

bluebird bio

Notes from the Road

Following bluebird's rather striking data at EHA over the weekend (see our note [here](#)), we had the opportunity to host management for two days of investor meetings and wanted to pass along some of the key takeaways. Not surprisingly, discussion focused largely on the new beta-thalassemia data. Management reiterated their (and KOL) surprise and enthusiasm for the results (especially the speed and quantity of the hemoglobin increases), describing it as a "best case" scenario. Investors across the board viewed this as a highly de-risking event. Other points of discussion were around the read-through from the B-Thal data to sickle-cell anemia (it's positive) and progress with the CCALD trial (which is on track). Overall, we continue to view BLUE – with its gene therapy platform – as a potentially transformative and disruptive company that appears to be much more than just a "big idea". Thus, we are reiterating our Overweight rating and increasing our YE14 target to \$53 (from \$44) on a higher probability of success assigned to the LentiGlobin program in B-Thal.

- **One of the main reasons for releasing the data early was to give doctors/patients more information as they consider trial enrollment.** BLUE noted that prior to this data release, doctors may have reserved the clinical trial option as an option of last resort for the sickest patients. However, the availability of these results at EHA – and of course the degree of benefit observed in the initial 2 patients – may alter the decision matrix now as docs/patients consider their options. To date, across both the HGB-205 and Northstar Ph1/2 trials, BLUE has enrolled 10/22 pts and 3 pts have been transplanted (2 of which were from the HGB-205 trial that we saw data for last wknd). The next data update is likely to be at ASH in December for both the HGB-205 and Northstar Ph1/2 trials. BLUE also plans on announcing when the 1st sickle cell disease patient is treated.
- **Approximately 80-90% of the improvements that produced the new LentiGlobin vector were process related, which strengthens exclusivity.** When asked whether academic labs could reproduce similar vectors, BLUE noted that the potency of their vector is highly process dependent, with industrialization being a key factor. The currently produced lentiviral products coming out of academic labs have a VCN ≤ 1 (vs. the 1.5 and 2.1 seen with the first 2 pts receiving BLUE's new product). Thus, in addition to specific IP, BLUE believes expertise/knowhow and scale are two key additional factors that will prevent duplication. BLUE does not believe any further optimization of LentiGlobin is going to be required and is targeting vector copy numbers of >1 .

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	-1.78

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

Overweight

BLUE, BLUE US

Price: \$36.47

▲ **Price Target: \$53.00**
Previous: \$44.00

Biotechnology

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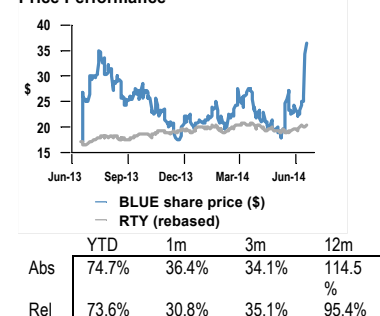
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Price Performance



Company Data

Price (\$)	36.47
Date Of Price	17 Jun 14
52-week Range (\$)	41.75-17.00
Market Cap (\$ mn)	882.57
Fiscal Year End	Dec
Shares O/S (mn)	24
Price Target (\$)	53.00
Price Target End Date	31-Dec-14

See page 5 for analyst certification and important disclosures.

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- **While many beta-thalassemia pts are located ex-US, BLUE believes the pharmacoeconomics of a cure will make sense to cash strapped governments.** Given the higher prevalence of B-Thal in tropical and sub-tropical countries (e.g. the Middle East, Southeast Asia), there were some questions on the actual market opportunity for a highly transformative (i.e. high tech and expensive) therapy. BLUE noted that the economic burden of constant (~1x/month) blood transfusions for these pts is large. They pointed to Thailand as an example of an ex-US government's willingness to pay for a curative treatment. In Thailand, the government has started paying for allogenic transplants in children as they recognize it is more cost effective.
- **The amount of corrected β AT87Q-globin seen with the new vector has positive read-through to sickle-cell disease.** In the most recent data, up to ~70% of the total amount of a patient's hemoglobin was β AT87Q-globin (vs. ~33% with the best performing pt – #1003 – from LG001), which BLUE believes could be sufficient to eliminate the sickle-cell phenotype. BLUE highlighted an example from nature, wherein pts with abnormally high fetal hemoglobin levels – which is functional/non-sickling – can have dramatic attenuation (and in some cases complete obliteration) of their sickle-cell disease. Data from these rare pts have shown that if just 15-30% of the total hemoglobin is fetal that can rescue the phenotype (clearly the 70% level seen in the most recent B-Thal data far exceeds that threshold).
- **No news is good news for CCALD as the Ph2/3 trial progresses as planned, and the push for newborn screening grows.** BLUE noted that they remain on track to finish Phase 2/3 enrollment for Lenti-D in CCALD sometime in 2015. BLUE indicated there is tremendous enthusiasm for this study worldwide, and noted that newborn screening has been implemented faster than they thought. Newborn screening has already been implemented in the state of NY (where 7 cases have been identified since the start of the program in Dec 2013), and CA and CT will hopefully follow suit shortly.
- **BLUE's cash position is strong with \$193M as of the end of 1Q, which should last into 2016 using conservative assumptions.** Management believes their current cash position is sufficient to run operations into 2016, even when assuming that OpEx ramps up to support continued Lenti-D and LentiGlobin development. They noted that this runway does not assume a raise or that the CAR-T collaboration with CELG produces any more milestones/fees.
- **Increasing price target to \$53 (from \$44) on higher probability of success for LentiGlobin in beta-thalassemia; significant dry powder still left in our model.** On the back of highly positive Ph1/2 data, we have bumped up our probability of success for LentiGlobin (in B-Thal only) to 50% (from 25%). We still don't include sickle cell disease in our valuation even though we are materially more optimistic about the program. Overall, we think our assumptions remain quite conservative, and if the data continue to trend in this direction, there is a substantial amount of upside still left in our model.

