5. If you look at the Macugen data and there was a question about that before and actually we look at the different arms, the average number of treatments of Visudyne with Macugen in the trial is also about two. So we're not expecting that the average number of retreatment would have any significant change in the marketplace with the availability of other agents.

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**David Maris - Banc of America Analyst**

If I understood that correctly and this will promise to be my last question what you're saying is that even if the retreatment rates go down slightly as they might have in the past couple of years, you are still seeing dramatic growth in the product due to just an expanding marketplace?

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**Paul Hastings - QLT, Inc. President & CEO**

Right, and also David, given that these drugs have different mechanisms of action and all kinds of representations are being made by a bunch of different people as to what one drug does versus the other, but they act very differently. And we blocked the leaky blood vessels. The other agents will prevent new blood vessels from sprouting, and will have an anti-permeability effect. But we do have the advantage of the unique mechanism of action, and people are going to probably come to the conclusion that they are going to need that along with using anti-antigenic agents. So it may grow, and you're right, it has been growing. It should continue to grow.

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**Operator**

Hari Sambasivam from Merrill Lynch.

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**Hari Sambasivam - Merrill Lynch Analyst**

Most of my questions have been answered, but just in relation to Triamcinolone plus Visudyne, are you preferentially seeing certain lesion types being treated with combos versus the others, or is it a fairly broad spread use among all three lesion types?

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**Paul Hastings - QLT, Inc. President & CEO**

Its clinical practice is very broad, and it is across all three lesion subtypes. And you know, a number of folks have done conference calls with the people that are using these combinations, and they explain their results or their practice. And so what you see is in the smaller lesions in minimally classic and occult they use Visudyne in combination with Triamcinolone; in larger lesions they may ask the patients or may inform the patient that they may expect them to pay out of pocket, and you're seeing that kind of use as well. But for the most part it is across all the three lesion subtypes.

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**Hari Sambasivam - Merrill Lynch Analyst**

Do you have a sense of the cost of Triamcinolone in practice, Paul?

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**Paul Hastings - QLT, Inc. President & CEO**

Its about eight dollars a vial.

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**Hari Sambasivam - Merrill Lynch Analyst**

And so three times a year at that price?

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**Paul Hastings - QLT, Inc. President & CEO**

Yes, and obviously there is the other cost of using Triamcinolone is the procedural cost and the monitoring cost, but yes, it is a generic version of a very old drug that is used pretty widespread in ophthalmology.

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**Hari Sambasivam - Merrill Lynch Analyst**

The second question I have is in terms of awareness, I know the CMS reimbursed in April but what level of awareness do the 1400 retinologists have about the reimbursement across all three lesion types? And the general sense of adoption among these people I mean I know about your additional sales in the second quarter were coming from minimally classic and occult, but I am just thinking in terms of the number of physicians out there who are practicing, do you sense that three quarters of them are aware of the reimbursement or all of them are aware of the reimbursement? Do you have some sense of that on a qualitative basis?

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**Paul Hastings - QLT, Inc. President & CEO**

I would say, Hari, that 99 percent of them are aware of the reimbursement. Most of them have been following this for quite some time. It comes up at all the meetings, and most of them are aware of it. Where we see the differences and awareness is in the investment community, and that's where we're trying to make people aware that the drug Visudyne is available, is reimbursed. We are FDA approved for the predominantly classic form of the disease but the drug is also reimbursed for certain patients with minimally classic and occult lesions, and saying that the drug is only

available for one subset is just not true.

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So in outside the United States it is widely approved for predominantly classic and occult in Europe, Australia, New Zealand and has three lesion subtypes in Japan. So we're not really concerned that people are going to limit Visudyne's use necessarily to just predominantly classic patients on a global basis or even in United States.

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**Operator**

(indiscernible) from CIBC.

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**Unidentified Speaker**

I just wanted to find out based on Macugen's introduction into the market, presumably there is going to have to be to some degree a ramp in sales and marketing expenditure on the QLT Novartis side. I just wanted to know if you expect that to impact your percent of the profit share.

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**Paul Hastings - QLT, Inc. President & CEO**

Never use the word expect, ramp up and expenses with our partner Novartis, we try not to do that. So we try to work together to maximize the return that we get on Visudyne and appropriately promote its use and appropriately do publications and meetings that we need to do and all those other things. So I am just going to be bold and tell you that I think the thought of hiring bazillions of reps to promote to 1400 retinal specialists is absolutely ludicrous. So I would not support that for anybody, and I certainly would not support that in our alliance. We have to get to these people with data and if we are going to spend money we ought to be spending it on doing clinical trials in combination with new agents as they are available. And I think that is the approach that one is going to need to take in this and one cannot be intimidated by the power of using large sales forces. And if you look at what that has yielded in mass marketing markets, it has yielded good results. If you look at that in specialty pharmaceutical markets like the one that we're in, it might actually annoy people. That is the retinal specialists. So it is really important to watch these expenses carefully. We're going to continue to do that. So where we need to ramp up some we may. Where we need to counter detail, absolutely. We haven't gotten to the actual budget for 2005 yet. We expect there will be some ramp up, but we have taken that into account at least in our guidance. And it is our position that we will continue to watch this carefully.

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**Operator**

This concludes our question-and-answer session; I will now like to turn the meeting back over to Ms. Hayes.

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**Therese Hayes - QLT, Inc. VP of IR**

Thanks everyone for your time; your interest and participation in the call. If you missed portions of the call or if you would like to listen to it again, you may call within seven days after this to hear a complete replay. To access the replay dial for 416-695- 5800. The pass code required for access is 3094375. Thank you.

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**Operator**

The conference has now ended. Please disconnect your lines at this time. We thank you for your participation and have a nice day.