Rodman &Renshaw®

Alimera Sciences, Inc. (ALIM)

COMPANY UPDATE

MEDICAL DEVICES

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Market Outperform / Aggressive Risk

Positive Signals from the 36-month readout of FAME Study…

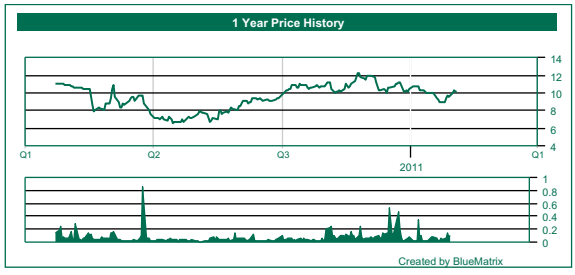
MARKET DATA	Intraday - 2/4/2011
Price	$10.04
Exchange	NASDAQ
Target Price	$13.00
52 Wk Hi - Low	$12.70 - $6.30
Market Cap(MM)	$312.9
EV(MM)	$258.2
Shares Out (MM)	31.2
Public Mkt Float (MM)	7.1
Avg. Daily Vol	106,845.0
Short Interest	991,889.00

BALANCE SHEET METRICS	
Cash (MM)	$4.9
Debt/Capital	NA
Cash/Share	NA
Book Value(MM)	NA
Book Value/Share	$1.62

EARNINGS DATA ($)			
FY - Dec	**2011E**	**2012E**	**2013E**
Q1 (Mar)	--	(0.05)	0.04
Q2 (Jun)	(0.23)	(0.04)	0.13
Q3 (Sep)	(0.23)	(0.01)	0.19
Q4 (Dec)	(0.29)	(0.02)	0.28
Full Year EPS	(0.96)	(0.09)	0.64
Revenue (MM)	0.0	42.1	81.0

VALUATION METRICS			
Price/Earnings	NM	NM	15.7x
EV/Revenue		6.1x	3.2x

INDICES	
DJIA	12,049.4
SP-500	1,304.9
NASDAQ	2,322.5
NBI	973.6



Key Takeaways

- ALIM released 36-month data on its FAME Study evaluating the safety & efficacy of Illuvien in DME. Specifically, per the Full Analysis Set (which the company contends is what the FDA will be honing in on), the low-dose Illuvien arm saw a BCVA #15 letter improvement in 28.7%, while the control arm saw 16.2% (p=0.002).
- Key things that caught our attention in this data set were that 1) control arm had >2x the number of off-label treatments than the treatment arm; 2) control arm had about 31.9% of data imputed with the treatment arm about 28.5% data imputed; 3) high IOP profile remained relatively flat going from 16.3% at 24-months to 18.4% at 36-months; 4) Incisional surgeries for treating high IOP also remained relatively flat at 4.8% at 36-months.
- What we don't know is what the modified-ART data set looks like. That data as far as we know, has not been released. But based on the company's meeting with the FDA earlier in the week, it seems that modified – ART data vis-à-vis the full analysis will not be a problem.
- The 36-month data compares favorably to the DRCR study conducted by the NIH a few years ago.
- The key thing in our mind is….what specifically was the FDA looking at the 24-month data set which caused them to ask for the 36-month data? Was there a specific risk-reward ratio they were looking at? Based on the data presented, it doesn't seem like the risk-reward ratio has changed significantly.
- Overall, we are incrementally comforted with the data release. While it is impossible to predict which way the FDA will swing their bat, if history is an indicator, then ALIM seems to be in a marginally better position now.

Valuation

We maintain our OutPerform rating and $13 PT. Our PT is based on our DCF analysis given peak Illuvien sales of $250 million in 2015, a long-term growth rate of 4% and a discount rate of 14%.

Risks

Regulatory Risk. Market Risk. Competitive Risk.

36-month readout of FAME Study

As announced yesterday by Alimera, the therapeutic response by Illuvien was maintained till 36-months. We wont go into all the details of trial design, etc as that has been done previously. We spend time only on key takeaways from the data presented and implications on regulatory approval.

