

## Quick Take

### Alimera Sciences — Outperform (1)

**ALIM: \$7.15**

### Quick Take: MAA Submission Comes A Few Weeks Ahead Of Expectations

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**Analysts**

**Ian Sanderson**  
 (617) 946-3922  
 ian.sanderson  
 @cowen.com

**Christopher Hamblett,**  
**Ph.D.**  
 (617) 946-3950  
 chris.hamblett  
 @cowen.com

**Steve Scala, R.Ph., CFA**  
 (617) 946-3923  
 steve.scala@cowen.com

**Ken Cacciatore**  
 (646) 562-1305  
 ken.cacciatore  
 @cowen.com

**Ziad Bakri, M.D.**  
 (646) 562-1326  
 ziad.bakri@cowen.com

### Iluvien NDA And MAA Submitted, Canada Filing Comes Next

This morning Alimera announced the submission of an Iluvien marketing authorization application (MAA) to the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom. The MAA is being submitted in Europe via the decentralized procedure, with the U.K. designated as the reference member state (RMS). MAAs for Iluvien also were submitted in Austria, France, Germany, Italy, Portugal, and Spain. Similar to the NDA submitted to the FDA on June 28<sup>th</sup>, the MAA submissions are based on the low-dose, 24-month data from the ongoing 36-month FAME trial of Iluvien in the treatment of diabetic macular edema (DME). The full 36-month data from the FAME trial, including a low-dose and a high-dose arm, will be released late this year.

Alimera plans to submit a Canadian marketing application for Iluvien later this quarter.

We project late-2011/early-2012 European approvals for Iluvien. Alimera plans to seek European marketing partner(s) for Iluvien closer to regulatory approval. We project Iluvien sales in Europe and Canada at \$20MM in 2012, \$40MM in 2013, \$80MM in 2014, and \$140MM in 2016; we project that Alimera yields 25% of ex-US Iluvien sales via royalties.

### Iluvien NDA Submitted As Expected, Seeking 6-Month Priority Review

On June 28<sup>th</sup>, Alimera announced submission of the Iluvien NDA for the DME indication to the FDA. Alimera requested a 6-month priority review designation. The FDA has 60 days from the date of submission to accept the Iluvien NDA submission and to make its decision on the priority review designation. For conservatism, we have assumed a 10-12 month review cycle at FDA, so a 6-month review cycle would be upside. If approved, Iluvien will be the first FDA-approved pharmaceutical treatment for DME, although other agents (intravitreal triamcinolone and anti-VEGF injections) currently are used off-label for the DME indication.

### We Project \$400MM+ WW Iluvien Sales In 2016...

Our clinical consultants project that Iluvien may be used in approximately 15% of patients currently treated for DME in the U.S., primarily in patients refractory to, or

inappropriate for, laser photocoagulation. That patient share translates to a \$300-400MM U.S. sales opportunity, and a \$200-300MM sales opportunity in Europe. We estimate WW Iluvien sales of \$15MM in H2:2011 (U.S. only), \$80MM in 2012, \$140MM in 2013, and \$405MM in 2016.

