GlaxoSmithKline

Upgrading to Neutral, upside from upcoming catalysts balances out earnings risk

▲ Neutral
Previous: Underweight

GSK.L, GSK LN
Price: 1,680p

▼ Price Target: 1,900p
Previous: 1,910p

We upgrade to Neutral (UW), setting a £19 PT, 13% potential upside. Whilst we believe cons.* expectations for 2014 Core EPS could prove slightly too ambitious, we see numerous datapoints over the next 6m that could drive upgrades. We focus on 3 opportunities: **(1) Breo for COPD**, where our proprietary physician survey suggests fairly strong uptake, **(2) Anoro for COPD**, where the Sep 10th AdCom panel should provide a significant share-price boost, assuming the FDA is comfortable with the LAMA dosing data, **(3) Darapladib** for Cardiovascular disease, which we see as high risk, but potentially high reward. Updating for upcoming divestments and Q2'13 results, for 2014-16E we trim Revenues 3-4%, trimming EPS 1-5%. Our EPS are 5-6% behind cons. 2014-16E. We believe GSK should trade on 14x 2015E PE, inline with where the sector should be in 12m, for an inline growth outlook (both 8% 2014-17E EPS CAGR).

- **Respiratory survey highlights: (1) Significant enthusiasm for Breo despite limited clinical differentiation,** uptake should offer some protection against the long-term threat of US generic Advair. Our 2017 Advair/Breo forecasts are 6% ahead of consensus, at £5.1bn. **(2) Strong uptake for Anoro, in the event of a positive AdCom panel on Sep 10th**. We conclude that whilst there is still some risk around umec PII dosing data, the most likely outcome is a +ve vote. If approved, Physicians expect LAMA/LABAs like Anoro, to take significant share from other classes, providing a much needed boost to GSK's respiratory franchise. Our 2017 Anoro forecasts of £0.9bn are 19% ahead of cons.
- **Numerous pipeline catalysts to drive performance in H2'13, inc. the high risk/high reward darapladib PIII results.** H2'13 will see Darapladib PIII results (cardiovascular events). We include nothing in our model, based on mixed PII data, though we see up to 9% EmV upside in the event of +ve results. We also see positive risk/reward around MAGE-A3 (PIII data H2'13 for NSCLC/Melanoma, high risk/low expectations), Drisapersen (PIII data Q4, DMD lower risk) and Vercinon (PIII in Q4 for Crohn's).
- **Forecast changes and PT:** We trim 2014-16E Revenues 3-4% and EPS 1-5%, on upcoming divestments, Q2'13 and a slower buyback. Vs. 2014-16 cons. we are 3-4% behind on Revenues, and 5-6% behind on Core EPS. Our mid-14 £19 PT (was £19.10) assumes 14x 2015E, a sector multiple for sector growth (8% 2014-17E EPS CAGR).

European Pharma

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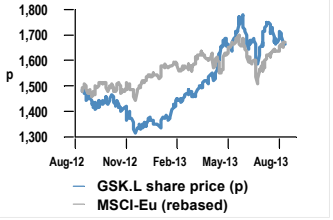
Price Performance



	YTD	1m	3m	12m
Abs	24.8%	-4.8%	-1.2%	12.4%
Rel	16.1%	-8.0%	-1.2%	-0.3%

** Company collated consensus*

GlaxoSmithKline (GSK.L;GSK LN)

FYE Dec	2012A	2013E (Prev)	2013E (Curr)	2014E (Prev)	2014E (Curr)
Revenue FY (£ mn)	26,431	27,036	27,027	28,044	27,105
Core COGS FY (£ mn)	(7,109)	(7,488)	(7,540)	(7,795)	(7,480)
Core SG&A FY (£ mn)	(7,905)	(7,945)	(8,016)	(8,329)	(8,120)
Core R&D FY (£ mn)	(3,485)	(3,570)	(3,536)	(3,600)	(3,572)
Core Op. Profit FY (£ mn)	8,238	8,364	8,268	8,572	8,194
Core EPS (diluted) FY (p)	111.36	119.4	117.66	125.3	119.76
Adj.P/E FY	15.1	14.1	14.3	13.4	14.0
Gross Yield FY (p)	74.00	79.00	79.00	84.00	84.00

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

Company Data	
Price (p)	1,680
Date Of Price	13 Aug 13
Price Target (p)	1,900
Price Target End Date	30-Jun-14
52-week Range (p)	1,816-1,314
Market Cap (£ mn)	82,521.60
Shares O/S (mn)	4,912

See page 37 for analyst certification and important disclosures, including non-US analyst disclosures.

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Executive summary

We upgrade to Neutral, setting a £19 PT, 13% potential upside.

We believe consensus expectations for 2014 Core EPS could prove slightly too ambitious, in light of upcoming divestments impacting the topline (Lucozade & Ribena taking £1bn off Consumer, Arixtra & Fraxiparin taking £0.4bn off Pharma), as well as a slightly higher share count, as we now model a buyback of £1.7bn for 2013, £1.8bn beyond (previously £2bn annually).

However we see numerous datapoints over the next 6m that could drive upgrades. In this note we focus on 3 opportunities:

(1.) Breo for COPD, where our proprietary physician survey suggests fairly strong uptake is likely, provided GSK can obtain formulary access.

(2.) Anoro for COPD, where the Sep 10th AdCom panel should provide a significant share-price boost, assuming the FDA is comfortable with the LAMA dosing data, and the panel votes in favour of approval.

(3.) Darapladib for Cardiovascular disease, which we see as high risk, but potentially high reward.

Updating for upcoming divestments and Q2'13 results, we trim Revenues and EPS 2-3%. Our EPS are 5-7% behind cons. 2014-16E. We believe GSK should trade on 14x 2015E PE, inline with where the sector should be in 12m, for an inline growth outlook (both 8% 2014-17E EPS CAGR).

Respiratory survey highlights: (1) Significant enthusiasm for Breo despite limited clinical differentiation, uptake should offer some protection against the long-term threat of US generic Advair. Our 2017 Advair/Breo forecasts are 6% ahead of consensus, at £5.1bn. **(2) Strong uptake for Anoro, in the event of a positive AdCom panel on Sep 10th**. We conclude that whilst there is still some risk around umec PII dosing data, the most likely outcome is a +ve vote. If approved, Physicians expect LAMA/LABAs like Anoro, to take significant share from other classes, providing a much needed boost to GSK's respiratory franchise. Our 2017 Anoro forecasts of £0.9bn are 19% ahead of cons.

Numerous pipeline catalysts to drive performance in H2'13, inc. the high risk/high reward darapladib PIII results. H2'13 will see Darapladib PIII results (cardio events). We include nothing in our model, based on mixed PII data, though we see significant upside to JPM and cons. estimates in the event of +ve results. We also see positive risk/reward around MAGE-A3 for NSCLC/Melanoma (high risk/low expectations), Drisapersen for DMD (lower risk, underappreciated potential) and Vercinon for Crohn's in Q4.

Forecast changes and PT: Reflecting the Q2'13 results, our expectations for upcoming divestments, and the slower than anticipated pace of the buyback, we trim Revenues and EPS 2-3%. In comparison to 2014-16 cons. we are 3-4% behind on Revenues, and 5-6% behind on Core EPS. Our £19 Mid-14 price target assumes 14x 2015 PE, the multiple we expect the sector to be on in 12 months' time. We believe an inline multiple is justified by EPS growth inline with the large cap sector (both 8% 2014-17 EPS CAGR).

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Key upcoming newsflow summary

Table 1: GSK key newsflow event summary

Timing	Product (Indication)	Peak sales (no risk adj.)	Comment
Sep 10th '13 (briefing docs Sep 6th) **AdCom**	**Anoro** COPD	c.£1.5bn (£1.5bn)	Whilst we do still see some remaining risk around the dose response data for umec (LAMA ingredient), we believe the most likely outcome is a positive panel vote, based on how comfortable the FDA were on the dosing data for Vilanterol (LABA ingredient), as part of the recent Relvar AdCom and approval. We forecast 2017 global sales of £900m, worth 70p per share. Our 2017 forecasts are 15% ahead of consensus, with greater consensus upside ahead of 2017.
Q4'13 **PIII data**	**MAGE-A3** Cancer	- (c.£1bn)	GSK are developing their cancer vaccine MAGE-A3 against both Melanoma and NSCLC, with PIII data in both indications expected in Q4 2013. We consider both indications high risk, based on the novel immune directed approach, and GSK's cautious commentary around the chances of success. We currently include no forecasts for MAGE-A3 in either indication. Should our caution prove misplaced, we believe peak sales of £0.3bn could be achievable for Melanoma, with up to £0.6bn for NSCLC. Success in these two indications could be worth 30p and 70p per share, for which we believe very little is currently reflected in consensus, based on the approach, the previous data, and GSK's very cautious comments on the project.
Q4'13 **PIII data**	**Darapladib** Cardio	- (£3bn)	Darapladib is GSK's inhibitor of f LpPLA2, an inflammatory mediator, whose inhibition may reduce cardiovascular events. Q4'13 will see headline results from the 15.5k patient STABILITY study, testing whether Darapladib can reduce the rate of major cardiovascular event in patients with coronary heart disease. If positive, this could have positive read-through to the 11k patient SOLID-TIMI study, in post ACS patients, expected in 2014. Success across these two indications could mean £4.5bn peak sales; however we include nothing in our model, based on: (1) failure to show a benefit on plaque stability in PIIb, (2) lack of darapladib a benefit on endpoints other than biomarkers, (3) recent failure of many other conceptual cardiovascular products, albeit these worked via different mechanisms. We believe consensus assumes little chance of Darapladib success, suggesting far more upside from success, than downside from failure.
Q4'13 **PIII data**	**Vercinon** Crohn's	£0.2bn.'(£1bn)	Vercinon, a CCR9 partnered with ChemoCentryx is expected to report PIII data from the SHIELD-1 study for Crohn's disease in Q4'13. Whilst this study is only the first of 4 PIIIs, we believe positive results could significantly increase expectations for the remaining studies due to report in 2014 and 2015. We see a good chance of success, based on the PII PROTECT-1 study. We currently include peak sales of £200m, worth 8p per share, but we believe sales could reach over a billion £, which could add c.40p to GSK's NPV. We believe consensus includes little for this asset.
Q4'13 **PIII data**	**Drisapersen** DMD	£0.5bn (£0.6bn)	Drisapersen is an exon skipping therapy for the inherited genetic disease DMD. GSK licensed Drisapersen from Prosensa, on which we recently initiated coverage (click here). Strong PII data has already been announced, and Drisapersen was awarded breakthrough designation by the FDA on June 27th. Based on the data reported so far, we see a high chance of success in the upcoming PIII. We currently include peak forecasts of £500m, which after factoring in the c.£300m of milestones payable by GSK, is worth c.40p per share. Our forecasts remain conservative, and Drisapersen sales could exceed £600m for exon-51, with up to £1.3bn from other DMD exon skipping therapies. We believe consensus includes very little for Drisapersen, based on the lack of disclosure from GSK, and misplaced concerns about the competitive threat from Sarepta's exon skipper, hence positive PIII data could drive material upgrades.

