

ATRIX LABORATORIES INC

Form 425

July 22, 2004

Filed by: QLT Inc.  
Pursuant to Rule 425 under the Securities Act of 1933  
and deemed filed pursuant to Rule 14a-12  
under the Securities Exchange Act of 1934

Subject Company: Atrix Laboratories, Inc.  
Commission File No. 0-18231

The following is the press release dated July 22, 2004 and a transcript of the conference call held on July 22, 2004 at 8:30 AM ET regarding QLT's second-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, containing a joint proxy statement/prospectus and other relevant materials. 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 web site 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 meetings 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 when it becomes available.

### **PRESS RELEASE**

#### **QLT ANNOUNCES Q2 RESULTS FOR 2004**

**For Immediate Release**

**July 22, 2004**

VANCOUVER, CANADA QLT Inc. (NASDAQ: QLTI; TSX: QLT) today reported financial results for the second quarter ended June 30, 2004. Unless specified otherwise, all amounts are in U.S. dollars and reported under U.S.

GAAP.

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## **Q2 2004 Visudyne® Sales**

For the three months ended June 30, 2004, Visudyne® sales were \$109.3 million. This represents an increase of 23% over sales in the second quarter of 2003, of which approximately four percentage points came from foreign exchange rate effects. Visudyne sales in the U.S. for the quarter were \$52.1 million, representing 48% of total sales for the quarter. This represents an increase of 15% over U.S. sales in the second quarter of 2003. The remaining \$57.2 million sales in the rest of the world are up 30% over the same period last year.

## **Q2 2004 Earnings per Share (EPS)**

GAAP EPS in the second quarter of 2004 was \$0.20, up \$0.04 from the prior year's second quarter. The increase was mainly due to strong Visudyne performance. EPS for both the second quarter and first half of 2004 are reported using the if converted basis as the Company's outstanding Convertible Notes met the test for conversion.

We are pleased with the increase in Visudyne usage in the occult and minimally classic forms of the disease now that the reimbursement implementation has been effective for a full quarter, said Paul Hastings, President and Chief Executive Officer. The expansion in Visudyne's market is clearly reflected in the U.S. sales growth this quarter and we expect to see this penetration into the occult and minimally classic segments continue for the balance of the year.

## **Q2 Results**

### **Revenues**

The company's revenues reached \$44 million in the second quarter, growing by 23% from the second quarter of 2003. QLT's share of Visudyne net profit (excluding the recovery of manufacturing and other costs) from the QLT/Novartis alliance for the second quarter is on track with our annual guidance at 30.3% of Visudyne sales.

### **Research and Development (R&D)**

Expenditures for R&D of \$11 million were 7% lower in the second quarter compared to the same period in 2003. The decrease in spending for the second quarter of 2004 is due primarily to the absence of spending on tariquidar in the current year.

### **Selling, General and Administrative (SG&A)**

For the second quarter of 2004, SG&A expenditures were \$3.6 million compared to \$3.4 million for second quarter of 2003.

### **Cash and Short-Term Investments**

The company's cash and short-term investments rose from \$509 million to \$524 million during the second quarter of 2004.

## **Atrix Merger**

On June 14, 2004, the Company entered into an Agreement and Plan of Merger with Atrix Laboratories, Inc. Under the terms of the merger agreement, each share of Atrix common stock outstanding at the closing of the merger will be exchanged for one QLT common share, and \$14.61 in cash. While QLT expects the merger with Atrix to close by the end of 2004, the figures provided in this press release do not take into account the impact of the acquisition.

**About Visudyne**

Visudyne therapy was approved in the U.S. in April 2000, and in Europe in July 2000, for the treatment of predominantly classic subfoveal choroidal neovascularization (CNV) due to age-related macular degeneration (AMD), the leading cause of severe vision loss in patients over 50. The treatment has now

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been approved in more than 70 countries with extended approvals in over 50 countries. QLT's revenue from Visudyne sales consists of 50% of the Visudyne profits of the Visudyne alliance with the Ophthalmics Business Unit of Novartis Pharma AG, and reimbursement for manufacturing and other costs.

QLT is a global pharmaceutical company specializing in the discovery, development and commercialization of innovative therapies to treat cancer, eye diseases, and dermatological and urological conditions. Combining expertise in ophthalmology, oncology and photodynamic therapy, QLT has commercialized two products to date, including Visudyne therapy which is one of the most successfully launched ophthalmology products. For more information, visit our web site at [www.qltinc.com](http://www.qltinc.com).

QLT Inc. will hold an investor conference call to discuss the second quarter results on Thursday, July 22 at 8:30 a.m. ET (5:30 a.m. PT). The call will be broadcast live via the Internet at [www.qltinc.com](http://www.qltinc.com). A replay of the call will be available via the Internet and also via telephone at 416-695-5800, access code 3076061.

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## QLT Inc. Financial Highlights

## CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(In accordance with United States generally accepted accounting principles)

(In thousands of United States dollars, except per share information)	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
<b>(Unaudited)</b>				
<b>Revenues</b>				
Revenue from Visudyne®	\$ 43,136	\$ 35,164	\$ 83,655	\$ 66,609
Contract research and development	1,263	845	2,055	2,371
	<u>44,399</u>	<u>36,009</u>	<u>85,710</u>	<u>68,980</u>
<b>Costs and expenses</b>				
Cost of sales	7,450	6,058	14,372	11,470
Research and development	11,257	12,087	20,667	22,962
Selling, general and administrative	3,607	3,432	8,388	6,465
Depreciation	916	715	1,725	1,441
Restructuring		(394)		(394)
	<u>23,230</u>	<u>21,898</u>	<u>45,152</u>	<u>41,944</u>
<b>Operating income</b>	<b>21,169</b>	<b>14,111</b>	<b>40,558</b>	<b>27,036</b>
<b>Investment and other income</b>				
Net foreign exchange gains	338	381	614	2,914
Interest income	2,268	2,045	4,750	3,644
Interest expense	(1,548)		(3,076)	
	<u>1,058</u>	<u>2,426</u>	<u>2,288</u>	<u>6,558</u>
<b>Income before income taxes</b>	<b>22,227</b>	<b>16,537</b>	<b>42,846</b>	<b>33,594</b>
<b>Provision for income taxes</b>	<b>(7,543)</b>	<b>(5,378)</b>	<b>(14,533)</b>	<b>(10,896)</b>
	<u></u>	<u></u>	<u></u>	<u></u>
<b>Income before extraordinary gain</b>	<b>\$ 14,684</b>	<b>\$ 11,159</b>	<b>\$ 28,313</b>	<b>\$ 22,698</b>

<b>Extraordinary gain</b>	<b>_____</b>	<b>_____</b>	<b>10,393</b>	<b>_____</b>
<b>Net Income</b>	<b>\$14,684</b>	\$11,159	<b>\$ 38,706</b>	\$ 22,698
	<b>_____</b>	<b>_____</b>	<b>_____</b>	<b>_____</b>
<b>Basic net income per common share</b>				
Income before extraordinary gain	\$ 0.21	\$ 0.16	\$ 0.41	\$ 0.33
Extraordinary gain	<b>_____</b>	<b>_____</b>	<b>0.15</b>	<b>_____</b>
Net income	\$ 0.21	\$ 0.16	\$ 0.56	\$ 0.33
<b>Diluted net income per common share</b>				
Income before extraordinary gain	\$ 0.20	\$ 0.16	\$ 0.40	\$ 0.33
Extraordinary gain	<b>_____</b>	<b>_____</b>	<b>0.13</b>	<b>_____</b>
Net income	\$ 0.20	\$ 0.16	\$ 0.53	\$ 0.33
<b>Weighted average number of common shares outstanding (in thousands)</b>				
Basic	<b>69,574</b>	68,705	<b>69,425</b>	68,611
Diluted	<b>80,045</b>	68,933	<b>79,794</b>	68,737

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## QLT Inc.

