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bluebird bio (BLUE - OUTPERFORM): First Patient Enrolled in CCALD Study, Reiterate OUTPERFORM

Price: \$22.95

12-Month Price Target: \$40

- Bluebird bio announced that the first patient in its pivotal “Starbeam” (ALD-102) study of Lenti-D to treat childhood cerebral adrenoleukodystrophy (CCALD) had been treated with an autologous hematopoietic stem cell transplanted modified with the gene therapy product candidate Lenti-D. Recall that the Starbeam trial is designed to be a pivotal, open-label study of Lenti-D, bluebird’s gene therapy, in 15 CCALD patients, with a primary endpoint of disease progression over 2 years.
- While there will not be interim safety or efficacy updates, we note that if something negative were to happen, it would likely require an announcement, so going forward a “no news is good news” status will be in effect. It takes roughly 1 month for stem cells to engraft, and we would look at no news in the next 4-8 weeks as a net positive, meaning the transplant has at least engrafted in the patient.
- Recall that 4 boys had been treated with a prior generation Lenti-D – like gene therapy. Three of the four boys stabilized between 16 and 30 months. One of the boys experienced worsening disease before stabilization. Lenti-D is an improved version of that vector, and we would expect at least similar, if not better efficacy in the final analysis.
- We estimate Lenti-D approval by 2017, with rapid adoption leading to \$116M in estimated revenues. Our pricing of \$1.5M per treatment is in line with Glybera, the only other approved gene therapy in the world, and, in our view, reasonable, given the potential curative, life-saving nature of the Lenti-D treatment.
- Bluebird’s second product candidate, LENTIGLOBIN, should begin enrolling patients in its Phase I/II studies for β -thalassemia and sickle cell disease (SCD), inherited hemoglobin mutations by YE:13/H1:14 (the trial is currently open for recruiting).
- Reiterate OUTPERFORM rating and \$40 price target. Our price target of \$40 is derived from applying an 8X multiple to estimated 2020 revenues of \$1.36B for LENTI-D and LENTIGLOBIN products, discounted 35% annually. We do not include CAR-T (chimeric antigen receptor T-cells, partnered with Celgene-Not Covered) in our valuation.
- Risks to the achievement of our price target include failure to gain approval for products in development, failure to achieve sales estimates for any marketed product and failure to achieve earnings estimates.

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Company	Disclosure
bluebird bio	1,3,5

Research Disclosure Legend

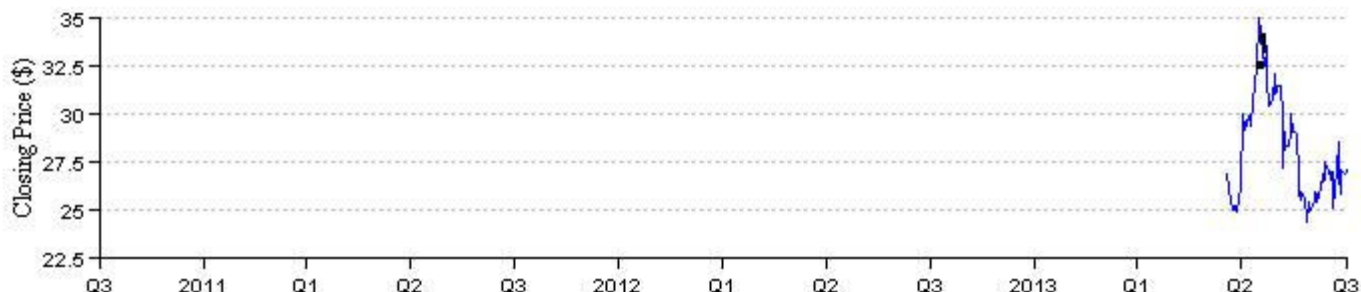
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BLUE

1) 07/15/13
OUTPERFORM \$40



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