

16 October 2012 | 16 pages

Pharmaceuticals (GICS) | Drugs (Citi)  
Europe | Germany

# Bayer AG (BAYGn.DE)

## €500m CTEPH Opportunity for Bayer. Pipeline Delivery to Continue. Buy

### ■ Company Update

<b>Buy</b>	<b>1</b>
Price (16 Oct 12)	€69.15
Target price	€75.00
Expected share price return	8.5%
Expected dividend yield	2.7%
<b>Expected total return</b>	<b>11.1%</b>
Market Cap	€57,183M
	US\$74,050M

### Price Performance (RIC: BAYGn.DE, BB: BAYN GR)



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

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- **Reiterate Buy on Bayer ahead of riociguat data at CHEST** — Bayer remains our top pick in EU Pharma and is the only pharmaceutical company on the Citi Focus List. Our positive thesis is driven by upwards consensus earnings revisions and improving long-term fundamentals for the Crop Science and Healthcare divisions. We anticipate a positive outcome for pipeline drug, riociguat, in both CTEPH and PAH pivotal trials which will be presented as late-breakers at the CHEST meeting on 23 October. This should awaken investor interest in this overlooked pipeline asset and we see risk/reward skewed to the upside going into the event.
- **CTEPH alone presents an untapped €500m opportunity** — CTEPH is a sub-type of Pulmonary Hypertension (high blood pressure in the arteries going to the lung) which our analysis suggests affects ~38k patients globally. Although surgery is curative in around half of patients, there are currently no approved medical treatments for inoperable cases. Peak 2020E sales potential for riociguat in CTEPH alone could be ~€500m supporting our current riociguat forecasts. Riociguat is a specialty drug with no royalty payaway and therefore a very high contribution margin.
- **Riociguat has a high chance of success** — Although small, an open-label study in 41 patients showed a significant improvement of 64m in 6MWD (6-minute walk distance) in CTEPH patients. This is the primary endpoint in the placebo-controlled, well-powered 261-patient CHEST-1 trial. However, we acknowledge the fact that other Pulmonary Hypertension drugs, including Actelion's Tracleer, failed to show a benefit in randomized controlled CTEPH trials despite encouraging early signs.
- **Opportunity in PAH likely constrained by competition** — Data will also be presented from the PATENT-1 trial in PAH, another sub-type of Pulmonary Hypertension. Although we also see this as most likely a successful trial, we believe it will be challenging to differentiate riociguat within the increasingly competitive PAH space. However, should the data surprise on the upside, use in just 5% of diagnosed PAH patients could add €250m to our 2020E sales estimate.

### Bayer AG (EUR)

Year to 31 Dec	2010A	2011A	2012E	2013E	2014E
Sales (€M)	35,116.0	36,444.4	39,388.9	41,553.9	43,450.1
Net Income (€M)	3,465.0	4,000.0	4,530.5	5,232.4	5,834.4
Diluted EPS (€)	4.19	4.84	5.48	6.33	7.06
Diluted EPS (Old) (€)	4.19	4.84	5.48	6.33	7.06
PE (x)	16.5	14.3	12.6	10.9	9.8
EV/EBITDA (x)	10.3	9.7	8.6	7.8	6.9
DPS (€)	1.50	1.65	1.86	2.09	2.26
Net Div Yield (%)	2.2	2.4	2.7	3.0	3.3