Relapse rates / Durability of efficacy

As presented in the data set, the control arm had almost 2x the number of off-label treatments (p<0.001). While laser use was prescribed by the protocol, a closer look at the data suggests that in its entirety the physician felt the need to do more laser treatments in the control arm than the treatment arm (p<0.001 in both trials). We do not know the amount of data imputed till 36-months in both the trials and the control arm. However, if we remember correctly, at 24-months the control arm had >50% of data imputed while the low-dose treatment arm had about 20% or so data imputed. We "assume" that imputation rates remain the same. What is confounding to us is how the control arm in trial A saw a 4% improvement in visual acuity between 24 & 36-months while the treatment arm went up only 2%. In Trail B, again, the control arm went up 1.1% over the period from 24 to 36-months whereas the treatment arm went down 1.6%. To us this is confusing. The data definitely seems lumpy, which probably explains why p-values did not hold up at 36-months.

Figure 1. Treatment protocol

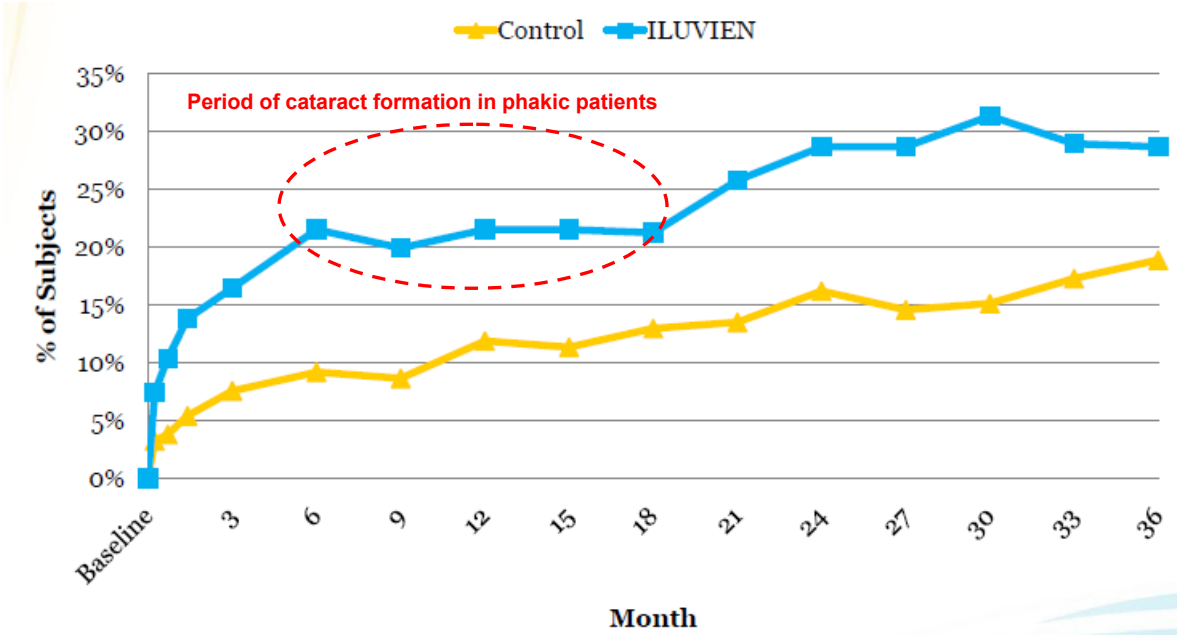
	Trials A & B Combined			
	Control N=185	ILUVIEN N=376	Control N=185	ILUVIEN N=376
	As of the Month 24 Data Base Lock		As of Trial Completion	
Study Treatments (Sham injection or ILUVIEN)				
1 treatment	76.2%	76.5%	71.4%	74.4%
2 treatments	19.5%	21.3%	23.8%	21.6%
≥ 3 treatments	4.3%	2.2%	4.8%	4.0%
Laser Treatments	48.6%	30.9%	62.2%	41.5%
p Value		<0 .001		<0 .001
Off-Protocol Treatments (IVTA, bevacizumab, ranibizumab, or vitrectomy)	28.6%	12.5%	33.0%	15.2%
p Value		<0 .001		<0 .001

Source: Company reports

Figure 2. Percentage of patients with BCVA ≥15 letters – Trial A & Trial B

	Trial A		
	Control N=95	ILUVIEN N= 190	p Value
	Percentage of Subjects Responding		
Month 24	14.7%	26.8%	0.029
Month 27	15.8%	25.8%	0.076
Month 30	14.7%	28.9%	0.011
Month 33	16.8%	28.4%	0.042
Month 36	18.9%	28.4%	0.106

