25 March 2014 | 14 pages

Pharmaceuticals
North America | United States

Bristol Myers Squibb (BMY)

How to Beat a High ASCO Hurdle? Jump it. Yervoy goes Early

- **Summary and Investment Conclusion.** We anticipate that Yervoy use in high risk stage III melanoma will increase relapse free survival by 30-40% versus placebo. We assess this is at least a peak $3bn/ annum opportunity with incremental >95% EBIT margins, an opportunity undiscounted by consensus. Our 2018 BMY forecasts are currently c.20% above cons; $2bn additional EBIT in 2018 from Yervoy adjuvant melanoma indication would increase our non GAAP EBIT forecasts by ~28%, putting us almost 50% above consensus. Positive data could materially diminish the outlook in metastatic melanoma for Merck, Incyte and AZN. More importantly, positive adjuvant (early disease) data should validate the potential for the use of Yervoy, nivolumab and other immmunotherapeutics in earlier settings in other larger cancers (lung, bladder, renal etc). Material adoption in early cancers would represent significant upside to our $35bn market estimate for immunotherapies (*Immunotherapy: Bigger, Broader, Bladder*). We continue to prefer BUY rated BMY and PFE in the US and Roche, Novartis and Novo in EU.
- **What's new? —** We anticipate that EORTC-run 950-patient Ph3 Yervoy adjuvant melanoma trial will show a very significant improvement in relapse free survival for Yervoy 10mg/kg dose compared with placebo in high risk stage III melanoma pts. We anticipate outcome measures to look materially superior and better tolerated compared with historic controls with IFN alpha, the current and meager gold standard. As with Roche's Avastin in breast cancer, we assume BMY will adopt patient price caps to offset 3 year treatment duration and higher 10mg/kg dosing.
- **What do we expect? —** We anticipate that Yervoy will demonstrate at least a 30-40% improvement in relapse free survival compared with the placebo treated patients. The historical improvement with IFN is a dubious c.10%. The anticipated clinical benefit of Yervoy will likely offset the expected immune related adverse event profile typical for Yervoy, even with prolonged usage. The predictive relevance of baseline tumor ulceration for Yervoy is unclear.
- **What next?** We anticipate BMY to initiate a three arm trial with Yervoy, nivolumab and the combination in a similar adjuvant melanoma setting. A trial evaluating two different doses of Yervoy (3mg/kg and 10mg/kg) in adjuvant melanoma is ongoing. We anticipate competitors AZN, Merck and Incyte to follow suit with various combinations but we don't expect Yervoy to face significant competition until 2019.

Buy	1
Price (25 Mar 14)	US$51.44
Target price	US$60.00
Expected share price return	16.6%
Expected dividend yield	2.8%
Expected total return	19.4%
Market Cap	US$85,235M

Price Performance
(RIC: BMY.N, BB: BMY US)

EPS	Q1	Q2	Q3	Q4	FY	FC Cons
2013A	0.41A	0.44A	0.46A	0.51A	1.81A	1.82A
2014E	0.48E	na	na	na	1.86E	1.78E
Previous	0.48E	na	na	na	1.86E	na
2015E	na	na	na	na	1.75E	1.67E
Previous	na	na	na	na	1.75E	na
2016E	na	na	na	na	2.16E	2.04E
Previous	na	na	na	na	2.16E	na

Source: Company Reports and dataCentral, Citi Research. FC Cons: First Call Consensus.

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See Appendix A-1 for Analyst Certification, Important Disclosures and non-US research analyst disclosures.

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BMY.N: Fiscal year end 31-Dec