## WE PROJECT THAT ILUVIEN CAPTURES 13-15% PATIENT SHARE IN U.S. DME TREATMENT MARKET

ESTIMATED U.S. DME MARKET BUILDUP (\$MM)*									
	2009	2010E	2011E	2012E	2013E	2014E	2015E	2016E	CGR
# Diagnosed diabetes patients US (MM)	18.3	19.0	19.8	20.6	21.4	22.3	23.2	24.1	+4%
# DME patients US - annual incidence (MM)	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.4	+4%
% Treated	50%	50%	50%	50%	50%	50%	50%	50%	- Patients treated with drug therapy
# DME patients treated (MM)	0.17	0.18	0.18	0.19	0.20	0.21	0.22	0.22	+4%
<b>% Treated with Laser Photocoagulation</b>	<b>50.0%</b>	<b>50.0%</b>	<b>50.0%</b>	<b>50.0%</b>	<b>50.0%</b>	<b>50.0%</b>	<b>50.0%</b>	<b>50.0%</b>	- ~50% of all treated DME patients receive laser therapy
# DME patients treated with LPT (MM)	0.09	0.09	0.09	0.10	0.10	0.10	0.11	0.11	- laser therapy remains the only approved treatment for DME
Cost per patient/per year (\$)	\$4,120	\$4,244	\$4,371	\$4,502	\$4,637	\$4,776	\$4,919	\$5,067	- patients receiving laser therapy are at risk for night vision loss
<b>Laser Photocoagulation Sales (\$MM)</b>	<b>\$350</b>	<b>\$375</b>	<b>\$402</b>	<b>\$430</b>	<b>\$461</b>	<b>\$494</b>	<b>\$529</b>	<b>\$567</b>	<b>+7%</b>
<b>Iluvien (ALIM) Patient Share</b>			<b>1.2%</b>	<b>4.4%</b>	<b>6.8%</b>	<b>9.6%</b>	<b>12.0%</b>	<b>13.5%</b>	- sustained-release corticosteroid fluocinolone acetonide
# DME patients treated with Iluvien (MM)			0.00	0.01	0.01	0.02	0.03	0.03	- 36-month intravitreal implant for DME
Cost per patient/per year (\$)			\$7,000	\$7,175	\$7,354	\$7,538	\$7,727	\$7,920	
<b>Iluvien Sales (\$MM)</b>			<b>\$15</b>	<b>\$60</b>	<b>\$100</b>	<b>\$150</b>	<b>\$200</b>	<b>\$240</b>	
<b>Ozurdex (AGN) Patient Share</b>	<b>1.2%</b>	<b>3.8%</b>	<b>6.2%</b>	<b>7.7%</b>	<b>8.9%</b>	<b>10.0%</b>	<b>10.1%</b>	<b>10.2%</b>	- 3-5 month bioerodable dexamethasone intravitreal implant
# DME patients treated with Ozurdex (MM)	0.00	0.01	0.01	0.01	0.02	0.02	0.02	0.02	- approved for macular edema following RVO in mid-'09
Cost per patient/per year (\$)	\$5,000	\$5,150	\$5,305	\$5,464	\$5,628	\$5,796	\$5,970	\$6,149	
<b>Ozurdex Sales (\$MM)</b>	<b>\$10</b>	<b>\$35</b>	<b>\$60</b>	<b>\$80</b>	<b>\$100</b>	<b>\$120</b>	<b>\$130</b>	<b>\$140</b>	<b>+46%</b>
<b>Lucentis (Roche) Patient Share</b>	<b>1.2%</b>	<b>1.7%</b>	<b>2.0%</b>	<b>2.4%</b>	<b>3.6%</b>	<b>4.6%</b>	<b>5.1%</b>	<b>5.5%</b>	- monoclonal antibody (mAb) ranibizumab
# DME patients treated with Lucentis (MM)	0.00	0.00	0.00	0.00	0.01	0.01	0.01	0.01	- currently in Phase III for DME
Cost per patient/per year (\$)	\$14,280	\$14,566	\$14,857	\$15,154	\$15,457	\$15,766	\$16,082	\$16,403	- off-label use for DME
<b>Lucentis Sales (\$MM)</b>	<b>\$30</b>	<b>\$45</b>	<b>\$55</b>	<b>\$70</b>	<b>\$110</b>	<b>\$150</b>	<b>\$175</b>	<b>\$200</b>	<b>+31%</b>
<b>Avastin (Roche) Patient Share</b>	<b>1.2%</b>	<b>1.4%</b>	<b>1.6%</b>	<b>1.8%</b>	<b>1.9%</b>	<b>2.0%</b>	<b>2.3%</b>	<b>2.6%</b>	- monoclonal antibody (mAb) bevacizumab