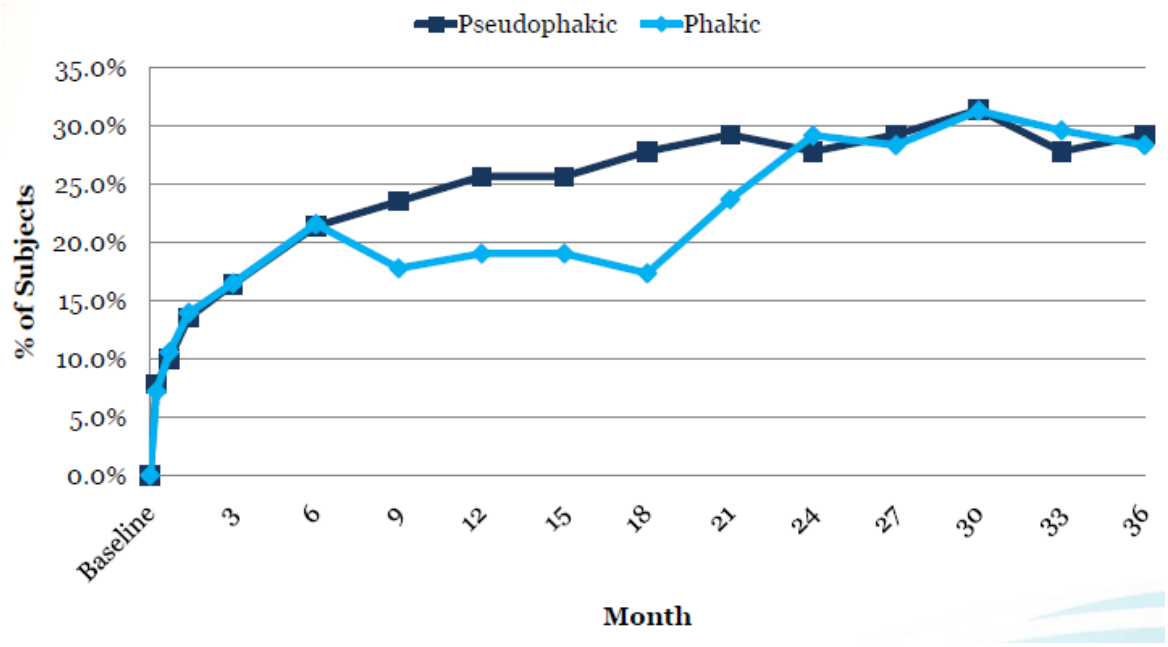
	Trial B		
	Control N=90	ILUVIEN N= 186	p Value
	Percentage of Subjects Responding		
Month 24	17.8%	30.6%	0.030
Month 27	13.3%	31.7%	0.001
Month 30	15.6%	33.9%	0.002
Month 33	17.8%	29.6%	0.046
Month 36	18.9%	29.0%	0.086



Source: Company reports

- *Phakic vs. pseudophakic patients*
  As is documented, about 80% of the phakic patients developed cataracts 12 months after randomization. Most of the cataract surgeries were done by 18-months and BCVA levels as can be seen dropped from 6 – 18 months. In other words, the pseudophakic patients depict a normalized curve for what the effect of Illuvien would be if cataracts were not an issue. There was more of an effect on BCVA between 18 and 24 months, but not between 24 and 36 months.

Figure 3. BCVA ≥15 letter profile for patients by status of lens



	Pseudophakic N=140	Phakic N= 236
	Percentage of Subjects Responding	
Month 24	27.9%	29.2%
Month 27	29.3%	28.4%
Month 30	31.4%	31.4%
Month 33	27.9%	29.7%
Month 36	29.3%	28.4%

Source: Company reports

- *Safety concerns*
  Our understanding from ALIM was that the FDA wanted to get a look at the IOP profile till 36-months. Interestingly enough, we believe it is safe to say that high IOP remained relatively stable, going from 16% at 24-months to 18% at 36-months. Moreover, IOP-related incisional surgeries went from 3.7% to 4.8% at 36-months, which is relatively flat. Per our analysis, about 31.9% of sham data and 27.4% of low dose data was imputed. Observed cases did a bit better for both low dose and controls (logical as people who don't do well are may apt to drop out).

