bluebird bio

Previewing Initial Look at LentiGlobin Gene Therapy Data in Beta-Thalassemia at EHA This Weekend

Overweight

BLUE, BLUE US
Price: $25.27

Price Target: $44.00

We are reiterating our OW on BLUE ahead of initial data from the Phase 1/2 HGB-205 study evaluating LentiGlobin in beta-thalassemia patients that will be presented this Sat June 14 at the European Hematology Association (EHA) Congress in Milan, Italy. A prior trial (LG001) demonstrated proof of concept (one patient achieved transfusion independence ~12 mos post-infusion), but other pts did not have as much success. As such, BLUE switched to a new vector that has higher transduction efficiency and expression of ß-globin protein in target cells. In the abstract for EHA released last month, this new vector showed vector copy numbers that were ~2.5-3.5x higher vs. the best performing pt using the old vector. On Sat at EHA, we expect results to show increases in Hb levels in the 2 pts with sufficient follow-up on the new vector. Specifically, we will be looking for a larger amount of βA-T87Q-globin vs. pts in the prior trial at comparable time points, and for a steeper rise in the increase of βA-T87Q-globin. Importantly, it is likely to be too soon to expect transfusion independence with only ~6 mos of follow-up. Overall, we continue to view BLUE as a potentially transformative and disruptive company and recommend owning shares in front of upcoming clinical trial updates.

- **What did we learn from the abstract?** Last month's EHA abstract included prelim data from the Ph1/2 HGB-205 study of LentiGlobin for B-thal that had promising potential read-through to clinical benefit. The first 2 patients enrolled (#1201 and #1202) showed vector copy numbers (VCNs) of 1.52 and 2.12, respectively. For context, this is ~2.5-3.5x higher using BLUE's new optimized vector (BB305) vs. the best performing pt (#1003 who has remained transfusion independent for 5+ years and counting, with a VCN of 0.61 after treatment) using the old vector (HPV569) in the prior study (the LG001 trial). Additionally, pt #1004 from the prior LG001 trial showed a VCN of 0.31 (with the old vector), and while she remains transfusion dependent, βA-T87Q-globin accounts for ~5% of total Hb 2 years post-treatment. In addition, the new vector also showed a faster time to neutrophil engraftment vs. the prior vector (14 days vs. 20-29 days).
- **What to expect from the EHA data presentation on Saturday.** On Saturday, June 14 (at 16:15 CEST, 10:15am ET), we will get an update on the transplant outcomes in these same 2 patients (patients #1201 and #1202) from the HGB-205 study with up to 6 months of follow-up (first patient was transplanted in early December and the second in early 2014; with data cutoff for EHA sometime likely in the last couple of weeks). The key question post the abstract is whether the higher VCN with the new BB305 vector translates into clinical benefit in patients.

Biotechnology

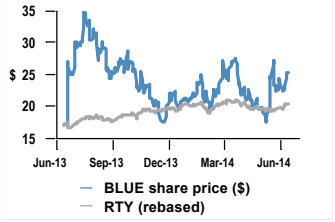
Cory Kasimov AC
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com
Bloomberg JPMA KASIMOV <GO>

Matthew J. Lowe, Ph.D.
(1-212) 622-0848
matthew.j.lowe@jpmorgan.com

Whitney G Ijem
(1-212) 622-4668
whitney.g.ijem@jpmorgan.com

Brittany Terner
(1-212) 622-8527
brittany.terner@jpmorgan.com
J.P. Morgan Securities LLC

Price Performance



	YTD	1m	3m	12m
Abs	20.4%	29.3%	-6.2%	48.6%
Rel	20.1%	23.9%	-4.5%	28.6%

bluebird bio, Inc. (BLUE;BLUE US)

FYE Dec	2013A	2014E
EPS reported ($)		
Q1 (Mar)	-	(0.44)A
Q2 (Jun)	(2.13)	(0.46)
Q3 (Sep)	(0.26)	(0.46)
Q4 (Dec)	(0.33)	(0.45)
FY	(2.02)	(1.80)
Bloomberg EPS FY ($)	-1.66	-1.79