Source: J. P. Morgan estimates, company reports

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Embedded Value

Table 2: JPMorgan Embedded Value summary

GSK Embedded Value (NPV per Share)									
	Peak Sales	**US**	**%**	**EU**	**%**	**ROW**	**%**	**NPV/Share**	**%**
Respiratory	**£14.8bn**								
Advair	£5.3bn	£0.73	4.6%	£0.28	1.8%	£0.69	4.3%	£1.70	10.8%
Relvar/ Breo	£2.7bn	£0.51	3.2%	£0.24	1.5%	£0.17	1.1%	£0.92	5.8%
Anoro (Zephyr)	£2.0bn	£0.51	3.2%	£0.14	0.9%	£0.11	0.7%	£0.76	4.8%
Flixotide/ Flovent	£0.8bn	£0.20	1.3%	£0.04	0.3%	£0.13	0.8%	£0.37	2.4%
Ventolin	£0.9bn	£0.26	1.7%	£0.06	0.4%	£0.19	1.2%	£0.51	3.2%
Other marketed	£1.1bn	£0.10	0.6%	£0.09	0.6%	£0.42	2.7%	£0.61	3.8%
FF mono	£0.8bn	£0.25	1.6%	£0.08	0.5%	£0.02	0.2%	£0.36	2.3%
UMEC mono	£1.0bn	£0.28	1.8%	£0.14	0.9%	£0.06	0.4%	£0.47	3.0%
Mepolizumab	£0.2bn	£0.03	0.2%	£0.02	0.2%	£0.02	0.1%	£0.08	0.5%
Anti-Virals	**£1.2bn**	£0.02	0.1%	£0.01	0.1%	£0.32	2.0%	£0.35	2.2%
CNS	**£1.8bn**	£0.08	0.5%	£0.08	0.5%	£0.39	2.5%	£0.55	3.5%
CV and urogenital	**£2.5bn**	£0.16	1.0%	£0.16	1.0%	£0.47	2.9%	£0.79	5.0%
Metabolic	**£0.8bn**	£0.10	0.6%	£0.11	0.7%	£0.18	1.1%	£0.40	2.5%
Antibacterials	**£1.5bn**	£0.01	0.1%	£0.08	0.5%	£0.72	4.5%	£0.81	5.1%
Oncology	**£2.2bn**	£0.49	3.1%	£0.30	1.9%	£0.30	1.9%	£1.08	6.8%
Dermatology	**£1.4bn**	£0.08	0.5%	£0.12	0.8%	£0.45	2.9%	£0.66	4.2%
Rare Diseases	**£0.9bn**	£0.15	1.0%	£0.30	1.9%	£0.15	1.0%	£0.61	3.9%
Immuno-inflammation	**£0.7bn**	£0.28	1.8%	£0.06	0.4%	£0.05	0.3%	£0.39	2.5%
Other Pharma	**£1.0bn**	£0.02	0.1%	£0.05	0.3%	£0.43	2.7%	£0.49	3.1%
Vaccines	**£5.3bn**	£0.73	4.6%	£0.72	4.5%	£1.16	7.4%	£2.61	16.5%
ViiV	**£2.1bn**	£0.44	2.8%	£0.43	2.7%	£0.31	2.0%	£1.18	7.5%
Total Pharma		**£5.44**	**34.4%**	**£3.52**	**22.3%**	**£6.74**	**42.7%**	**£15.70**	**99.3%**
of which Pipeline (Relvar, Anoro, FF mono, Albiglutide, Trametinib, Dabrafenib, Dolutegravir)		**£2.00**	**12.7%**	**£0.88**	**5.6%**	**£0.54**	**3.40%**	**£3.42**	**21.6%**
Pharma: Marketed + Pipeline		**£5.44**	**34.4%**	**£3.52**	**22.3%**	**£6.74**	**42.7%**	**£15.70**	**99.3%**
	Peak Sales								
Wellness	**£3.2bn**							£1.42	9.0%
Oral care	**£3.1bn**							£1.37	8.6%
Nutrition	**£1.8bn**							£0.80	5.0%
Skin health	**£0.4bn**							£0.20	1.2%
Total Consumer								**£3.78**	**23.9%**
Ph III / IV R&D costs								-£0.97	
Net Debt								-£2.48	
Other								**-£0.23**	
Pension Liability								-£0.63	
Legal Provision								£0.00	
2013E Disposals/Acquisitions								-£0.14	
Minority Stakes/Payments								£0.15	
Royalty Income								£0.39	
Total Other Items								**-£3.67**	
Total								**£15.81**	

Source: J. P. Morgan estimates

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Newsflow summary

Table 3: GSK newsflow summary

Expecting Timing	Products	Event	Indication	Details
Pipeline				
Q3 2013	FF mono (fluticasone mono)	Trial read-out	Asthma	114496 PIII study already completed. Data now in-house
Q3 2013	Tykerb	Trial read-out	Head & Neck cancer	EGF102988 study results (est completion Dec 2012)
H2 2013	**MAGE-A3**	**Trial read-out**	**Melanoma / Lung cancer**	**PIII DERMA / UARK 2003-26 study in Melanoma. PIII MAGRIT study in Lung cancer likely 2014**
Q4 2013	**Vercinon / GSK1605786A**	**Trial read-out**	**Crohn's disease**	**SHIELD-1 H2'13, SHIELD-4 2013/14 and SHIELD-2 & 3 in 2015**
Q4 2013	**Drisapersen**	**Trial read-out**	**DMD**	**Pivotal data for Duchene muscular dystrophy. To be presented at a conference in 2013 – granted Breakthrough therapy by the FDA (in 2Q13)**
H2 2013	**Darapladib**	**Trial read-out**	**Primary prev of MI/ stroke**	**First Phase III data, from the STABILITY study, SOLID-TIMI 52 and AIM III studies not expected until 2014**
H2 2013	Tykerb	Trial read-out	Adjuvant BC	ALTO in combination with Herceptin
Late 2013	Trametinib/ vemurafinib combo	Trial read-out	Melanoma	Recruitment completed in Metastatic Melanoma. Phase III in Adjuvant Melanoma started in Feb 2013
Late 2013	744	Trial read-out	HIV	PIIa/PIIb data for once monthly or once yearly integrase inhibitor, and PIII go/no-go decision
Mid 2014	Arzerra	Trial read-out	Refractory DLBCL	H2H study ve Rituxan ORCHARRD study
Mid 2014	Mepolizumab	Trial read-out	Severe asthma	115588 PIII study scheduled to complete Mar '14
H2 2014	Benlysta Sub Q	Trial read-out	Lupus	NCT01484496 data expected 2H 2014
H2 2014	Zoster vaccine	Trial read-out	Shingles	PIII studies 113077 and 110390
Late 2014	Amigal / Miglustat HCl	Pivotal data	Fabry disease	PIII '012 Amigal vs. ERT
2015	Relvar	Trial read-out	Asthma / COPD	Salford real-world usage study
2015	**Relvar**	**Trial read-out**	**COPD**	**SUMMIT Mortality/Morbidity study in 16k patients with history, or risk of CV disease.**
2015	Sirukamab	Trial read-out	Rheumatoid arthritis	SIRROUND-T ph3 study, SIRROUND-D Ph3 study in 2016
Regulatory submissions				
H2 2013	Votrient	US	Ovarian Cancer	
H2 2013	FF mono	US + Japan sub	Asthma	
H2 2013	Trii, Dolutegravir FDC	US / EU sub	HIV	
Regulatory approvals				
Q1'14	**trametinib MEK**	**EU approval**	**Metastatic Melanoma**	**Filed in Feb 7 2013 along with filing for indication for combination therapy with dabrafenib**
Aug 17th 2013	**6olutegravir monotherapy**	**US approval**	**HIV**	**Filed 17 Dec 2012, priority review**
Sep-13	Relvar	EU approval	COPD / Asthma	Filed Jul 13th 2012
Sep-13	**Anoro (Zephyr)**	**US Ad Com**	**COPD**	**Filed 18th Dec 2012**
Oct-13	dabrafenib BRAF / Tafinlar	EU approval	Metastatic Melanoma	Filed in Aug 2nd 2012 (pos opinion received 28th Jun '13)
18-Dec-13	**Anoro (Zephyr)**	**US approval**	**COPD**	**Filed 18th Dec 2012 – PUDFA date**
Late 2013	**Anoro (Zephyr)**	**EU approval**	**COPD**	**Filed 9th Jan 2013**
Late 2013	Trametinib/ vemurafinib combo	EU approval	Melanoma (metastatic)	Filed on 7th Feb 2013 for mono and combo use
Q1 2014	Dolutegravir monotherapy	EU approval	HIV	Filed 17 Dec 2012
15th April 2014	Albiglutide	US approval	Type 2 diabetes	Filed with FDA on 14 Jan 2013, 3m delay
Q1 2014	Anoro (Zephyr)	Jpn approval	COPD	Filed 22 April 2013
Q2 2014	Albiglutide	EU approval	Type 2 diabetes	Filed March 7th 2013
Q1 2014	umec mono	US approval	COPD	LAMA monotherapy filed April 30, 2013 in the US
Q1 2014	Votrient	Jpn approval	RCC	Approval in RCC (filed in 1Q13)
Mid 2014	umec mono	EU approval	COPD	LAMA monotherapy filed April 26, 2013 in Europe
Jul-14	Trametinib/ vemurafinib combo	US approval	Melanoma	Both drugs approved as monotherapies in May '13
H2 2014	Trii, Dolutegravir FDC	US/EU approval	HIV	Assume H2 2013 submission
2014	Relvar	Jpn approval	Asthma	Filed Q2' 2013 for Asthma, COPD withdrawn
Company events				
Oct 23rd 2013	-	Q3'13 results		
Competition				
H2 2013	Advair EU	Pot. Generics.	Asthma/COPD	Mylan MDI submission
H2 2013 or beyond	Advair UK	Pot. Generics.	Asthma/COPD	Cipla MDI approval in the UK
Mar 2014	**Advair US**	**Generic update**	**Asthma/COPD**	**IPAC conf will see FDA comments on new OIP guidelines, could see increased clarity on timing and substitutability in US**
Mid 2014	**Advair EU**	**Pot. Generics.**	**Asthma/COPD**	**Potential launch of Sandoz/Vectura's VR315 generic**

Source: Company reports, J. P. Morgan estimates

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Anoro AdCom, some Umec dosing risk remains, +ve vote most likely outcome

On Friday September 6th, the FDA will release briefing documents ahead of the September 10th Advisory Committee meeting to vote on US approval of GSK's Anoro, their LAMA/LABA for the treatment of COPD.

US Anoro approval would be a significant positive catalyst for GSK, with £1.5bn global peak sales potential, £1bn of which we expect to come from the US, where we expect pricing to be 5x that ex-US, and around 30% above GSK's existing COPD blockbuster, Advair.

We see Anoro as particularly important to GSK, as at best, GSK's recently approved Advair follow-on, Breo, will only take share within the LABA/ICS class, whereas Anoro, as a potential first to market LABA/LAMA, can take share from multiple other COPD therapeutic categories, and will most likely do so at a significant price premium to the existing LABA/ICS'.

Our model assumes a positive Anoro panel vote, leading to FDA approval by December 18th; however we do still see some risks around this application, which we set out below.

We expect the panel to focus on Umeclidinium LAMA dosing, the incremental benefits of vilanterol LABA in the combo, and umeclidinium's cardio profile:

1. **Umeclidinium LAMA dose selection, would twice daily be better?** Based on the noisy dose response data, the panel could question whether the optimal daily dose and dosing frequency has been indentified.
2. **Umeclidinium cardiovascular profile,** potentially an issue, with LAMA receptors on the heart providing a potential mechanistic rationale for increased risk QT interval, and hence increased risk of cardiovascular events. Umec hasn't shown a particularly concerning cardiovascular profile, but this is a concern for the class, and could raise questions on dosing.
3. **Is the combo rule satisfied, i.e. is vilanterol providing a significant benefit?** Combination products are expected to show a significant benefit for the combo vs. each of the ingredients as a monotherapy. Whilst this was generally achieved, the panel could question how much benefit is provided by the vilanterol ingredient. We believe Anoro should pass on this issue, as two placebo adjusted trials do show a significant benefit.

We believe the following issues are now fairly <u>unlikely</u> to be contentious:

1. **Vilanterol LABA dose selection**, again on magnitude and frequency. We now see this as a fairly low risk, in light of Breo (which also contains Vilanterol 25mcg as part of a combo, for COPD) achieving a positive panel vote on April 18th, with FDA approval obtained on May 10th.
2. **Elipta device approvability**, again, with Breo having recently been approved with the same device, this doesn't seem a significant risk.

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Potential issue 1. Umec dose selection, still some risk panel questions dose response data, but most likely acceptable

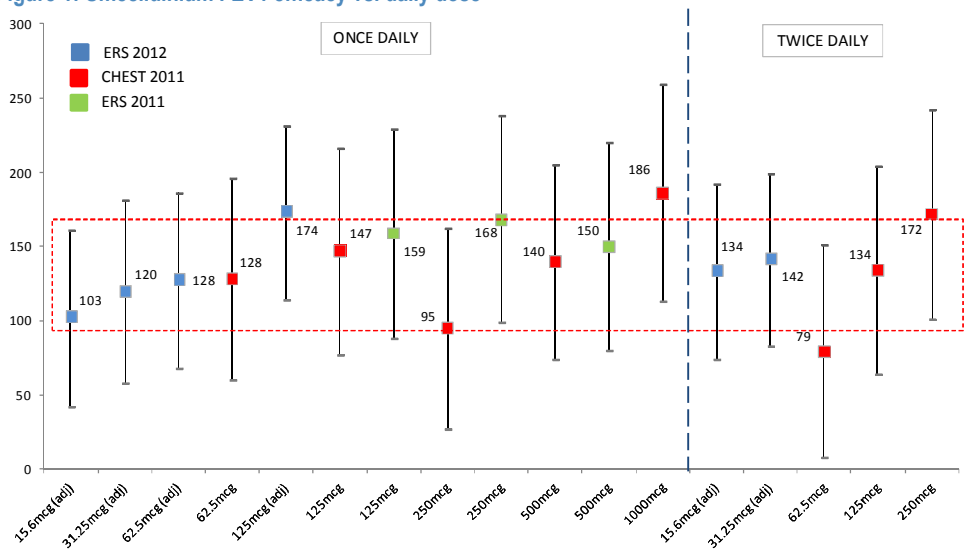
As we have discussed in previous research, we believe the PII umeclidinium LAMA monotherapy dosing data in the Anoro application does still have some unanswered questions, though the FDA's relaxed stance on Relvar, and the fact that the FDA accepted the Anoro filing (which they didn't for Novartis' LAMA/LABA, QVA) is encouraging for benign briefing docs, and a positive panel.

