# Alnylam Pharmaceuticals

## R&D Day Highlights Impressive Pipeline Progress; Raising PT to $55

**Overweight**

**ALNY, ALNY US**
Price: $43.53

▲ **Price Target: $55.00**
Previous: $28.00

Yesterday, we attended Alnylam's R&D day, where the 5X15 program was reviewed in detail. Overall, we are very encouraged with the progress with the 5X15 program, particularly the lead ATTR program (see details below). Indeed, in conjunction with the R&D day, Alnylam announced positive data from the phase 1 healthy volunteer study of ALN-TTRsc, which showed >80% TTR knockdown (p<0.01). Given that TTR knockdown is predictive of clinical benefit in ATTR, we are now including ALN-TTRsc in our model (WW peak opportunity could exceed $2B). Looking forward, there will be plenty of data flow and progress with the 5X15 programs over the next 12-24 months. As such, we are reiterating our Overweight rating on ALNY shares. We are establishing a Dec 2014 price target of $55 (prior Dec 2013 price target of $28).

- **TTR02 in ATTR Familial Amyloidotic Polyneuropathy (FAP):** Alnylam reviewed known data related to TTR02, including recently presented multi-dose data, which showed sustained ~80-90% TTR knockdown over 2 doses (regardless of wild-type vs. mutant form of the disease) with a dose response. Final phase 2 results will be presented at the FAP Symposium (11/10-11-13; Brazil). Importantly, a phase 3 study is on track to start by YE13 (no change to timelines). Interestingly, the company noted that the final study duration is still being discussed with regulators but is likely to be only 12-18 months. From a competitive standpoint, while approved in the EU, Dr. Philip Hawkins (University College, London) indicated that the evidence for Vyndaqel (tafamidis) was "border line" and is not currently being reimbursed in the UK, showing the need for more effective therapies.

- **ALN-TTRsc in ATTR Familiar Amyloidotic Cardiomyopathy (FAC):** Earlier today, Alnylam announced phase 1 results that showed a statistically significant knockdown in TTR with ALN-TTRsc in healthy volunteers, with >80% knockdown (p<0.01). There were no major safety concerns. Full results will be presented at the Heart Failure Society meeting (9/22-9/25; Orlando). A phase 2 trial is expected to start by YE13, with a pivotal trial in 2014 (no change in timelines). Dr. Hawkins highlighted that FAC patients suffer from progressive heart failure, which can lead to death in <5 years. Additionally, FAC treatment is largely limited to supportive care.

**Biotechnology**

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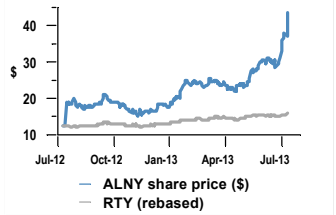
**Price Performance**




| | YTD | 1m | 3m | 12m |
|---|---|---|---|---|
| Abs | 138.5 % | 42.3% | 88.0% | 253.9 % |
| Rel | 120.2 % | 37.0% | 78.9% | 223.5 % |

**Alnylam Pharmaceuticals (ALNY;ALNY US)**

| FYE Dec | 2011A | 2012A | 2013E | 2014E (Prev) | 2014E (Curr) | 2015E (Prev) | 2015E (Curr) |
|---|---|---|---|---|---|---|---|
| EPS Reported ($) | | | | | | | |
| Q1 (Mar) | (0.38) | (0.25) | (0.15)A | - | - | - | - |
| Q2 (Jun) | (0.33) | (0.25) | (0.31) | - | - | - | - |
| Q3 (Sep) | (0.31) | (0.38) | (0.32) | - | - | - | - |
| Q4 (Dec) | (0.33) | (1.20) | (0.32) | - | - | - | - |
| FY | (1.36) | (2.11) | (1.11) | (1.72) | (1.79) | (1.84) | (1.98) |

Source: Company data, Bloomberg, J.P. Morgan estimates.

| Company Data | |
|---|---|
| Price ($) | 43.53 |
| Date Of Price | 11 Jul 13 |
| 52-week Range ($) | 44.65-11.78 |
| Market Cap ($ mn) | 2,575.51 |
| Fiscal Year End | Dec |
| Shares O/S (mn) | 59 |
| Price Target ($) | 55.00 |
| Price Target End Date | 31-Dec-14 |