Price: US$51.44; TP: US$60.00; Market Cap: US$85,235m; Recomm: Buy

Profit & Loss (US$m)	2012	2013	2014E	2015E	2016E
Sales revenue	17,621	16,385	15,434	14,929	16,253
Cost of sales	-4,610	-4,619	-3,981	-3,932	-4,263
Gross profit	13,011	11,766	11,453	10,997	11,990
Gross Margin (%)	73.8	71.8	74.2	73.7	73.8
EBITDA (Adj)	7,259	4,017	4,129	3,922	4,856
EBITDA Margin (Adj) (%)	41.2	24.5	26.7	26.3	29.9
Depreciation	-382	-295	-309	-324	-340
Amortisation	-607	-626	-636	-649	-665
EBIT (Adj)	4,676	3,454	3,563	3,329	4,231
EBIT Margin (Adj) (%)	26.5	21.1	23.1	22.3	26.0
Net interest	-76	-95	-159	-153	-162
Associates	183	166	5	5	5
Non-op/Except	-1,858	-276	4,025	450	550
Pre-tax profit	2,339	2,891	7,054	3,250	4,244
Tax	161	-311	-498	-485	-642
Extraord./Min.Int./Pref.div.	-542	-17	-17	-16	-21
Reported net profit	1,958	2,563	6,539	2,749	3,581
Net Margin (%)	11.1	15.6	42.4	18.4	22.0
Core NPAT	3,362	3,019	3,144	2,979	3,711
Per share data	**2012**	**2013**	**2014E**	**2015E**	**2016E**
Reported EPS ($)	1.16	1.54	3.87	1.61	2.09
Core EPS ($)	1.99	1.81	1.86	1.75	2.16
DPS ($)	1.37	1.41	1.44	1.49	1.52
CFPS ($)	4.11	1.95	4.41	2.13	2.52
FCFPS ($)	3.79	1.70	4.16	1.86	2.23
BVPS ($)	8.32	8.35	10.70	10.44	10.58
Wtd avg ord shares (m)	1,670	1,649	1,672	1,688	1,699
Wtd avg diluted shares (m)	1,688	1,667	1,690	1,706	1,717
Growth rates	**2012**	**2013**	**2014E**	**2015E**	**2016E**
Sales revenue (%)	-17.1	-7.0	-5.8	-3.3	8.9
EBIT (Adj) (%)	-33.1	-26.1	3.2	-6.6	27.1
Core NPAT (%)	-14.1	-10.2	4.1	-5.3	24.6
Core EPS (%)	-12.6	-9.1	2.8	-6.2	23.8
Balance Sheet (US$m)	**2012**	**2013**	**2014E**	**2015E**	**2016E**
Cash & cash equiv.	2,829	3,986	9,158	9,111	9,433
Accounts receivables	3,083	3,174	2,989	2,892	3,148
Inventory	1,657	1,509	1,329	1,312	1,428
Net fixed & other tangibles	6,440	6,557	6,686	6,827	6,980
Goodwill & intangibles	16,413	16,449	16,502	16,569	16,649
Financial & other assets	5,475	5,450	5,431	5,421	5,447
Total assets	35,897	37,125	42,096	42,132	43,086
Accounts payable	2,202	2,400	2,249	2,203	2,286
Short-term debt	826	826	826	826	826
Long-term debt	6,568	7,885	9,135	9,726	10,226
Provisions & other liab	12,663	12,133	11,858	11,678	11,715
Total liabilities	22,259	23,244	24,068	24,433	25,053
Shareholders' equity	13,623	13,866	18,013	17,684	18,018
Minority interests	15	15	15	15	15
Total equity	13,638	13,881	18,028	17,699	18,033
Net debt	4,565	4,725	803	1,441	1,619
Net debt to equity (%)	33.5	34.0	4.5	8.1	9.0

Valuation ratios	2012	2013	2014E	2015E	2016E
PE (x)	25.8	28.4	27.6	29.5	23.8
PB (x)	6.2	6.2	4.8	4.9	4.9
EV/EBITDA (x)	11.7	22.0	20.9	21.6	17.5
FCF yield (%)	7.4	3.3	8.1	3.6	4.3
Dividend yield (%)	2.7	2.7	2.8	2.9	3.0
Payout ratio (%)	69	78	77	86	71
ROE (%)	13.2	18.6	41.0	15.4	20.1
Cashflow (US$m)	**2012**	**2013**	**2014E**	**2015E**	**2016E**
EBITDA	5,079	4,017	4,129	3,922	4,856
Working capital	558	250	-43	-101	-279
Other	1,304	-1,016	3,374	-184	-249
Operating cashflow	6,941	3,251	7,460	3,638	4,328
Capex	-548	-412	-438	-465	-493
Net acq/disposals	-6,179	-662	-689	-716	-745
Other	0	0	0	0	0
Investing cashflow	-6,727	-1,075	-1,127	-1,181	-1,238
Dividends paid	-2,286	-2,320	-2,393	-2,532	-2,598
Financing cashflow	-4,333	-1,020	-1,161	-2,503	-2,768
Net change in cash	-4,120	1,157	5,172	-47	321
Free cashflow to s/holders	6,393	2,839	7,022	3,173	3,835

For definitions of the items in this table, please click here.