GSK have submitted Anoro containing two different umec doses, 62.5mcg and 125mcg, both once daily, with the entire Anoro PIII program having been conducted using once daily dosing, based on the trends seen in PII umec monotherapy dosing data. With the FDA's focus on approving the lowest necessary dose, we believe the most likely outcome is approval for Anoro at just the 62.5mcg umec dose level.

GSK have a commercial rationale to seek approval with once daily dosing, with Boehringer's Spiriva LAMA monotherapy already approved as a once daily product, and the newer LABA's, such as GSK's vilanterol (part of once daily Breo) also approved once daily, as are Novartis' Indacaterol and Boehringer's Olodaterol.

As summarised in our meta-analysis of the FEV1 response to different Umec doses, from PII, shown below, GSK haven't demonstrated a very clear trend between the dose of umec and the level of FEV1 efficacy. In particular, it can be seen that the 62.5mcg dose as a once daily therapy provides a 128 mL FEV1 improvement, below the FEV1 improvement being achieved by 31.25mcg, split into twice daily dosing (142mL). Similarly, umec 125mcg once daily provided a 147mL improvement in FEV1, which was also only inline with the 142 mL benefit for the 32.25mcg dose split into twice daily dosing. Another issue that could be raised is the lack of clear dose response, with umec 250mcg showing a far lower FEV1 benefit than the lower doses.

Figure 1: Umeclidinium FEV1 efficacy vs. daily dose



Source: ERS 2012, CHEST 2011, ERS 2011. Note "adj" refers to adjustments GSK have made to remove observations from a site with poor clinical compliance, more details below.

The case for once daily Umec dosing won't just be based on the 24 hour FEV1 benefit by dose, it will also be based on the FEV1 efficacy over 24 hours for once and twice daily dosing. We haven't seen GSK present this data, but we expect this data to show similar trends to the above data, i.e. that twice daily dosing would allow a lower total daily dose to provide the same FEV1 benefit over the course of 24 hours.

Arguments in favour of the umec dosing data being sufficient for a positive panel vote and approval

1. FDA accepted the Anoro filing, Novartis never got this far

We assume umeclidinium dosing data was discussed with the FDA ahead of GSK initiating the PIII program with once daily umeclidinium dosing, which would suggest the FDA was supportive of the PII dosing data.

The same could be said for Novartis LAMA/LABA program, which was taken into PIII, with once daily LAMA dosing, only for the FDA to subsequently shift their stance post PIII reporting, requesting further LAMA dosing work to be done, with Novartis apparently now doing further studies involving twice daily LAMA dosing.

However GSK's US Anoro development differs from Novartis' US development of QVA149 in that Novartis never got as far as filing QVA149 in the US, with the FDA apparently taking issue with their dosing data even ahead of submission. This could therefore be read to suggest the FDA does see GSK's data-set as being more convincing.

2. Adjusted umec data is more supportive of dose response

GSK have argued poor compliance at one investigative site, which means some values should be excluded**.** For abstract 2012 at ERS 2012, GSK identified that one trial site had poor compliance with good clinical practice, suggesting observations from this site should be excluded. Data with these observations excluded was presented at ERS in September 2012, and this adjusted data looks more supportive of a clear dose response.

We have included these adjusted (labeled "adj") values on the chart on the previous page, though we note that even with the adjustments, whilst the dose response looks more logical (ie higher dose gives more efficacy), the once vs. twice daily issue remains, with twice daily dosing appearing to allow half the daily dose to be used.

Table 4: Umec FEV1 efficacy by dose, with and without adjustments for site with poor compliance

mITT POPULATION	**Umeclidinium**			
Trough FEV1 diff vs Placebo (mL)	15.6mcg 111	31.25mcg 100	62.5mcg 122	125mcg 167
Excluding bad site	**Umeclidinium**			
Trough FEV1 diff vs Placebo (L)	15.6mcg 100	31.25mcg 120	62.5mcg 130	125mcg 175
Change	-11	+20	+8	+8

Source: ERS 2012

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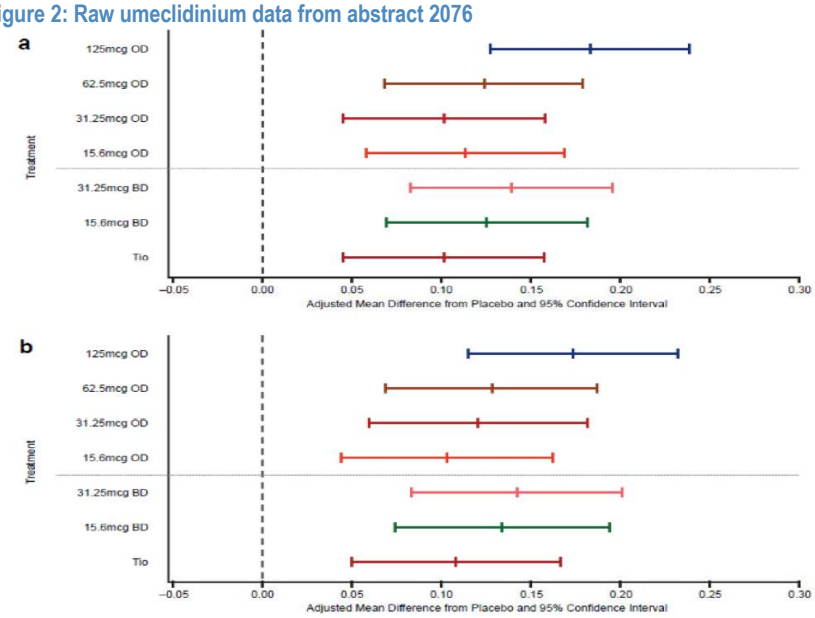
3. Modeling data is more supportive of umec dose response

CHEST 2012 saw GSK present abstract 2076, which included both raw umec FEV1 data, and a modeling exercise, both summarised below. In the raw data (directly below), it can be seen that the twice daily doses (below the dotted line) generate more efficacy than the same total daily dose, given once daily.

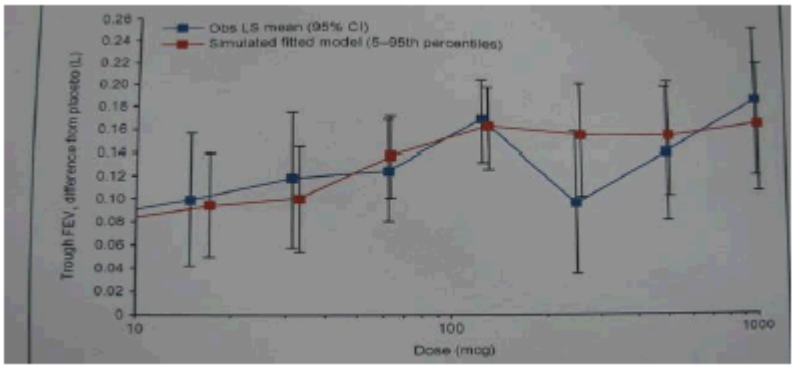
Figure 2: Raw umeclidinium data from abstract 2076



Source: CHEST 2012

Using the population model, below, an actual median FEV1 and a "modeled" FEV1 was presented, with the "modeled" FEV1 unsurprisingly showing a superior dose response trend. At the time of the presentation, we discussed the modeling technique with the poster presenter (Donohue), and our understanding was effectively that the modeling technique removed outliers to create smoother trends. We aren't surprised that removing outliers gave a cleaner trend, but we weren't convinced as to the statistical validity of such an approach.

Figure 3: modeled umeclidinium data from abstract 2076



Source: CHEST 2012

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The second piece of analysis at CHEST 2012, shown below, is an analysis which sought to determine the probability of achieving a given FEV1 response with different doses and dose frequencies. This modeling came to the conclusion that once daily 62.5mcg or 125mcg umec are the optimal doses, based on these doses having higher probabilities of achieving given FEV1 benefits. The analysis found there to be a 96% probability that 62.5mcg OD would lead to a 100mL FEV1 improvement, but only a 64% probability that 15.6mcg BID would achieve the same improvement. Very limited details of the modeling technique were described, but from our discussions, it appeared that this is largely a function of there being broader confidence intervals around these lower, or twice daily, doses. We remain unsure how convinced the FDA will be by this analysis, which arguably highlights a high level of uncertainty on the efficacy of lower or twice daily dosing, which should be investigated further.

Figure 4: modeled umeclidinium data from abstract 2076

(A) UMEC dose (mcg)	80mL	100mL	130mL	150mL
15.6 OD	72	44	11	3
31.25 OD	76	50	16	5
62.5 OD	100	96	63	27
125 OD	100	100	91	66
250 OD	99	96	77	56
500 OD	99	96	79	57
1000 OD	99	96	85	66
15.6 BID	85	65	27	10
31.25 BID	84	64	23	7
62.5 BID	98	92	70	46
125 BID	99	94	76	51
250 BID	99	97	87	75

Source: CHEST 2012

GSK are not the first company to perform modeling of this sort; we recall Novartis' Indacaterol LABA dose response modeling, which struggled to gain FDA acceptance at their March 2011AdCom panel. In GSK's favour, the studies they have merged together are more similar, vs. Novartis' attempt to merge many different studies together, in each of which, a patient had only received a single dose level.

4. FEV1 24 hour data shows a similar FEV1 profile to Spiriva

One further argument we see GSK making is that umec has a similar 24 hour profile to Boehringer's Spiriva, justifying once daily dosing. As shown in the chart below, GSK have show that for the all of the doses tested, umec's placebo adjusted efficacy is similar from 4 to 24 hours, supporting a 24 hour duration of action. Whilst this data is supportive, we do see two pushbacks: (A) There is no twice daily vs. once daily comparison in this chart, and hence, it remains the case that twice daily might achieve the same coverage with half of the dose. (B) Spiriva was approved almost 10 years ago, and should Spiriva be filed now, it is uncertain whether this would be approved as a once daily product. It could therefore be a dangerous assumption that because this profile was good enough for Spiriva, this can be extrapolated to umec.

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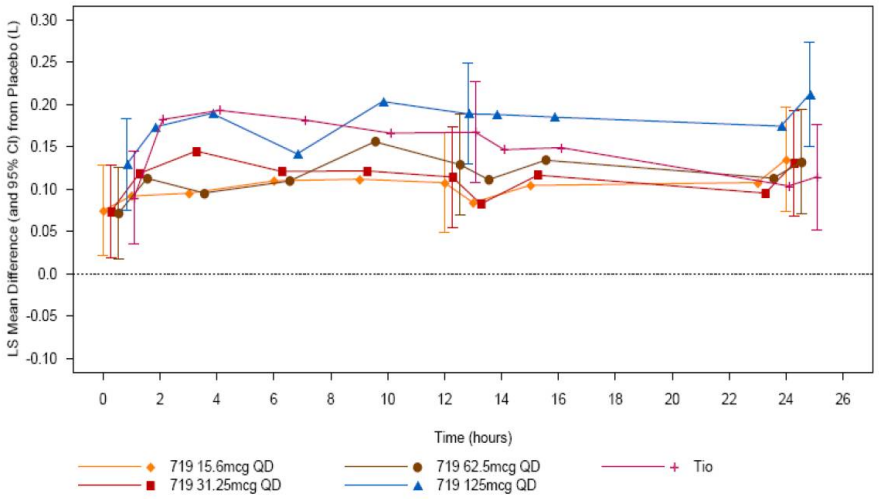
Figure 5: Low dose umec serial FEV1 study



Source: ERS 2012

5. Compliance advantages could support once daily

We note that in the recent Breo panel (not involving a LAMA, but also involving once daily COPD drug approval), panel members were very enthusiastic on once daily dosing, commenting on its advantages even when voting on questions for which it wasn't a directed discussion topic.

Whilst this is technically irrelevant to whether GSK have sufficient data to support the umeclidinium dose they have taken into PIII, it is possible, that as with Breo, panel support for once daily dosing will to some extent over-ride the scientific arguments. The efficacy data by dose cannot be analysed in isolation without considering the potential for increased adverse events at higher umeclidinium doses; please see page 12 for our thoughts on this issue.

On balance, based in part of the recent positive Breo panel, we believe the questionable umec dosing data probably won't be enough to derail the panel vote, but we do still see this as the biggest risk to Anoro approval.

Potential issue 2: umeclidinium cardiovascular profile, most likely considered acceptable

Umeclidinium is a LAMA (Long Acting Muscurimic Antagonist), exerting its effect through blocking the effects of acetylcholine on muscarinic receptors to reverse airway obstruction.

Some systemic exposure is observed. Inhalation of a LAMA results in most of activity occurring on-target, within the lungs; however there is always some systemic absorption, which means a LAMA like umeclidinium could also exert its effects elsewhere in the body.