Figure 4. Adverse Event Profile at 36-months

	Trials A & B Combined			
	Control N=121	ILUVIEN N= 235	Control N=121	ILUVIEN N= 235
	As of the Month 24 Data Base Lock		As of Trial Completion	
	Percentage of Subjects Responding			
Cataract Formation	46.3%	80.0%	50.4%	81.7%
Cataract Surgery	23.1%	74.9%	27.3%	80.0%

	Trials A & B Combined			
	Control N=185	ILUVIEN N= 375	Control N=185	ILUVIEN N= 375
	As of the Month 24 Data Base Lock		As of Trial Completion	
	Percentage of Subjects Responding			
IOP > 30 mmHg	2.7%	16.3%	4.3%	18.4%
Trabeculoplasty	0.0%	1.3%	0.0%	1.3%
IOP Lowering Surgeries				
Trabeculectomy	0.0%	2.1%	0.0%	2.7%
Vitrectomy	0.0%	0.3%	0.0%	0.3%
Other Surgery Performed	0.5%	1.6%	0.5%	2.1%
Patients Requiring One or More IOP Lowering Surgeries	0.5%	3.7%	0.5%	4.8%

Source: Company reports

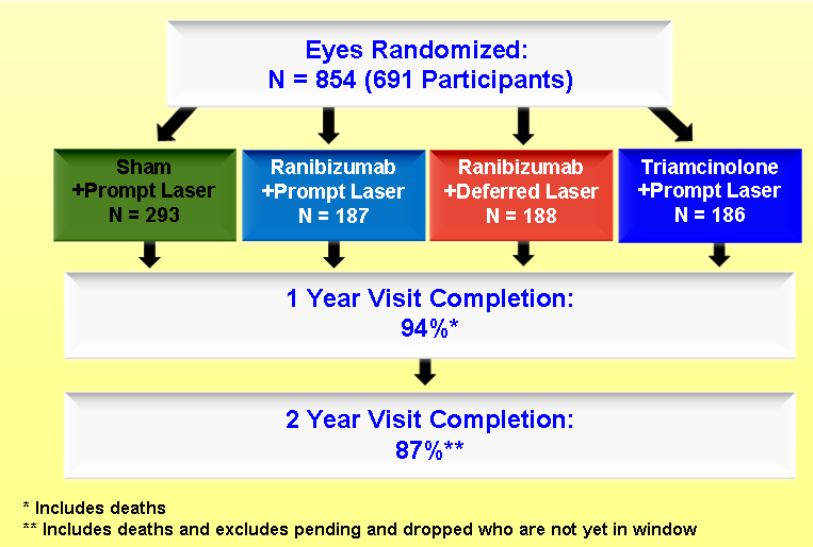
Summary

1) While the primary readout was for 24 months per trial protocol, the 36-month readout resulted in non-significant p-values, which seemed primarily due to higher off-label treatments in the control arm and high use of laser treatments in the control arm.
2) High IOP profile remained relatively flat. Remember, for Retisert the high IOP profile increased from 18% at 24-months to about 30% at 36-months.
3) Finally, as compared to the DRCR study, BCVA ≥15 letter improvements seemed relatively in-line with a slightly higher IOP profile when Illuvien was used (recap of study in next page).

The DRCR Study evaluating Lucentis

We highlight again some of the results from the DRCR study funded by the NIH, results of which were presented a few years ago. This randomized study enrolled 691 participants (854 study eyes); some patients had DME in one eye and others with two eyes. A snapshot of the trial design is shown below. Based on the data published by the DRCR, visual acuity scores at 2-years improved by approximately 7 letters in the Lucentis + prompt laser group, about 10 letters in the Lucentis + deferred laser group, and no change in the triamcinolone acetonide + laser group as compared to control. The Lucentis + prompt laser group demonstrated statistically significant improvement in mean BCVA at 1-year of 30% over baseline, and this went down to 26% at 2-years (Mean VA improvement = 9 letters; p<0.001 at 1-year; Mean VA improvement = 7 letters; p=0.01 at 2-years). The Lucentis + deferred laser group showed BCVA ≥15 letter improvement over baseline of 28% (Mean VA improvement = 9 letters; p<0.001), and this was held up at the 2-year point of 29% (Mean VA improvement = 10 letters; p<0.001). In the ranibizumab group, only a few eyes lost more than 10 letters of vision from the time the study started, whereas eyes losing vision of more than 10 letters in the steroid group and laser-alone group gradually increased throughout the study. Subgroup analysis for visual acuity is shown in the next few figures.