How BMY Beats ASCO Expectations

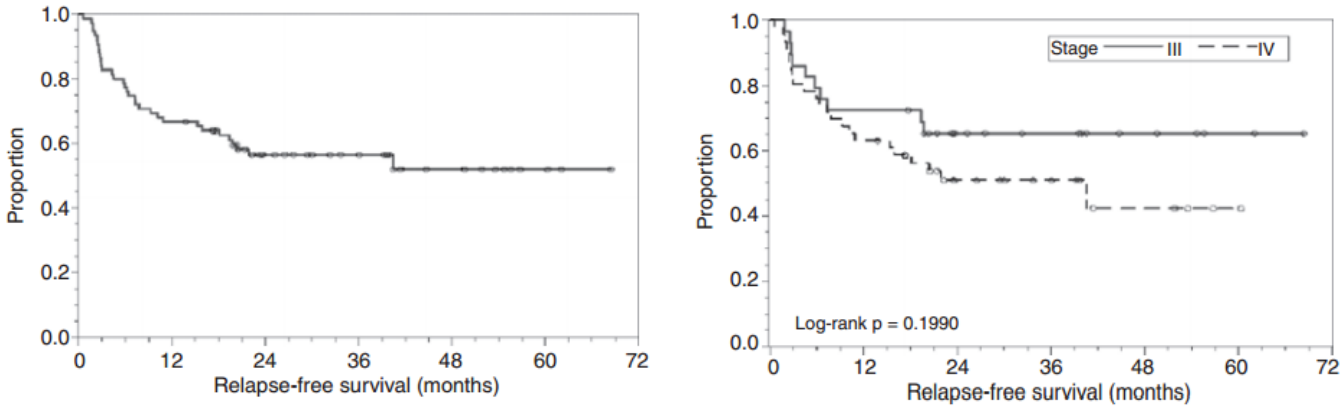
We anticipate BMY to present clinically significant positive phase III data with Yervoy in adjuvant melanoma at ASCO 2014; a $3bn pa, high margin opportunity

Market is not anticipating Yervoy activity in phase III adjuvant melanoma. While our high conviction BUY rating on BMY is based on deep long term fundamental analysis, we remain sensitive to challenges for some healthcare investors positioning their portfolio ahead of the AACR and ASCO conference. We believe that the market is underestimating BMY's ability to meet lofty ASCO related expectations. Our perception is that short term positioning is beginning to favour less expensive IO names such as Roche and AZN. Following detailed analysis of the pending phase III Yervoy adjuvant trial in high risk early stage melanoma, we remain comfortable holding the name through and beyond ASCO. Given our in-depth long term fundamental analysis and recent BMY profit taking, we continue to prefer BUY rated BMY, Roche and NEUTRAL-rated AZN among the immuno-oncology names. Our positive thesis on Immunotherapy was initially described in our May 2013 report (*Immunotherapy – The Beginning of the End for Cancer*) and more recently in our extensive update last month (*Immunotherapy: Bigger, Broader, Bladder*).

We anticipate a significant c.30-40% reduction in relapse free survival versus placebo making it the standard of care in adjuvant melanoma until the end of the decade

BMY will present a 950-patient phase III EORTC trial in adjuvant melanoma at ASCO in high risk stage III patients. The trial is 90% powered to detect a Yervoy to placebo hazard ratio of 0.75 (a 25% improvement in relapse free survival).We anticipate at least a 30-40% relative improvement in relapse free survival compared with the placebo arm. An initial 75 patient trial in stage IIIC/IV patients showed a median RFS (relapse free survival) >40 months compared with c.12-24 months for historic controls.

Figure 1. Data from a 75-patient pilot trial showed a significant RFS benefit with Yervoy in Stage IIIC and IV melanoma patients.

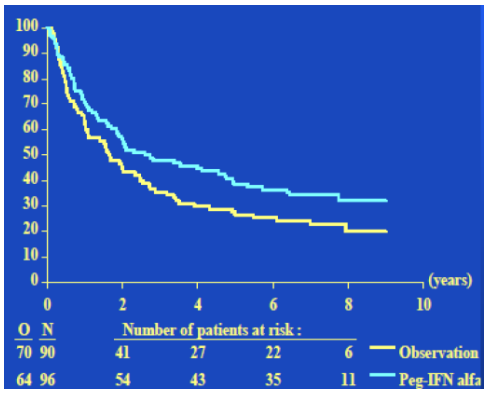


Source: Citi Research. *Sarnaik AA, et al. Clin Cancer Res. 2011;17(4):896-906.*

Unlike modest efficacy of current gold standard IFN alpha, Yervoy could show improvement in RFS in both patients with and without ulcerated tumours.