**CONDENSED CONSOLIDATED BALANCE SHEETS**

(In accordance with United States generally accepted accounting principles)

<b>(In thousands of United States dollars)</b>	<b>June 30, 2004</b>	<b>December 31, 2003</b>
<b>(Unaudited)</b>		
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	<b>\$204,940</b>	\$262,408
Short-term investment securities	<b>319,290</b>	233,022
Accounts receivable	<b>42,776</b>	35,395
Inventories	<b>23,418</b>	26,808
Deferred income tax assets	<b>10,871</b>	11,801
Other	<b>13,258</b>	16,150
	<b>614,553</b>	585,584
<b>Property and equipment</b>	<b>47,315</b>	43,262
<b>Other long-term assets</b>	<b>6,430</b>	5,876
	<b>\$668,298</b>	\$634,722
<b>LIABILITIES</b>		
<b>Current liabilities</b>		
Accounts payable	<b>\$ 6,135</b>	\$ 8,683
Income taxes payable	<b>1,742</b>	
Other accrued liabilities	<b>9,503</b>	13,574
Deferred revenue	<b>4,515</b>	6,594
	<b>21,895</b>	28,851
<b>Long-term debt</b>	<b>172,500</b>	172,500
	<b>194,395</b>	201,351
<b>SHAREHOLDERS EQUITY</b>		
<b>Common shares</b>	<b>409,296</b>	395,627

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<b>Retained earnings (deficit)</b>	<b>30,622</b>	(8,084)
<b>Accumulated other comprehensive income</b>	<b>33,985</b>	45,828
	<u>473,903</u>	<u>433,371</u>
	<u>\$668,298</u>	<u>\$634,722</u>

As at June 30, 2004, there were 69,582,317 issued and outstanding common shares and 7,066,877 outstanding options to purchase common shares.

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## QLT Inc.

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In accordance with United States generally accepted accounting principles)

(In thousands of United States dollars)	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
<b>(Unaudited)</b>				
<b>Cash flows from operating activities</b>				
Net income	\$ 14,684	\$ 11,159	\$ 38,706	\$ 22,698
Adjustments to reconcile net income to net cash provided by operating activities:				
Depreciation	916	715	1,725	1,441
Amortization of deferred financial expenses	264		503	
Unrealized foreign exchange loss	5,863	1,401	7,951	2,099
Extraordinary gain			(10,393)	
Deferred income taxes	5,835	5,378	12,825	10,896
Restructuring		(394)		(394)
Changes in non-cash operating assets and liabilities				
Accounts receivable	(4,211)	(1,310)	(8,081)	1,030
Inventories	4,210	(956)	2,564	(291)
Other assets	(2,904)	(266)	2,739	(4,218)
Accounts payable	(2,757)	(953)	(3,668)	(2,322)
Income taxes payable	1,708		1,708	
Accrued restructuring charge		(286)		(2,005)
Other accrued liabilities	3,569	3,645	(5,324)	(16)
Deferred revenue	(188)	(4,088)	(1,916)	(4,598)
	<u>26,989</u>	<u>14,045</u>	<u>39,339</u>	<u>24,320</u>
<b>Cash (used in) provided by investing activities</b>				
Short-term investment securities	(85,537)	18,357	(94,757)	(1,692)
Purchase of property and equipment	(1,932)	(250)	(5,101)	(2,212)
Other long-term assets	(718)		(718)	
Purchase of Kinetek Pharmaceuticals Inc., net of cash acquired			(2,316)	
	<u>(88,187)</u>	<u>18,107</u>	<u>(102,892)</u>	<u>(3,904)</u>
<b>Cash provided by financing activities</b>				

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Long term debt (net)	<b>(34)</b>		<b>(105)</b>	
Issuance of common shares	<b>2,076</b>	1,635	<b>13,772</b>	2,640
	<u>2,042</u>	<u>1,635</u>	<u>13,667</u>	<u>2,640</u>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<b>(5,402)</b>	11,918	<b>(7,582)</b>	20,667
	<u>(5,402)</u>	<u>11,918</u>	<u>(7,582)</u>	<u>20,667</u>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(64,558)</b>	45,705	<b>(57,468)</b>	43,723
<b>Cash and cash equivalents, beginning of period</b>	<b>269,498</b>	126,156	<b>262,408</b>	128,138
	<u>269,498</u>	<u>126,156</u>	<u>262,408</u>	<u>128,138</u>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 204,940</b>	\$ 171,861	<b>\$ 204,940</b>	\$ 171,861
	<u>\$ 204,940</u>	<u>\$ 171,861</u>	<u>\$ 204,940</u>	<u>\$ 171,861</u>

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QLT CONTACTS:

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*Visudyne® is a trade mark of Novartis AG*

QLT Inc. is listed on The Nasdaq Stock Market under the trading symbol **QLTI** and on The Toronto Stock Exchange under the trading symbol **QLT**.

Additional Information

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The second quarter financial results for QLT in this press release are preliminary and unaudited and are not a complete disclosure of our quarterly financial results. Certain statements in this press release constitute forward-looking statements of QLT within the meaning of the Private Securities Litigation Reform Act of 1995, which involve 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 expectation that the acquisition of Atrix will close before year end, our expectation with respect to QLT's share of Alliance profit for the year, and the statement containing the words we expect. These statements are only predictions and actual events or results may differ materially. Factors that could cause actual events or results to differ materially from any future results express or implied by such statements include, but are not limited to: the risk that future sales of Visudyne may be less than expected, uncertainty of and timing of pricing and reimbursement may limit the future sales of Visudyne, the timing and impact of new product launches by competitors, currency fluctuations in our primary markets may impact our financial results, the outcome of pending patent and securities litigation against the Company may be unfavorable and have an adverse impact on our financial results, the risk that the proposed merger with of Atrix Laboratories, Inc. will not be successfully completed or that the businesses 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 combined company's results, and other risk factors which are described in detail in QLT's Annual Information Form on Form 10-K, quarterly reports on Form 10-Q and other filings with the U.S. Securities and Exchange Commission and Canadian securities regulatory authorities. Forward-looking statements are based on our current expectations and QLT does not assume any obligation to update such information to reflect later events or developments, except as may be required by law.

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## Conference Call Transcript

### CORPORATE PARTICIPANTS

**Therese Hayes**

*QLT, Inc. VP IR*

**Paul Hastings**

*QLT, Inc. President & CEO*

**Mike Doty**

*QLT, Inc. SVP & CFO*

**Bob Butchofsky**

*QLT, Inc. VP Marketing & Sales*

**Mohammad Azab**

*QLT, Inc. EVP & Chief Medical Officer*

### CONFERENCE CALL PARTICIPANTS

**Dimi Ntantoulis**

*UBS Analyst*

**Doug Mieh**

*RBC Capital Analyst*

**Matthew Geller**

*CIBC World Markets Analyst*

**Michael Lachman**

*ThinkEquity Partners Analyst*

**Christine Charette**

*BMO Nesbitt Burns Analyst*

**Hari Sambasivam**

*Merrill Lynch Analyst*

**David Martin**

*Dundee Securities Analyst*

**Douglas Chow**

*Haywood Securities Analyst*

**John Stevenson**

*Somerset Research Analyst*

## PRESENTATION

### Operator

Good morning, ladies and gentlemen, and welcome to the QLT, Inc. 2004 second-quarter earnings results conference call. I would now like to turn the meeting over to Ms. Therese Hayes, Vice President Investor Relations. Please go ahead Ms. Hayes.

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

Hello everyone. Good morning, and welcome to QLT second quarter conference call. If you have not yet received a copy of the press release, you can find it by visiting our website at [www.QLTINC.com](http://www.QLTINC.com). The conference call is being webcast live and will be available on our website for the next 30 days. Presenting today is Paul Hastings our President and CEO, as well as Mike Doty, Senior VP and CFO. During the Q&A portion of the call we will also have Mohammad Azab, Executive VP and Chief Medical Officer and Bob Butchofsky, Vice President of marketing and sales planning available to answer questions.

