

	Annual EPS	Annual Revenue	Target
Today's Changes	2014E \$(1.48) from \$(1.40)	2014E \$25.3M from \$27.3M	\$45.00, no change
	2015E \$(1.62) from \$(1.52)	2015E \$25.0M from \$27.3M	

# bluebird bio

BLUE: NASDAQ: US\$25.91

**Target: US\$45.00** 

Salveen Richter, CFA - Canaccord Genuity Inc. (US)
srichter@canaccordgenuity.com 212.389.8052
Andrew Goldsmith, PhD - Canaccord Genuity Inc. (US)
agoldsmith@canaccordgenuity.com 212.389.8053

#### **COMPANY STATISTICS:**

 52-week Range:
 17.03 - 36.25

 Market Cap (M):
 US\$616

 Avg. Daily Vol. (000s):
 188

 Shares Out (M):
 23.78

 Cash (M):
 US\$67.01

### **EARNINGS SUMMARY:**

FYE Dec		2012A	2013A	2014E
EPS:		(13.79)	(2.02)	(1.48)
Revenue (M):	Q1		1.1	6.3
	Q2		6.3	6.3
	Q3		6.4	6.3
	Q4		6.3	6.3
Total		0.3	20.2	25.3
EPS:	Q1		(19.94)	(0.29)
	Q2	-	(2.13)	(0.34)
	Q3		(0.26)	(0.38)
	Q4	-	(0.34)	(0.48)
Total		(13.79)	(2.02)	(1.48)

### **SHARE PRICE PERFORMANCE:**



Source: Interactive Data Corporation

# **COMPANY DESCRIPTION:**

bluebird bio is a clinical-stage biotechnology company focused on gene therapy approaches to severe genetic and orphan disorders. The lead product is Lenti-D for CCALD. The second product is LentiGlobin for beta-thalassemia and sickle cell disease, and bluebird is also developing CAR T-based cancer therapies thorough a partnership with Celgene. bluebird is based in Cambridge, MA.

All amounts in US\$ unless otherwise noted.

# Life Sciences -- Biotechnology

# Q4 EPS: KEY DATA FROM TWO P1/2 TRIALS IN LATE-14

BLUE reported Q4 GAAP EPS of \$(0.34), below consensus of \$(0.31) and in line with CGe of \$(0.34). We continue to be optimistic on both of BLUE's programs – although we are more confident in the odds of success for the P2/3 Lenti-D trial for childhood cerebral adrenoleukodystrophy (CCALD) given clinical data and physician feedback, we expect positive LentiGlobin data from two P1/2 LentiGlobin trials in late-2014: HGB-204 (France) and Northstar (U.S.). Specifically, we expect increasing investor interest in this name and shares to trade up into interim data demonstrating that genetically modified hematopoietic stem cells have engrafted into beta-thalassemia patients' bone marrow with no signs of clonal expansion (a precursor to leukemia).

- Plenty in the clinic: BLUE has three clinical trials currently ongoing: 1) ALD-102 a pivotal P2/3 trial of Lenti-D for CCALD (enrollment completed in 2015); 2) Northstar a P1/2 trial of LentiGlobin for beta-thalassemia in the U.S. (first patient to be transplanted early-14); and 3) HGB-205 a P1/2 beta-thalassemia / sickle cell disease (SCD) trial in France. BLUE intends to file a LentiGlobin IND for treatment of SCD in the U.S. in mid-14. We model for Lenti-D launches in mid-18 (U.S.) and early-19 (E.U.), with peak Lenti-D revenue recognized by BLUE of \$207M in 2028. For LentiGlobin, we model for launches for beta-thalassemia in mid-20 (U.S.) and early-21 (E.U.), with peak revenue recognized by BLUE of \$1.23B in 2026.
- Q4 financials: BLUE reported \$6.3M in Q4 revenue (\$6.25M of which was recognized revenue from the CELG partnership), below consensus of \$6.4M and below CGe of \$6.9M. BLUE exited Q4 with \$206.3M in cash and equivalents, which we expect to be sufficient to fund operations into H2/16.