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

Company Data	
Price ($)	25.27
Date Of Price	12 Jun 14
52-week Range ($)	36.25-17.00
Market Cap ($ mn)	611.53
Fiscal Year End	Dec
Shares O/S (mn)	24
Price Target ($)	44.00
Price Target End Date	31-Dec-14

See page 7 for analyst certification and important disclosures.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

- **We would be encouraged if the data showed increases in "marked" Hb levels.** We note that it is likely too soon to expect transfusion independence with only 6 months of follow-up. Recall it was ~12 months post infusion before pt #1003 in the prior LG001 trial became transfusion independent. *Specifically, at EHA we will be looking for a larger amount (g/dL) of "marked" Hb (βA-T87Q-globin) to show up in pts #1201 and #1202 vs. pt #1003 from the LG001 trial at comparable time points, and for a steeper rise in the increase of "marked" Hb.* βA-T87Q-globin is Hb coming from the integrated transgene (basically a direct result of the gene therapy). For reference, the Hb component concentrations for pt #1003 ("marked" Hb = βA-T87Q = the red bar) can be seen in Figure 1. Production of βA-T87Q-globin is expected to appear sooner in pts #1201 and #1202 vs. pt #1003 (when it took ~4 months after LentiGlobin treatment) as the assay used now is more sensitive to detection of βA-T87Q-globin in blood vs. the assay used in the LG001 trial (so this is not an apples-to-apples comparison). More production of βA-T87Q-globin should in turn mean less requirement for transfused blood (and maybe also a lower frequency of transfusions), which can be seen, in a way, as a partial response (patient is being weaned off transfusions) and that the patient is potentially on his/her way to achieving transfusion independence, which is the ultimate goal.

- **Expecting follow-up data from the prior LG001 trial at EHA but not anticipating much change.** At the EHA presentation on Saturday, we will also see longer term follow-up data for pt #1003 (who achieved transfusion independence ~12 months post-infusion) and pt #1004 (who did not fare as well) from the prior LG001 trial. However, expectations are for no major changes from the data in the abstract for these 2 patients.

- **These are obviously very small patient numbers, which represents a risk when trying to compare updates from the HGB-205 and LG001 studies.** Sample size needs to be kept in perspective. At EHA, we will get updated transfusion data from just 2 patients (patients #1201 and #1202) using the new vector (BB305), and this data will be compared to data also from just 2 patients (patients #1003 and #1004) using the old vector (HPV569). Given there is bound to be some patient-patient variability, the risk with these kinds of data update is the variability inherent between different patients' responses.