Before turning the call over to Paul I would like to take a few moments to go over the Safe Harbor statement. I need to remind you this call contains forward-looking statements of QLT within the meaning of the private securities litigation reform act of 1995 which involve 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 anticipated levels of 2004 sales of Visudyne; estimates of QLT's 2004 EPS; estimates of QLT's 2004 profit share from the alliance and R&D and SG&A expenses; our tax rate forecast, our expectations with regard to our progress with our clinical trials and when the data will be available as well as statements with respect to QLT's proposed acquisition of Atrix Laboratories.

Including our expectation that the transaction will be successfully completed; our anticipated combined revenue and expenses potential dilution and accretion projected combined earnings per share. The combined companies capabilities and the potential and the anticipated timing of closing. Words such as expects, anticipates, intends, plans, will, believes, estimates and other expressions are intended to identify such forward-looking statements. These statements are only predictions and actual events or results may differ materially. Factors that can cause such actual events or results expressed or implied by such forward-looking statements could differ materially from any future results expressed or implied by such statements include, but are not limited to, the risk that future sales of Visudyne or products (indiscernible) may be less than expected, our future operating results are uncertain and likely to fluctuate, currency fluctuations





in our primary markets may impact our financial results, uncertainty of pricing and reimbursement may limit the future sales of Visudyne and the product of Atrix. Clinical development programs may not be successful. The outcome of the pending patent securities litigation against QLT and Atrix respectively may be unfavorable and have an adverse impact on financial results.

QLT is dependent on third parties to commercialize Visudyne to timing and impact of new product launches by competitors, the risk that the QLT Atrix merger fails to close because of closing conditions are not satisfied. Our ability to successfully integrate the two companies and other factors described in detail in the annual information form on form 10-K. Quarterly reports on form 10-Q and other filings with U.S. Securities and Exchange Commission and Canadian securities regulatory (indiscernible) by QLT and Atrix. Forward-looking statements are based on QLT's current expectations and QLT assumes no obligation to update such information to reflect later events or developments except as required by law.

I now also need to provide the following additional information because of our pending merger with Atrix. In connection with QLT's proposed merger with Atrix Laboratories, Inc. QLT has filed with the SEC registration form S4 containing a joint proxy statement prospectus and other relevant materials. Investors and security holders of QLT and Atrix are urged to read the preliminary joint proxy statement and 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 document filed by QLT or Atrix within 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 meetings 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 direct request to QLT, Inc. Attn: Investor Relations, 887 Great Northern Way, Vancouver B.C. Canada, V5T4Z5. 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 at 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 proxy through 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 was filed with the SEC's 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 as set forth in the proxy statement for Atrix's 2004 annual meeting of stockholders which was filed with the SEC on April 6, 2004.

Investors and security holders may obtain more detailed information regarding the direct and indirect interest of QLT, Atrix and the respective officers and directors in the transaction by reading the definitive proxy statement/prospectus regarding this transaction when it becomes available. And with that I will turn the call over to Paul.

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

Thanks, Therese, and we apologize for the length of that forward-looking statement today. I am sure you already had an opportunity to review our release and noticed that we've had another very good quarter with \$109.3 million in Visudyne sales and 20 cents in earnings per share. We are pleased to report continued growth in Visudyne sales with year-over-year sales up 23 percent and that is 8 percent over the first quarter of this year. This was really the first full quarter following the Center for Medicare Services reimbursement implementation for occult and minimally classic disease and as a direct result U.S. sales increased 15 percent to 52 million versus the prior year and represented essentially the lion's share of the incremental sales in quarter two.

Since the expanded reimbursement implementation there has been a number of questions from investors and analysts regarding the extent of penetration into the occult and minimally classic segments of this disease, and while we're encouraged by the increase in sales and can readily attribute the majority of that increase to that expanded reimbursement, as most of you know without a full chart review this data is sometimes close to impossible to pinpoint exactly. What we can tell you is the growth we saw in the second quarter was consistent with our expectations for both occult as well as minimally classic market penetration and we previously provided macro numbers for the additional number of patients that expansion into occult and minimally plastic represent which is in the range of 40 to 60,000 patients, additional patients per year. Which in effect represents an overall doubling of our potential U.S. market.

However, all these patients would clearly not receive treatment in the first quarter. So as we progress through the year and we have more quarters under our belt with the extended reimbursement we will have a clearer view on the penetration into minimally classic and the occult portions of the market. We also initiated analysis of claims data to quantify the amount of usage in occult and minimally classic AMD patients and expect to have preliminary findings available in the Fall. But in the meantime we have also

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conducted an attitude and usage survey, and we did this survey with 106 retinal specialists in the United States.

The objectives of the survey, which was conducted in early May now the caveat to this survey was it was done just one month after the CMS implemented the coverage decision, so people were just getting used to the idea of treating these patients and that they were going to get reimbursed. But the objectives were to gain a better understanding of the current usage patterns for Visudyne, as well as triamcinolone and potential future competitors. So we tested Visudyne, Visudyne plus triamcinolone, Macugen, Retane (ph), Lucentis, we looked at everything, we asked them lots of questions, and we were quite encouraged by the results of this survey as they validate many of our internal expectations.

Most particularly with respect to the potential for the expansion of Visudyne in both occult as well as minimal classic forms of this disease. Even though this survey was conducted only a month following the implementation of this reimbursement decision, we already see our expectations of usage patterns reflected in the qualitative comments made in the survey. Physicians specifically reported that they expect ongoing increases in Visudyne usage due to the new reimbursement policies for occult and minimally classic. And of course we have concrete evidence that that usage now that the reimbursement implementation has made effective for a full quarter, and this expansion in the Visudyne market is clearly reflected in the sales growth for this quarter.

So let me talk a little bit about the key findings in this survey. First of all, 90 percent of the physicians respondents in the survey support Visudyne use in occult AMD. Clearly the results of good familiarity with the numerous data points supporting Visudyne's use in occult, which includes the first Phase III VIP trial and the anticipation of the subsequent Phase III VIO trial which we will have results for by the end of this year. The support for minimally classic is slightly lower at 75 percent, so you have 90 percent with occult and 75 percent with minimally classic, so it was slightly lower but again that is pretty consistent with our expectations in this highly data-driven population. As the data for minimally classic right now is not as widely known based on the Phase II trial that we did which showed very good results, but it is not as widely known as all the Phase III work we've done with the occult form of the disease. So it doesn't it hasn't shown as yet the extent of evidence that the occult population has shown. Twenty-five percent is not bad either.

So based on the survey it appears that the initial usage in occult and minimally classic may be focused mainly in smaller lesions, particularly as monotherapy. And this is also consistent with percentages of those patient populations that we've identified as those eligible for treatment under the expanded reimbursement. For example, according to the survey in smaller occult lesions, those covered by the CMS, physicians report treating approximately 50 percent of those patients with Visudyne alone,

and an additional 25 percent with combination therapy. Now again this is one month after the implementation.

And in minimally classic patients approximately 40 percent of reimbursement eligible patients are now reportedly being treated with Visudyne monotherapy and an additional 25 percent with combination therapy based on the results of this survey. So as many of you know, one of the topics of great interest to retinal specialists this year in the treatment of AMD has been the combination of triamcinolone or Kenalog with Visudyne. this treatment regiment was one of the major highlights of the Association for Research and Vision and Ophthalmology, the ARVO meeting, which is an annual meeting in Fort Lauderdale held in May.

Now there are literally dozens of these investigator sponsored studies ongoing worldwide, and we are seeking continued evidence of the interest in the combination approach. Our alliance has provided unrestricted grants to support this important clinical research, as well as planning further company-sponsored trials in this important area. Just in June we announced that QLT and the National Eye Institute signed a cooperative research and development agreement known as CRADA to study the effects of preservative free triamcinolone in combination with Visudyne.

So this is Kenalog essentially minus the preservative.