Canaccord Genuity is the global capital markets group of Canaccord Genuity Group Inc. (CF: TSX | CF.: LSE)

The recommendations and opinions expressed in this research report accurately reflect the Investment Analyst's personal, independent and objective views about any and all the Designated Investments and Relevant Issuers discussed herein. For important information, please see the Important Disclosures section in the appendix of this document.



Figure 1: Q4/13 variance table

(\$thousands, except per share data)

	Dec	Dec	Variance	Variance	Y/Y	Q/Q
	4Q13A	4Q13E	A-E	%	%	%
Revenue						
Lenti-D Total Revenue	\$ -	\$ -	-	n/a	n/a	n/a
Lenti-D - U.S.	-	-	-	n/a	n/a	n/a
Lenti-D - E.U.	-	-	-	n/a	n/a	n/a
LentiGlobin Total Revenue	\$ -	\$ -	-	n/a	n/a	n/a
LentiGlobin - U.S.	-	-	-	n/a	n/a	n/a
LentiGlobin - E.U.	-	-	-	n/a	n/a	n/a
Total other revenue	\$ 6,335	\$ 6,916	(581)	-9%	n/a	-1%
Total Revenue	\$ 6,335	\$ 6,916	\$ (581)	-9%	7353%	-1%
COGS	-	-	-	n/a	n/a	n/a
Gross profit	6,335	6,916	(581)	-9%	7353%	-1%
Operating expense						
R&D (GAAP)	9,765	10,223	(458)	-5%	50%	12%
SG&A (GAAP)	4,685	4,772	(87)	-2%	84%	22%
Stock-based compensation	2,788	2,788	-	0%	n/a	245%
Total operating expense	14,450	14,995	(545)	-4%	60%	15%
Operating income (loss)	(8,115)	(8,079)	(36)	0%	-9%	32%
Other (expense) income, net	34	10	24	69%	-181%	-23%
Income Before Income Taxes	(8,081)	(8,068)	(13)	0%	-10%	32%
Income Tax Provision	-	-	-	n/a	n/a	n/a
Net loss applicable to common shareholders	\$ (8,081)	\$ (8,068)	(13)	0%	-198%	32%
GAAP EPS (diluted)	\$ (0.34)	\$ (0.34)	(0.00)	0%	-101%	32%
Weighted shares outstanding						
basic and diluted - GAAP	23,741	23,741	-	0%	7867%	0%

Source: Canaccord Genuity research, Company reports

Figure 2: Upcoming milestones

Product	Indication	Timing	Milestone
LentiGlobin	β-thalassemia	1Q14	First patient in Phase 1/2 (HGB-204 / Northstar) trial
LentiGlobin	SCD	mid-14	IND submission; U.S. Phase 1/2 trial initation
LentiGlobin	β-thalassemia / SCD	4Q14	Interim Phase 1/2 (HGB-205 and Northstar) data
LentiGlobin	β-thalassemia / SCD	2015	Complete Phase 1/2 (HGB-204, -205) enrollment
Lenti-D	CCALD	2015	Complete Phase 2/3 (ALD-102 / Starbeam) enrollment
Lenti-D	CCALD	2H15	Interim Phase 2/3 data