Systemic exposure could impact the heart. Muscarinic receptors are not just found in the airways; for example, M2 receptors are also located on cardiac tissue where they play a prominent role in cardiac function. For this reason, excessive systemic

release of a LAMA such as umeclidinium could impact cardiac rate (increased beats per minute, tachycardia) and rhythm (prolonged QT interval, Torsades).

Cardiac concerns are already an issue in COPD. Cardiac concerns are heighted Cardiovascular risk is a particular concern in COPD patients, who are already at increased risk from cardiovascular disease, even without LAMA therapy. A meta-analysis combining data for from 17 studies of existing approved Muscurimic Antagonist for COPD has found that there is 1.6x the usual risk of a major cardiovascular event, from receiving a LAMA, vs. not receiving a LAMA for COPD, which was statistically significant ($p<0.001$), though there was no statistically significant impact on mortality ($p=0.06$).

Spiriva Respimat has also heightened focus on this issue. The FDA could be sensitive to the cardiovascular profile of LAMAs in light of the suggestion of increased cardiovascular risk from administration of Boehringer Ingelheim's Spiriva through the Respimat mist-haler device. It has been hypothesised that this device delivers a high systemic dose of the LAMA tiotropium (1.3-3.0x higher than in the US approved Handihaler device) and that this high systemic dose could be causing increased cardiovascular risk. The above meta-analysis didn't show an overall statistically significant increase in cardiovascular mortality for Muscurimic Antagonist products overall; however Spiriva Respimat did show an overall statistically significantly higher cardiovascular mortality. This finding has since been refuted, and the TIOSPHIR study, testing the rate of cardiovascular events on Spiriva Respimat vs. Spiriva Handihaler, was recently completed, and we believe results may be presented next month, at ERS in September.

Umec safety in itself is unlikely to be an issue; however safety concerns could lead to a requirement for lower dosing. In light of the potential cardiac risks, we believe the FDA will want to ensure both a low systemic exposure to Umec, and will also want to approve the lowest dose necessary, to reduce the chance of adverse cardiac events. The data we have seen for Anoro isn't suggestive of a particular cardiovascular issue, with a safety study (A1487 at ATS 2013) showing that there was no difference in QT interval (a heart rhythm) between UMEC/VI 125/25mcg or UMEC 500mcg and placebo, and with other efficacy focused studies not reporting elevated cardiovascular issues, we don't see umec's cardio profile as likely in itself to remain Anoro won't be approved, though it could prompt the FDA to seek more data on lower dosing, to reduce the risk of elevated cardiovascular events in a larger patient population.

Potential issue 3. Incremental benefit of vilanterol? Data should support a positive vote

There could be a question as to whether Anoro satisfies the combo rule. When assessing the Anoro application, we expect the panel to consider whether each of the two ingredients, umeclidinium LAMA, and vilanterol LABA are each providing significant efficacy benefits for patients, to justify their inclusion in the combo.

Placebo adjusted studies are supportive. As summarised below in Table 5, across the PIII program, Anoro has shown statistically significant benefits vs. placebo, and vs. each of the two individual constituents in both of the large placebo controlled studies, which should satisfy the panel.

Active controlled studies are mixed:

The active controlled study with a vilanterol mono comp showed a strong umec contribution. On the active controlled studies, the study comparing Anoro to the vilanterol monotherapy ingredient and to the approved LAMA mono Spiriva showed statistically significant benefits vs. both comparators, again, what the panel would want to see.

The active study with an umec comp showed a modest vilanterol contribution. The second active controlled study, which compared Anoro to the Umeclidinium LAMA monotherapy ingredient, and to Spiriva, showed a significant benefit vs. Spiriva, but not vs. Umeclidinium monotherapy ingredient. We believe the panel could discuss this, as it questions whether the vilanterol ingredient is providing a significant benefit across the trial program.

Overall we believe vilanterol's lower efficacy contribution shouldn't be a barrier to approval.

Table 5: Anoro PIII data summary

Trial	Comparison	Dose	Trough FEV1	p value
Placebo controlled study 1	Anoro vs. Placebo	125/25mcg	238mL	p<0.001
patients: 1,493	Anoro vs. umeclidinium	125/25mcg		p<0.001
	Anoro vs. vilanterol	125/25mcg		p<0.001
	Vilanterol vs. Placebo	25mcg	124mL	p<0.001
	umeclidinium vs. Placebo	125mcg	160mL	p<0.001
Placebo controlled study 2	Anoro vs. Placebo	62.5/25mcg	167mL	p<0.001
patients: 1,536	Anoro vs. umeclidinium	62.5/25mcg		p≤0.004
	Anoro vs. vilanterol	62.5/25mcg		p≤0.004
	Vilanterol vs. Placebo	25mcg	72mL	p<0.001
	umeclidinium vs. Placebo	62.5mcg	115mL	p<0.001
Active comparator study 1	Anoro vs vilanterol or Spiriva	125/25mcg	88mL	p<0.001
patients: 846	Anoro vs vilanterol or Spiriva	62.5/25mcg	90mL	p<0.001
Vilanterol: 25mcg, Tiotropium:18mcg				
Active comparator study 2	Anoro vs Spiriva	125/25mcg	74mL	p=0.003
patients: 872	Anoro vs umeclidinium	125/25mcg	37mL	**p=0.142**
719: 125mcg, Tiotropium:18mcg	Anoro vs Spiriva	62.5/25mcg	60mL	p=0.018
	Anoro vs umeclidinium	62.5/25mcg	22mL	**p=0.377**

Source: company reports

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How big could Anoro be for GSK?

We forecast 2020 Anoro sales of £1.5bn, with sales of £1bn by 2017, and we include these forecasts in our model without risk adjustment. This equates to an EmV of 70p per share, 50p of which comes from the US. Therefore US Anoro represents 3% of our GSK EmV.

Expect 2/3 of sales to come from the US

As shown below, 2/3 of our Anoro forecasts come from the US, based on our assumption that Anoro US pricing will be c5x the EU price, and based on the tougher competitive environment in the EU vs. the US, with Novartis' LAMA/LABA already approved in the EU, but not expected to be approved and launched in the US until at least 2016.

We assume US pricing is ~5x that in the EU

In the US we assume Anoro is launched at a c.20% premium to the US Advair price (c.$270 per patient per month). This assumption is based on the fact that Spiriva (LAMA monotherapy) is priced inline with Advair, and we don't expect GSK to launch their combo at this price, when presumably they intend to eventually launch umec mono at price parity to Spiriva. In the EU, Advair (branded as Seretide) is sold at just $50 a month, as is Spiriva; hence we assume Anoro pricing of only c.$65 per patient per month.

In the US, Anoro would be the first LAMA/LABA to market

If approved at the end of this year, Anoro would be the first LAMA/LABA approved in the US. Anoro could be joined by Boehringer's LAMA/LABA in 2015, assuming the questions over Respimat device safety are resolved (expect TIOSPIR Respimat safety data at ERS this Sep), and this could also be a once daily therapy. Competition from Novartis' QVA149 could come in 2016, and this could be in the form of a twice or once daily product. Finally Astra could also launch their PT003 LAMA/LABA in 2016, though this is twice daily, and in a pMDI, rather than dry powder inhaler.

In the EU, Anoro will likely be second to market, following Novartis' QVA149

Novartis received CHMP approval for Ultibro (QVA149 LAMA/LABA) in late July, and with Anoro potentially approved late 2013, Novartis has a 6 month head-start on Anoro. In the EU we also expect competition from Boehringer's LAMA/LABA by 2015.

Table 6: Anoro forecast summary - £m

	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E
Anoro	**164**	**401**	**649**	**941**	**1,242**	**1,366**	**1,462**
- USA	105	263	425	617	814	895	967
- Europe	35	81	130	189	250	275	288
-EMAP	12	29	47	68	89	98	103
- RoW	12	29	47	68	89	98	103

Source: J. P. Morgan estimates

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How could GSK move around the Anoro Panel? +3%/-5%

As summarised below, our Anoro forecasts are 20-30% ahead of consensus, which could be a reflection of lower peak consensus expectation, or the fact that we don't carry a risk adjustment on our forecasts.

Assuming consensus shared our margin and geographic expectations would suggest c.3% down, with potentially only 1% upside around the panel.

However we believe the sentiment impact would be greater, particularly as respiratory is the key therapy area investors associate with GSK, and Anoro marketing will have limited incremental cost on top of the Breo salesforce, meaning it will be a significant driver of margin expansion for the company, and an indirect defense against Advair generics (as we expect some LABA/ICS switch to LAMA/LAMA).

We therefore believe that in the event of a unanimously positive panel verdict, or unanimously negative vote, GSK could be up 3% or down 5%.

Table 7: Anoro – JPM vs. Consensus - £m

	2013E	2014E	2015E	2016E	2017E	2014-17E CAGR
JPM	**-**	**164**	**401**	**649**	**941**	**79.0%**
Consensus	10	127	326	549	791	84.0%
	-	29.1%	22.9%	18.2%	19.0%	

Source: J. P. Morgan estimates, company collated consensus

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US respiratory survey highlights enthusiasm for both Breo and Anoro

With the US success of Breo and Anoro over the next few years likely to be a key determinant of GSK's growth profile, we performed a survey of US physicians to understand their expectations for the evolution of the US COPD market.

Our key conclusions were:

1. Share of COPD patients given LABA/ICS expected to fall c.20% in 3 years

Across the Primary care physicians and Pulmonologists, LABA/ICS (eg Advair) are currently prescribed to 46% of COPD patients. When questioned on their expectations for their prescribing in 3 years time, on average survey participants expected their prescribing of this class to be reduced by 8pp, or almost 20%, with this share switching over to the new option of the LABA/LAMA class, assuming Anoro approval.

2. Breo uptake could balance out LABA/ICS class contraction

Whilst use of the LABA/ICS class may fall following LAMA/LABA approval, we believe this is likely to be largely offset by GSK's increased share of the LABA/ICS class, due to the launch of Breo. For patients who will be prescribed LABA/ICS, physicians anticipated prescribing Breo to 20% of their existing patients, and 28% of their new to ICS/LABA patients, which would mean GSK share of 56% of existing patients and 60% of new patients, once also factoring in continued prescribing of Advair.

3. Dosing frequency and patient co-pay were attributed similar importance, dosing frequency was seen as materially better, but there were copay concerns.

Relative to other attributes, Exacerbation efficacy was given the highest importance weighting by physicians surveyed given a score of 8.7/10. Dosing frequency was scored 7.7/10 for importance, which was toward the lower end of the scores given, though still a fairly high score, patient co-pay was scored 7.9/10 for importance, slightly above dosing frequency.

When questioned on Breo vs. Advair, physicians saw Breo's dosing frequency as a highly differentiated, scoring this attribute 8.2/10, with 10 being better, 5 the same, and 0 worse. On patient copays, physicians were more cautious, scoring Breo 4.8/10, i.e. very slightly worse than Advair. This was a speculative question, with copays as yet unannounced, though we do believe this will be the key challenge for GSK.

We note the announcement by US managed care organization, CVS, not to cover Breo, and we believe formulary positioning will be the key challenge for GSK. However we assume GSK will manage to get Breo on many formularies, potentially by offering attractive rebates.

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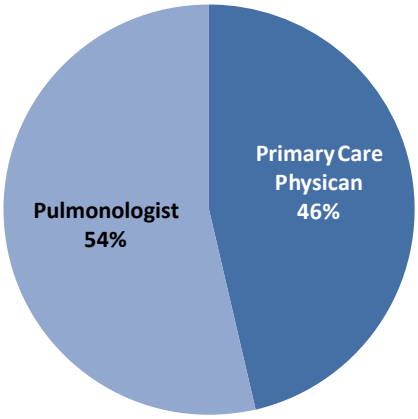
Respiratory Survey details

We surveyed 41 US Physicians to better understand physicians' expectations for their future prescribing in the US COPD market, with the survey completed by the week ending August 9th.

To be eligible to participate in the survey physicians were required to: (1) Be a Primary Care or Pulmonology specialist, (2) Have at least 2 years of clinical experience, (3) Treat at least 150 COPD patients, and (4) Have at least some familiarity with GSK's Breo.

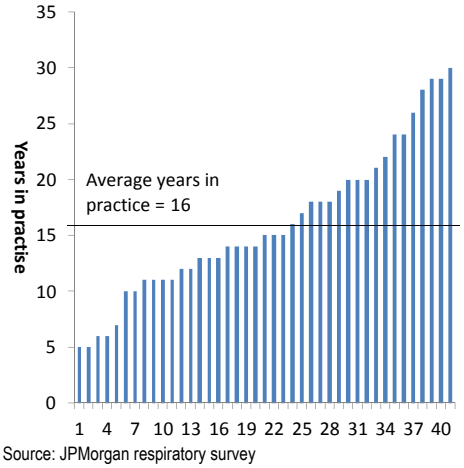
- **41 physicians were surveyed**, of which 19 identified their specialty as Primary Care Physicians (PCPs), with another 22 identifying themselves as Pulmonologists. No other physician specialties were eligible to participate. We believe the survey population was weighted further toward specialists (54%) than clinical practice, where we believe c.2/3 of COPD prescriptions are written by Primary Care docs.
- **On average participants had 16 years in practice.**
- **The average participant treated 470 COPD patients**, with a Primary care physician on average treating 350 COPD patients, and Pulmonologists 570 COPD patients.
- **38% of docs initially sampled were very/somewhat familiar with the Breo data** set. Of those included 78% classed themselves as "Somewhat familiar", with 22% describing themselves as "Very familiar". All the Physicians who classified themselves as "Very familiar" were Pulmonologists.