Another older immunotherapy, IFN alpha is the current gold standard with an insignificant and marginal improvement in RFS versus placebo. But interestingly, IFN alpha leads to a 40% improvement in RFS in the subgroup of patients with lower disease burden and ulcerated tumors. Patients with ulcerated tumors typically have the worst prognosis, but appear to benefit the most from IFN alpha. We speculate that unlike IFN alpha, Yervoy may lead to improvement in RFS in both patients with and without ulcerated lesions. *(see section below)*

Figure 2. Data from the EORTC 18991 trial shows a significant improvement from IFNa in recurrence free survival only in patients with lower disease burden and ulcerated lesions.



Source: Citi Research, Eggermont et al. ASCO 2011. EORTC 18991 trial.

Metastatic opportunity for competitors MRK, AZN and Incyte could be affected by greater Yervoy adjuvant use.

A significant reduction in RFS associated with Yervoy could diminish the size of the metastatic melanoma indication for competitors MRK (with MRK-3475), Incyte (with IDO) and AZN (with tremi and anti-PDL1).

We anticipate few adverse event surprises with Yervoy. The immune related adverse events of Yervoy in the metastatic setting are well characterized. We note that this adjuvant indication requires prolonged duration of Yervoy therapy (up to three years) with a 10mg/kg dose compared to the 3mg/kg dose currently approved in metastatic setting. However the anticipated >30% incidence of grade III adverse events is likely outweighed by the lower relapse rate in this very high risk patient population. In addition, the emergence of immunodiagnostics targeting safety (such as baseline IL10 levels) and efficacy (such as baseline CD25 and LDH), as well as superior management of adverse events may further improve the therapeutic window for Yervoy in the adjuvant setting.

Positive Yervoy adjuvant data will likely spur other adjuvant trials in this indication, but Yervoy will likely remain standard of care until 2019 at least.

Yervoy is likely standard of care until 2019. The anticipate success of Yervoy in this setting should precipitate a raft of additional adjuvant melanoma trials with CTLA4, PD1, IDO and other mechanisms. As with the metastatic setting, we anticipate combination approaches to garner the most interest in high risk patients. BMY already has a head to head trial of Yervoy vs IFN alpha underway, evaluating both the 3mg/kg and 10mg/kg Yervoy dosages. We anticipate BMY will initiate a three arm trial with nivolumab, Yervoy and the combination in adjuvant melanoma indication. We anticipate the earliest competition for Yervoy in the adjuvant setting will come as late as 2019. Post 2019 we anticipate that Yervoy will be replaced in the adjuvant setting by Yervoy free regimens centered on PD1 and IDOi.

Adjuvant melanoma is at least a $3bn commercial opportunity for Yervoy with very high incremental margins

$3bn opportunity for Yervoy, with c.95% margins. We estimate a total commercial opportunity for Yervoy of $3bn in the adjuvant melanoma indication, on top of the opportunity in metastatic melanoma. There are c.45,000 pts. with Stage III melanoma diagnosed every year in the US and EU-5 (roughly 2.5x Stage IV metastatic melanoma pts) with stage IIIB and IIIC constitute a third of all Stage III patients. BMY is evaluating Yervoy 10mg/kg dose over a maximum duration of 3 years (15 injections in total). We have conservatively assumed only a year of treatment (7 injections) and model the same pricing for the 10mg/kg dose as for the 3mg/kg dose approved for the metastatic indication. We expect Bristol to introduce price caps similar to Avastin in breast cancer.