**See page 5 for analyst certification and important disclosures.**

- **ALN-AT3 for hemophilia:** Alnylam reviewed preclinical data and outlined the clinical development plans for ALN-AT3. After single- and multi-dose trials (similar to the ATTR program; phase 1 trial to start by YE13—no change in timelines), pivotal trials could be run in severe hemophilia A patients, hemophilia A/B inhibitor patients, and patients with rare bleeding disorders. ALN-AT3 is not currently included in our model. Interestingly, Dr. Craig Kessler (Georgetown) noted that while there are additional therapies coming into the market in the near future, there will still be an unmet need in hemophilia (for example, in patients that develop inhibitors, ~35% patients; associated with increased costs, as well as risks of complications and death).

- **ALN-AS1 in Acute Intermittent Porphyria (AIP):** Alnylam noted that a lead drug candidate would be selected by YE13 with an IND planned for 2014 (no change in timelines). A phase 1 study will assess ALN-AS1 in "high excretor" AIP patients (~n=20 patients), and a phase 2/3 study will be run in AIP patients with recurrent attacks, with the goal of reducing frequency and severity of attacks. Dr. Robert Desnick (Mount Sinai) highlighted a major unmet need in AIP, with the need for overall better therapies with a more suitable safety profile, faster onset of action, and one that is effective for prophylaxis. Interestingly, our sense is that the Porphyrias Consortium (top 6 key opinion leaders in the space) should help with recruitment in early studies of ALN-AS1.

- **Additional 5X15 programs:** ALN-PSC (hypercholesterolemia)—Alnylam highlighted pre-clinical data showing PSCK9 knockdown and LDL-C lowering with a subcutaneous formulation. ALN-CC5 (complement mediated diseases)—A development candidate will be selected by late 2013 (no change in timelines).

- **Adding ALN-TTRsc to our model:** We use a prevalence estimate of ~40K for the FAC population subset and conservatively assume orphan pricing of ~$150K. Our baseline assumption is a late 2016 launch, and we estimate peak WW sales could exceed $2 billion (estimate ~$25 in share value).

- **Adjusting estimates:** We have taken up R&D a bit in the out-years given progress with the 5X15 programs. Additionally, as mentioned before, we now include ALN-TTRsc, though there is no revenue impact until 2016 with a more meaningful contribution in 2017. Based on these and other minor changes, our 2014-2015 GAAP EPS estimates change to -$1.79 and -$1.98, respectively, from -$1.72 and -$1.84.

- **Reiterate Overweight rating.** We are establishing a Dec 2014 price target of $55 versus a Dec 2013 price target of $28 previously.

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## Changes to Our Model

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**Table 1: Changes to Our Model - ALNY**

| | 2013E OLD | 2013E NEW | 2014E OLD | 2014E NEW | 2015E OLD | 2015E NEW |
|---|---|---|---|---|---|---|
| Total Revenue | 45.6 | 45.6 | 35.0 | 35.0 | 44.7 | 40.9 |
| R&D | 89.6 | 89.6 | 98.6 | 103.1 | 106.5 | 113.4 |
| SG&A | 25.8 | 25.8 | 46.5 | 46.5 | 58.1 | 58.1 |
| Total Op Ex | 115.4 | 115.4 | 145.1 | 149.5 | 169.9 | 176.4 |
| Net income | -67.8 | -67.8 | -109.1 | -113.5 | -123.3 | -133.5 |
| **GAAP EPS ($)** | **-1.11** | **-1.11** | **-1.72** | **-1.79** | **-1.84** | **-1.98** |
| Shares | 61.3 | 61.3 | 63.5 | 63.5 | 67.0 | 67.0 |

Source: J.P. Morgan estimates.