Source: Canaccord Genuity research, Company reports



5 March 2014

Figure 3: Changes to model

(\$thousands, except per share data)	FY	14E	FY.	15E	FY1	16E	FY	17E	FY1	8E	FY1	19E	FY2	20E	FY:	21E	FY	22E	FY2	23E
	New	<u>Prior</u>	<u>New</u>	<u>Prior</u>	New	<u>Prior</u>	New	Prior	New	Prior	New	<u>Prior</u>	New	<u>Prior</u>	New	Prior	<u>New</u>	Prior	New	<u>Prior</u>
Revenue																				
Lenti-D (CCALD) Total Revenue	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 3,152	\$ 3,152	\$ 30,577	\$ 30,577	\$ 70,093	\$ 70,093	\$ 115,317	\$ 115,317	\$ 143,128	\$ 143,128	\$ 162,538	\$ 162,53
Lenti-D - U.S.	-	-	-	-	-	-	-	-	3,152	3,152	15,950	15,950	34,514	34,514	53,080	53,080	64,452	64,452	72,634	72,63
Lenti-D - E.U.	-	-	-	-			-		-		14,627	14,627	35,579	35,579	62,237	62,237	78,676	78,676	89,904	89,90
LentiGlobin (β-thalassemia) Total Revenue LentiGlobin - U.S.	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 4,456	\$ 4,456 4,456	\$ 147,849	\$ 147,849	\$ 403,487	\$ 403,487	\$ 723,633	\$ 723,63
LentiGlobin - U.S. LentiGlobin - E.U.	-	-		-	•	-		-	-	-	-	-	4,456	4,456	19,409 128,440	19,409 128,440	41,421 362,066	41,421 362,066	62,027 661,605	62,02° 661.60°
Total other revenue	\$ 25.340	\$ 27.325	\$ 25.000	\$ 27.325	\$ 5.208	\$ 7,533		\$ 1.163	s -	e -	s -		s -	٠.	120,440	120,440	\$ 2,000	\$02,000	\$ -	e -
	,	7	,		, .,				*		*	• -	*	•	Ψ -		•		•	φ -
Total Revenue	\$ 25,340	\$ 27,325	\$ 25,000	\$ 27,325	\$ 5,208	\$ 7,533	\$ -	\$ 1,163	\$ 3,152	\$ 3,152	\$ 30,577	\$ 30,577	\$ 74,549	\$ 74,549	\$ 263,166	\$ 263,166	\$ 546,615	\$ 546,615	\$ 886,171	\$ 886,17
COGS	-	-	-	-	-	-	-	-	788	788	6,727	6,727	14,910	14,910	47,370	47,370	98,391	98,391	159,511	159,51
Gross profit	25,340	27,325	25,000	27,325	5,208	7,533	-	1,163	2,364	2,364	23,850	23,850	59,639	59,639	215,796	215,796	448,224	448,224	726,660	726,66
Operating expense																				
R&D (GAAP)	41,217	41,217	42,511	42,511	45,222	45,222	48,003	48,003	50,223	50,223	52,112	52,112	54,223	54,223	56,132	56,132	58,232	58,232	60,211	60,21
SG&A (GAAP)	19,828	19,828	21,812	21,812	24,323	24,323	34,015	34,015	36,522	36,522	45,131	45,131	53,502	53,502	56,002	56,002	58,512	58,512	61,099	61,09
Stock-based compensation	9,800	9,800	11,311	11,311	12,812	12,812	14,290	14,290	15,777	15,777	17,219	17,219	18,778	18,778	20,210	20,210	21,716	21,716	23,211	23,21
Total operating expense	61,045	61,045	64,323	64,323	69,545	69,545	82,018	82,018	86,745	86,745	97,243	97,243	107,725	107,725	112,134	112,134	116,744	116,744	121,310	121,31
Operating income (loss)	(35,705)	(33,720)	(39,323)	(36,998)	(64,337)	(62,012)	(82,018)	(80,856)	(84,381)	(84,381)	(73,393)	(73,393)	(48,086)	(48,086)	103,662	103,662	331,480	331,480	605,350	605,350
Other (expense) income, net	34	33	18	17	24	24	38	38	25	25	10	10	(1)	(0)	31	31	171	171	484	484
Net gain (loss)	(35,671)	(33,687)	(39,305)	(36,981)	(64,313)	(61,988)	(81,980)	(80,818)	(84,356)	(84,356)	(73,383)	(73,383)	(48,086)	(48,086)	103,693	103,693	331,651	331,651	605,834	605,83
Income Tax Provision	- '	- 1	- 1	-	- 1	-	-	- 1	- 1	-		- '	- '	-	-	-	39,798	39,798	193,867	193,86
Net loss applicable to common shareholders	\$ (35,671)	\$ (33,687)	\$ (39,305)	\$ (36,981)	\$ (64,313)	\$ (61,988)	\$ (81,980)	\$ (80,818)	\$ (84,356)	\$ (84,356)	\$ (73,383)	\$ (73,383)	\$ (48,086)	\$ (48,086)	\$ 103,693	\$ 103,693	\$ 291,853	\$ 291,853	\$ 411,967	\$ 411,96
GAAP EPS (diluted)	\$ (1.48)	\$ (1.40)	\$ (1.62)	\$ (1.52)	\$ (2.38)	\$ (2.29)	\$ (2.75)	\$ (2.71)	\$ (2.80)	\$ (2.80)	\$ (2.41)	\$ (2.41)	\$ (1.57)	\$ (1.57)	\$ 3.23	\$ 3.23	\$ 8.82	\$ 8.82	\$ 11.82	\$ 11.8
Weighted shares outstanding																				
basic and diluted	24,039	24,039	24,280	24,280	27,023	27,023	29,793	29,793	30,091	30,091	30,392	30,392	30,696	30,696	32,072	32,072	33,106	33,106	34,864	34,86