Figure 6: Enrolled physician specialty split



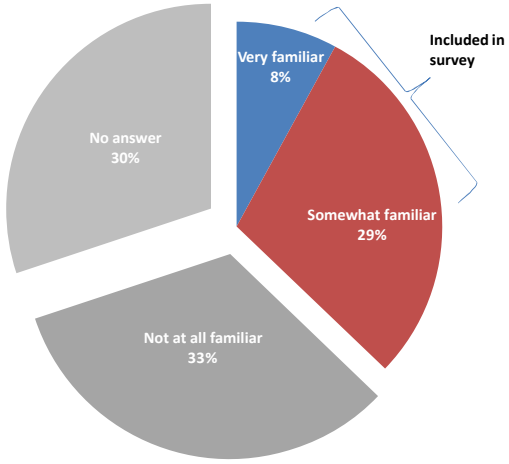
Source: JPMorgan respiratory survey

Figure 7: Enrolled physicians years in practice



Source: JPMorgan respiratory survey

Figure 8: Physician familiarity with Breo data



Source: JPMorgan respiratory survey

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Key survey conclusions from a Breo perspective

From a Breo perspective, our key questions were:

1. **How will the overall number of patients treated with the LABA/ICS class likely to change over the next few years?**

2. **What share of the LABA/ICS class, is Breo likely to take?**

1. Share of COPD patients given LABA/ICS expected to fall almost 20% in 3 years

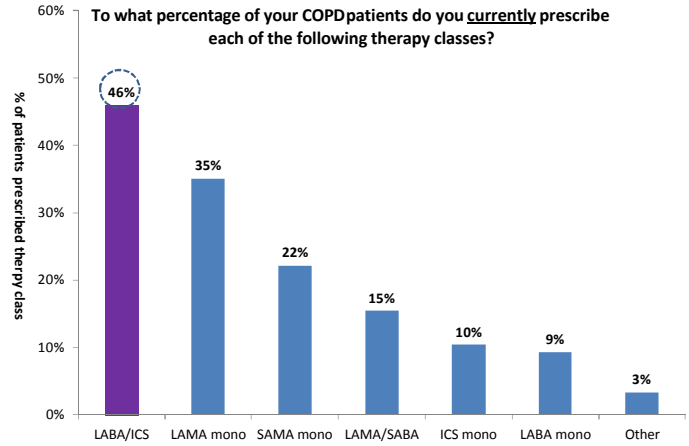
Across the Primary care physicians and Pulmonologists, LABA/ICS (eg Advair) are currently prescribed to 46% of COPD patients.

When questioned on their expectations for their prescribing in 3 years time, on average survey participants expected their prescribing of this class to be reduced by 8pp, or almost 20%, with this share switching over to the new option of the LABA/LAMA class, assuming Anoro approval.

Whilst the LABA/ICS class was expected to be the biggest contributor of Anoro LAMA/LABA patients, there was also the expectation that LAMA mono share would decline 4pp, SAMA mono down 2pp, LAMA/SABA by 2pp, and ICS mono and LABA mono, both down 1pp.

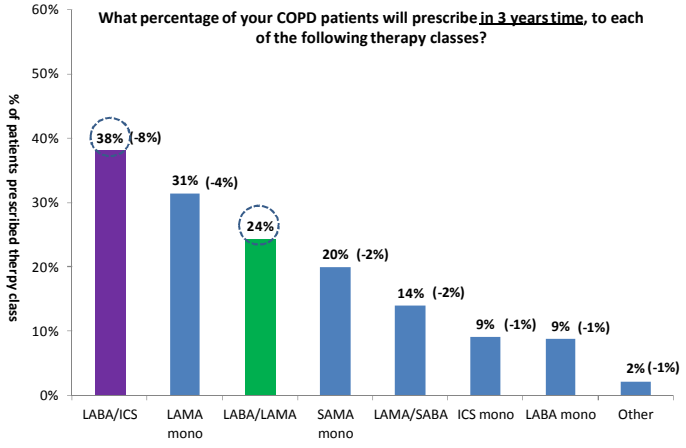
Anoro was expected to be prescribed to 24% of COPD patients after just 3 years. We believe these results could also underestimate potential Anoro share, with physicians likely to be fairly unfamiliar with the product's profile, ahead of an approval or journal publication of the PIII data, though on the other hand, including the suggestion of Anoro approval in the question title could slightly weight answers toward this.

Figure 9: Current COPD prescribing by class



Source: JPMorgan respiratory survey

Figure 10: COPD prescribing by class in 3 years time



Source: JPMorgan respiratory survey

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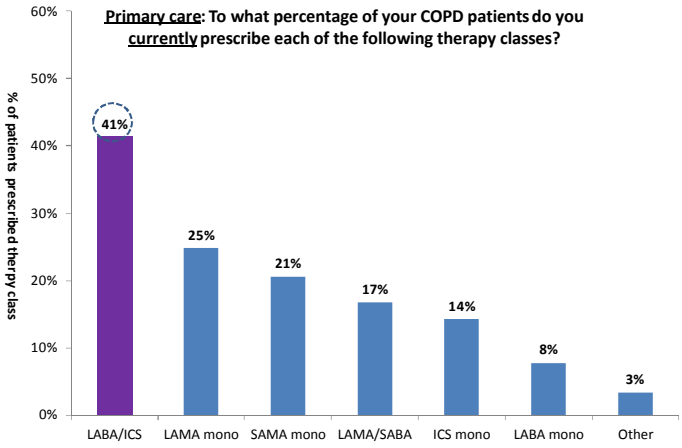
PCPs to prescribe 12% less LABA/ICS in 3 years time

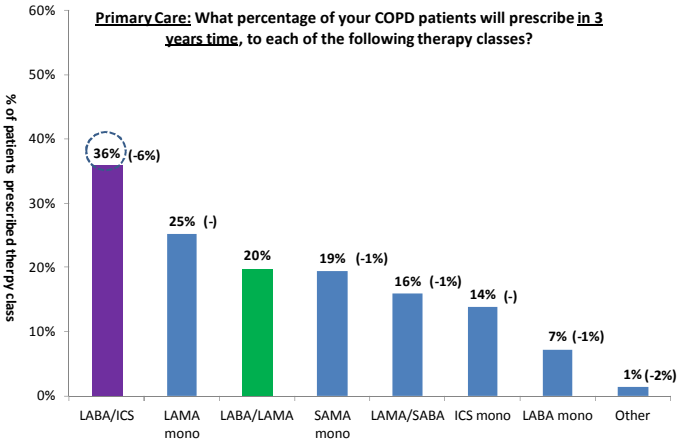
As shown below, PCPs currently prescribe LABA/ICS to 41% of their COPD patients, and they expect this to fall 6pp, to 36% of patients, if Anoro is launched. PCPs expect to use Anoro in 20% of their COPD patients.

Figure 11: Primary care: Current COPD prescribing by class



Source: JPMorgan respiratory survey

Figure 12: Primary care: COPD prescribing by class in 3 years time

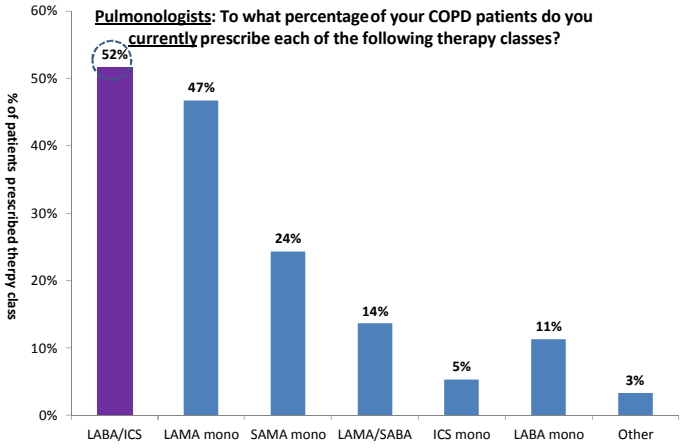


Source: JPMorgan respiratory survey

Pulmonologists to prescribe 21% less LABA/ICS in 3 years time

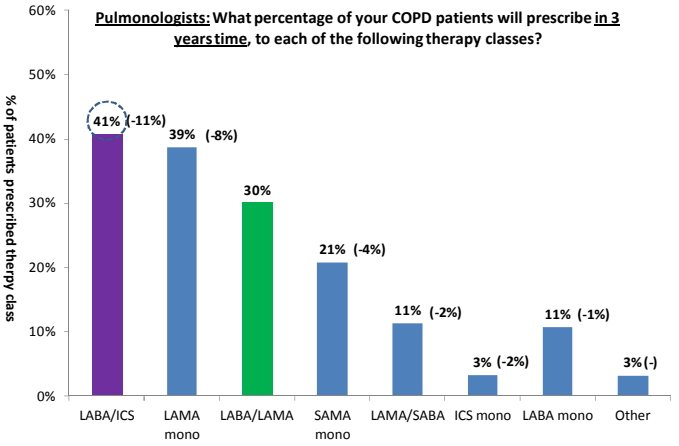
Pulmonologists were more aggressive in their treatment of COPD at present, prescribing LABA/ICS to 52% of their COPD patients. Pulmonologists anticipated a greater reduction in LABA/ICS use, forecasting an 11pp reduction in LABA/ICS use, and anticipating using LAMA/LABA in 30% of their COPD patients.

Figure 13: Pulmonologists: Current COPD prescribing by class



Source: JPMorgan respiratory survey

Figure 14: Pulmonologists: COPD prescribing by class in 3 years time



Source: JPMorgan respiratory survey

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2. Breo uptake should partially offset LABA/ICS class contraction

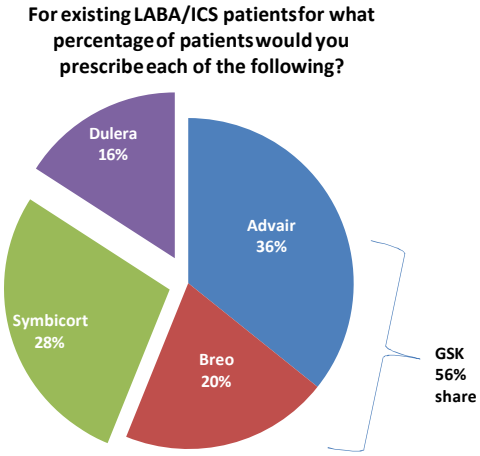
Whilst use of the LABA/ICS class may fall, following LAMA/LABA approval, we believe this is likely to be largely offset by GSK's increased share of the LABA/ICS class, due to the launch of Breo.

At present, based on US IMS volume data GSK has 69% share of LABA/ICS volumes, across both COPD and Asthma. Based on Dulera not being approved for COPD, and Symbicort gaining Asthma approval ahead of COPD approval, we believe Advair COPD share is a little higher than this.

As summarised below, for patients who will be prescribed LABA/ICS, physicians anticipated prescribing Breo to 20% of their existing patients, and 28% of their new to ICS/LABA patients, which will mean GSK share of 56% of existing patients and 60% of new patients.

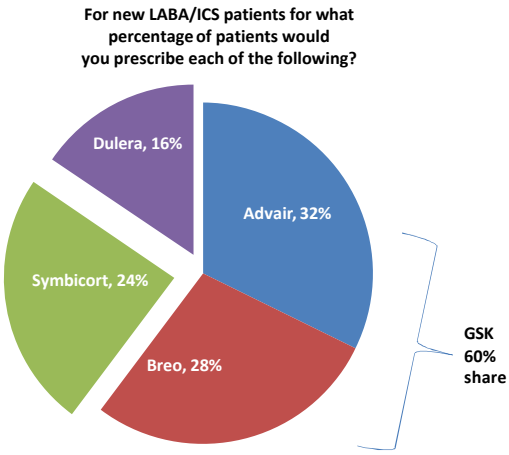
Surprisingly Physicians anticipated prescribing Dulera to 16% of COPD patients (despite there being no approval for COPD) and Symbicort to 24-28% of patients, inline with current US prescription trends.