# DME patients treated with Avastin (MM)	0.00	0.00	0.00	0.00	0.00	0.00	0.01	0.01	- currently in Phase II for DME
Cost per patient/per year (\$)	\$9,690	\$9,884	\$10,081	\$10,283	\$10,489	\$10,699	\$10,913	\$11,131	- off-label use for DME
<b>Avastin Sales (\$MM)</b>	<b>\$20</b>	<b>\$25</b>	<b>\$30</b>	<b>\$35</b>	<b>\$40</b>	<b>\$45</b>	<b>\$55</b>	<b>\$65</b>	<b>+18%</b>
<b>Trivaris (AGN) Patient Share</b>	<b>2.0%</b>	<b>7.4%</b>	<b>8.7%</b>	<b>11.5%</b>	<b>13.9%</b>	<b>16.1%</b>	<b>17.9%</b>	<b>19.5%</b>	- Injectable corticosteroid triamcinolone acetonide for uveitis
# DME patients treated with Trivaris (MM)	0.00	0.01	0.02	0.02	0.03	0.03	0.04	0.04	- used in the treatment of uveitis and other ocular disorders
Cost per patient/per year (\$)	\$1,500	\$1,530	\$1,561	\$1,592	\$1,624	\$1,656	\$1,689	\$1,723	- expected off-label use for DME
<b>Trivaris Sales (\$MM)</b>	<b>\$5</b>	<b>\$20</b>	<b>\$25</b>	<b>\$35</b>	<b>\$45</b>	<b>\$55</b>	<b>\$65</b>	<b>\$75</b>	<b>+47%</b>
<b>Triesence (ACL) Patient Share</b>	<b>1.4%</b>	<b>7.4%</b>	<b>10.5%</b>	<b>13.1%</b>	<b>15.5%</b>	<b>17.5%</b>	<b>19.3%</b>	<b>20.8%</b>	- Injectable corticosteroid triamcinolone acetonide for uveitis
# DME patients treated with Triesence (MM)	0.00	0.01	0.02	0.03	0.03	0.04	0.04	0.05	- used in the treatment of uveitis and other ocular disorders
Cost per patient/per year (\$)	\$1,499	\$1,529	\$1,560	\$1,591	\$1,623	\$1,655	\$1,689	\$1,722	- preservative free synthetic corticosteroid
<b>Triesence Sales (\$MM)</b>	<b>\$4</b>	<b>\$20</b>	<b>\$30</b>	<b>\$40</b>	<b>\$50</b>	<b>\$60</b>	<b>\$70</b>	<b>\$80</b>	<b>+56%</b>
<b>Triamcinolone Generic Patient Share</b>	<b>43.0%</b>	<b>32.0%</b>	<b>25.0%</b>	<b>15.0%</b>	<b>10.0%</b>	<b>8.0%</b>	<b>7.0%</b>	<b>6.0%</b>	- synthetic corticosteroid triamcinolone
# DME patients treated with Kenalog (MM)	0.07	0.05	0.05	0.05	0.05	0.05	0.04	0.04	- off-label use for DME
Cost per patient/per year (\$)	\$206	\$212	\$219	\$225	\$232	\$239	\$246	\$253	
<b>Kenalog Sales (\$MM)</b>	<b>\$15</b>	<b>\$11</b>	<b>\$11</b>	<b>\$12</b>	<b>\$12</b>	<b>\$11</b>	<b>\$11</b>	<b>\$9</b>	<b>-7%</b>
<b>Other Treatments Patient Share</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>	<b>0.0%</b>	- other synthetic corticosteroids and versions of triamcinolone
# DME patients treated with Other (MM)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
Cost per patient/per year (\$)	\$515	\$530	\$546	\$563	\$580	\$597	\$615	\$633	
<b>Other Sales (\$MM)</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	
<b>Total Estimated DME Market (\$MM)</b>	<b>\$434</b>	<b>\$531</b>	<b>\$628</b>	<b>\$762</b>	<b>\$918</b>	<b>\$1,085</b>	<b>\$1,235</b>	<b>\$1,376</b>	<b>+18%</b>
% Change	+20%	+22%	+18%	+21%	+20%	+18%	+14%	+11%	- New corticosteroids and anti-VEGFs could drive upside