This study will enroll about 300 patients in the multicenter randomized prospective Phase III trial that will look at safety and efficacy of the combination compared to Visudyne alone. We are doing this to provide the definitive evidence of efficacy of triamcinolone with a combination of Visudyne in a large controlled using for the first time a formulation that is specifically designed for ophthalmic use. That is the preservative free form. The attitude and usage survey mentioned earlier in this call also supported and validated the interest we've seen in this use of triamcinolone in all three lesion types, predominately classic, occult as well as minimally classic. And perhaps most importantly demonstrates retinal specialists real and continued interest in pursuing combination therapy with a large majority of respondents expecting future potential competitors or other therapies used in this disease to be used in combination. And 90 percent of those respondents expecting that combination, of course, would be with Visudyne.

So rounding out the report on Visudyne for the quarter, while there was unit growth in Europe, Q2 sales were slightly lower than Q1, which we think may simply be due to strong ordering patterns in Q1 in Europe. The positive (indiscernible) in the quarter was the UK which has notoriously been a difficult market for us. And with the third consecutive quarter of over 15 percent growth. So finally as many of you know, we received formal reimbursement approval in Japan and launched the drug Visudyne in May with a drug price of about 17 50 per vial.

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We reported in the first quarter that 15 lasers had been placed in Japan; this has now grown to 37 lasers placed, and we are on track to reach the goal of having about 50 lasers in placed by the year end in Japan. As a reminder we expect the ramp to be somewhat slower in Japan than what we saw in the U.S. as patients are initially required to stay overnight in hospitals and receive therapy, and hospitals need to purchase the lasers to do the therapy. That being said we are pleased with the sales performance in Japan and with this quarter's results coming in slightly ahead of our expectations for that market.

Let me now turn to our update on some of our clinical trials. Our upcoming clinical milestones include the analysis of our one-year primary endpoint of the second large Phase III trial in occult patients. This is known as the VIO trial. We completed enrollment of 364 patients or subjects in September of 2003. Now we expect to present the data at the American Academy of Ophthalmology meeting in October and to file for the syndication by the first quarter of 2005.

Verteporfin or QLT0074 trials are ongoing and progressing well in both alopecia as well as benign prostatic hyperplasia. And the newest indication acne as well. Acne will enter clinical trials this month in a Phase I trial with a projected enrollment of 96 subjects for which preliminary data is expected to be available at year end.

The alopecia Phase III program completed enrollment of 96 patients in February and the initial six-month results are expected in the fourth quarter of '04. We also have completed enrollment of the first four of five light doses in the benign prostatic hyperplasia trial which is a Phase I-II trial with no major safety issues and so far the efficacy from this uncontrolled study is encouraging, and we anticipate more complete results by the end of this year. The next phases of both programs which would be further clinical trials for alopecia and BTH respectively are under development.

Let me talk a little bit about Atrix. Our report on the quarter would certainly not be complete without discussion of this very significant event which was our June 14th announcement that we will combine with Atrix to create a world-class leading biopharmaceutical company with a focus in the key therapeutic areas of ocular oncology, urology and dermatology. All areas that both companies have been pursuing. Since we announced the transaction, I've had the opportunity to speak to many of you either face-to-face during roadshow or by telephone, and I think the value and growth potential of this combined Company is now much better understood.

For those of you that are not as familiar with the deal, let me (indiscernible) some of the key points. This combined Company will have a diversified revenue base with two marketed products, Visudyne and AMD and Eligard for prostate cancer as well as an expanding dermatology business with Novartis. We also have the potential for an additional two products on the market in '05 with a very unique six-month sustained release formulation of Eligard

which was filed earlier this year and it is expected to be launched in Q1 '05 and an innovative and proprietary topical acne product called Atrisone for which an NDA is expected to be filed in Q3 of this year.

So with these multiple revenue drivers we will have the capability to maximize other exciting products in the combine development pipeline and leverage Atrix's unique delivery technologies including the potential for these products to be used in ocular delivery. The terms of the deal are one share of QLT plus \$14.61 for each share of Atrix. And we expect to have modest dilution in '05 and to be accretive in 2006 and are targeting annual revenue growth of between 15 and 20 percent. And compound annual cash EPS growth of 20 to 25 percent in the combined Company.

So in the week since the announcement we have filed the S4 and we been granted early termination for the waiting period. Under HSR or Hart-Scott-Rodino Improvements Act by the Federal Trade Commission and we expect it to close by year end. So with that update I'd like Mike Doty to run you through the financial results.

**Mike Doty - QLT, Inc. SVP & CFO**

Thanks, Paul. As Paul said Visudyne sales set another record in the second quarter reaching \$109 million US dollars, exceeding sales for the prior year second quarter by 23 percent. The primary growth driver was unit sales again, which contributed 18 of the 23 percentage point of the gain. Changes in foreign currency exchange rates, particularly the strengthening euro against the U.S. dollar, also contributed to the comparative gain. Specifically, exchange rate changes contributed about 4 of the 23 percentage points of the gain against the prior year second quarter, while changes in pricing added about a percentage point.

Also for your information, Visudyne sales in the second quarter would have been about a little more than \$1 million higher if not for a reduction in inventory levels at the U.S. Visudyne distributors. For the year-to-date, sales reached 210 million, exceeding the first half of 2003, also by 23 percent. Again, unit growth was the primary driver of this year-on-year advance, contributing about 16 of the 23 percentage points of this gain. 6 percentage points of the gain came from foreign exchange rate effects, and the remaining increase came from pricing gains.

Turning to QLT's second-quarter revenues, these reached 44 million, which are up 23 percent from the prior year second quarter. This revenue growth was slightly better than the growth in Visudyne sales, despite significantly higher marketing and distribution expenses by our alliance partner, Novartis. Specifically, these expenses rose by about 7 million US\$ compared to the prior year second quarter. The bulk of this increase came from higher spending in advertising and promotion and field sales, but additionally a charge of \$1.6 million was booked to reflect an obligation to repay a development grant in Japan, driven by the

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commercial launch of Visudyne in that country during the second quarter. Consequently, QLT's share of the alliance profits came in at 30.3 percent of sales, down from the prior year rate of 30.7 percent of sales.

Offsetting a portion of the higher charges by Novartis were increases in contract revenues which were up about \$400,000, due to increased activities in clinical trials run by QLT but jointly funded by our alliance with our alliance partners. So for the year-to-date QLT's revenues totaled \$86 million which are about 24 percent higher than the same period last year. Further, QLT's profit share rate for the alliance with Novartis came in at 31 percent for the first half of 2004, up from 30.2 percent for the first half last year as the continued solid growth of Visudyne sales more than offset the increase second-quarter charges that I mentioned a minute ago.

Now moving on to research and development expenditures, these amounted to \$11 million in the second quarter bringing the year-to-date research and development spend to about \$21 million. QLT's R&D spending in the first half was down by about \$2 million from the first half of last year, and the prior expense the prior year expenditures on Tariquidar and multiple basal cell carcinoma trials were partially replaced by increased work on the Visudyne minimally classic and the QLT0074 trials and by research expenditures primarily associated with the (indiscernible) targets from the acquisition of Kinetek.

Selling, general and administrative expenses were just 3.6 million in the second quarter of 2004 bringing the 2004 year-to-date total to \$8.4 million. Compared to the first half of 2003, SG&A expenditures were up by about \$1.9 million. Half of this increase resulted from the effects of the stronger Canadian dollar against the U.S. dollar with the remainder coming primarily from compensation increases.

Two other smaller items for you modeling mavens, depreciation expense is up through the first half by about \$300,000 due to capital assets from Kinetek as well as the computer systems upgrade we did recently. And just as a reminder, the prior year results included a \$400,000 gain from the truing up of the costs associated with reduction of force of 2002.

So now turning to exchange rate effects on earnings, as you probably recall in early 2004 we again put foreign currency hedges in place with the objective of minimizing foreign exchange rate risks to the company's 2004 earnings and cash flows. The net effect of the various exchange rate changes during the first half of 2004 did not have a huge effect on QLT's prehedged earnings and cash flows during the second half. Consequently our year-to-date hedging gain was relatively small at about \$600,000.