Figure 15: LABA/ICS prescribing for existing patients



Source: JPMorgan respiratory survey

Figure 16: LABA/ICS prescribing for new patients



Source: JPMorgan respiratory survey

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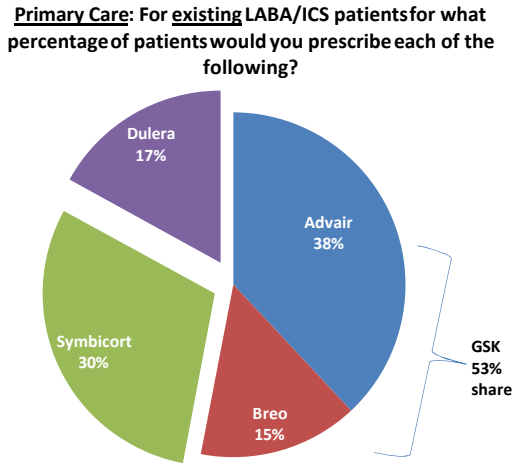
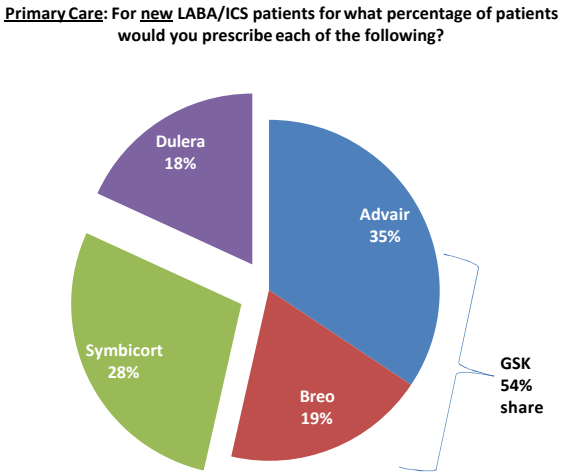
PCPs anticipate using Breo in 15% of existing patients and 19% of new to LABA/ICS therapy patients

Figure 17: LABA/ICS prescribing for existing patients



Source: JPMorgan respiratory survey

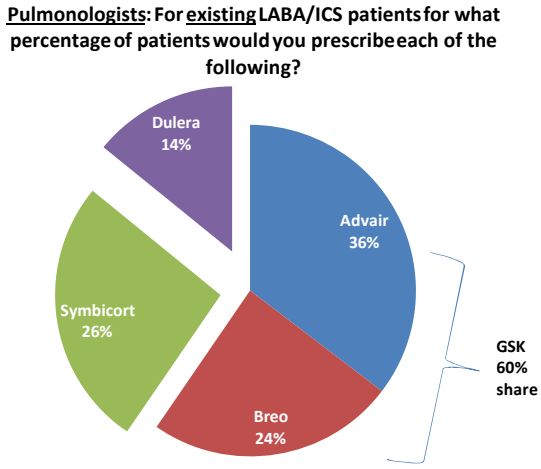
Figure 18: LABA/ICS prescribing for new patients



Source: JPMorgan respiratory survey

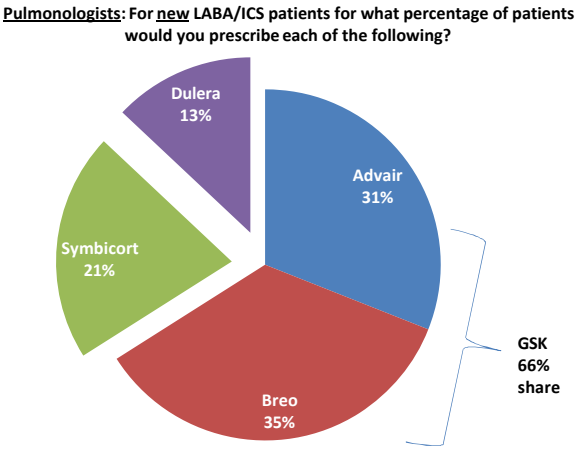
Pulmonologists anticipate using Breo in 24% of existing patients, 35% of new to LABA/ICS patients

Figure 19: LABA/ICS prescribing for existing patients



Source: JPMorgan respiratory survey

Figure 20: LABA/ICS prescribing for new patients



Source: JPMorgan respiratory survey

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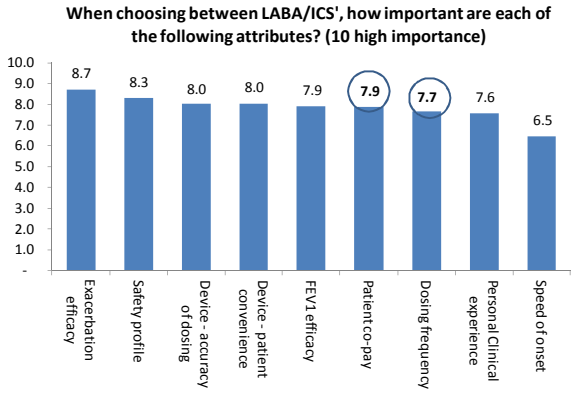
3. Dosing frequency and patient co-pay were attributed similar importance

To better understand LABA/ICS prescribing dynamics, we questioned the importance of different product characteristics for physicians prescribing choices.

Relative to other attributes, Exacerbation efficacy was given the highest importance weighting by physicians surveyed. Whilst Breo isn't differentiated from Advair on exacerbation frequency, there is no evidence that efficacy is any worse, and this is therefore unlikely to be importance in choosing between therapies. Dosing frequency was scored 7.7/10 for importance, which was toward the lower end of the scores given, though still a fairly high score. Patient co-pay was scored 7.9/10, slightly above dosing frequency, suggesting an unfavourable copay for Breo could more than offset dosing frequency advantages.

Figure 21: LABA/ICS product characteristic importance rating

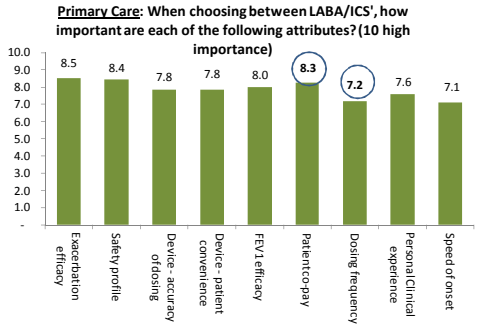


Source: JPMorgan respiratory survey

Dosing frequency was of greater importance to Pulmonologists than PCPs

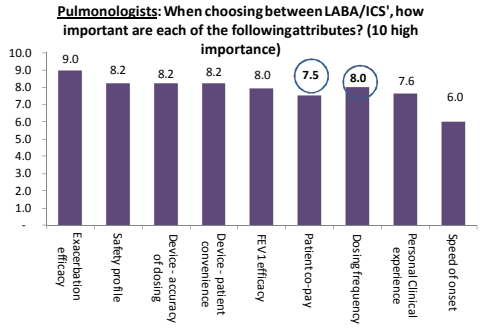
When comparing between specialties, Primary care physicians assigned slightly greater emphasis on patient copays than dosing frequency. In contrast Pulmonologists assigned greater importance to dosing frequency than patient copays.

Figure 22: Primary Care LABA/ICS product characteristic importance rating



Source: JPMorgan respiratory survey

Figure 23: Pulmonologist LABA/ICS product characteristic importance rating



Source: JPMorgan respiratory survey

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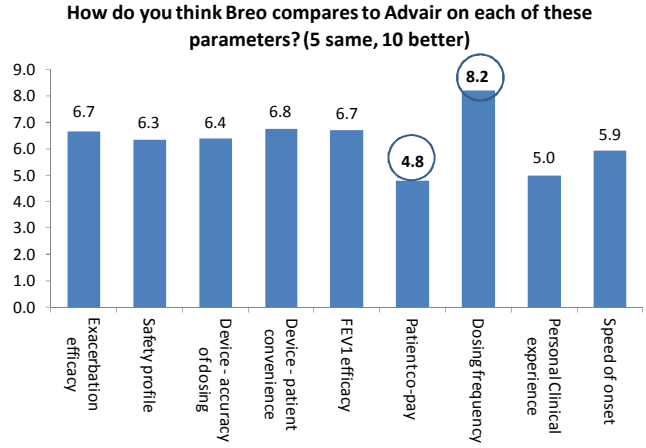
4. Breo's dosing frequency was seen as materially better than Advair, but there was concern copays could be worse

When contrasting Breo with Advair, physicians saw Breo's dosing frequency as a highly differentiated, scoring this attribute 8.2/10, with 10 being better, 5 the same, and 0 worse.

On patient copays, physicians were more cautious, scoring Breo 4.8/10, i.e. very slightly worse than Advair. This was a speculative question, with copays as yet unannounced, though we do believe this will be the key challenge for GSK.

Generally Breo was perceived as having better exacerbation efficacy, safety profile etc, despite this not being supported by the clinical data to date.

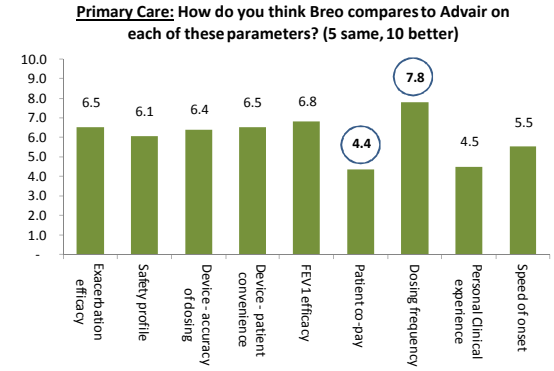
Figure 24: Breo vs. Advair, characteristics comparison



Source: JPMorgan respiratory survey

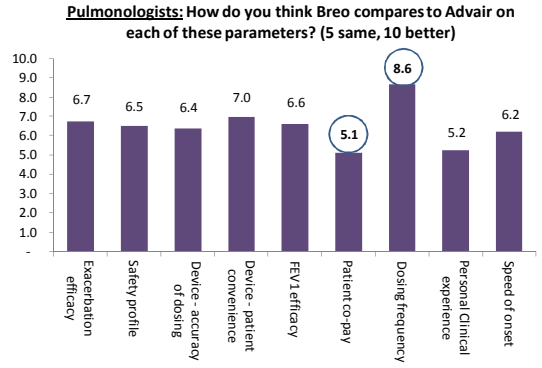
Pulmonologists rated the dosing frequency differentiation more highly than PCPs, and were also slightly less concerned on the issue of co-pays.

Figure 25: Primary Care Breo vs. Advair, characteristics comparison



Source: JPMorgan respiratory survey

Figure 26: Pulmonologist Breo vs. Advair, characteristics comparison



Source: JPMorgan respiratory survey

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Survey suggests LAMA/LABAs could hit $2.4bn annual sales within a few years

As summarised below, Physicians anticipated using LABA/LABA's in 24% of their COPD patients, which compares to using LABA/ICS in 46% of COPD patients at present.

For 2013 we forecast US sales of Advair and Symbicort of $5.2bn, of which we assume 55% or ~$2.9bn is for COPD.

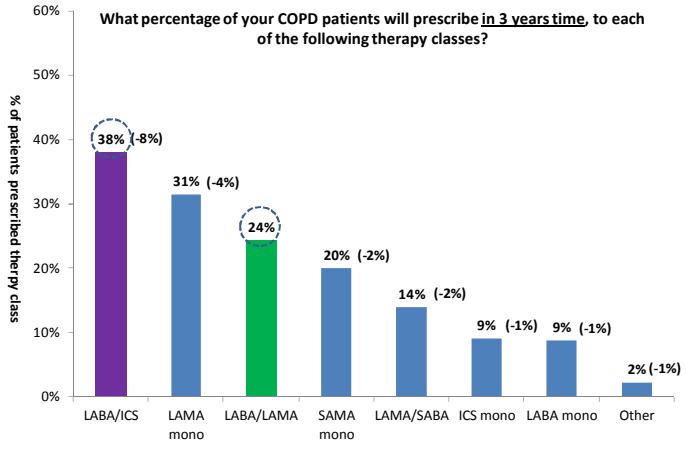
Based on the above physician projections for LAMA/LABA use, within 3 years, by volume the LAMA/LABA class could be 60% as big as the LABA/ICS class is at present.

Should this happen, with LAMA/LABA's priced at a 20% premium to the LABA/ICS', this would mean the category would be worth $2.2bn.

If Anoro were able to take 50% share of this (conservative, in light of first mover advantage and solid data), this would equate to sales of $1.1bn (£0.7bn) in 3 years time.

We believe this is supportive of our forecasts for US Breo sales of £0.65 bn by 2016.