\* Note: Patient share percentages add to more than 100% given broad combination use of treatments  
Source: IMS; Cowen and Company estimates

## ALIM Shares

Iluvien's efficacy profile in DME appears to be slightly superior to that of competitive agents, including triamcinolone injections and Roche's Lucentis. However, Iluvien has the advantage of delivering a very low corticosteroid dose directly to the back of the eye over 24- to 36-months, improving efficacy and compliance, and potentially reducing long-term side effects associated with other DME therapies. That advantage is partially offset by a high cataract formation rate (80%) and elevated intra-ocular pressure (IOP) side effects. Assuming a 15% DME patient share in the U.S. and a 10% patient share in Europe, coupled with Alimera's modest infrastructure requirements, we believe Iluvien can drive rapid profit growth for Alimera in 2012-2016. As visibility rises on Iluvien's FDA approval and launch timing over the next 6-9 months, we believe investors will re-value the Iluvien opportunity. Based on our DCF and sum-of-the-parts valuation analyses, we believe ALIM shares can outperform the market by 30-40% over the next 12 months.

## ILUVIEN DEVELOPMENT MILESTONES

Event	Projected Timing
<b>NDA submission - low-dose Iluvien</b> ✓	<b>Jun-10</b>
<b>Priority review notification (60 days)</b>	<b>Aug-10</b>
<b>Projected regulatory filings in Europe, Canada</b>	<b>Q3:2010</b>
FAME Phase III 36-month data readouts	<b>Q4:2010</b>
Projected build out of Iluvien salesforce	<b>Q4:2010</b>
<b>Possible FDA approval of low-dose Iluvien (assumes 6-month review)</b>	<b>Dec-10</b>
<b>Possible U.S. market launch (assumes 6-month review)</b>	<b>Q1:2011</b>
Iluvien Phase II results in AMD (dry, wet) and RVO	<b>2011</b>
Projected EMEA approval	<b>H1:2012</b>
Projected E.U. market launches (via partner)	<b>H1:2012</b>

Source: Company reports; Cowen and Company

## ILUVIEN BEING TESTED IN OTHER INFLAMMATORY EYE DISEASES

## ILUVIEN - CLINICAL STUDIES SUMMARY

INDICATION	TRIAL	STATUS	EFFICACY OBJECTIVE	PATIENT ENROLLMENT	DATA REPORTED
<b>DME</b>	Phase III FAME A	In Process	36-Month Visual Acuity	n=481 (completed)	12/09, 12/10
<b>DME</b>	Phase III FAME B	In Process	36-Month Visual Acuity	n=475 (completed)	12/09, 12/10
<b>DME</b>	Phase II PK Study	In Process	36-Month FA Plasma Exposure	n=37 (completed)	9/09, 9/10
<b>Dry AMD</b>	Phase II MAP GA	In Process	24-Month Geographic Atrophy Baseline Change	n=40 (targeted)	2011
<b>Wet AMD</b>	Phase II MAP	In Process	6-Month Visual Acuity	n=30 (targeted)	2011
<b>RVO</b>	Phase II FAVOR	In Process	3-Month Visual Acuity	n=20 (targeted)	2011

Source: Company reports; Cowen and Company

**ALIMERA SCIENCES - R&D PIPELINE**

Therapeutic Class/Product	P-C	I	II	III	NDA	MKT	Comments
<b>DME</b>							
Iluvien				•	Q2:10	Q1:11	Sustained-release fluocinolone acetonide non-bioerodible intravitreal implant for the treatment of DME evaluated in 2 registration Phase III studies – FAME; 36-month Phase III readouts expected in H2:10; targeted NDA filing in Q2:10; targeted MAA filing in Q3:10 based on 24-month data
<b>Age-Related Macular Edema</b>							
Iluvien			•				Geographic atrophy associated with dry AMD (MAP GA Phase II currently enrolling); as an adjunctive therapy to Lucentis in wet AMD (MAP Phase II currently enrolling)
NADPH Oxidase Inhibitor Program	•						Geographic atrophy associated with dry AMD
<b>Retinal Vein Occlusion</b>							
Iluvien			•				Phase II FAVOR study in retinal vein occlusion (RVO) currently enrolling
<b>Other Ocular Diseases</b>							
NADPH Oxidase Inhibitor Program	•						Allergic conjunctivitis, wet AMD, and diabetic retinopathy
<b>Total Drugs In Development</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>1</b>			<b>2</b>