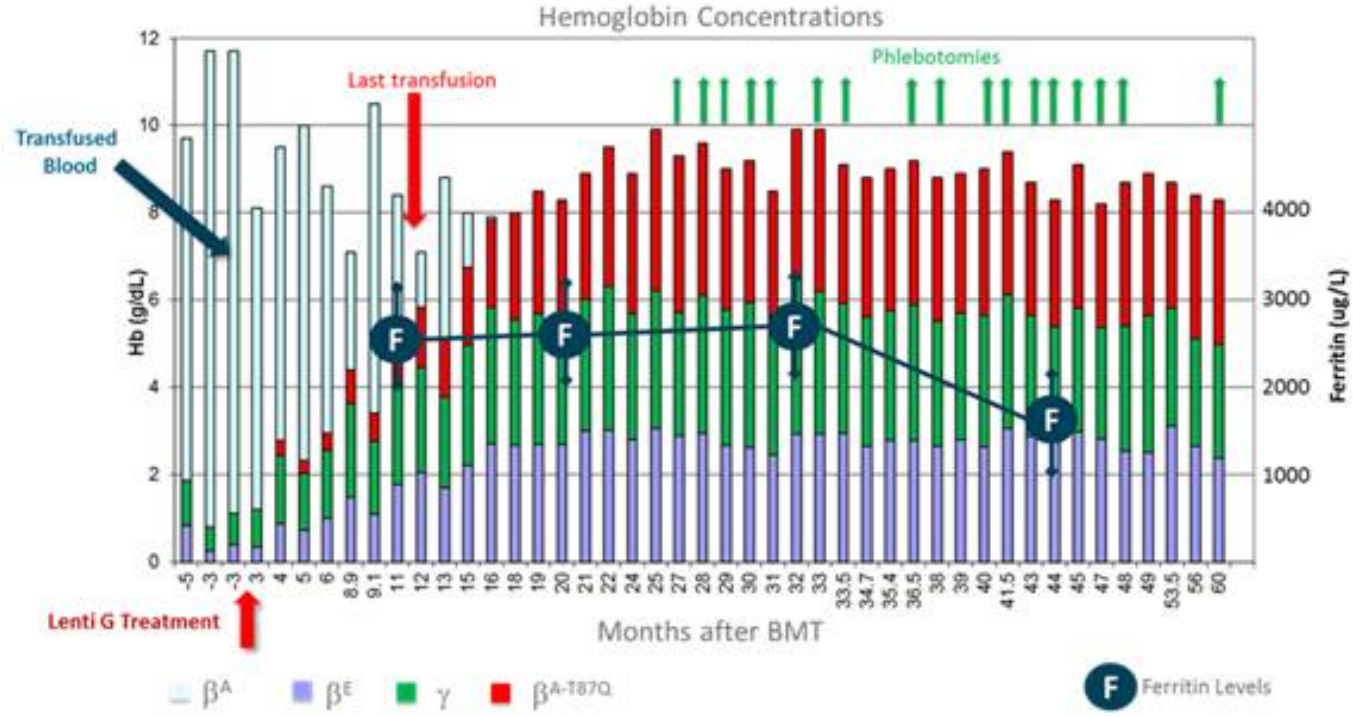
- **Safety is another risk but one that's been successfully navigated thus far.** Importantly, there have not been adverse safety events during the multi-year span of the CCALD program with Lenti-D (BLUE's other gene therapy program) or the beta-thalassemia program to date. In addition, the EHA abstract stated that neither pt #1003 or #1004 (from the LG001 trial) had experienced a cell infusion related adverse event, and no evidence has emerged to date of transplant rejection commonly associated with allogeneic stem cell transplant. We also believe bluebird's *ex vivo* (outside the body) approach to gene therapy provides added safety margins. As such, we are not expecting any adverse safety finding at the EHA presentation on Saturday. While the risk of insertional oncogenesis remains a concern for gene therapy, preclinical work on the new LentiGlobin BB305 vector has shown that it appears to also cause increased production of a protein associated with benign tumors.

- **How will the data be announced on Saturday?** For those not attending EHA in person, BLUE will press release the data on Saturday at the time of the presentation (16:15 Milan time; 10:15am EST), but the slides presented at the conference may not be able to be released until BLUE's conference call on Monday morning.

- **Why has BLUE switched to using the new vector (BB305) from the old vector (HPV569)?** 4 patients were enrolled in the prior LG001 study, although only 3 patients were treated and successfully transplanted with the HPV569 drug product (1 patient was ineligible due to pre-transplant complications). Only 2/3 patients that were successfully transplanted achieved successful engraftment, and 1 of those patients became transfusion independent ~1 year after treatment (producing >1/3rd of his Hb from the gene therapy treatment, see figure 1, and while the patient is still mildly anemic, his condition is no longer life-threatening). The achievement of transfusion independence in pt #1003 appears to be a direct benefit of that patient being treated with the HPV569 drug product, as there do not appear to be any reported cases of spontaneous transfusion independence in patients with beta-thalassemia in the literature. However, while pt #1004 is stable, she is still transfusion dependent, with BLUE indicating that the patient is transducing at a lower level than it would have hoped for. With this patient not responding so well to LentiGlobin treatment, BLUE decided to switch to a modified βA-T87Q vector (BB305) based on higher transduction efficiency and expression of ß-globin protein in target cells vs. the HPV569 vector, and a similar preclinical safety profile. BLUE believes that the problems experienced in pt #1004 can be overcome by using its next-generation vector. We have already seen the improvements introduced into the vector manufacturing process translate to a higher VCN (from the EHA abstract data), and now we are expecting this to translate into greater clinical efficacy and an improved clinical benefit by virtue of a higher level of production of normally functioning Hb (expected at EHA on Saturday), and ultimately a higher probability of achieving transfusion independence.