BAYGn.DE: Fiscal year end 31-Dec						Price: €69.15; TP: €75.00; Market Cap: €57,183m; Recomm: Buy					
Profit & Loss (€m)	2010	2011	2012E	2013E	2014E	Valuation ratios	2010	2011	2012E	2013E	2014E
Sales revenue	35,116	36,444	39,389	41,554	43,450	PE (x)	16.5	14.3	12.6	10.9	9.8
Cost of sales	-17,103	-17,975	-18,858	-20,262	-21,240	PB (x)	3.0	3.0	2.8	2.5	2.2
Gross profit	18,013	18,469	20,530	21,292	22,210	EV/EBITDA (x)	10.3	9.7	8.6	7.8	6.9
Gross Margin (%)	51.3	50.7	52.1	51.2	51.1	FCF yield (%)	7.5	5.9	6.5	7.9	9.1
EBITDA (Adj)	7,101	7,613	8,575	9,064	9,767	Dividend yield (%)	2.2	2.4	2.7	3.0	3.3
EBITDA Margin (Adj) (%)	20.2	20.9	21.8	21.8	22.5	Payout ratio (%)	36	34	34	33	32
Depreciation	-1,248	-1,341	-1,570	-1,362	-1,411	ROE (%)	6.9	13.0	13.8	19.0	19.2
Amortisation	-2,308	-1,425	-1,721	-1,404	-1,387	Cashflow (€m)	2010	2011	2012E	2013E	2014E
EBIT (Adj)	5,906	6,406	7,028	7,702	8,356	EBITDA	6,286	6,918	7,736	9,006	9,709
EBIT Margin (Adj) (%)	16.8	17.6	17.8	18.5	19.2	Working capital	1,002	-112	-397	-569	-386
Net interest	-641	-671	-746	-587	-483	Other	-2,430	-2,645	-2,119	-3,051	-2,678
Associates	-239	-80	-43	-41	-39	Operating cashflow	4,858	4,161	5,220	5,386	6,645
Non-op/Except	-130	-35	0	0	0	Capex	-1,514	-1,615	-1,601	-1,686	-1,762
Pre-tax profit	1,721	3,366	3,656	5,612	6,389	Net acq/disposals	122	183	0	0	0
Tax	-411	-891	-907	-1,459	-1,629	Other	-633	-2,130	543	554	578
Extraord./Min.Int./Pref.div.	-9	-2	-2	-2	-2	Investing cashflow	-2,025	-3,562	-1,058	-1,132	-1,183
Reported net profit	1,301	2,473	2,748	4,151	4,758	Dividends paid	-1,160	-1,242	-1,364	-1,540	-1,727
Net Margin (%)	3.7	6.8	7.0	10.0	11.0	Financing cashflow	-2,704	-1,639	-3,364	-2,540	-1,727
Core NPAT	3,465	4,000	4,531	5,232	5,834	Net change in cash	115	-1,067	798	1,713	3,735
Per share data	2010	2011	2012E	2013E	2014E	Free cashflow to s/holders	4,283	3,372	3,704	4,522	5,202
Reported EPS (€)	1.57	2.99	3.32	5.02	5.75						
Core EPS (€)	4.19	4.84	5.48	6.33	7.06						
DPS (€)	1.50	1.65	1.86	2.09	2.26						
CFPS (€)	5.87	5.03	6.31	6.51	8.04						
FCFPS (€)	5.18	4.08	4.48	5.47	6.29						
BVPS (€)	22.78	23.23	24.91	28.06	31.73						
Wtd avg ord shares (m)	827	827	827	827	827						
Wtd avg diluted shares (m)	827	827	827	827	827						
Growth rates	2010	2011	2012E	2013E	2014E						
Sales revenue (%)	12.7	3.8	8.1	5.5	4.6						
EBIT (Adj) (%)	11.7	8.5	9.7	9.6	8.5						
Core NPAT (%)	15.4	15.4	13.3	15.5	11.5						
Core EPS (%)	15.2	15.4	13.3	15.5	11.5						
Balance Sheet (€m)	2010	2011	2012E	2013E	2014E						
Cash & cash equiv.	2,840	1,773	2,570	4,283	8,018						
Accounts receivables	6,668	7,061	7,554	7,969	8,333						
Inventory	6,104	6,368	6,578	6,956	7,175						
Net fixed & other tangibles	11,009	11,134	11,349	11,657	11,977						
Goodwill & intangibles	20,163	19,455	18,135	16,835	15,555						
Financial & other assets	4,722	6,977	6,934	6,894	6,855						
Total assets	51,506	52,768	53,120	54,594	57,914						
Accounts payable	3,497	3,779	4,084	4,309	4,505						
Short-term debt	1,889	3,684	1,684	684	684						
Long-term debt	9,944	7,995	7,995	7,995	7,995						
Provisions & other liab	17,280	18,036	18,698	18,335	18,425						
Total liabilities	32,610	33,494	32,461	31,323	31,610						
Shareholders' equity	18,833	19,212	20,595	23,206	26,237						
Minority interests	63	59	61	63	65						
Total equity	18,896	19,271	20,656	23,269	26,302						
Net debt	8,993	9,906	7,109	4,396	661						
Net debt to equity (%)	47.6	51.4	34.4	18.9	2.5						

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For definitions of the items in this table, please click [here](#).

## Summary and Investment Conclusion

Our '13-'18 Core EPS growth of 7% is in-line with our sector average for a PE of 10.8x vs the sector of 12.4x.

Riociguat has slipped off investor radar-screens

CTEPH opportunity alone could be €500m by 2020E

Bayer is already familiar with physicians in the space ex-US through Ventavis

We reiterate our Buy rating on Bayer. Bayer remains our top pick in EU Pharma and is the only pharma company on the Citi Focus List. Our positive thesis is driven by continued upwards consensus earnings revisions and improving long-term fundamentals for Crop Science and Healthcare divisions along with long-term potential for value creation through the separation of Material Science. Pipeline delivery plays a core part of this thesis and we expect riociguat to join Bayer's growing list of newly launched drugs in 2013. Pivotal clinical data in Chronic Thromboembolic Pulmonary Hypertension (CTEPH) and Pulmonary Arterial Hypertension (PAH) will be presented as late-breakers at the CHEST meeting on 23 October. This should awaken investor interest in this overlooked pipeline asset in our view. Our core EPS forecasts are 2-16% above consensus with our DCF-derived Intrinsic Value of €90 implying substantial upside potential.

With the recent launch of Xarelto for stroke prevention, strong data for Alfaradin and regorafenib in cancer and the imminent launch of Eylea for eye disease, we believe the potential of riociguat is over-looked by investors. Although we agree that it may be challenging to differentiate the drug in the well-served and increasingly competitive PAH space, we believe that the opportunity in CTEPH alone is under-appreciated. Riociguat would be the only drug therapy approved in this disease, which we estimate affects ~38,000 patients globally.

Our analysis suggests that ~18,000 patients globally, who are unable to undergo surgery for CTEPH or who have relapsed, could be eligible for treatment with riociguat. Over half of these patients currently receive unapproved PAH therapies off-label. Our physician consultants would use riociguat as both a preferred first-line therapy in new patients or to switch patients who are not well-controlled. Assuming pricing similar to branded therapies, such as Tracleer or Letairis in PAH, and a ~50% utilisation rate, CTEPH could create a €500m opportunity alone and support our current forecasts (Figure 1). Given riociguat is a specialty drug with no royalty pay-away we expect a high contribution margin. We note Bayer's long-standing relationships with PAH/CTEPH physicians through its ex-US marketing of Ventavis for PAH.