Figure 27: COPD prescribing by class in 3 years time



Source: JPMorgan respiratory survey

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JPM respiratory forecasts vs. consensus

Table 8: Respiratory forecast summary

		2013E	2014E	2015E	2016E	2017E	2014-17E CAGR
Advair	**JPM**	**5,350**	**5,205**	**4,823**	**4,394**	**3,841**	**-9.6%**
	Consensus	5,250	5,081	4,811	4,347	3,886	-8.5%
	% diff	1.9%	2.4%	0.3%	1.1%	-1.2%	
Breo	**JPM**	**34**	**305**	**643**	**975**	**1,261**	**60.5%**
	Consensus	45	253	513	756	947	55.3%
	% diff	-24.4%	20.6%	25.2%	29.0%	33.1%	
Advair + Breo	**JPM**	**5,384**	**5,510**	**5,466**	**5,370**	**5,101**	**-2.5%**
	Consensus	5,295	5,334	5,324	5,103	4,833	-3.2%
	% diff	1.7%	3.3%	2.7%	5.2%	5.5%	
Anoro	**JPM**	**-**	**164**	**401**	**649**	**941**	**79.0%**
	Consensus	10	127	326	549	791	84.0%
	% diff	-100.0%	29.1%	22.9%	18.2%	19.0%	

Source: JPMorgan estimates, company collated consensus

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Darapladib - $4.5bn peak sales potential, but we see a fairly low chance of success

GSK's Darapladib is an oral inhibitor of the enzyme LpPLA2, an enzyme which is involved in both the deposition of fatty deposits on arterial walls, and in inflammation of the artery walls. Darapladib is in development for the treatment of cardiovascular disease, or more specifically for reducing the occurrence of MACE (Major Adverse Cardiovascular Events, such as death, heart attach or stroke).

Despite mixed PII results, GSK are currently running two PIII studies, the first of which, STABILITY in 15,500, patients is due to report by year end, with the 11,500 patient SOLID-TIMI expected by mid 2014.

Due to the enormous number of people with cardiovascular disease, Darapladib could have huge commercial potential if successful; we forecast peak potential sales of £4.5bn. We currently carry no darapladib forecasts in our model, but in the event of positive data, reflecting these peak sales in our model would add 140p / 9% to our Embedded value, and 2pp to our 2014-17E Core EPS CAGR.

However based on the clinical data previously announced, we believe failure is the most likely outcome, and we carry no forecasts in our model. We are not alone in our caution, with consensus forecasts including little for Darapladib. Of those analysts that do include Darapladib forecasts, risk adjusted 2020 sales are currently forecast at £700m, which suggests significant risk adjustments are being applied.

We believe the market's probability of success was slightly increased by GSK's April 2012 acquisition of Human Genome Sciences (HGSI), whom GSK would have had to pay a 10% sales royalty on Darapladib, as well as having to offer them North American co-promotion rights. Whilst the HGSI acquisition was largely about Benlysta, we believe the deal does suggest GSK still anticipate some chance of success for this project.

Darapladib mode of action – reducing the chance of plaque rupture

The enzyme LpPLA2 is hypothesised to make existing atherosclerotic plaques more vulnerable to rupture (by contributing to inflammatory processes in the plaque). Plaque rupture is the cause of acute events such as MI or stroke. Hence inhibition of LpPLA2, with darapladib may stabilise the plaque, and thus help reduce cardiovascular events.

Phase IIa: Good effect on biomarkers, but clinical relevance unclear:

In a randomized 959-patient 12-week phase II study, darapladib was shown to inhibit Lp-PLA2 in a dose-dependent fashion. Looking at other inflammatory biomarkers, in the highest dose, darapladib also showed a decrease of IL-6 and a trend to decreased CRP.

Table 9: Darapladib Phase II biomarker results summary

Parameter	Placebo	Darapladib 40mg	Darapladib 80mg	Darapladib 160mg
Patient #	**177**	**166**	**161**	**161**
LP-PLA2				
Baseline	123	123	123	123
12 weeks	124	68	56	43
Absolute change	+1	-55	-67	-80
% reduction	-1%	43%	55%	66%
Significance	-	p < 0.001	P < 0.001	p < 0.001
IL-6				
Baseline	2.45	2.57	2.35	2.73
12 weeks	2.28	2.17	2.17	2.14
Absolute change	0.17	0.40	0.18	0.59
% reduction	-6.9%	-15.5%	-7.3%	-21.5%
Significance	-	p <0.05	-	p <0.05
hs-CRP (mg/l)				
Baseline	1.09	1.14	1.03	1.28
12 weeks	1.06	1.02	1.02	1.02
Absolute change	-0.03	-0.12	-0.01	-0.26
% reduction	-3.3%	-10.5%	-1.5%	-20.2%
Significance	-	-	-	p <0.05

Source: J. Am. Coll. Cardiol 2008;51;1632-1641. J. P. Morgan estimates

However, the clinical relevance of those effects on biomarkers remains unclear, as circulating biomarkers may not be predictive of what is going on in the arterial wall or inside the vessel.

Phase IIb: Imaging proof–of-concept study failed primary endpoint.

Subsequently, darapladib was evaluated in a 300-patient placebo-controlled phase IIb (IBIS-2) IVUS imaging study. This study used relatively new, but validated IVUS methodology (IVUS-based palpography), that measured the mechanical properties of the plaque (IVUS-palpography has also been referred to as 'virtual histology').

The hypothesis was for darapladib to stabilise the coronary plaque and thus reduce plaque deformability by 20%. However, there was no statistical difference between darapladib and the placebo arm. There was also no difference in the co-primary endpoint of CRP reduction.

Darapladib was generally well tolerated, with similar withdrawal rates on darapladib and placebo. One unusual side effect was malodour (particularly bad smelling urine and feces) which occurred in 16% of darapladib treated patients, vs. 3% on placebo.

Investigators speculated that failure to detect a significant effect from darapladib on the biomechanical properties of the plaque could have been the result of an unexpectedly high percentage of patients (37%) without high strain on the study that may have reduced the statistical power to demonstrate a statistical difference between the two treatment arms. Support for this hypothesis comes from a pre-specified sensitivity analysis demonstrating a significant reduction in high strain in the darapladib group (p=0.009) when only patients with highly deformable plaque at baseline were analysed.

Rationale to move into phase III

In our view, GSK's "phase III go decision" was based to a very large extent on encouraging secondary imaging endpoint from IBIS-2: In placebo patients, necrotic core volume increased significantly but darapladib halted those increases; those plaque composition changes occurred without a significant treatment difference in total atheroma volume. It is exactly this expansion of the necrotic core that GSK hopes to achieve by LpPLA2 inhibition; hence this is an intriguing finding.

In addition, data from a pig model provides further mechanistic proof:

Pigs have plasma-lipoprotein profile that is closest to humans, whereas a mouse model is inadequate for studying the effects of LpPLA2 inhibition. A study published in *Nature* in September 2008 showed that pigs with induced diabetes and hypercholesterolemia, when treated with darapladib for 28 weeks, had reduced development of advanced coronary atherosclerosis and substantially reduced expression of 24 genes associated with macrophage and T-lymphocyte functioning.

Darapladib STABILITY interim was supportive of an acceptable safety profile

GSK announced in October 2009 that the PIII STABILITY study didn't show any unexpected safety or tolerability issues at interim, which prompted initiation of the SOLID-TIMI-52 study.

Ongoing clinical studies and critical timelines

GSK is valuating darapladib in two outcome studies, both of which are event-driven:

- STABILITY (n=15,500, data expected in H2 2013) is evaluating patients with chronic coronary heart disease and at least one additional CV risk factor.
- In contrast, SOLID-TIMI-52 (n=11,500, expect to report in 2014), is conducted in ACS patients within 30 days after an ACS (acute coronary syndrome) event treated with PCI.

There is 3rd phase III study listed for darapladib (AIM III), which is however not sponsored by GSK, but conducted by the Mayo Clinic. This is a mechanistic study, and thus technically not a Phase III study. The main goal of AIM III is to assess and quantify the effect of long-term administration of darapladib Lp-PLA2, on coronary endothelial function, progression of coronary atherosclerosis as determined by IVUS, and atherosclerosis in patients with early atherosclerosis.

Table 10: Ongoing trial summary

Study	Patient #	Design	Patients	Primary	Completion (Initiation)
STABILITY	15,500	Darapladib 160mgvs. placebo, on top of standard therapy	Chronic Coronary Heart Disease with at least one additional CV risk factor	Time to first occurrence of MACE	Oct '12 (Dec '08)
SOLID-TIMI	11,500	Darapladib 160mg vs. placebo, on top of standard therapy	Within 30 days of an ACS event treated with PCI	Time to first occurrence of MACE	Apr '14 (Dec '09)
AIM III	80	Darapladib 160mg vs. placebo,	Patients with early atherosclerosis, as determined by intracoronary administration of acetylcholine during angiography and IVUS.	Pre-treatment and post-treatment difference in % change CAD (Ach) and % change CBF (Ach) at 6 months	Feb '14 (Feb '10)

Source: clinicaltrials.gov. CAD – Coronary Artery Diameter, CBF – Coronary Blood Flow

Why is the market skeptical?

The market currently attributes little value to darapladib, based on a number of general and project-specific considerations:

- The concept of reducing CV risk by way of inhibiting LpPLA2 has not been validated.
- Other promising anti-inflammatory agents that promised activity in phase II (AstraZeneca's AGI 1067) have failed in phase III, and beyond specifically anti-inflammatory agents, the market has recently seen a number of high profile cardiovascular products fail to show a benefit in cardiovascular disease (eg Roche's dalcetrapib and aleglitazar).
- Darapladib has shown a good effect on biomarkers, but clinical relevance of reduction of circulating biomarkers on what is going on in the plaque or vessel wall is unclear.
- Imaging proof–of-concept phase IIb study missed the primary endpoint – despite the fact that GSK used cutting-edge imaging technology designed to look inside the vessel wall.

Market opportunity

Darapladib initially targets the primary prevention setting with STABILITY, and the 2nd study SOLID looks at a more acute population; however we believe in either setting, use would be on top of statins in patients at high cardiovascular risk.

We think the overall market opportunity is significant, with 8 million ACS patients in the US, 10 million ACS patients in the EU, and the market is growing. Should darapladib show a significant benefit in reducing major cardiovascular events, even with modest penetration assumptions, there could be 2.5 million patients on therapy. Using conservative pricing of $6 a day in the US and $4 a day in the EU, this would generate peak sales of $4.5bn. Even this forecast could prove conservative, should a strong benefit on the rate of cardiovascular events, and a clean safety and tolerability profile be shown.

Table 11: Darapladib Forecast summary

	2015E	2016E	2017E	2018E	2019E	2020E
US						
No of patients with ACS (prevalence, m)	8.5	8.7	9.0	9.3	9.6	9.8
darapladib penetration	**1.00%**	**3.00%**	**5.50%**	**8.00%**	**10.50%**	**13.00%**
No of patients treated (m)	0.1	0.3	0.5	0.7	1.0	1.3
Price per day ($)	6.0	6.0	6.0	6.0	6.0	6.0
Annual Treatment cost ($)	2,190	2,190	2,190	2,190	2,190	2,190
Sales ($, mill)	**186**	**574**	**1,085**	**1,625**	**2,196**	**2,801**
ex-US						
No of patients with ACS (prevalence, k)	10.6	10.9	11.3	11.6	11.9	12.3
darapladib penetration	**0.00%**	**1.50%**	**3.50%**	**5.50%**	**7.50%**	**9.50%**
No of patients treated (m)	-	0.2	0.4	0.6	0.9	1.2
Price per day ($)	4.0	4.0	4.0	4.0	4.0	4.0
Annual Treatment cost ($)	1,460	1,460	1,460	1,460	1,460	1,460
Sales ($, mill)	**-**	**239**	**575**	**931**	**1,308**	**1,706**
Total $m	**186**	**814**	**1,660**	**2,556**	**3,504**	**4,507**
Total £m	**122**	**535**	**1,092**	**1,681**	**2,305**	**2,965**