Source: Canaccord Genuity research, Company reports



5 March 2014

Figure 4: BLUE Income statement

(\$thousands, except per share data)

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	FY	FY	Mar	Jun	Sep	Dec	FY	Mar	Jun	Sep	Dec	FY	FY	FY	FY						
	2011A	2012A	1Q13A	2Q13A	3Q13A	4Q13A	2013A	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Revenue																					
Lenti-D (CCALD) Total Revenue	\$ -	\$ -	-	- 1	-	-	\$ -	-	-	-	-	\$ -	\$ -	\$ -	\$ -	\$ 3,152	\$ 30,577	\$ 70,093	\$ 115,317	\$ 143,128	\$ 162,538
Lenti-D - U.S.	-	-	-	- 1	-	-		-	- 1	-	-	-	-	-	-	3,152	15,950	34,514	53,080	64,452	72,634
Lenti-D - E.U.	_	-		- 1	-	-		-	-	-	-	-		-	-		14,627	35.579	62,237	78,676	89,904
LentiGlobin (β-thalassemia) Total Revenue	s -	rs .			_		٠	- 1	- 1	-		· .	s -	s -	s -	s -	s -	\$ 4,456	\$ 147,849	\$ 403,487	\$ 723,633
LentiGlobin - U.S.		_			_	_	, T	_	_	_	_	,				*		4,456	19,409	41,421	62.027
LentiGlobin - E.U.	_	_			-	-		- 1	-			-	_	_	-		-	4,450	128,440	362,066	661,605
	e 000	- 340	4 407	6.334	C 20F		- - - -	6 225	6 225			- 05 040	ė 25 000	£ 5000							6001,000
Total other revenue	\$ 882	\$ 340	1,127	.,	6,385	6,335	\$ 20,181	6,335	6,335	6,335	6,335	\$ 25,340	\$ 25,000	\$ 5,208	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Total Revenue	\$ 882	\$ 340	\$ 1,127	\$ 6,334	\$ 6,385	\$ 6,335	\$ 20,181	\$ 6,335	\$ 6,335	\$ 6,335	\$ 6,335	\$ 25,340	\$ 25,000	\$ 5,208	\$ -	\$ 3,152	\$ 30,577	\$ 74,549	\$ 263,166	\$ 546,615	\$ 886,171
COGS	-	-	-	- 1	-	-		-	-	-	-	-	-	-	-	788	6,727	14,910	47,370	98,391	159,511
Gross profit	882	340	1,127	6,334	6,385	6,335	20,181	6,335	6,335	6,335	6,335	25,340	25,000	5,208	-	2,364	23,850	59,639	215,796	448,224	726,660
Operating expense																					
R&D (GAAP)	11.409	17,210	5,284	7,247	8,706	9,765	31,002	9,246	9,776	10,313	11,882	41,217	42,511	45,222	48.003	50.223	52,112	54,223	56.132	58.232	60.211
SG&A (GAAP)	4,615	6,846	2,324	3,281	3,836	4,685	14,126	4,111	4,612	5,102	6,003	19,828	21,812	24,323	34,015	36,522	45,131	53,502	56,002	58,512	61,099
				1 .			_					_									
Total operating expense	16,024	24,056	7,608	10,528	12,542	14,450	45,128	13,357	14,388	15,415	17,885	61,045	64,323	69,545	82,018	86,745	97,243	107,725	112,134	116,744	121,310
Operating income (loss)	(15,142)	(23,716)	(6,481)	(4,194)	(6,157)	(8,115)	(24,947)	(7,022)	(8,053)	(9,080)	(11,550)	(35,705)	(39,323)	(64,337)	(82,018)	(84,381)	(73,393)	(48,086)	103,662	331,480	605,350
Other (expense) income, net	(456)	46	(63)	(389)	44	34	(374)	10	9	8	7	34	18	24	38	25	10	(1)	31	171	484
Net gain (loss)	(15,598)	(23,670)	(6,544)	(4,583)	(6,113)	(8,081)	(25,321)	(7,012)	(8,044)	(9,072)	(11,543)	(35,671)	(39,305)	(64,313)	(81,980)	(84,356)	(73,383)	(48,086)	103,693	331,651	605,834
Income Tax Provision	-	(==,==,=,	. (3,5 1.1)	- (,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	-		- (=5,5=1,7	- (1,512)	-	- (-,,	- (11,515)	- (23,211,	-		-	-	-	-	-	39,798	193,867