Figure 1. Riociguat consensus forecasts look achievable

	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Riociguat global sales potential in CTEPH (€m)	-	44	126	232	348	430	477	502
Upside potential in PAH @ 5% market share (€m)	-	10	44	90	139	190	219	250
Total upside sales potential (€m)	-	54	170	322	487	620	697	752
<b>Consensus (€m)</b>	<b>24</b>	<b>91</b>	<b>161</b>	<b>215</b>	-	-	-	-
Citi current riociguat forecasts (€m)	54	135	216	292	373	443	491	524

Source: Vara Research, Citi Research

Convincing early data and substantial patient numbers give us confidence in CTEPH outcome

Although small, an early open-label study in 41 patients showed a significant improvement of 64m in 6MWD in CTEPH patients as well as significant improvements in other supportive endpoints. 6MWD is the primary endpoint for Ph3 with patient numbers on drug increased to ~130. However, we acknowledge the fact that other PAH drugs, including Actelion's Tracleer, failed to show a benefit in randomised controlled CTEPH trials despite encouraging early signs.

PAH trial most likely to succeed although commercialisation challenging

With eight branded therapies already approved for PAH, physicians believe it will be difficult for riociguat to differentiate itself unless the PATENT-1 trial materially over-delivers (6MWD in the range of 60m+, significant functional class and hemodynamic improvement plus good tolerability in treatment-naïve patients). We see this as unlikely. Commercialisation will likely be hampered by the imminent genericisation of Pfizer's Revatio, which works on the same pathway as riociguat, albeit at a different step. However, should the data surprise on the upside, use in just 5% of diagnosed PAH patients could add €250m to our 2020E sales estimate.

Additional upside possible from other PH subtypes such as heart failure patients with left heart dysfunction; key data 5 Nov

We expect Bayer to initiate late-stage trials in other untreated PH subtypes in 2013 which could also drive additional upside longer-term. Ph2 results from the LEPHT study in heart failure patients with PH due to systolic left ventricular dysfunction (PH-sLVD) will be presented on 5 November at the AHA 2012 meeting.

## Riociguat – overlooked and underappreciated

**PAH and CTEPH have some similarities; hence the same drugs could be effective in both diseases**

Both PAH and CTEPH are sub-groups of Pulmonary Hypertension

Both PAH and CTEPH patients suffer from Pulmonary Hypertension (PH), a condition where there is continuous high blood pressure in the pulmonary artery, a critical blood vessel which channels blood from the heart to the lungs for re-oxygenation. PAH and CTEPH are two of the five subgroups of the World Health Organisation classification of PH.

There are believed to be two main factors contributing to the increased vascular resistance (and hence raised blood pressure) that characterises PH:

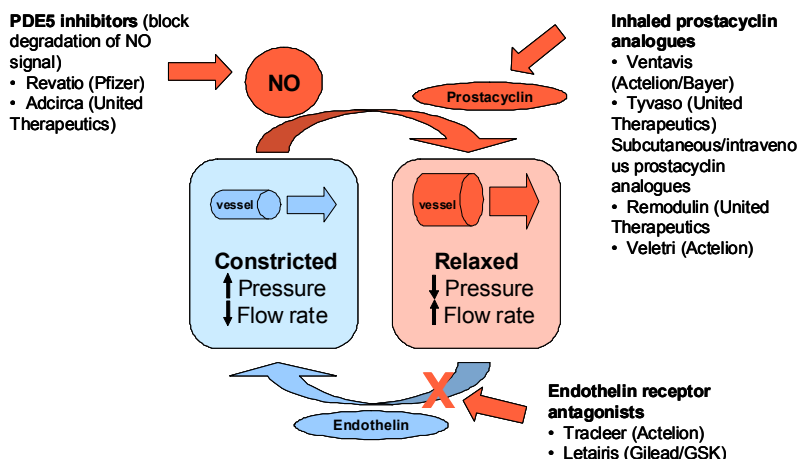
1. **Vasoconstriction** (narrowing of the blood vessels resulting from contraction of the smooth muscular wall of the vessels);
2. **Remodelling** (narrowing of the blood vessels due to uncontrolled cellular growth).

In patients with PH, the right side of the heart has to work harder to pump blood through the narrowed arteries which can ultimately lead to right ventricular failure and death.

Some of the mechanisms causing PAH may also be faulty in CTEPH patients; hence drugs may work in both diseases

This vasoconstriction and remodelling in PAH is characterised by an imbalance between endogenous vasodilators (nitric oxide and prostacyclin) and vasoconstrictors (endothelin) as shown in Figure 2. There is evidence to suggest that similar processes may play a role in the development of CTEPH and hence drugs that are known to be effective in PAH through targeting these pathways might also have a beneficial effect in certain patients with CTEPH.