## Investment Thesis

Alnylam is an early stage biotech company that focuses on development of therapeutics based on RNA interference (RNAi). The core strategy for the company is called the "Alnylam 5X15," program. The lead program, ALN-ATTR, has been de-risked in both the FAP (TTR02) and FAC (ALN-TTRsc) subset populations. We estimate a peak market potential of ~$3B for the ATTR program. Additionally, other pre-clinical programs have strong scientific rationale and should be entering the clinical in the next 6-18 months. Overall, we view the company's technology platform as de-risked.

## Valuation

We are establishing a December 2014 price target of $55 (prior December 2013 price target of $28). Our December 2013 PT of $55 is based on an SOTP analysis of WW TTR02 sales in FAP, ALN-TTRsc in FAC, net cash, and attributed value for the company's technology platform. We assume an 8% discount rate and a 70% and 55% probability of success for TTR02 and ALN-TTRsc, respectively. Taken together, the value of TTR02 (~$15/share), ALN-TTRsc (~$25/share), net cash (~$5/share), and technology value ($10/value) results in our $55/share December 2014 target price.

## Risks to Rating and Price Target

Risks to our Overweight rating and price target include: (1) Clinical trials are difficult to predict, especially in orphan disorders where trial design is disease specific. Lead program ALN-ATTR, fails to demonstrate encouraging results in clinical trials. Outside of ALN-ATTR and ALN-PSC, most other programs in the "Alnylam 5X15" are preclinical and have not been de-risked with early-stage clinical results. (2) Even if Alnylam is able to get positive results for its therapeutics, there is no guarantee that regulators will approve a drug. (3) Commercial risk / pricing and reimbursement.

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# Alnylam Pharmaceuticals: Summary of Financials

| Income Statement - Annual | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|
| Revenues | 67 | 46 | 35 | 42 |
| Cost of products sold | 0 | 0 | 0 | (5) |
| Gross profit | 67 | 46 | 35 | 37 |
| SG&A | (45) | (26) | (46) | (58) |
| R&D | (87) | (90) | (103) | (113) |
| Operating income | (129) | (70) | (115) | (135) |
| EBITDA | (129) | (70) | (115) | (135) |
| Net interest (income) / expense | 1 | 1 | 1 | 2 |
| Other income / (expense) | - | - | - | - |
| Income taxes | 11 | 1 | 0 | 0 |
| Net income - GAAP | (106) | (68) | (114) | (133) |
| Net income - recurring | (106) | (68) | (114) | (133) |
| Diluted shares outstanding | 50 | 61 | 63 | 67 |
| EPS - excluding non-recurring | (2.11) | (1.11) | (1.79) | (1.98) |
| EPS - recurring | (2.11) | (1.11) | (1.79) | (1.98) |

| Income Statement - Quarterly | 1Q13A | 2Q13E | 3Q13E | 4Q13E |
|---|---|---|---|---|
| Revenues | 19A | 9 | 9 | 9 |
| Cost of products sold | 0A | 0 | 0 | 0 |
| Gross profit | 19A | 9 | 9 | 9 |
| SG&A | (6)A | (6) | (7) | (7) |
| R&D | (22)A | (22) | (23) | (23) |
| Operating income | (10)A | (20) | (20) | (20) |
| EBITDA | (10)A | (20) | (20) | (20) |
| Net interest (income) / expense | 0A | 0 | 0 | 0 |
| Other income / (expense) | - | - | - | - |
| Income taxes | 1A | 0 | 0 | 0 |
| Net income - GAAP | (9)A | (19) | (20) | (20) |
| Net income - recurring | (9)A | (19) | (20) | (20) |
| Diluted shares outstanding | 59A | 62 | 62 | 62 |
| EPS - excluding non-recurring | (0.15)A | (0.31) | (0.32) | (0.32) |
| EPS - recurring | (0.15)A | (0.31) | (0.32) | (0.32) |