Net loss applicable to common shareholders	\$ (20,591)	\$ (3,613)	\$ (6,544)	\$ (4,583)	\$ (6,113)	\$ (8,081)	\$ (25,321)	\$ (7,012)	\$ (8,044)	\$ (9,072)	\$ (11,543)	\$ (35,671)	\$ (39,305)	\$ (64,313)	\$ (81,980)	\$ (84,356)	\$ (73,383)	\$ (48,086)	\$ 103,693	\$ 291,853	\$ 411,967
GAAP EPS (diluted)	\$ (171.59)	\$ (13.79)	\$ (19.94)	\$ (2.13)	\$ (0.26)	\$ (0.34)	\$ (2.02)	\$ (0.29)	\$ (0.34)	\$ (0.38)	\$ (0.48)	\$ (1.48)	\$ (1.62)	\$ (2.38)	\$ (2.75)	\$ (2.80)	\$ (2.41)	\$ (1.57)	\$ 3.23	\$ 8.82	\$ 11.82
Weighted shares outstanding																					
basic and diluted	120	262	328	2,151	23,623	23,741	12,555	23,860	23,979	24,099	24,220	24,039	24,280	27,023	29,793	30,091	30,392	30,696	32,072	33,106	34,864
Margin Analysis:		l																			
Cost of product sales	nm	nm	nm	1 8	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	25%	22%	20%	18%	18%	18%
Product gross margin	nm	nm	nm	1 3	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	75%	78%	80%	82%	82%	82%
R&D (GAAP)	nm	469%	469%	114%	136%	154%	154%	146%	154%	163%	188%	163%	170%	868%	nm	1594%	170%	73%	21%	11%	7%
SG&A (GAAP)	nm	206%	206%	52%	60%	74%	70%	65%	73%	81%	95%	78%	87%	467%	nm	1159%	148%	72%	21%	11%	7%
Stock-based compensation expense	nm	18%	59%	26%	39%	44%	38%	32%	36%	40%	48%	39%	45%	246%	nm	501%	56%	25%	8%	4%	3%
Total operating expense	nm	nm	nm	166%	196%	228%	224%	nm	227%	243%	282%	241%	257%	1335%	nm	2752%	318%	145%	43%	21%	14%
Operating margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	39%	61%	68%
Income tax provision	nm	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	12%	32%
Net margin (GAAP)	nm	nm	nm	-72%	-96%	-128%	-125%	nm	-127%	-143%	-182%	-141%	-157%	-1235%	nm	-2677%	-240%	-65%	39%	53%	46%
Y/Y change:		l						- 1									l	l			
Total revenue	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	26%	-1%	-79%	-100%	nm	870%	144%	253%	108%	62%
Lenti-D revenue	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	870%	129%	65%	24%	14%
LentiGlobin revenue	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	3218%	173%	79%
R&D (GAAP)	nm	51%	37%	116%	149%	nm	80%	75%	35%	18%	22%	33%	3%	6%	6%	5%	4%	4%	4%	4%	3%
SG&A (GAAP)	nm	48%	71%	147%	139%	nm	106%	77%	41%	33%	28%	40%	10%	12%	40%	7%	24%	19%	5%	4%	4%
Stock-based compensation expense	nm	0%	184%	990%	1259%	nm	853%	204%	36%	0%	8%	29%	15%	13%	12%	10%	9%	9%	8%	7%	7%
Total operating expense	nm	50%	46%	125%	145%	nm	88%	76%	37%	23%	24%	35%	5%	8%	18%	6%	12%	11%	4%	4%	4%
		57%		-9%	23%		5%	8%		47%			10%	64%	27%	3%		-34%			83%
Operating income	nm		26%	1		nm			92%		42%	43%					-13%		-316%	220%	
Net income (GAAP)	nm	-82%	3%	-22%	-2041%	nm	601%	7%	76%	48%	43%	41%	10%	64%	27%	3%	-13%	-34%	-316%	181%	41%
GAAP EPS (diluted)	nm	-92%	-30%	-91%	-123%	nm	-85%	-99%	-84%	45%	40%	-26%	9%	47%	16%	2%	-14%	-35%	-306%	173%	34%
Shares outstanding - GAAP	nm	118%	47%	754%	8490%	nm	4692%	7169%	1015%	2%	2%	91%	1%	11%	10%	1%	1%	1%	4%	3%	5%