Now on to interest income and expense. In the first half of the year interest income was up by 1.1 million over the prior year as the higher cash balance more than compensated for marginally lower

market interest rates. On the other hand, interest expense for the same period was up by 3.1 million due entirely to obligations of the convertible notes issued last August.

On the tax front the effective tax rate for the first half of 2004 was 33.9 percent. It was up 1.5 percent points higher than the rate for the first half of last year even though the 2004 full year rate of 33.9 is about a percentage point below the 2003 full year rate. This of course implies that the tax rate for the first half of 2003 was lower than the rate of the second half of that year, which was in fact the case.

As a reminder, the primary drivers for increasing the effective tax rate in the second half last year were increased profit expectations and lower R&D tax credit expectations than had been predicted earlier in that year. So the effective tax rate of 33.9 percent forecast for the second half of this year will compare favorably to the prior year second half rate, which was 37.1 percent. So before I go to earnings per share specifics, I need to briefly explain accounting, our accounting conclusions relative to shares underlying the convertible notes.



As the conversion tests for these notes were satisfied at the end of the first quarter, the noteholders had the right to convert their notes to common stock at anytime during the second quarter, which by the way none did. The conversion test was not passed at the end of the second quarter the notes are no longer convertible until a conversion test is met again. So again since the conversion test was met at the end of the first quarter U.S. GAAP requires that we report earnings per share before extraordinary items using the method that produces the most dilutive results. So we choose between treating the notes as though they had been converted to common or treating them as though they had not been converted.

So the punch line here is that we are required to report earnings per share for both the second-quarter of 2004 and for the first half of 2004 on the if-converted basis, which we have done. So earnings per share reached 20 cents in the second quarter of 2004 on the U.S. converted basis, up 4 cents per share when compared with the same period last year. In summary, higher Visudyne profitability contributed to a 6 cent increase while the dilutive effect of the convertibles reduced this by about 2 cents.

For the year-to-date earnings per share also determined on the if-converted basis totaled 53 cents, up 20 cents per share from the full year I'm sorry, from the prior year first half. The primary drivers of this increase in earnings per share include 15 cents from the extraordinary gain in the first quarter resulting from the acquisition of Kinetek and 10 cents from higher Visudyne profitability reduced by about 5 cents from the dilutive effect of the convertible notes.

QLT's cash position continued to grow during the quarter to \$524 million U.S. dollars on June 30th. Compared to the beginning of the year cash is up by 29 million U.S. dollars despite unfavorable

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exchange rates rate effects of about, reducing the effect by about \$9 million U.S. Finally, turning to the outlook, outlook for the rest of the year we are reiterating our Visudyne sales guidance range for 2004 at \$430 to \$455 million. This range assumes foreign exchange rate changes remain about where they are currently.

We are also reiterating our earnings per share outlook at 81 to 91 cents per share on the if-converted basis or 86 to 90 cents per share on the if-not-converted basis. We continue to think in terms of the profit share rate in the 30 to 31.5 percent sales range and research and development expenditures in the 45 to \$50 million range, which is a reminder provides for approximately \$5 million to accelerate developments in the ILK targets acquired with Kinetek in the first quarter.

And SG&A is expected in the \$16 to \$18 million range, up in U.S. dollars primarily from the relative strengthening Canadian dollar. And finally, we reiterate our effective tax rate at 34 percent. And of course all of these forward-looking views exclude potential effects of our pending transaction with Atrix Laboratories. And now back to Paul for his closing remarks.

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

Thanks, Mike. I just wanted to reiterate you may have heard Mike say 86 to 90 cents on an if-converted basis, and it was 86 to 96 cents on an if-converted basis for the EPS range.

**Mike Doty - QLT, Inc. SVP & CFO**

Correct. Thank you, Paul.

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

Thanks for joining us, and we are presenting next week at the Bank of America conference in New York and hope to have the opportunity to see some of you there. As a reminder, we also have Bob Butchofsky, VP of marketing and sales as well as Mohammed Azab, Executive Vice President and chief medical officer available during this Q&A period.

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

Operator, if you could just queue for questions, please.

## QUESTION AND ANSWER

### Operator

(OPERATOR INSTRUCTIONS) Dimi Ntantoulis from UBS.

### **Dimi Ntantoulis - UBS Analyst**

Paul, perhaps you could comment is there any change in retreatment patterns seen with the combined use of Kenalog with Visudyne? Have you seen any change in the retreatment or usage patterns there? And secondly just a question for Mike your R&D guidance reiterated 45 to 50 million I mean your run rates for first half is just under 21 million. What else are you planning besides the \$5 million spent in the ILK targets for Kinetek? What else do you plan, because you need to have a significant step-up in the H2 (ph) to sort of meet the 45 to \$50 million R&D guidance you've provided.

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

Let me take a crack at both of those. We've been hearing all along that there is a change in the retreatment pattern when people combine triamcinolone with Visudyne and is looking at about 2.5 or 3 treatments total when they do that. It's really not a big change from the way they use Visudyne as monotherapy, but there is probably a reduction or slight reduction there. The interesting thing was that in that survey we conducted where physicians were asked to tell us how many times they retreated with Visudyne monotherapy or with Visudyne plus triamcinolone, the numbers were remarkably similar. Now this doesn't mean that this is the way they are practicing. It probably means that they are still determining what the best approach is with a combination therapy. So there may be some reductions, although I don't think they are as dramatic as some people may think, and this particular combination has been going on now for over a year, although the numbers are increasing now.

But I do not think that overall it is really bringing down the number of retreatments dramatically from say, last year. So I don't think the run rate is being affected overly by these number of retreatments despite what we hear subjectively from people when you ask them one-on-one. So it's tough to say. In terms of the R&D spend, we are starting a Phase I/II acne trial. That is the other expense that's going to happen this year. There is a lot of work being done on the ILK program as well and we are completing the BPH trial, the alopecia trial and the VIO trial. So there's a lot of things going on in the latter half of the year, and even if expenses were to be as high as one might have expected them in the first half on some of these trials, those expenses can ramp up in the second half of the year. That has been our

experience.

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**Dimi Ntantoulis - UBS Analyst**

But it's really the acne trial that sort of .

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

That is the additional one, yes.

**Dimi Ntantoulis - UBS Analyst**

Just back on the retreatment rates, I suppose it is too early to know what sort of occult type of retreatment rates, whether it is monotherapy or combo therapy that physicians are perhaps thinking about going forward with the new CMS reimbursement. Was that addressed at all in your survey?

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

Yes, as I mentioned we surveyed them both on occult as well as minimally classic as well as predominately classic. And in occult it was a higher percentage of people who were using Visudyne monotherapy as well as Visudyne overall even in combination. But there was an additional well, I think it was 25 percent who were using it in combination there. And the difference between the number of retreatments and the combination approach as quoted by them in the monotherapy approach was really not that dramatically different.

**Dimi Ntantoulis - UBS Analyst**

In either minimally classic or occult?

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

Right, did I say that correctly, Bob? Do you want to add anything there?

**Bob Butchofsky - QLT, Inc. VP Marketing & Sales**

You did, but again it's reiterating what their expectations are for retreatment.

**Dimi Ntantoulis - UBS Analyst**

Great. Thank you.

**Operator**

Doug Miehm from RBC Capital Markets.

**Doug Miehm - RBC Capital Analyst**

Good morning, Paul and everyone. Just curious with respect to what we saw on the revenue side in the US. Did you see an acceleration in that revenue from April, May through June associated with the reimbursement and the physicians getting more comfortable with the reimbursement process?

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

Absolutely. April was lighter than May, which was lighter than June.

**Doug Miehm - RBC Capital Analyst**

Okay. Then if we look at rest-of-world sales, I realize that you only launched in Japan, but could you comment where you might expect Japan to be as a percentage of total rest-of-world sales as we come towards the end of the year?