Figure 2. Three different pathways are targeted with current PAH therapies



Source: Bayer, Citi Research

Over 90% of PAH patients in registries are treated with 1 of 8 approved PAH medicines

Riociguat works on the NO pathway at a different step to PDE-5 inhibitors

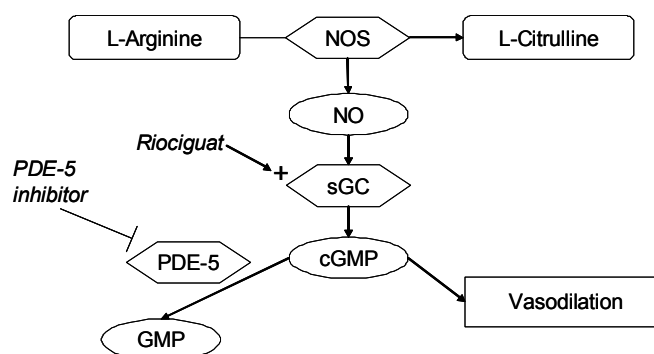
Riociguat has a dual mode of action which could provide some advantages vs PDE-5s

Registries of PAH patients suggest that over 90% of diagnosed PAH patients are treated with one or more PAH-specific medications targeting these pathways. Sales of branded therapies in PAH in 2011 globally were greater than \$3.5bn.

### Riociguat has a novel mechanism of action but targets the NO pathway

Riociguat is an oral drug that stimulates soluble guanylate cyclase (sGC), a key component of the nitric oxide (NO) signalling pathway with a dual model of action. When sufficient NO is present, riociguat acts in synergy with NO by stabilising the binding of NO to sGC. However, it can also stimulate sGC directly when NO is absent or scarce. This latter activity distinguishes it from the phosphodiesterase (PDE)-5 inhibitors which act further downstream in the pathway, preventing degradation of cyclic guanosine monophosphate (cGMP) as shown in Figure 3. The PDE-5s require the presence of NO to function and may have limited effect in the presence of very low NO levels, as is sometimes observed in patients with PAH.

Figure 3. There are several PDE-5 inhibitors approved in PAH; riociguat targets a different step in the pathway



Source: Kim et al Eur Respir Rev 2010;19 115, 68-71, Citi Research; Notes: NOS = NO synthase

### Surgery should be the treatment of choice in CTEPH....where possible...

Up to 4% of patients who have had a PE could progress to CTEPH

The defining feature of CTEPH, however, is the obstruction of the pulmonary arteries with fibrotic material as well as the remodelling which leads to increased pulmonary artery pressure and right ventricular failure. Up to 75% of patients with CTEPH have experienced a previous acute pulmonary embolism (PE). This is a blood clot that has travelled from elsewhere in the body, through the bloodstream, to block the main artery of the lung. Despite continued treatment with anticoagulants to resolve and prevent further PEs, up to 4% of patients go on to develop CTEPH where existing or new clot(s) continue to obstruct the pulmonary vessels.

Up to 60% of patients have surgery although 10-15% will relapse

CTEPH is a potentially correctable cause of PH and in up to 60% of patients, these clots can be removed through surgery, known as a pulmonary endarterectomy. However, not all patients are eligible for surgery due to the location of the clots, the relative contribution of small vessel disease or serious co-morbidities. In addition, PH can persist or reappear in 10-15% of patients after treatment. It is in these inoperable or relapsed patients that medical therapies may provide a benefit.

### Up to 50% of inoperable CTEPH patients receive PAH medications

To date, three randomised controlled trials on approved PAH therapies have been performed in CTEPH. However, as shown in Figure 4, none succeeded in delivering a convincing enough data-package to support approval for this additional indication.

No randomized controlled trials have shown a convincing benefit of a PAH medication in CTEPH patients

**Figure 4. Three approved PAH therapies have failed to demonstrate convincing efficacy in CTEPH in RCTs**

	Ventavis	Revatio	Tracleer
Target pathway	Prostacyclin	Nitric oxide	Endothelin
Patients	57 CTEPH (203 total)#	19 CTEPH	157 CTEPH
Duration of study	12 weeks	12 weeks	16 weeks
Primary end-point	6MWD + NYHA functional class	6MWD	6MWD or PVR <sup>∞</sup>
Primary end-point met?	Yes (total study population)	No	Yes: PVR, No: 6MWD
Change in PVR vs placebo (dyn.2.cm <sup>-5</sup> )	-105* (pre-inhalation); -335 <sup>1</sup> (post inhalation)	-197*	-176*
Change in 6MWD vs placebo (m)	+36.4* (PPH=58.8; nPPH=12)	+17.5	+2.2

Source: Kim et al Eur Respir Rev 2010; 19: 115, 68-71, Citi Research. PVR: pulmonary vascular resistance; 6MWD: 6-min walking distance; NYHA: New York Heart Association; PPH: primary pulmonary hypertension; nPPH: nonPPH (including CTEPH and pulmonary hypertension associated with anorexigen use or scleroderma). # separate analyses for the CTEPH subgroup were not presented but type of pulmonary hypertension was stated to have no significant effect on the response to treatment; <sup>∞</sup> independent co-primary end-points; <sup>1</sup> significance versus placebo not assessed. \*: p<0.05.

Despite the lack of regulatory approval, data from a large European and Canadian CTEPH registry suggests that over 50% of inoperable patients currently receive PAH medicines off-label at diagnosis, with the majority taking either PDE-5s or endothelin antagonists (ERAs) as shown in Figure 5.