Source: Company reports; Cowen and Company

**ALIMERA - VALUATION PERSPECTIVES**

ALIMERA SCIENCES - CURRENT VALUATION PARAMETERS								
ALIMERA Share Price:	\$7.13							
Diluted Shares Outstanding (MM):	34.3							- Includes in-the-money options and employee shares
Equity Market Capitalization (\$MM):	\$244							128% - Post-money valuation
Plus: LT Debt (\$MM)	\$0							0% - \$15MM obligation to pSivida repaid post IPO
Less Cash: (\$MM)	\$53							- Includes net IPO proceeds of \$66.3MM
Total Enterprise Value (\$MM):	\$191							- Net enterprise value (EV)
	<b>2009</b>	<b>2010E</b>	<b>2011E</b>	<b>2012E</b>	<b>2013E</b>	<b>2014E</b>	<b>2015E</b>	<b>2016E Comments</b>
Implied Multiples:								
Estimated Revenues (MM)	\$0.0	\$0.0	\$15.0	\$65.0	\$110.0	\$170.0	\$225.0	\$300.0
Implied EV/Revenue			12.8x	2.9x	1.7x	1.1x	0.9x	0.6x
Estimated EBITDA (MM)	(\$19.2)	(\$25.7)	(\$25.3)	\$8.7	\$35.3	\$78.9	\$112.3	\$159.5
Implied EV/EBITDA				22.0x	5.4x	2.4x	1.7x	1.2x
Estimated Net Income (MM)	(\$29.3)	(\$28.5)	(\$25.0)	\$5.8	\$23.2	\$51.8	\$73.7	\$104.8
Implied Equity Value/Earnings (P/E)				33.1x	8.2x	3.7x	2.6x	1.8x

Source: Company reports, Cowen and Company estimates

ALIMERA - SUM OF THE PARTS VALUATION ANALYSIS (\$MM)								
	<b>2009</b>	<b>2010E</b>	<b>2011E</b>	<b>2012E</b>	<b>2013E</b>	<b>2014E</b>	<b>2015E</b>	<b>2016E Comments</b>
<b>Product Sales (\$MM)</b>								
<b>Iluvien - US Sales</b>	\$0.0	\$0.0	\$15.0	\$60.0	\$100.0	\$150.0	\$200.0	\$265.0 - 24-36 month fluocinolone acetonide implant
Est'd Gross Margin			85.0%	84.0%	83.0%	84.0%	84.0%	83.9% - Net of Psivida profit share (20%)
Est'd Operating Margin				13.4%	32.1%	46.4%	49.9%	53.2% - High margin contribution
Est'd EBIT			(\$25.3)	\$8.0	\$32.1	\$69.6	\$99.8	\$140.9
Terminal Multiple	8.0							- NDA to be filed June 2010; priority review
Discount Rate	25%							- Marketed in US, Canada by Alimera
<b>Present Value</b>	<b>\$364</b>							- Phase II for dry AMD
<b>Per Share Valuation</b>	<b>\$10.61</b>							
<b>Royalties</b>	\$0.0	\$0.0	\$0.0	\$5.0	\$10.0	\$20.0	\$25.0	\$35.0 - Assume 25% average royalty on ex-US sales
Terminal Multiple	10.0							- EMEA filing in Q3:2010
Discount Rate	25%							- Will partner in Europe
<b>Present Value</b>	<b>\$102</b>							
<b>Per Share Valuation</b>	<b>\$2.97</b>							
<b>Pipeline/Other</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0 - early-stage programs/other revenues
Terminal Multiple	6.0							
Discount Rate	35%							
<b>Present Value</b>	<b>\$0</b>							
<b>Per Share Valuation</b>	<b>\$0.00</b>							
<b>TOTAL VALUATION (\$MM)</b>	<b>\$466</b>							
Less: Debt	\$0							- \$15MM obligation to pSivida repaid post IPO
Plus: Cash & Investments	\$53							- Includes net IPO proceeds of \$66.3MM
<b>Net Equity Value</b>	<b>\$519</b>							
<b>Per Share Value</b>	<b>\$15.13</b>							

Source: Company reports, Cowen and Company estimates

## Addendum

### STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name
ALIM	Alimera Sciences

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**Cowen and Company, LLC. New York** (646) 562-1000 **Boston** (617) 946-3700 **San Francisco** (415) 646-7200  
**Chicago** (312) 516-4690 **Cleveland** (440) 331-3531 **Atlanta** (866) 544-7009 **Dallas** (214) 978-0107 **London**  
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Rating	Definition
Outperform (1)	Stock expected to outperform the S&P 500
Neutral (2)	Stock expected to perform in line with the S&P 500
Underperform (3)	Stock expected to underperform the S&P 500

(a) Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period.