- **Upcoming events.** Beyond clinical data from the ongoing Phase 1/2 HGB-205 Study of LentiGlobin for the treatment of beta-thalassemia major being presented at the EHA Congress in Milan, Italy on June 14, BLUE also expects to present additional Phase 1/2 data for LentiGlobin in beta-thalassemia (from the HGB-205 and Northstar studies) in late 2014 (we assume at ASH). Finally, BLUE now has an active IND for LentiGlobin in the US for sickle cell disease (SCD); the US trial will be called HGB-206, and the company expects to transplant the first SCD patient with LentiGlobin in 2014 (in the HGB-205 or HGB-206 studies).

Figure 1: Conversion of pt #1003 in the LG001 Trial to Transfusion Independence Following Treatment with LentiGlobin



Source: Cavazzana-Calvo et al., 2010 – Leboulch Nature.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

Investment Thesis, Valuation and Risks

bluebird bio *(Overweight; Price Target: $44.00)*

Investment Thesis

We have an OW rating on BLUE. In our view, BLUE, with its gene therapy platform, is one of the more potentially transformative and disruptive companies we've come across in some time. Importantly, BLUE has already established promising proof of concept for its two lead products, Lenti-D and LentiGLobin, and it is going after orphan indications (such as CCALD and beta-thalassemia) with a very high unmet medical need that could bolster the ultimate probability of success.

Valuation

We have a Dec 2014 price target of $44 for BLUE. Our valuation methodology is based on a blended average of our risk-adjusted NPV model (33%), our proprietary scenario analysis (33%), and a DCF analysis (33%) and reflects a 50% probability of success for Lenti-D (~$250M in peak sales) and 25% for LentiGlobin (~$1B peak). We assign each valuation method a 15% discount rate, which we believe is appropriate given the probability-adjustments made to each development program.

BLUE Valuation Summary

BlueBird Bio : Valuation Summary

Discount rate	15%		
Main value driver	**Prob of approval**	**Peak sales est (avg. scenario)**	**Avg peak yr**
CCALD	50%	$ 260	2022
B-Thalassemia	25%	$ 1,204	2023
Sickle Cell Disease	0%	$ -	-
Valuation methodology	Value	Weighting	Adj. value/ share
P/E 2015	$ -	0%	$ -
Real options scenario analysis	$ 43.14	33%	14.4
Risk adjusted NPV analysis	$ 34.33	33%	11.4
DCF analysis	$ 53.87	33%	18.0
Total			$ 43.78
Catalyst/liquidity discount			0%
YE14 Valuation			**$ 44**

Source: J.P. Morgan estimates.

Risks to Rating and Price Target

Downside risks to our OW recommendation include the standard issues that apply to the entire biotechnology industry, including development, regulatory, commercial, manufacturing, financing, and IP pitfalls. Other risks specific to BLUE include clinical trial risk with ongoing studies involving Lenti-D or LentiGlobin, regulatory uncertainty surrounding gene therapy, the company's ability to deliver gene therapies on a commercially viable scale, and competition within the gene therapy field.

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

J.P.Morgan

bluebird bio: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E
Revenues	20	25	25	-
Cost of products sold	0	0	0	-
Gross profit	-	-	-	-
SG&A	(14)	(23)	(26)	-
R&D	(31)	(48)	(51)	-
Operating income	(25)	(45)	(51)	-
EBITDA	(25)	(45)	(51)	-
Net interest (income) / expense	0	0	2	-
Other income / (expense)	(0)	0	0	-
Income taxes	0	0	0	-
Net income - GAAP	(25)	(45)	(49)	-
Net income - recurring	(25)	(45)	(49)	-
Diluted shares outstanding	13	25	26	-
EPS - excluding non-recurring	(2.02)	(1.80)	(1.88)	-
EPS - recurring	(2.02)	(1.80)	(1.88)	-

Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	238	207	170	-
Accounts receivable	0	0	0	-
Inventories	-	-	-	-
Other current assets	0	0	0	-
Current assets	238	207	170	-
PP&E	0	0	0	-
Total assets	238	232	233	-
Total debt	0	0	0	-
Total liabilities	77	62	54	-
Shareholders' equity	161	170	178	-
Net income (including charges)	(25)	(45)	(49)	-
D&A	6	8	8	-
Change in working capital	69	0	0	-
Other	7	0	0	-
Cash flow from operations	63	(31)	(36)	-
Capex	0	0	0	-
Free cash flow	63	(31)	(36)	-
Cash flow from investing activities	0	0	0	-
Cash flow from financing activities	108	0	0	-
Dividends	-	-	-	-
Dividend yield	-	-	-	-

Income Statement - Quarterly	1Q14A	2Q14E	3Q14E	4Q14E
Revenues	6A	6	6	6
Cost of products sold	0A	0	0	0
Gross profit	-	-	-	-
SG&A	(6)A	(6)	(6)	(6)
R&D	(11)A	(12)	(12)	(12)
Operating income	(11)A	(11)	(11)	(12)
EBITDA	(11)A	(11)	(11)	(12)
Net interest (income) / expense	0A	0	0	0
Other income / (expense)	0A	0	0	0
Income taxes	0A	0	0	0
Net income - GAAP	(11)A	(11)	(11)	(11)
Net income - recurring	(11)A	(11)	(11)	(11)
Diluted shares outstanding	24A	25	25	25
EPS - excluding non-recurring	(0.44)A	(0.46)	(0.46)	(0.45)
EPS - recurring	(0.44)A	(0.46)	(0.46)	(0.45)

Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Sales growth	5835.6%	25.6%	0.0%	-
EBIT growth	5.2%	80.2%	14.4%	-
EPS growth - recurring	-	(10.6%)	4.1%	-
Gross margin	-	-	-	-
EBIT margin	(123.6%)	(177.4%)	(203.0%)	-
EBITDA margin	(123.6%)	(177.4%)	(203.0%)	-
Tax rate	0.0%	0.0%	0.0%	-
Net margin	(125.5%)	(176.2%)	(195.2%)	-
Net Debt / EBITDA	953.6%	459.7%	331.4%	-
Net Debt / Capital (book)	307.8%	561.2%	(2128.9%)	-
Return on assets (ROA)	(16.5%)	(19.0%)	(21.3%)	-
Return on equity (ROE)	(22.5%)	(27.0%)	(28.4%)	-
Enterprise value / sales	11.5	10.4	11.8	-
Enterprise value / EBITDA	NM	NM	NM	-
Free cash flow yield	19.8%	(5.0%)	(5.4%)	-

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

Cory Kasimov
(1-212) 622-5266
cory.w.kasimov@jpmorgan.com

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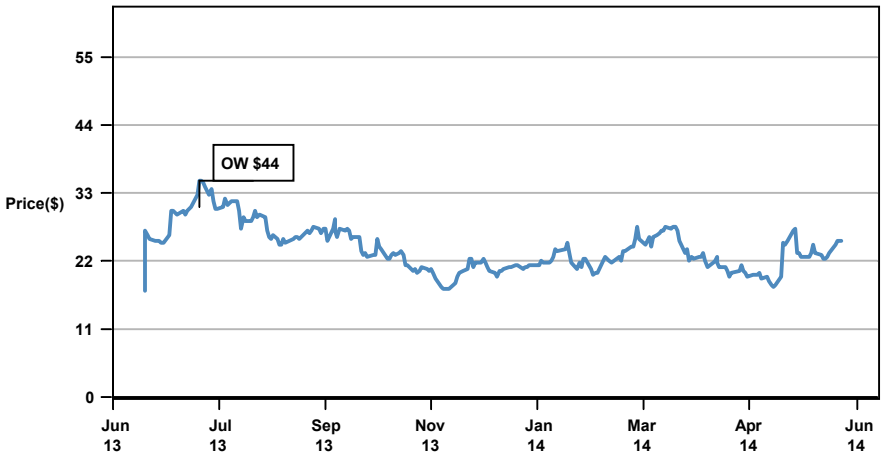
bluebird bio (BLUE, BLUE US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
15-Jul-13	OW	30.65	44.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Jul 15, 2013.

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IB clients*	58%	49%	40%
JPMS Equity Research Coverage	45%	48%	7%
IB clients*	78%	67%	60%

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