Investment Thesis, Valuation and Risks

bluebird bio (Overweight; Price Target: \$53.00)

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 \$53 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 50% 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	50%	\$ 1,204	2023
Sickle Cell Disease	0%	\$ -	-
Valuation methodology	Value	Weighting	Adj. value/ share
P/E 2015	\$ -	0%	\$ -
Real options scenario analysis	\$ 58.60	33%	19.5
Risk adjusted NPV analysis	\$ 45.14	33%	15.0
DCF analysis	\$ 53.87	33%	18.0
Total			\$ 52.53
Catalyst/liquidity discount			0%
YE14 Valuation			\$ 53

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.

bluebird bio: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E	Income Statement - Quarterly	1Q14A	2Q14E	3Q14E	4Q14E
Revenues	20	25	25	-	Revenues	6A	6	6	6
Cost of products sold	0	0	0	-	Cost of products sold	0A	0	0	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(14)	(23)	(26)	-	SG&A	(6)A	(6)	(6)	(6)
R&D	(31)	(48)	(51)	-	R&D	(11)A	(12)	(12)	(12)
Operating income	(25)	(45)	(51)	-	Operating income	(11)A	(11)	(11)	(12)
EBITDA	(25)	(45)	(51)	-	EBITDA	(11)A	(11)	(11)	(12)
Net interest (income) / expense	0	0	2	-	Net interest (income) / expense	0A	0	0	0
Other income / (expense)	(0)	0	0	-	Other income / (expense)	0A	0	0	0
Income taxes	0	0	0	-	Income taxes	0A	0	0	0
Net income - GAAP	(25)	(45)	(49)	-	Net income - GAAP	(11)A	(11)	(11)	(11)
Net income - recurring	(25)	(45)	(49)	-	Net income - recurring	(11)A	(11)	(11)	(11)
Diluted shares outstanding	13	25	26	-	Diluted shares outstanding	24A	25	25	25
EPS - excluding non-recurring	(2.02)	(1.80)	(1.88)	-	EPS - excluding non-recurring	(0.44)A	(0.46)	(0.46)	(0.45)
EPS - recurring	(2.02)	(1.80)	(1.88)	-	EPS - recurring	(0.44)A	(0.46)	(0.46)	(0.45)
Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E	Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	238	207	170	-	Sales growth	5835.6%	25.6%	0.0%	-
Accounts receivable	0	0	0	-	EBIT growth	5.2%	80.2%	14.4%	-
Inventories	-	-	-	-	EPS growth - recurring	-	(10.6%)	4.1%	-
Other current assets	0	0	0	-	Gross margin	-	-	-	-
Current assets	238	207	170	-	EBIT margin	(123.6%)	(177.4%)	(203.0%)	-
PP&E	0	0	0	-	EBITDA margin	(123.6%)	(177.4%)	(203.0%)	-
Total assets	238	232	233	-	Tax rate	0.0%	0.0%	0.0%	-
Total debt	0	0	0	-	Net margin	(125.5%)	(176.2%)	(195.2%)	-
Total liabilities	77	62	54	-	Net Debt / EBITDA	953.6%	459.7%	331.4%	-
Shareholders' equity	161	170	178	-	Net Debt / Capital (book)	307.8%	561.2%	(2128.9%)	-
Net income (including charges)	(25)	(45)	(49)	-	Return on assets (ROA)	(16.5%)	(19.0%)	(21.3%)	-
D&A	6	8	8	-	Return on equity (ROE)	(22.5%)	(27.0%)	(28.4%)	-
Change in working capital	69	0	0	-	Enterprise value / sales	29.5	24.8	26.2	-
Other	7	0	0	-	Enterprise value / EBITDA	NM	NM	NM	-
Cash flow from operations	63	(31)	(36)	-	Free cash flow yield	13.7%	(3.5%)	(3.8%)	-
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	-	-	-	-					

Source: Company reports and J.P. Morgan estimates.

Note: \$ in millions (except per-share data). Fiscal year ends Dec

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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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