~50% of inoperable patients receive PAH drugs off-label; most take PDE-5s or ERAs

**Figure 5. Registries suggest extensive use of PAH therapies off-label in CTEPH, particularly in inoperable patients**

	All patients (n=679)	Operable Patients (n=427)*	Inoperable patients (n=247)*	P (exploratory)
PAH-targeted therapy, % (n)	37.9 (676)	28.3 (427)	53.8 (247)	<0.0001
PDE-5 inhibitor (%)	17.5	16.2	19.4	0.2923
ERA (%)	21.7	12.2	37.7	<0.0001
Prostacyclin analogue (%)	2.7	1.6	4.5	0.0443
Combination therapies (%)	4.0	1.6	7.7	0.0002

Source: Citi Research, Pepke-Zaba et al Circulation 2011;124:1973-1981. P values from fisher exact test, (n): patients with assessment. \*5 patients had no data on operability

PAH drugs likely have a “real” effect in some patients; trial size and endpoints have likely confounded outcomes to date

Our physician consultants believe that these drugs confer benefits in many symptomatic inoperable patients with CTEPH and that the failure to demonstrate significance in the controlled trials to date is most likely due to the heterogeneity of the inoperable CTEPH group exacerbated by small trial sizes. This group incorporates patients both with distal disease and a lower clot burden which is not accessible to surgeons (and is potentially more similar to PAH) and proximal disease with a higher clot burden which either do not want the operation or who have co-morbidities. This latter group may be much less responsive to medical treatment than the former and hence the ability to show significant benefits on endpoints such as 6MWD in randomised trials will depend on the sheer size and make-up of that cohort.

The choice of endpoint and duration of the studies could also have played a role. Haemodynamic endpoints may be more responsive in CTEPH patients than 6MWD, as was the case in the Tracleer Benefit trial, but although these endpoints are meaningful for physicians, they have not historically met regulatory hurdles for approval.



## Riociguat has demonstrated efficacy in Ph2 both CTEPH and PAH

### Ph2 riociguat study demonstrated efficacy in both PAH and CTEPH subgroups

Results of a 12-week, Ph2 study of riociguat given orally three times per day in 72 patients with CTEPH or PAH were released at ATS in May 2009. Although this was a relatively small, open-label, uncontrolled study with safety and tolerability as the primary endpoint, riociguat showed significant benefits on efficacy endpoints such as 6MWD and haemodynamics as shown in Figure 6.

Figure 6. Riociguat demonstrated significant improvements in both 6MWD and PVR in the Ph2 study in CTEPH and PAH patients

	6MWD			PVR (dyn.s.cm <sup>-5</sup> )	
	Baseline (m)	Mean change from baseline after 12 weeks and 95% CI (m)		Baseline	Median change from baseline after 12 weeks and interquartile range
CTEPH (n=41)	382.9 ± 88.1	+64.3 (44.2 - 84.4)**	CTEPH (n=30)	691 (533-854)	-200 (-288 - -115)***
PAH (n=31)	316.7 ± 127.4	+73.5 (42.7 - 104.3)**	PAH (n=20)	748 (448-1342)	-245(-560 - -142)***
All patients (n=72)	354.4 ± 111.0	+68.4 (54.2 - 85.6)**	All patients (n=50)	709 (521-970)	-215 (-327 - -117)***

Source: ATS 2009 Bayer presentation, ERJ 2010; 36: 792-799; Citi Research. \*\* p<0.001, \*\*\* p<0.0001. Note that 6MWD are mean values, PVR are median.

### Hypotension is likely to be the side effect of most concern

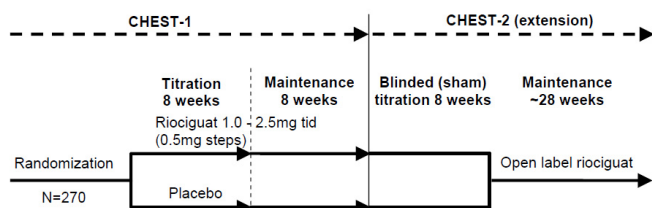
In general, riociguat was well tolerated, with dyspepsia, headache and fluid retention the most common adverse events. Riociguat does cause some systemic vasodilation; hence individual dose titration is required during initiation of the study to optimise the balance between promoting pulmonary vasodilation and controlling systemic effects. In the Ph2 study, 72% of the patients were able to titrate up to the maximum dose of 2.5mg three times per day. There were nine cases of asymptomatic hypotension (low blood pressure in the trial) although seven of these resolved without dose reduction and a lower dose was well-tolerated in the other two patients. Hypotension and its symptomatic effects, such as syncope, will be a key area to watch during the Ph3 programme.

## Both CTEPH and PAH trials have a good chance of success

### Experts believe both trials most likely to work; CHEST is the one generating most anticipation

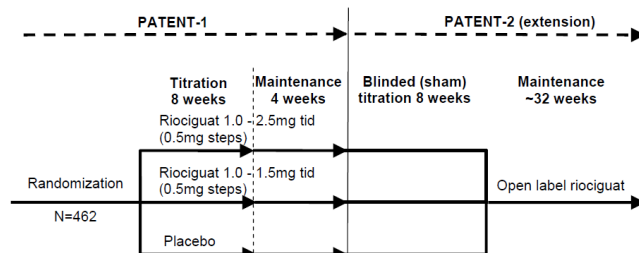
Schematic outlines of both trials are shown in Figure 7 and Figure 8. As well as the supportive data from the Ph2 trial and previous dose-ranging studies, both trials are well-powered versus historical randomised controlled trials in similar settings which should maximise their chances of success; particularly in the CTEPH setting. Our expert consultants in the space believe that both trials are likely to succeed, although they are more positive about the outcome for the CTEPH programme, given the high unmet need.

