

# THE HEALTHCARE DAILY

MONDAY, DECEMBER 27, 2010

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**Highlights: ALIM**

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## ESTIMATE / TARGET PRICE CHANGES

<b>Alimera Sciences (ALIM)</b>	<b>OUTPERFORM [V]</b>	<b>M. Faerm</b>
<b>CP: US\$ 11.22</b>	<b>TP: US\$ 13</b>	<b>212 538 1771</b>

### Reiterate Outperform Post FDA Response, Revising Estimates and Lowering Target Price to \$13 (from \$16)

- We continue to believe that Iluvien will ultimately be approved and will be a \$500 MM+ revenue drug. FDA's complete response letter (CRL) extends Iluvien's timeline and adds some risk to approval, but is not surprising given the imminence of the 3 year FAME data.
- CRL is as noteworthy for what it didn't say as for what it said. The CRL deferred FDA's decision until analyses of the 36 month FAME data are submitted (expected in 1Q11). However FDA did not request any new studies, nor question the missed statistical significance in trial A of FAME.
- Approval timeline likely pushed back about 9-12 months. ALIM plans to submit its response to the CRL by end 1Q11, after a meeting with FDA (which it has already requested). If FDA deems a Class 2 resubmission, an approval could follow as early as end 3Q11. We assume a 1Q12 launch in our revised estimates to allow for modest delays to this timeline.
- Resolution of manufacturing issues needs further clarification. ALIM has stated that its 2 suppliers with cGMP deficiencies are working to resolve them, but more detail is needed from ALIM on the issues and expected timeline, as ALIM has no readily available backup suppliers. We are assuming that the issues are resolvable in time to allow a 1Q12 launch, but may need to reassess if additional information becomes available.
- Our 2010-2012 EPS estimates are revised. 2010 increases from -\$1.37 to -\$1.17 due to reduced prelaunch marketing expenses. 2011 and 2012 decrease from \$0.27 to -\$0.70 and \$1.53 to \$0.71 due to launch delay.
- We remain buyers of ALIM for the long term, but the stock may remain flat for 1H:2011. Our DCF-based target price is reduced from \$16 to \$13 due to launch delay and some increase to approval risk (our probability estimate is reduced from 75% to 65%).

[\[Full Note\]](#)

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#### Companies Mentioned (Price as of 24 Dec 10)

Alimera Sciences (ALIM, \$11.22, OUTPERFORM [V], TP \$13.00)

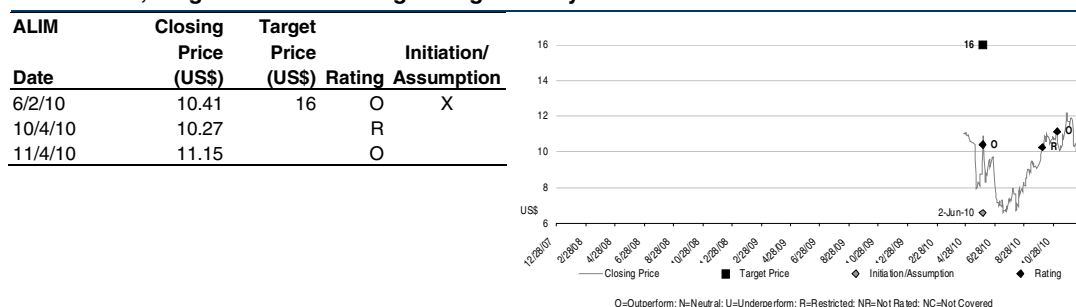
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### 3-Year Price, Target Price and Rating Change History Chart for ALIM



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**Price Target:** (12 months) for (ALIM)

**Method:** Our \$13 target price for ALIM is based on a discounted cash flow analysis (DCF). We have estimated ALIM's future cash flows by forecasting the company's income statement, balance sheet and cash flows through 2020 (the year of patent expiration), and by assuming a fading of cash flows to zero by 2030, with no terminal value. We have used this methodology because we believe that the vast majority of ALIM's value is attributable to a single product, Iluvien, with a finite commercial life. We have applied a 65% probability of success adjustment to our cash flow estimates to account for the risks to approval and launch of the Iluvien. We have used a 12% discount rate for our DCF, applied to the probability-adjusted cash flows. Our ALIM revenue forecast is based on our estimates for the addressable patient population in diabetic macular edema, and our assumption that Iluvien will achieve a peak penetration rate of 15%.

**Risks:** Risks to our \$13 target price include: (1) single product risk (ALIM's value is virtually entirely attributable to Iluvien, and the company's near to medium term revenues, profits and value depend on the FDA's approval and Alimera's successful commercialization of Iluvien in diabetic macular edema. There is little visibility on additional indications for Iluvien or on the new product pipeline; (2) regulatory risk to timely Iluvien approval, due to missed statistical significance on the MART data set, the possibility that the FDA may wait for 3 year FAME data before issuing an approval decision, and the the possibility that FDA may not grant priority review; (3) commercial risk, due to the presence of several established treatments for DME and competing companies that are better-capitalized and have a longer-standing presence in the ophthalmology community than ALIM; (4) liquidity and financing risk, due to the potential need for ALIM to raise additional funds, particularly if Iluvien approval is delayed beyond the expected December 2010; and (5) reimbursement risk, as securing reimbursement from payors is crucial to Iluvien's success and the fact that Iluvien will compete against some relatively inexpensive products.

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