| Balance Sheet and Cash Flow Data | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|
| Cash and cash equivalents | 43 | 6 | 23 | 34 |
| Accounts receivable | 1 | 1 | 1 | 1 |
| Inventories | - | - | - | - |
| Other current assets | 4 | 4 | 4 | 4 |
| Current assets | 105 | 37 | 55 | 66 |
| PP&E | 14 | 14 | 13 | 13 |
| Total assets | 119 | 51 | 68 | 79 |
| | | | | |
| Total debt | - | - | - | - |
| Total liabilities | 81 | 81 | 81 | 81 |
| Shareholders' equity | 38 | (30) | (13) | (2) |
| | | | | |
| Net income (including charges) | (106) | (68) | (114) | (133) |
| D&A | 5 | 5 | 6 | 6 |
| Change in working capital | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 |
| Cash flow from operations | (101) | (62) | (108) | (127) |
| | | | | |
| Capex | (5) | (5) | (5) | (5) |
| Free cash flow | (106) | (67) | (113) | (132) |
| Cash flow from investing activities | 15 | 25 | 25 | 25 |
| Cash flow from financing activities | 59 | 0 | 100 | 114 |
| Dividends | - | - | - | - |
| Dividend yield | - | - | - | - |

| Ratio Analysis | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|
| Sales growth | (19.4%) | (31.6%) | (23.3%) | 18.6% |
| EBIT growth | 136.2% | (46.1%) | 64.1% | 17.8% |
| EPS growth - recurring | 55.8% | (47.6%) | 61.6% | 11.0% |
| | | | | |
| Gross margin | 100.0% | 100.0% | 100.0% | 88.0% |
| EBIT margin | (194.2%) | (152.9%) | (327.2%) | (324.9%) |
| EBITDA margin | (194.2%) | (152.9%) | (327.2%) | (324.9%) |
| Tax rate | (9.1%) | (0.8%) | 0.0% | 0.0% |
| Net margin | (159.1%) | (148.6%) | (324.4%) | (320.1%) |
| | | | | |
| Net Debt / EBITDA | - | - | - | - |
| Net Debt / Capital (book) | - | - | - | - |
| | | | | |
| Return on assets (ROA) | (52.9%) | (79.5%) | (190.5%) | (181.2%) |
| Return on equity (ROE) | (135.8%) | (1582.5%) | 530.8% | 1737.2% |
| | | | | |
| Enterprise value / sales | 32.7 | 48.6 | 62.9 | 52.8 |
| Enterprise value / EBITDA | NM | NM | NM | NM |
| Free cash flow yield | (4.8%) | (2.5%) | (4.1%) | (4.5%) |

Source: Company reports and J.P. Morgan estimates.
Note: $ in millions (except per-share data).Fiscal year ends Dec

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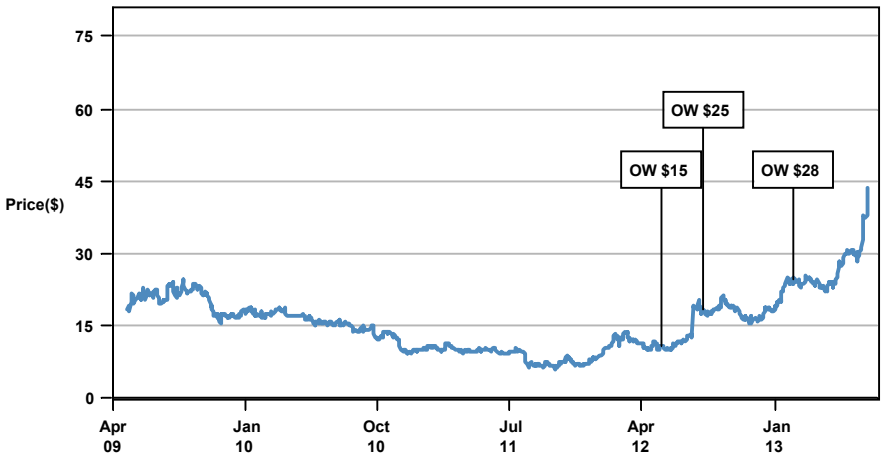
**Alnylam Pharmaceuticals (ALNY, ALNY US) Price Chart**




| Date | Rating | Share Price ($) | Price Target ($) |
|---|---|---|---|
| 08-May-12 | OW | 10.61 | 15.00 |
| 06-Aug-12 | OW | 18.44 | 25.00 |
| 07-Feb-13 | OW | 24.40 | 28.00 |

**Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.**
**Initiated coverage May 08, 2012.**

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|---|---|---|---|
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