Figure 7. CHEST study design



Source: Bayer, Citi Research

Figure 8. PATENT study design



Source: Bayer, Citi Research

Both have 6MWD as the primary endpoint with secondary endpoints including hemodynamics, change in functional class and time to clinical worsening. Patients in the PATENT-1 trial are either treatment-naïve or being treated with an endothelin receptor antagonist or prostacyclin analogue. Our expectations from the primary trial results are as follows:

**Our experts would view ~20m 6MWD plus haemodynamic improvements as a successful outcome in CHEST-1**

■ **CHEST-1:** Physicians do not expect the 6MWD improvement in CTEPH patients to be as large as that in PAH. Hence physicians would view a ~20m improvement in 6MWD along with a significant improvement in hemodynamic measures as a clinically meaningful outcome.

**40-50m 6MWD is our expectation from PATENT-1**

■ **PATENT-1:** 40-50m improvement in 6MWD plus significant improvement in haemodynamics in treatment-naïve patients. 20-30m on top of endothelins. This would put efficacy in-line with the approved PDE-5 inhibitors Revatio (Pfizer) and Adcirca (United Therapeutics). Our physician experts would want to see 6MWD in the range of 60m+, significant functional class and hemodynamic improvements, plus good tolerability in treatment-naïve patients to truly differentiate from existing PDE-5 inhibitors.

**Both trials will be presented from 9.30-11.00pm UK time on 23<sup>rd</sup> Oct**

Both PATENT-1 and CHEST-1 will be presented as late-breakers at the CHEST 2012 respiratory medical meeting in Atlanta on 23 October. The session runs from 4.30-6.00PM EDT (9.30-11pm UK time). Bayer is holding an investor call at 1pm CEST on 24 October. The extension trials are ongoing and we believe data from the full 52 weeks will be needed for regulatory filing, suggesting approval in the 1H14 timeframe. Riociguat has orphan drug status for both CTEPH and PAH in Europe.

### **CTEPH could be an underappreciated opportunity**

**We believe prevalence forecasts are likely to underestimate the extent of the disease**

Prevalence estimates of the numbers of patients with CTEPH are rare, often conflicting and likely, we believe, under-estimate the burden of disease. Bayer has recently stated that it believes there were 20,000 patients diagnosed with the condition in the US, top five EU and Japanese markets combined in 2009. We believe that is a conservative estimate and forecast that the globally diagnosed market could be as large as 60,000 patients by 2020E, growing from our current estimate of around 37,000. Confidence in our more bullish estimates comes from several factors:

**CTEPH patient population could be 40% the size of PAH**

■ PH registries suggest that the **number of diagnosed CTEPH patients is up to 40% of those diagnosed with PAH**. Back-calculating from the number of patients taking PAH-specific medications, assuming ~10% off-label use in non-PAH patients, would suggest that there could have been over 12,000 patients diagnosed and living with CTEPH in the US alone in 2009. A number of this magnitude is supported by analysis of insurance databases in the US.

**Evidence suggests that CTEPH diagnosis rates are increasing rapidly**

■ Recent studies have suggested that **~3% of the survivors of an acute pulmonary embolism will suffer from CTEPH within a year**. Assuming 600k acute PE cases in the US per year, and a 2/3 survival rate, implies over 12,000 new CTEPH cases per year. However, we acknowledge that many of these will not be diagnosed.

■ The **diagnosed incidence of CTEPH in a UK registry has increased ten-fold** from 0.3 to 3.7 cases per million per year between 2001 and 2009. The total number of all PH patients being actively treated in the UK's NHS has risen from 1,500 in 2004 to 5,000 in 2011.



**The availability of an approved therapy is likely to increase diagnosis rates**

- As has been the case with PAH, the availability of licensed medicines to treat the disease, and the accompanying marketing push, is likely to raise awareness and increase diagnosis and treatment rates, particularly in areas where there are less skilled surgeons available to perform surgery.

Our analysis suggests that ~18,000 patients globally, who are unable to undergo surgery for CTEPH or who have relapsed, could be eligible for treatment with riociguat at launch. Over half of these patients currently receive unapproved PAH therapies off-label. Our physician consultants would use riociguat as both a preferred first-line therapy in new patients or to switch patients who are not well-controlled. Assuming pricing similar to branded therapies such as Tracleer or Letairis in PAH and a ~50% utilisation rate, CTEPH could create a €500m opportunity alone and support our current estimates, as shown in Figure 9.

**Figure 9. Summary CTEPH riociguat patient model**

Summary patient model	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Diagnosed CTEPH patients	44,929	48,336	51,331	54,331	57,308	60,381	63,551
% ineligible for surgery	40%	40%	40%	40%	40%	40%	40%
<b>Non-operable patients</b>	<b>17,972</b>	<b>19,335</b>	<b>20,532</b>	<b>21,732</b>	<b>22,923</b>	<b>24,152</b>	<b>25,420</b>
% relapsers	12%	12%	12%	12%	12%	12%	12%
Relapsed patients	3,235	3,480	3,696	3,912	4,126	4,347	4,576
<b>Total eligible patients</b>	<b>21,206</b>	<b>22,815</b>	<b>24,228</b>	<b>25,644</b>	<b>27,049</b>	<b>28,500</b>	<b>29,996</b>
Market share	7%	18%	31%	44%	52%	56%	56%
No. pts on riociguat	1,382	4,100	7,479	11,209	14,121	15,880	16,701
US/ROW price (\$)	50k / 32k	50k / 32k	50k / 32k	50k / 32k	50k / 32k	50k / 32k	50k / 32k
Global sales (\$m)	56	163	299	449	554	616	647
<b>Global sales (€m)</b>	<b>44</b>	<b>126</b>	<b>232</b>	<b>348</b>	<b>430</b>	<b>477</b>	<b>502</b>