Figure 5. DRCR Study on Lucentis plus laser in DME



Source: drcr.net

Figure 6. Change in visual acuity scores at 2-year

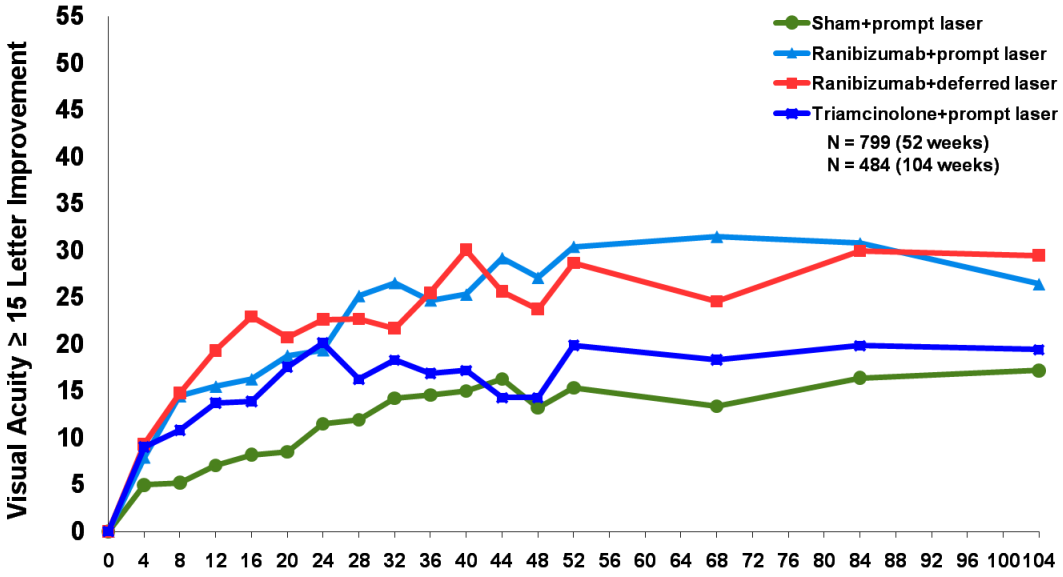
Change in Visual Acuity (letters)	Sham +Prompt Laser N = 163	Ranibizumab +Prompt Laser N = 106	Ranibizumab +Deferred Laser N = 112	Triamcinolone +Prompt Laser N = 103
Mean	+2	+7	+10	0
Difference in mean change from Sham +Prompt Laser [*P* Value]**		+5.0 [*P* = 0.01]	+7.2 [*P*<0.001]	-1.6 [*P* = 0.43]

Source: drcr.net

A closer look at the safety profile of the Lucentis and TA arm highlights that about 25% of the corticosteroid group patients had IOP >30 mm Hg, while only about 3% of the Lucentis arm patients had high IOP's. In terms of cataract surgeries, more than 50% of the TA patients had undergone surgery at 24-months, compared to 13% with Lucentis. Retinal thickness as

measured by OCT saw a mean change of approximately 160 um decrease over 2-years, thereby demonstrating clinical activity with Lucentis.

Figure 7. BCVA ≥15 letters (X-axis = weeks)



Source: drcr.net

Figure 8. In order: Major ocular adverse events at 2 years; Elevated IOP during 2-yr f/u; Cataract surgery at 2 yrs;

	Sham +Prompt Laser N = 293	Ranibizumab +Prompt Laser N = 187	Ranibizumab +Deferred Laser N = 188	Triamcinolone +Prompt Laser N = 186
Number of injections		1833	2140	685
Endophthalmitis*	1 (<1%)	2 (1%)	2 (1%)	0
Pseudoendophthalmitis†	1(<1%)	0	0	1 (1%)
Ocular vascular event‡	1 (<1%)	1 (1%)	1 (1%)	3 (2%)
Retinal detachment§	0	0	1 (1%)	0
Vitrectomy	15 (5%)	4 (2%)	7 (4%)	2 (1%)
Vitreous Hemorrhage	27 (9%)	6 (3%)	8 (4%)	7 (4%)