Figure 3. Metastatic melanoma is a $3bn commercial opportunity using conservative estimates

	US	EU-5
Stage IV melanoma	8,900	9,200
Stage III melanoma	22,250	23,000
of which:		
Stage IIIA	*15,575*	*16,100*
Stage IIIB	*4,450*	*4,600*
Stage IIIC	*2,225*	*2,300*
Total pt population (50% Stage IIIA + Stage IIIB + IIIC)	14,463	14,950
no of injections/year	4-7	4-7
Total duration of use (yrs)	3	3
Total possible injections	15	15
Assumed duration of use (yrs)	1	1
Assumed no of injections	7	7
Price per injection ($)	30,000	25,000
% penetration	50%	50%
Total sales ($m)	1,519	1,308

Source: Citi Research, Company data. *we have conservatively assumed only 50% of Stage IIIA patients are eligible for Yervoy treatment.*

Are ulcerations required for Yervoy activity? IFN alpha has minimal treatment effect in patients with non-ulcerated tumors (c.60% of stage III patients). Ulcerated melanomas are associated with high expression of SOCS1/2 (Suppressor of Cytokine Signaling) that impairs IFN gamma signaling. Treatment with exogenous IFN alpha appears to overcome the impact of high SOCS expression overcoming immune-tolerance, creating T memory cells and subsequently drive longer median RFS. We speculate that the patients with ulcerated tumors partly overlap with the inflamed/hot phenotype associated with higher levels of TILs (Tumour infiltrating Lymphocytes).

Ulcerated patients have poorer prognosis than patients with non-ulcerated lesions despite anticipated greater immune activation. The efficacy of CTLA4 blockade with Yervoy depends on IL2, derived from CD4+Lag3+ cells compared with PD1 and IFN alpha which both depends on IFN receptor signaling.

Yervoy activity is mediated by IL2 rather than IFN alpha receptor signaling. Consequently, unlike IFN alpha it is possible that Yervoy will translate into clinical benefit in both patients with and without ulcerated lesions. We are unaware whether BMY has enriched the stage III melanoma patient population in this trial. We anticipate that resistance to Yervoy may be driven by soluble CD25 levels that act as a decoy to Yervoy binding.

We expect immunotherapy sponsors to initiate more trials in the adjuvant setting in multiple tumour types.

More immunotherapy adjuvant trials to come. We anticipate that BMY and other immunotherapy sponsors will also explore trials with immunotherapeutics in other adjuvant solid tumor settings- particularly NSCLC (lung), RCC (renal) and bladder where the patient populations are materially larger than melanoma. Importantly, the pharmaco-economics for the adjuvant setting are typically more favorable than the metastatic setting once adjusted for patient price caps.

We continue to have continued low expectations for MAGE-A3 and BRAF/MEK in adjuvant melanoma

We continue to maintain a high level of skepticism over the ongoing adjuvant MAGE A3 DERMA trial (*MAGE-A3 Cancer Vaccine. Positive Surprise Or Misplaced Optimism?*). We ascribe only a 10% probability of a significant DFS vs placebo given the absence of antigen specific CD8 cells. Data is due 1Q 2015. Separately, we anticipate GSK's dabrafenib+trametinib adjuvant trial in BRAF mutated tumors to report out in 2015. We note this trial is relevant to c.50% of the adjuvant patient population who are BRAF+ although we anticipate a lesser improvement in RFS compared with immunotherapy based trials.

Companies mentioned:

(AZN.L; £38.92; 2); (BMY.N; US$51.04; 1); (GSK.L; £16.22; 2); (INCY.O; US$53.57; Not Rated); (MRK.N; US$55.19; 2); (NOVN.VX; SFr72.05; 1); (NOVOb.CO; Dkr239.60; 1); (PFE.N; US$31.82; 1); (ROG.VX; SFr265.70; 1)

Bristol Myers Squibb

Company description

Bristol-Myers Squibb (BMY) is a leading research-based pharmaceutical company that focuses on drug discovery for human diseases. The company has key franchises in oncology, virology and immunoscience. In 2013, BMY generated approximately $16.4bn in pharmaceutical sales. BMY is one of the leading players in the emerging field of immunotherapy.

Investment strategy

We rate BMS Buy. We anticipate a 2014E-19E EPS CAGR of 20%, compared with the US large cap pharma average of c.10%.

Among global multinationals, BMS appears most closely aligned with our “Shrink, Smarten and Spin” industry framework given its well-entrenched search and development strategy and historically strong execution track record. BMS also has several pipeline assets in the exciting immunotherapy space that is likely to have a paradigm-changing impact on treatment of several cancers. We believe immunotherapies will likely become the treatment backbone in up to 60% of cancers over the next few years, presenting at least a $35bn revenue potential for the industry.