Source: Citi Research

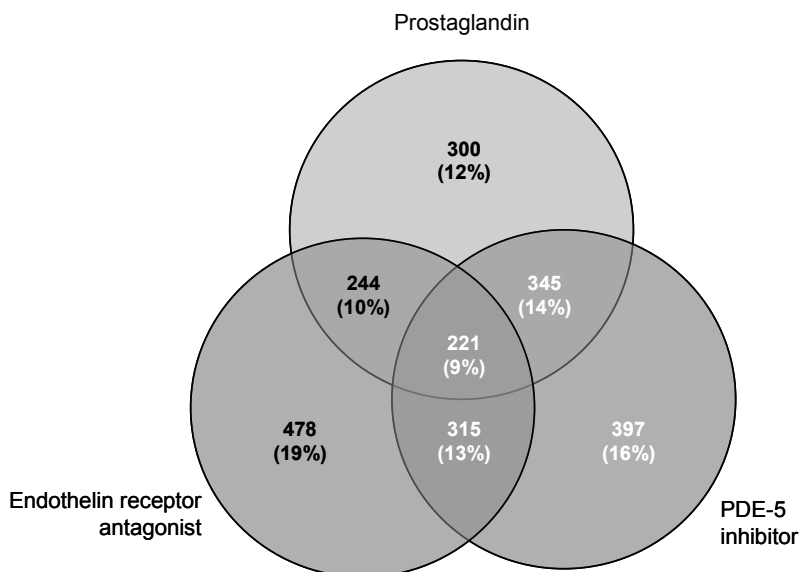
We note that currently only United Therapeutics appear to be running active clinical trials in CTEPH, with its study using subcutaneous Remodulin. We hence see limited approved competition to riociguat, should the CHEST-1 trial be successful.

### **PAH likely to provide a more challenging operating environment**

**Riociguat would need to show clear differentiation vs existing therapies to garner material market share in PAH**

With eight branded therapies already approved for PAH, physicians feel that there are enough options currently available for patients unless a new drug shows clear differentiation versus well-entrenched existing therapies. According to the REVEAL US registry, over 90% of diagnosed PAH patients receive at least one PAH-specific medication as shown in Figure 10. The majority of physicians use PDE-5s as their first-line agent given cost and side-effect advantages, then moving on to endothelin antagonists at failure either as monotherapy or in combination.

**Figure 10. PAH specific medication use at enrollment among previously diagnosed patients in the REVEAL registry**



Source: McGoon et al Eur Respir Rev 2012; 21: 123, 8–18, Citi Research. 184 (7%) of patients were not on a prostaglandin, phosphodiesterase type-5 inhibitor or endothelin receptor antagonist. Of these, 88 were on calcium channel blockers for the treatment of pulmonary arterial hypertension.

**60m+ 6MWD plus supportive secondary endpoints could support an upside scenario**

Although riociguat works at a different step in the NO pathway than the PDE-5s and may be able to work in patients with particularly low levels of NO, physicians we have spoken to cannot see a compelling rationale for initiating treatment with riociguat instead of PDE-5s unless the PATENT-1 trial demonstrates a profile that appears substantially beneficial for patients. This profile would need to be 6MWD in the range of 60m+, significant functional class and hemodynamic improvement, plus good tolerability in treatment-naïve patients. Given the data we have seen to date, physicians see this as an unlikely outcome and view a profile more similar to either Revatio or Adcirca as the most likely scenario. Given this, it's difficult to see riociguat being able to gain material market share in the PAH market, particularly given its 3x per day dosing schedule.

**The imminent genericisation of the PDE-5 Revatio provides a commercial headwind**

From a commercial perspective, pricing in the PAH market is also likely to be difficult for riociguat. The PDE-5s are priced at a substantial discount to the endothelin antagonists (annual treatment costs in the region of \$20k in the US vs \$50k for Tracleer/Letairis). Hence pricing competitively vs the PDE-5s in PAH could prevent more attractive pricing which Bayer may be able to command in CTEPH as the only approved therapy. Further pressure is likely to come from the imminent genericisation of Pfizer's Revatio.

**We expect Bayer to initiate late-stage trials in other PH subtypes in 2013...**

However, should the data surprise on the upside, and riociguat sees some use in patients failing PDE-5s, a market share of just 5% of diagnosed PAH patients could add €250m to our 2020E sales estimate. We expect Bayer to initiate late-stage trials in other untreated PH subtypes in 2013 which could also drive additional upside longer-term. The Ph2 results from the LEPHT study in heart failure patients with PH due to systolic left ventricular dysfunction (PH-sLVD) will be presented on 5 November at the AHA 2012 meeting.

**...The Ph2 LEPHT trial in heart failure patients with PH and left heart dysfunction will be presented on 5 Nov**

## Bayer AG

### Company description

Bayer is a Chemical and Healthcare conglomerate participating in prescription and consumer pharmaceuticals, crop and material sciences. In 2010, Bayer had HealthCare sales of €16.9bn, CropScience sales of €6.8bn and MaterialScience sales of €10.1bn. We anticipate the relative contribution of Healthcare to group sales and EBIT to increase due to the increasing contribution of Bayer's pharmaceutical pipeline to group revenues.