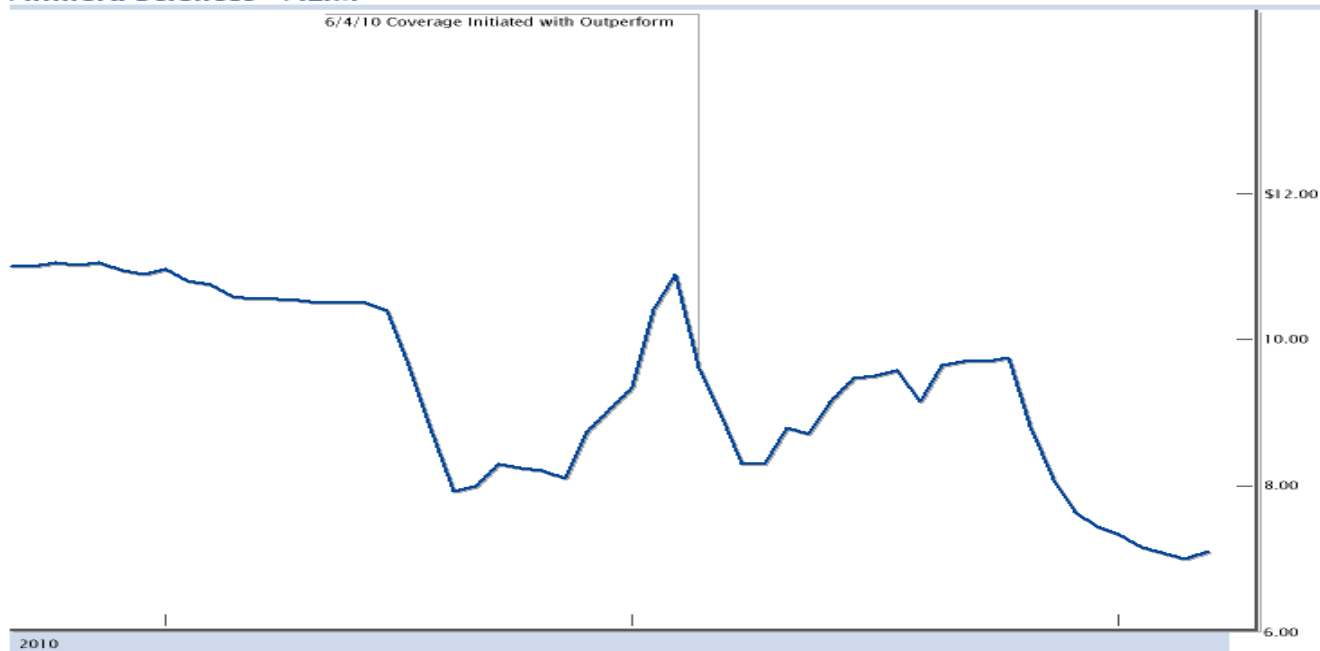
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Rating	Pct of companies under coverage with this rating	Pct for which Investment Banking services have been provided within the past 12 months
Buy (b)	47.8%	3.3%
Hold (c)	48.1%	1.0%
Sell (d)	4.1%	0.0%

(a) As of 06/30/2010. (b) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions (see above). (c) Corresponds to "Neutral" as defined in Cowen and Company, LLC's ratings definitions (see above). (d) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions (see above). Note: "Buy," "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with NASD and NYSE regulations.

Cowen and Company Price and Ratings History

**Alimera Sciences - ALIM**



Pricing data provided by Reuters America. Chart as of 7/7/10 in \$US.