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

No, we'd rather not do that now just because it is the first year of launch in Japan. And I do not think we've given out the Japanese number, and I think for now we want to manage overall R&D as one chunk of a number.

**Doug Miehm - RBC Capital Analyst**

Okay, and then just beside UK, any other update in terms of reimbursement in Europe, any changes there?

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

Bob, would you like to comment on that?

**Bob Butchofsky - QLT, Inc. VP Marketing & Sales**

Yes, we basically have reimbursement throughout the major countries for occult in Europe. France has come on board, and basically in the first quarter or near the end of the first quarter. Italy reimburses on a province or regional basis, and a little bit more than half of the regions are covered. Germany is the exception to reimbursement where we haven't filed for occult reimbursement yet because of some significant changes occurring within the German marketplace. Spain we have reimbursement in place, and the UK is the other exception that is lagging in terms of occult reimbursement. We don't expect to get occult probably until next year or even beyond.

**Doug Mieh** - *RBC Capital Analyst*

Just to follow-up to the first question. Can you tell me perhaps how many new patients were treated in Q2? That would have been associated with minimally classic or occult, and I will leave it there.

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

Yes, can we throw a number on that, Bob, or do we want to not take a wild guess at that?

**Bob Butchofsky** - *QLT, Inc. VP Marketing & Sales*

I think we have most of the incremental sales that occurred in the second quarter in the US are due to new patients. We believe that most of those new patients were primarily in the occult to minimally classic range. So there were probably a ballpark of 4500 to 5000 new patients that were eligible for reimbursement that were treated in the quarter.

**Doug Mieh** - *RBC Capital Analyst*

That's great. Thank you.

**Operator**

Matt Geller from CIBC.

**Matthew Geller** - *CIBC World Markets Analyst*



First of all, first of all, how do you see Visudyne fitting in with the upcoming competitive environment with products that are now completing clinical trials that might be on the market? Which ones do you see as potential competitors? How do you see potential combination usage with other approaches?

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

Thanks, Matt. I mean, we do not look at these drugs necessarily as competitors. We look at them as additional therapies, which will probably be used at the physicians' discretion in combination with Visudyne. What is nice about that is that survey validated that. The survey basically said that 90 percent of those 106 physicians said that the future of therapy will be combination therapy with the new therapies that were mentioned in the survey, and they were all the ones that you can think of. And 90 percent of the combination would be with Visudyne. So we are encouraged by that, and we believe that like any other disease that's multifactorial, that the future treatment in the disease as well as in some diseases the present treatment is the combination approach.

How that will impact all of these drugs I think the bottom line and I think we all have to really understand this is that when a retinal specialist is interested is how quickly can I stabilize this disease with as few treatments as possible. And so when they think about combination therapy they are going to be thinking about using fewer intravitreal injections, fewer everything in order to get the best possible outcome. So they would be looking at it from a number of different ways. As time goes on we think they would probably be looking at when they are happy with their initial results, can they get better results by treating more often.

So it is likely that this combination therapy is the future of this whole disease space. But even with our experience with Visudyne and we expect this to be the same with other agents as they become available, the number of times people use these drugs is never the amount of or the number of times they use them in clinical trials. But having said that, with all of that information we had nice growth in Visudyne sales over the last four years, and we expect that to continue. So we're not expecting a huge pickup from other therapies becoming available since they all have very different mechanisms of action. There's only one drug in that category of drugs for AMD that may or may not get approved by the way, that works on the basal membrane and that drug is Visudyne. So we stop the leaking blood vessels. The other drugs work upstream from that, so we believe that there is no reason this drug Visudyne will not be the cornerstone of therapy.

**Matthew Geller - CIBC World Markets Analyst**

Second question is in longer-term plans for QLT to what extent do you plan to rely on MNA, acquisitions, partnerships in terms of future products and to what extent do you plan to rely on internal development?

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

Well the fact that we just announced our intention to merge with Atrix, we're going to have plenty of pipeline for quite some time. So there may be the occasional opportunity that comes our way, which is synergistic with the pipeline we will have with the combined Atrix and QLT pipelines. But right now, and particularly for the remainder of this year and more than likely for the entire year next year, we will be focused on maximizing our potential with our combined pipelines, which is quite robust at this point in time between all the programs that QLT has and the Phase II results that we will have by the end of this year. And all the programs that Atrix has including the product launches that are upcoming, we think we're in really good shape as a combined company one company combined that our pipeline will be enough to suffice for us going forward.

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**Matthew Geller - CIBC World Markets Analyst**

Thanks a lot, Paul.

**Operator**

Michael Lachman from ThinkEquity Partners.

**Michael Lachman - ThinkEquity Partners Analyst**

I just want to get a better understanding if I can of what you believe the historical usage, I understand that it is hard to gauge what happened in the last three months since the reimbursement has changed. But historically how highly penetrated do you think the newly reimbursed segments were already based on the fact that if defining a lesion type can be a bit ambiguous or let me ask another way what percentage of U.S. sales prior to this quarter do you think were being used already in occult and minimally classic lesions?

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

We thought it was somewhere around the 10 percent range, but again going back to what you said first, Michael, which is we don't and none of us can control how a physician diagnoses the disease and what lesion type he diagnoses it at, so because of the nature of the differential diagnosis being enforced in angiograms, it is hard for us to tell based on patient records or Medicare records, whether the diagnosis was actually correct. But we feel pretty good about the fact that the number we predicted, which was between again about 0 and 10 percent, was about the right amount on a percentage basis of people who were being treated for occult and minimally classic before the CMS reimbursement decision.

**Michael Lachman - ThinkEquity Partners Analyst**

And again, I guess kind of a follow on to that, and I'm not sure I understood correctly or clearly what you had said regarding the survey result, but when you pointed out the percentage of respondents that talked about using Visudyne in minimally classic and occult lesions either in monotherapy or combination therapy I think the numbers were like 50 percent, 25 percent, 40 percent, 20 percent - pretty meaningful numbers. Are those numbers indicative of what these physicians intend to do, or is that indicative of what these physicians were already doing as of early May?

### **Unidentified Company Representative**

So the way the survey question was asked was what are you doing now. But given that was one month after the implementation and again you can't control how people answer questions, and when we read the survey results and you always have to look at survey

results with these things in mind, that it is possible that they were quoting what they're doing or what they want to do. So it is an attitude and usage survey. What is their attitude about the product and how are they using the product? So you have to balance between those two. So some of the answer was their attitude towards how they were treated, and some of it was what we're doing already. But for the most part when they answered the question it came out with this is what we're doing already. So having said that, our point of view is it is probably a lot of attitude versus what is going on already and how they're going to use the product.

### **Michael Lachman - *ThinkEquity Partners* Analyst**

That helps clear that up. And a more mundane question here on some basic division. When I look at the net income number and divide it by the fully diluted share count I don't get the diluted EPS. Is there an interest addback that I need to make? What is the amount of that?

### **Mike Doty - *QLT, Inc.* SVP & CFO**

For the second quarter it is 1.1 million, for the first half it is 3.2 million.

### **Michael Lachman - *ThinkEquity Partners* Analyst**

Great. Thanks a lot.

**Operator**

Christine Charette from BMO Nesbitt Burns.

**Christine Charette - *BMO Nesbitt Burns* Analyst**

I have a broader question and a couple of detail questions. Regarding Novartis, they just announced a restructuring; the ophthalmology division will be brought into a bigger specialty division. Do you see that impacting your costs going forward, your SG&A costs for the joint venture going forward?

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

Yes, so Novartis Ophthalmics has recently become a part of a broader division which includes oncology, ophthalmics and transplants. That entire division will be run by David Epstein, who was the global head of the oncology division, and a longtime Novartis exec. That's good news for us. One of the things that hopefully they will leverage with this new combination is SG&A. So we don't expect to see increases if that's what you're asking. If anything, I would expect to see leverage there because they should

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have access to more country operations and more people in these country operations in this particular division.