Elevated Intraocular Pressure/Glaucoma	Sham +Prompt Laser N = 293	Ranibizumab +Prompt Laser N = 187	Ranibizumab +Deferred Laser N = 188	Triamcinolone +Prompt Laser N = 186
Increase ≥10 mmHg from baseline	8%	9%	6%	42%
IOP ≥30 mmHg	3%	2%	3%	27%
Initiation of IOP-lowering meds at any visit*	5%	5%	3%	28%
Number of eyes meeting ≥1 of the above	11%	11%	7%	50%
Glaucoma surgery**	<1%	1%	0	1%

Source: drcr.net

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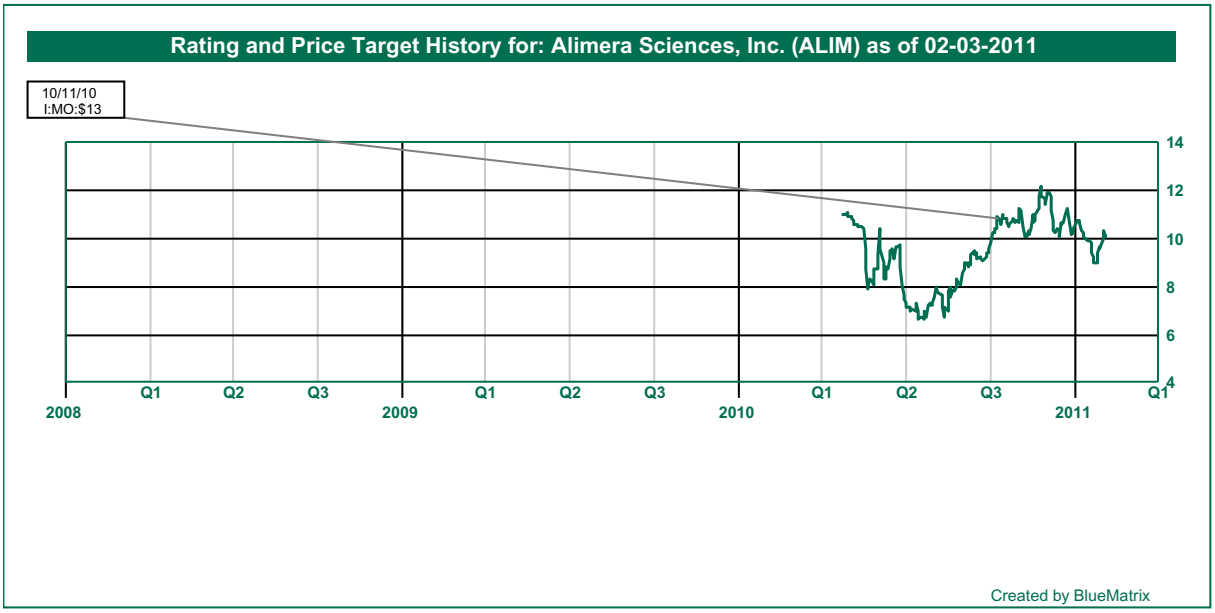
RETURN ASSESSMENT

- Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector, as defined by First Call.
- Market Perform (Hold): The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector, as defined by First Call.
- Market Underperform (Sell): The common stock of the company is expected to underperform a passive index comprised of all the common stock of companies within the same sector, as defined by First Call.

RISK ASSESSMENT

- Speculative - The common stock risk level is significantly greater than market risk. The stock price of these equities is exceptionally volatile.
- Aggressive - The common stock risk level is materially higher than market level risk. The stock price is typically more volatile than the general market.
- Moderate - The common stock is moderately risky, or equivalent to stock market risk. The stock price volatility is typically in-line with movements in the general market.



RATING SUMMARY

Distribution of Ratings Table

			IB Serv./Past 12 Mos	
Rating	Count	Percent	Count	Percent
Market Outperform(MO)	186	76.90%	46	24.73%
Market Perform(MP)	44	18.20%	4	9.09%
Market Underperform(MU)	9	3.70%	0	0.00%
Under Review(UR)	3	1.20%	0	0.00%
Total	242	100%	50	100%

Investment Banking Services include, but are not limited to, acting as a manager/co-manager in the underwriting or placement of securities, acting as financial advisor, and/or providing corporate finance or capital markets-related services to a company or one of its affiliates or subsidiaries within the past 12 months.

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