Source: Canaccord Genuity research, Company reports



## **Valuation**

We arrive at our 12-month price target of \$45 via averaging two valuation methods: 1) a sum-of-the-parts discounted cash flow analysis equating to \$44 a share which ascribes \$14/share from Lenti-D, \$23/share for LentiGlobin and \$7/share in cash, with the following assumptions: we assign Lenti-D a 75% chance of success and LentiGlobin a 30% chance of success and we assign a WACC of 10% and a 1% terminal growth rate; and 2) a discounted EPS equating to \$46/share, applying a 35x multiple to our FY22 fully diluted GAAP EPS estimate of \$8.82, discounted back to YE14 at 27%.

### Investment risks

The primary risks for bluebird include the following:

- 1. Lenti-D clinical development risk: efficacy will the Phase 2/3 trial demonstrate efficacy that compares favorably against the natural history trial (we note that the primary endpoint of no major functional disabilities is stringent and the new vector used in this trial has not been evaluated in the clinic; and safety --will a safety signal emerge (particularly leukemia or pre-leukemic clonal expansion)?
- 2. LentiGlobin clinical development risk: efficacy -- will the two Phase 1/2 trials demonstrate efficacy in beta-thalassemia patients (particularly sufficient hemoglobin for patients to become transfusion independent) and safety?
- 3. Commercial risk, including the possibility that Lenti-D and LentiGlobin do not achieve the peak commercial revenue estimates in our model (due to patient identification, market size, penetration rates, and/or pricing/reimbursement -- particularly given the anticipated price of \$1.5M+).
- 4. Regulatory risk: including failure to secure U.S. and E.U. approval for both Lenti-D and LentiGlobin.
- 5. Product competition, for Lenti-D, advances in hematopoietic stem cell transplant using non-related donors or other techniques to prevent demyelination or development of competing gene therapy techniques; for LentiGlobin, other gene therapy approaches or advances in the ability to upregulate the fetal gamma globin gene.
- 6. Financing risk -- we model for one equity offering (\$200M; 5M shares @ \$40/share) in mid-2016.



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# **Price Chart:\***



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Coverage Universe							
Dating	ш	0/	IB Clients				
Rating	#	%	%				
Buy	564	57.0%	38.1%				
Speculative Buy	47	4.7%	42.6%				
Hold	325	32.8%	11.4%				
Sell	50	5.1%	6.0%				
	990*	100.0%					

<sup>\*</sup>Total includes stocks that are Under Review

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Company	Disclosure
bluebird bio	1A, 2, 3, 5, 7

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