But again, having said that we are going to pay for the amount of headcount that people apply to Visudyne from Novartis. That number shouldn't change just because they've reorganized. And if anything, it should go down based on most people who reorganized tend to look for synergies when they reorganized. That is kind of how we're thinking but having said that we're not predicting any reductions or any increases, we are predicting that what we predicted is going to happen. Regardless of the change.

**Christine Charette - *BMO Nesbitt Burns* Analyst**

Regarding the survey you said that the number of retreatments in combination mono was very similar. Could you put numbers to that with what the numbers? And a question for Bob. You talked about 4500 to 5000 new patients based on the incremental sell (ph). Can you tell me how you came up with that number, and did you take into account the extra wholesale inventory that was sold in Q1 and the reduction in the wholesale inventory in Q2? And if you do take that into account, how does your number change?

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

On the number of retreatments what was the difference between the number of retreatments from monotherapy and combination therapy? I'd rather not talk about the total number of retreatments but just the difference between the two.

**Bob Butchofsky - *QLT, Inc.* VP Marketing & Sales**

They were relatively light. It depends on the market segment, and again I think the thing to clarify here, Christine, is that these are expectations for retreatment rates. So they were within between the different market segments we surveyed, they were within one retreatment overall within all three market segments predominately classic occult and minimally classic.

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

And that number is very consistent with what we have been saying all long which is about 3 total treatments right now that we are seeing in the first year in Visudyne. And then the second question, Bob, on the Q1 and Q2 inventory levels and the effect of those on the number of new patients treated in Q2.

**Bob Butchofsky - QLT, Inc. VP Marketing & Sales**

The inventory levels at the end of the second quarter were lower than what the wholesalers typically carry. They were down to less than a week's inventory and a more reasonable level for them to

carry is slightly more than a week's inventory. So it wasn't a substantial difference. They typically don't carry a ton of inventory. They carry around 3000 vials, in that ballpark.

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

Do you have another question, Christine?

**Christine Charette - BMO Nesbitt Burns Analyst**

The question was in the first quarter in eight states you were selling to wholesalers for the first time, and on the conference call you had told us that was providing an extra \$3 million in sales for Q1. If you took that into account, I think that the increase in Q1 and Q2 the differential would be higher. And how would that impact your assumptions of new treatments, or would it?

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

It really wouldn't. Q1 was the inventory load for the first time essentially. So we loaded about 2500 vials or something in that vicinity with the wholesalers. We ended Q2 with around 1500 vials and now that is what Mike referred to in the call about \$1 million reduction in inventory.

**Christine Charette - BMO Nesbitt Burns Analyst**

Okay, thanks.

**Operator**

Hari Sambasivam from Merrill Lynch.

**Hari Sambasivam - *Merrill Lynch* Analyst**

Paul, just on the survey do you get a sense that physicians are actually following the lesion size restriction that the CMS put on for the occult and minimally classic as well as the risk of progression criteria, that's the first question. Second question is that right now if you stay flat at Q2 levels for the year Visudyne would probably end up at about 430 million. And given sort of your sentiment as to growth going forward I am just kind of curious as to why you are staying with the 430 to 450 range for Visudyne. And lastly, just a question on marketing. Given that you've got Macugen and potentially Retane coming out next year how exactly is your marketing or your detailing message being changed or combined so that physicians are thinking about Visudyne in relation to those?

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

First of all, physicians were readily able to quote the lesion size restriction on the number of patients they treat and appeared to be doing that with ease. So they were very much aware. We did see in the survey that the larger lesions got more of the combination patient than the smaller lesions got. And we didn't dovetail that to get reimbursement for that. We just felt their attitude was that in a larger lesion with either one of those two subtypes they probably combined the drug with triamcinolone more than with the smaller lesion where they may use monotherapy first.

The guidance 430 by the way to 455, not 450. And you're right, if sales remain flat for the remainder of this year sales will be coming in at about the low end of our guidance. We've never stated that we were worried about the lower end and we are not. There's a number of assumptions that go into this range, and the only thing I think that didn't happen in the second quarter was we didn't break out - we had a very nice second quarter but we didn't break out of the top of that range in terms of where we're running right now. So we wanted to keep the range relatively stable. But we're not expecting right now that sales are ramping towards the low end of that range at all, because sales have been growing quarter-over-quarter we expect that to continue.

In terms of the detailing message, the detailing message is much more difficult to articulate than what's going to happen in the market because most of the physicians who are using Visudyne or Visudyne in combination with triamcinolone or who will use Visudyne in combination with other agents are not relying on salespeople to give them the information that will drive to that conclusion. Most of that information is exchanged at scientific meetings for which there are abundant numbers of in the retinal community. So these people are data driven, and the detailing message by any large pharmaceutical company is going to be very much in line with labeling.

Of course, they can answer questions and they can refer people to medical affairs to get answers and under the FEDOMA (ph) rules in terms of occult and minimally classic given that there are studies published and reimbursement is given, they can certainly respond to questions that they are asked. But I don't think there is a proactive detailing message that goes along with combination therapy, nor would there be with even the other competitors because under the FDA guidelines you can't do that unless you do a combined clinical trial, with these two agents or these number of agents. So you're going to have to look at this the same way you might look at oncology drugs and the way they are used in combination, very few of which can actually be detailed that way.

**Operator**

David Martin from Dundee securities.

**David Martin - Dundee Securities Analyst**

You had addressed the retreatment rates in combination with Kenalog versus monotherapy. I am wondering if you see any difference at all in occult minimally classic versus predominately classic? And the physicians survey I am wondering was that mainly large centers that you were polling, or did it include a mix of major centers in the smaller centers?

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

All the lesion types were relatively similar in terms of retreatment rates, and the 106 retinal specialists were identified, and it was a mixture, is that right Bob?

**Bob Butchofsky - QLT, Inc. VP Marketing & Sales**

That's correct. There is a mixture of solo, group, academic and nonacademic centers.

**David Martin - Dundee Securities Analyst**

Okay, so I think you said that 50 percent of occult patients are being treated with monotherapy, and 50 percent with combination. So they are reporting sorry, retreating 100 percent of the occult patients now?

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

What we said was that 75 they reported that they would treat 75 percent of those patients with monotherapy and an additional 25 percent with combination therapy. And that was an attitude, not actual usage.

**David Martin - Dundee Securities Analyst**

So does that mean 100 percent of the occult patients that they see are getting treated with Visudyne, then?

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

No, it means that 100 percent of the occult patients that they will treat the occult patients that they will treat probably 75 percent of them according to them at the time would be getting monotherapy; an additional 25 percent would be getting combination therapy. It wasn't that 100 percent of their total number of patients would be getting therapy, it is 100 percent of the patients they would treat. It would be broken down into 75/25. Did I get that right Bob?

**Bob Butchofsky - *QLT, Inc.* VP Marketing & Sales**

Just one clarification. It is 50 percent and 25 percent.

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

I m sorry; 50 and 25.

**David Martin - Dundee Securities Analyst**

Okay, and are there any patients with small lesions occult that they are not treating and would there be a reason for it?

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

They did not mention that they are not treating smaller legions, but as Bob just quoted you the number being 50 and 25, obviously they are not treating everybody and then maybe reasons for that that have to do with things outside of the lesion type, maybe how long the patients had the disease, maybe they have a small lesion but they are not progressing, and it is just a whole host of reasons that one might not treat right away.

**David Martin - Dundee Securities Analyst**

Okay, thank you.

**Operator**

(indiscernible)

**Unidentified Speaker**

You talked about the new patients getting Visudyne use. I was curious if you saw any trends in terms of new users in terms of new physicians coming online as users of Visudyne. My second question is in terms of the BPH data you expect from QLT0074, is that going to be complete data on all the doses, or is that just going to be a subset of the ultimate data?

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

On the BPH trial that will be the full data set from the Phase I/II trial. And on your first question, there are about 1400 plus lasers placed in the United States for Visudyne I'm sorry 700 lasers, and there are 1400 retinal specialists. So I don't know if Bob has actually seen any new users, but that's a very high penetration of lasers for retinal specialists. Bob, do you have any comments on that?