BMY has a very broad checkpoint agent portfolio (including its anti-PD1 antibody nivolumab and Yervoy already on the market), making it uniquely positioned to capture a very significant share of an emergent checkpoint agent market that we think is worth $24bn. We estimate peak immunotherapy revenues for BMY will exceed $10bn by 2022, with consequent significant P&L leverage. With the recent divestment of the diabetes assets, we see OPEX flexibility in developing and commercializing these assets and consequent greater P&L leverage longer term. We expect BMY to engage in more business development in 2014 using debt/cash as well as equity financing.

Valuation

Our Target Price of $60 implies a c.32x 2014E multiple, a significant premium to the large cap pharma sector but more in line with the valuations of large-cap biotech stocks. Our DCF-derived Intrinsic Value is $53. We project free cash flows for an explicit forecast period of 10 years and thereafter apply terminal growth assumptions. We employ a CAPM-derived WACC of 8.0% and assume a 0% terminal growth rate. A three-stage DCF that extends beyond our forecast horizon of 10 years gives us an intrinsic value of $60/share, which we believe more accurately captures the durability and profitability of the emerging immunotherapy franchise.

Risks

We identify several downside risks over the medium to long term. In particular, i) our forecasts for the immunotherapy franchise could prove to be too optimistic due to lesser than anticipated efficacy or unexpected severe adverse events or greater competitive pressures; ii) our peak sales estimates for key drug Eliquis may fail to materialize, due to reimbursement pressures, competition or other impediments to commercial uptake; iii) The company's historical success has been linked to its risk appetite both for internal pipeline candidates as well as external deals. We expect BMY to engage in more business development in 2014 to bolster their leading

position in immuno-oncology. Potential value destruction from a large expensive deal could present downside risk.

Upside risks that could lead to significant price outperformance include: i) Strong efficacy in adjuvant indications, higher duration of use, combination therapy could materially increase commercial sales potential of BMS' anti-PD1 franchise; ii) despite being widely well-understood, the market could be materially underestimating the ultimate long-term commercial potential and/or profitability of novel oral anticoagulants atrial fibrillation market.

If the impact on the company from any of these factors proves to be greater/less than we anticipate, the stock will likely have difficulty achieving our target price or could outperform it.

Appendix A-1

Analyst Certification

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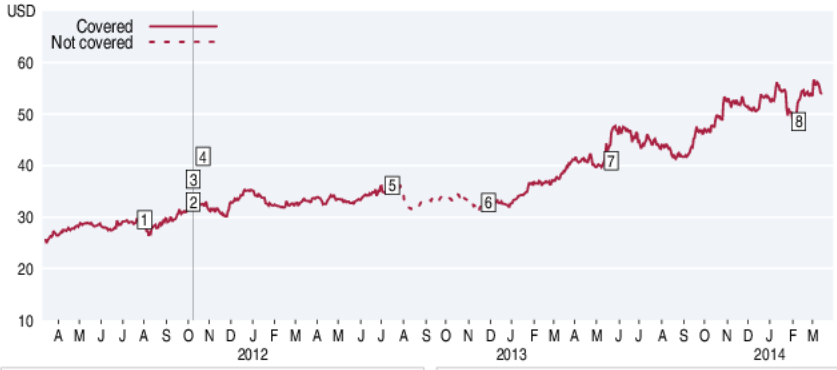
IMPORTANT DISCLOSURES

Bristol Myers Squibb (BMY)
Ratings and Target Price History
Fundamental Research
Analyst: Andrew S Baum
Covered since November 29 2012



	Date	Rating	Target Price	Closing Price
1	2-Aug-11	1M	*39.00	28.04
2	8-Oct-11	Stock rating system changed		
3	8-Oct-11	*1	39.00	32.38
4	24-Oct-11	1	*40.00	32.53
5	17-Jul-12	Coverage terminated		
6	29-Nov-12	*2	*33.00	32.82
7	22-May-13	*1	*55.00	46.40
8	11-Feb-14	1	*60.00	52.62

* Indicates change

Rating/target price changes above reflect Eastern Standard Time

Bristol Myers Squibb (BMY)
Ratings and Target Price History
Best Ideas Research
Relative Call (3 Month)
Analyst: Andrew S Baum
Covered since November 29 2012

	Date	Rating	Target Price	Closing Price
1	13-Apr-11	*ADD MP	-	27.33
2	17-Jul-12	*REM MP	-	35.98

* Indicates change

Rating/target price changes above reflect Eastern Standard Time

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