### Investment strategy

We rate Bayer Buy. We see 8-10% upside to 2013E-14E consensus core EPS, driven by: (i) operating leverage from Bayer's late-stage pharma pipeline (principally Xarelto); (ii) strong anticipated performance from CropScience and EM, and (iii) an expected fall in the company's effective tax rate from 28% to 25% by 2014. We forecast a 5-year core EPS CAGR of 5.4% (2013E-18E), in line with the peer group. In HealthCare, we believe the market underestimates the opportunity for Xarelto in atrial fibrillation (AF) ex-US. In CropScience, near-term volumes and margins should be supported by high crop prices while, longer term, we forecast margins to move towards 24%, driven by Bioscience. We note that the near-term outlook for MaterialScience remains challenging.

### Valuation

Our €75 target price reflects a target multiple of c.12x 2013E core earnings, c.10% ahead of where the sector trades, reflecting Bayer's higher core EPS growth outlook (ex buyback) and lower risk premium, given its strong asset and geographical diversification. We calculate a DCF-derived Intrinsic Value of €90. We arrive at this by projecting free cash flows for an explicit 10-year period, thereafter applying terminal growth assumptions. Consistent with our sector methodology, which makes use of the CAPM to arrive at a cost of equity, we calculate a WACC of 7.9% and assume a 0% terminal growth rate. Our Sum-of-the-Parts valuation is €73 based on 2013E EV/EBITDA multiples.

### Risks

Near-term investment risks include worsening weakness in demand for MaterialScience products, as well as higher raw material costs exerting pressure on margins, and market over-reaction to likely slow Xarelto Rx uptake in the US.

Longer-term, the CropScience division is highly cyclical and is subject to generic competition and the phase out of older technologies. Its pricing power is highly dependent on grain prices. Low grain prices would have a materially adverse impact on profitability. The MaterialScience division is also driven by the cyclical supply/demand balance of its key products polyurethanes and polycarbonates. Weak economic growth of capacity expansion could substantially impact the profit outlook for this division. If the impact of these risk factors is more negative than we currently assume, then the share price might not reach our target price.

# Appendix A-1

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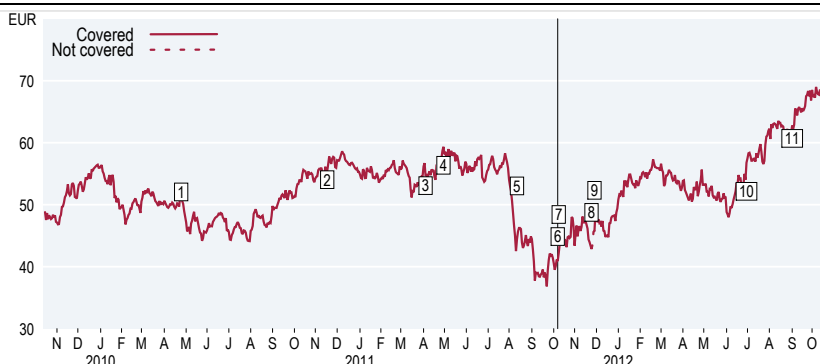
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### Bayer AG (BAYGn.DE)

#### Ratings and Target Price History Fundamental Research

Analyst: Andrew S Baum

Covered since November 29 2011



	Date	Rating	Target Price	Closing Price
1	24-Apr-10	1M	*58.00	51.51
2	17-Nov-10	1M	*63.00	55.44
3	5-Apr-11	1M	*65.00	54.65
4	29-Apr-11	1M	*66.00	59.35

\* Indicates change

	Date	Rating	Target Price	Closing Price
5	11-Aug-11	1M	*60.00	44.42
6	7-Oct-11	Stock rating system changed		
7	8-Oct-11	*1	60.00	40.90
8	24-Nov-11	Coverage terminated		

	Date	Rating	Target Price	Closing Price
9	29-Nov-11	1	*61.00	45.79
10	29-Jun-12	1	*64.00	56.78
11	3-Sep-12	1	*75.00	62.78

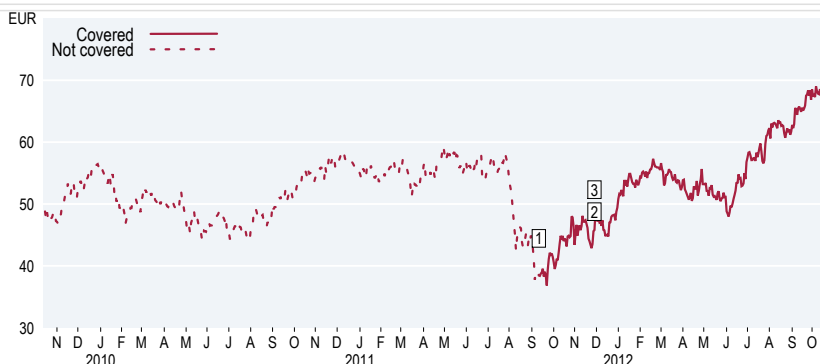
Rating/target price changes above reflect Eastern Standard Time

### Bayer AG (BAYGn.DE)

#### Ratings and Target Price History Best Ideas Research Relative Call (3 Month)

Analyst: Andrew S Baum

Covered since November 29 2011



	Date	Rating	Target Price	Closing Price
1	12-Sep-11	*ADD MP	-	38.44

\* Indicates change

	Date	Rating	Target Price	Closing Price
2	29-Nov-11	*REM MP	-	45.79

	Date	Rating	Target Price	Closing Price
3	29-Nov-11	*ADD MP	-	45.79

Rating/target price changes above reflect Eastern Standard Time

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