**Bob Butchofsky - QLT, Inc. VP Marketing & Sales**

There's been relatively few new users. It is not a major driver. What is a more important factor is there are more centers that are getting multiple lasers to either place in satellite offices and that is helping drive a little bit more sales.

**Operator**

Douglas Chow from Haywood securities.

**Douglas Chow - Haywood Securities Analyst**

I have a general question about the Atrix acquisition. It appears that the stock price may have reacted negatively to the proposed acquisition. Does that make you rethink at all about that? And also does the acquisition represent a change in your strategy going forward in terms of the types of products you will be acquiring in the future in terms of looking at more types of agents that are existing on the market? And just a reformulation or are you going to continue to look at developing new entities?

And my second question is related to the Atrix technology. You are developing it currently for the growth hormone releasing factor. I was wondering if that technology could potentially be applied to GLP-1 for diabetes because as you know as their technologies also has a they are working with their technology to allow delivery through the skin. Do you think that could also be applied to GLP-1 peptide?

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

Let me go through your four questions, Doug. Yes, that could be applied. Any protein peptide or small molecule has the potential to go into the Atrigel system. And the beauty of the gel system is that you're injecting a liquid subcutaneously that turns into a solid or semi-solid dose form under the skin, and so any protein peptide or small molecule that you would need to inject subcutaneously is a candidate for that technology.

The answer to the first two questions is absolutely not. We are not rethinking the acquisition of Atrix because of reactions or because of the share price of both companies at the moment. And we certainly are not changing our view on pipeline products. We have a proprietary pipeline of products that includes, by the way, both Atrix as well as QLT. So when all of the Atrix products are patented products, most of them right now, the ones that are on the market today are going out to 2016, 2018 and in some cases 2020. So these are proprietary products put into proprietary system or the proprietary product when the product is put into this proprietary system.

So one could say it is a reformulation, but you can also use the Atrigel formulation as well as the other delivery platforms in Atrix to deliver proprietary agents, and that is all the partnerships that

they have. Just like the partnership we have with Visudyne with Novartis. They have a number of partnerships with not only big pharma but also biotech companies on delivering proprietary products in the Atrigel system. So we certainly are looking at pipeline and future products to be combined with Visudyne or in the areas of BPH or anything else, we would be looking at putting proprietary as well as less proprietary compounds into a proprietary system.

So there is no change in our strategy of being a proprietary drug company. The Atrix technology can be applied to so many different areas, and the patent on that technology is owned by Atrix, not somebody else.

**Douglas Chow - Haywood Securities Analyst**

One follow-up question regarding the Atrigel GHRP-1, you indicated that it is a Phase I product, have you revealed what has already been done with that at the moment?

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

No, they haven't, and one of the things about doing those kinds of collaborations on a non-exclusive basis is you do not get as much information on those. But as we get that information we will be happy to share it with you, but at the moment we are not sharing where they are with that program.

**Douglas Chow - Haywood Securities Analyst**

Okay, thanks.

**Operator**

(indiscernible) BMO Nesbitt Burns.

**Unidentified Speaker**

Just a quick question about where you're at with the share repurchasing program.

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

We still have the share repurchasing program in place, and I certainly cannot do that during the period of signing and closing of this transaction.

**Operator**

John Stevenson from Somerset Research.

**John Stevenson - Somerset Research Analyst**

Most of my questions have been answered actually already but you spoke a bit about the use and combination minimally classic as well as occult, and I was just curious first of all what percentage of the predominately classic usage is currently combination with triamcinolone and where you see this going, for example by the time Macugen enters the market. And then lastly what impact that could have on the potential market dynamics when the next competitor Macugen does enter.

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

So, let me just make a statement; I think with the combination of Visudyne plus triamcinolone and the experience people are getting with that in any form of this disease that is becoming standard of care if it is not already. So probably Macugen will be looked upon as a if they are looking at combination therapy as how do you use it, do you use it in combination with both, with one or what have you?

In terms of the number of patients who get monotherapy versus combination therapy and predominately classic in the survey, Bob, could you comment, I don't remember the actual number.

**Bob Butchofsky - QLT, Inc. VP Marketing & Sales**



It is slightly higher in predominately classic group; monotherapy averages around 55 to 60 percent, and combination is again around 25 to 30 percent.

**Unidentified Speaker**

Do you have a sense for how they use the combination therapy today compares to say a year ago? I assume it's got to be higher.

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

It's growing. It is visibly growing.

**Unidentified Speaker**

I guess this is the last quick question, I don't know if you mentioned this before, but the National Eye Institute study, at what point is that going to start enrolling patients, or has it already?

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

Mohammed, can you speak to that?

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

Yes, Paul. That protocol is being finalized now as we speak. And it's got several approval process to go through but the centers have already been selected, most of them, and we're expecting to have patients before the end of the year.

**Unidentified Speaker**

Great. Thank you.

**Operator**

(indiscernible)

**Unidentified Speaker**

I was wondering if you could comment on the licensing agreement that Atrix announced yesterday with BEMA was that something you were aware of when you signed the deal, and could you give us some sort of sense of how significant it is?

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

So the BEMA technology is a technology that was in the pipeline of Atrix. We were, I think it is fair to say that we were more interested in the Atrigel platform than in the BEMA platform. The fact that they were able to license it to another company who could then fully develop it off the P&L of Atrix we think is a good thing. How significant is it? Well, it is one technology that they own in a myriad of technologies that they own. So it is a small program within a much larger number of programs, and we were not as interested in developing that as we were in the Atrigel and the topical dermatology delivery system. So we view it as a positive thing.

**Operator**

(indiscernible)

**Unidentified Speaker**

Going back to the competition and I think you addressed the question very well, you mentioned that the combination therapy with Visudyne will be the future therapy for AMD. Now Retane does not appear to work with in combination with Visudyne. Do you think that if there are more competitive drugs that are not able to work properly with Visudyne that will have any impact on the sales, and what your thoughts on that?

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

Let me ask you first how you determine whether Retane is or isn't a combination therapy with anything.

**Unidentified Speaker**

Actually there was an article in (indiscernible) medicine that said that it does not appear to work in combination with PDT.

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

Right, they did a small, so far small Phase II study which they didn't get the full results of. It doesn't mean that the drug can't be used in combination with Visudyne. It means that the study that they did not indicate to them that this was an area that they wanted to pursue. But I do not think that anyone believes in the retinal community and this is who is going to determine how these drugs are used, that this is not something you would combine with other agents. And I think indeed that most of the companies including our company that is developing these drugs realize that is the case.

And you probably people don't develop drugs as combination therapies because they want to get a monotherapy label with monotherapy reimbursement. So I think you have to keep that in mind as well. But the real proof in how drugs are going to be used once they are on the market is once they are on the market and physicians use them the way they want to.

**Operator**

Christine Charette from BMO Nesbitt Burns.

**Christine Charette - *BMO Nesbitt Burns* Analyst**

I just have a follow-up question for Bob. You talked about 10 percent of the occult market was penetrated before you received reimbursement. Just wondering where that data comes from and how solid is it.

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

Actually what we said Christie was 10 percent of our use earlier was off label, (multiple speakers) occult.

**Christine Charette - *BMO Nesbitt Burns* Analyst**

And how did you determine that number?

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

Based on a number of different things looking at some of the market research we've done, and chart survey data that we were able to do earlier that we can't do anymore, we felt that between objective and subjective analyses, it was about 10 percent because nothing is more scientific than that.

**Christine Charette - BMO Nesbitt Burns Analyst**

Thank you.

**Operator**

There are no further questions registered at this time, I would like to turn the meeting back over to you Mr. Hastings.

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

Well, Therese, do you have any final things to say other than thank you for attending the call?

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

Yes, I will just provide for people if they would want to listen to the session again that they can call 416-695-5800 and quote the reservation number 3076061, the tape will be available for the next seven days. thanks very

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

Thank you everybody.

**Operator**

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