Source: J. P. Morgan estimates

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JPM P&L

Table 12: GSK P&L - £ m, except per share data

	2012A R	2013E	2014E	2015E	2016E	2017E
Group Net Sales	**26,431**	**27,027**	**27,105**	**28,029**	**28,705**	**29,580**
yoy growth	-3.5%	2.3%	0.3%	3.4%	2.4%	3.0%
FX	-2.5%	1.5%	-	-	-	-
CER	-1.0%	0.8%	0.3%	3.4%	2.4%	3.0%
CER ex divestments	0%	1.2%	3.6%	3.4%	2.4%	3.0%
Cost of Sales	(7,925)	(7,986)	(7,976)	(8,185)	(8,340)	(8,647)
Core COGs including Theravance Royalty		(7,545)	(7,534)	(7,743)	(7,898)	(8,205)
% sales		*-27.9%*	*-27.8%*	*-27.6%*	*-27.5%*	*-27.7%*
Group SG&A	(8,789)	(8,468)	(8,402)	(8,457)	(8,570)	(8,766)
% sales	*-33.3%*	*-31.3%*	*-31.0%*	*-30.2%*	*-29.9%*	*-29.6%*
Core SG&A	(7,905)	(8,016)	(8,120)	(8,257)	(8,370)	(8,566)
% sales	*-29.9%*	*-29.7%*	*-30.0%*	*-29.5%*	*-29.2%*	*-29.0%*
Group R&D	(3,979)	(3,748)	(3,761)	(3,799)	(3,841)	(3,883)
% sales	*-15.1%*	*-13.9%*	*-13.9%*	*-13.6%*	*-13.4%*	*-13.1%*
Core Group R&D	(3,485)	(3,536)	(3,572)	(3,610)	(3,652)	(3,694)
% sales	*-13.2%*	*-13.1%*	*-13.2%*	*-12.9%*	*-12.7%*	*-12.5%*
Other operating income / (expense)	1,562	2,043	417	419	422	425
Core Royalties	306	337	315	319	322	325
Royalty income (HPV royalty)	306	337	315	319	322	325
OOI	1,256	1,706	101	100	100	100
Operating Profit	7,300	8,868	7,383	8,007	8,376	8,709
margin %	*27.6%*	*32.8%*	*27.2%*	*28.6%*	*29.2%*	*29.4%*
Core Operating profit	**8,238**	**8,268**	**8,194**	**8,737**	**9,107**	**9,439**
margin %	*31.2%*	*30.6%*	*30.2%*	*31.2%*	*31.7%*	*31.9%*
Share of profits/(losses) of joint ventures and associates	29	69	72	76	80	84
Profit before interest and tax	7,329	8,966	7,455	8,083	8,456	8,792
Core Net interest payable	(724)	(671)	(657)	(572)	(575)	(576)
Profit before Tax	6,600	8,290	6,799	7,511	7,881	8,216
Core Profit before tax	*7,543*	*7,666*	*7,610*	*8,241*	*8,612*	*8,947*
Reported Tax	(1,922)	(2,053)	(1,563)	(1,676)	(1,724)	(1,754)
Reported Tax rate	*29.1%*	*24.8%*	*23.0%*	*22.3%*	*21.9%*	*21.3%*
Core Tax	(1,838)	(1,832)	(1,781)	(1,887)	(1,929)	(1,959)
Core implied tax rate	*-24.4%*	*-23.9%*	*-23.4%*	*-22.9%*	*-22.4%*	*-21.9%*
Profit after Taxation	4,678	6,237	5,235	5,835	6,158	6,462
Core Profit after tax	5,705	5,834	5,829	6,354	6,683	6,987
Minority Interest	(179)	(195)	(218)	(224)	(218)	(217)
Core Minority interest	(179)	(220)	(218)	(224)	(218)	(217)
Profit Attributable to Shareholders	4,499	6,042	5,017	5,611	5,939	6,245
Core Net Profit	5,470	5,614	5,611	6,130	6,465	6,770
Weighted Average No of Shares (m)	4,912	4,771	4,685	4,610	4,540	4,475
Earnings per share (p)	91.6p	126.6p	107.1p	121.7p	130.8p	139.6p
"Core" EPS	**111.4p**	**117.7p**	**119.8p**	**133.0p**	**142.4p**	**151.3p**
Growth	-1.2%	5.7%	1.8%	11.0%	7.1%	6.2%
Core EPS growth at CER		3.8%	1.8%	11.0%	7.1%	6.2%

Source: JPMorgan estimates

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Consensus comparison

Table 13: GSK consensus comparison - £m, except per share data

		2013E	2014E	2015E	2016E	2017E	2014-17E CAGR
Revenues	**JPM**	**27,027**	**27,105**	**28,029**	**28,705**	**29,580**	**3.0%**
	Consensus	26,937	27,909	28,968	29,876	30,738	3.3%
	% diff	0.3%	-2.9%	-3.2%	-3.9%	-3.8%	
COGS	**JPM**	**(7,545)**	**(7,534)**	**(7,743)**	**(7,898)**	**(8,205)**	**2.9%**
	Consensus	(7,381)	(7,535)	(7,763)	(7,977)	(8,238)	3.0%
	% diff	2.2%	0.0%	-0.3%	-1.0%	-0.4%	
COGS margin	**JPM**	**-27.9%**	**-27.8%**	**-27.6%**	**-27.5%**	**-27.7%**	
	Consensus	-27.4%	-27.0%	-26.8%	-26.7%	-26.8%	
	% diff	-52bps	-80bps	-83bps	-81bps	-94bps	
SG&A	**JPM**	**(8,016)**	**(8,120)**	**(8,257)**	**(8,370)**	**(8,566)**	**1.8%**
	Consensus	(8,042)	(8,241)	(8,454)	(8,643)	(8,850)	2.4%
	% diff	-0.3%	-1.5%	-2.3%	-3.2%	-3.2%	
R&D	**JPM**	**(3,536)**	**(3,572)**	**(3,610)**	**(3,652)**	**(3,694)**	**1.1%**
	Consensus	(3,561)	(3,640)	(3,727)	(3,824)	(3,913)	2.4%
	% diff	-0.7%	-1.9%	-3.1%	-4.5%	-5.6%	
Royalties	**JPM**	**337**	**315**	**319**	**322**	**325**	**1.0%**
	Consensus	344	337	344	347	352	1.5%
	% diff	-2.0%	-6.4%	-7.4%	-7.3%	-7.7%	
Core EBIT	**JPM**	**8,268**	**8,194**	**8,737**	**9,107**	**9,439**	**4.8%**
	Consensus	8,350	8,813	9,350	9,738	10,087	4.6%
	% diff	-1.0%	-7.0%	-6.6%	-6.5%	-6.4%	
Core EBIT margin	**JPM**	**30.6%**	**30.2%**	**31.2%**	**31.7%**	**31.9%**	**1.8%**
	Consensus	31.0%	31.6%	32.3%	32.6%	32.8%	1.3%
	% diff	-41bps	-135bps	-110bps	-87bps	-91bps	
Associates	**JPM**	**69**	**72**	**76**	**80**	**84**	**5.0%**
	Consensus	46	45	46	47	50	3.6%
	% diff	50.0%	61.0%	65.4%	69.9%	67.7%	
Interest	**JPM**	**(671)**	**(657)**	**(572)**	**(575)**	**(576)**	**-4.3%**
	Consensus	(722)	(689)	(651)	(633)	(633)	-2.8%
	% diff	-7.1%	-4.7%	-12.1%	-9.2%	-8.9%	
Tax	**JPM**	**(1,832)**	**(1,781)**	**(1,887)**	**(1,929)**	**(1,959)**	**3.2%**
	Consensus	(1,834)	(1,928)	(2,038)	(2,114)	(2,186)	4.3%
	% diff	-0.1%	-7.6%	-7.4%	-8.8%	-10.4%	
Tax rate	**JPM**	-23.9%	-23.4%	-22.9%	-22.4%	-21.9%	
	Consensus	-23.9%	-23.6%	-23.3%	-23.1%	-23.0%	
	% diff	0bps	20bps	40bps	70bps	110bps	
Net Income	**JPM**	**5,614**	**5,611**	**6,130**	**6,465**	**6,770**	**6.5%**
	Consensus	5,603	5,997	6,451	6,766	7,074	5.7%
	% diff	0.2%	-6.4%	-5.0%	-4.5%	-4.3%	
Share-count	**JPM**	**4,848**	**4,762**	**4,687**	**4,617**	**4,552**	**-1.5%**
	Consensus	4,810	4,722	4,617	4,523	4,408	-2.3%
	% diff	0.8%	0.8%	1.5%	2.1%	3.3%	
Core EPS	**JPM**	**117.7**	**119.8**	**133.0**	**142.4**	**151.3**	**8.1%**
	Consensus	116.4	127.0	139.8	149.9	160.4	8.1%
	% diff	1.1%	-5.7%	-4.9%	-5.0%	-5.7%	

Source: JPMorgan estimates, company collated consensus

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Forecast Changes

We have updated our model for:

- **Divestments:** Within Consumer, we reflect divestment of Lucozade and Ribensa, with £500m of sales being sold for £1bn. Within Pharma, we reflect Arixtra and Fraxiparine divestment, sales of c£400m, sold for £700m. Both completing late 2013.
- **A slower buyback:** now £1.7bn in 2013, £1.8bn beyond, previously £2bn in perpetuity.

Table 14: GSK forecast changes

£m, except per share data

	2012A	2013E	2014E	2015E	2016E	2017E	2014-17E CAGR
Group sales - New	**26,431**	**27,027**	**27,105**	**28,029**	**28,705**	**29,580**	3.0%
Group sales - previous	26,431	27,036	28,044	29,132	29,814	30,799	3.2%
% Change	**0.0%**	**0.0%**	**-3.3%**	**-3.8%**	**-3.7%**	**-4.0%**	
Core COGS - New	**(7,078)**	**(7,540)**	**(7,480)**	**(7,623)**	**(7,706)**	**(7,941)**	2.0%
Core COGS - Previous	(7,078)	(7,488)	(7,795)	(8,156)	(8,347)	(8,623)	3.4%
% Change	**0.0%**	**0.7%**	**-4.0%**	**-6.5%**	**-7.7%**	**-7.9%**	
Core SG&A - New	**(7,855)**	**(8,016)**	**(8,120)**	**(8,257)**	**(8,370)**	**(8,566)**	1.8%
Core SG&A - Previous	(7,855)	(7,945)	(8,329)	(8,536)	(8,646)	(8,870)	2.1%
% Change	**0.0%**	**0.9%**	**-2.5%**	**-3.3%**	**-3.2%**	**-3.4%**	
Core R&D - New	**(3,474)**	**(3,536)**	**(3,572)**	**(3,610)**	**(3,652)**	**(3,694)**	1.1%
Core R&D - Previous	(3,474)	(3,570)	(3,600)	(3,632)	(3,667)	(3,738)	1.3%
% Change	**0.0%**	**-1.0%**	**-0.8%**	**-0.6%**	**-0.4%**	**-1.2%**	14.1%
Other Operating Income - New	**1,562**	**2,043**	**417**	**419**	**422**	**425**	0.7%
Other Operating Income - Previous	1,562	443	417	419	422	425	0.7%
% Change	**0.0%**	**361.1%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**	
Core Operating Profit - New	**8,330**	**8,268**	**8,194**	**8,737**	**9,107**	**9,439**	4.8%
Core Operating Profit - Old	8,330	8,364	8,572	8,974	9,229	9,557	3.7%
% Change	**0.0%**	**-1.1%**	**-4.4%**	**-2.6%**	**-1.3%**	**-1.2%**	-34.6%
Core Operating Margin - New	**31.5%**	**30.6%**	**30.2%**	**31.2%**	**31.7%**	**31.9%**	1.8%
Core Operating Margin - Old	31.5%	30.9%	30.6%	30.8%	31.0%	31.0%	0.5%
Core Profit Before Tax - New	**7,635**	**7,666**	**7,610**	**8,241**	**8,612**	**8,947**	5.5%
Core Profit Before Tax - Old	7,635	7,718	7,908	8,399	8,656	8,987	4.4%
% Change	**0.0%**	**-0.7%**	**-3.8%**	**-1.9%**	**-0.5%**	**-0.4%**	
Core Net Profit - New	**5,536**	**5,614**	**5,611**	**6,130**	**6,465**	**6,770**	6.5%
Core Net Profit - Old	5,536	5,697	5,867	6,260	6,488	6,770	4.9%
% Change	**0.0%**	**-1.5%**	**-4.4%**	**-2.1%**	**-0.4%**	**0.0%**	
Share-count - New	**4,912.0**	**4,771.3**	**4,685.0**	**4,609.5**	**4,539.6**	**4,474.8**	-1.5%
Share-count - Old	4,912.0	4,771.3	4,680.7	4,596.8	4,519.1	4,447.1	-1.7%
% Change	0.0%	0.0%	0.1%	0.3%	0.5%	0.6%	
Core EPS - New	**112.7**	**117.7**	**119.8**	**133.0**	**142.4**	**151.3**	**8.1%**
Core EPS - Old	112.7	119.4	125.3	136.2	143.6	152.2	6.7%
% Change	**0.0%**	**-1.5%**	**-4.5%**	**-2.4%**	**-0.8%**	**-0.6%**	

Source: JPMorgan estimates, company collated consensus

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Investment Thesis, Valuation and Risks

GlaxoSmithKline *(Neutral; Price Target: 1,900p)*

Investment Thesis

With Breo and Dolutegravir approved, and Anoro looking likely to follow suit, we believe investors can now be fairly confident in topline and operating profit growth from 2014 onward. Over the next few years we see GSK offering topline growth of ~3%, which combined with some modest operating leverage, and further cost savings, should see Operating profit growth of ~5%. Factoring in some further progress on cost of debt, a declining tax rate, and the continuing share-buyback, and we forecast EPS growing ~8%, inline with GSK's large cap pharma peers.

The bull case is GSK's late stage pipeline, which potentially offers some upside to the above base, particularly Darapladib, which has the potential to take EPS growth up to low double digit. Upside to our forecasts could also come from further cost saving programs, or from significant divestments funding enlarged buybacks.

The bear case is that consensus forecasts still look a little too ambitious, particularly for 2014, once upcoming divestments are factored in. Whilst generating cash through the divestment on non-core assets is clearly a positive, and GSK will no doubt point to underlying growth, our new Core EPS forecasts are 5-6% below consensus, which suggests near-term upgrades are unlikely to be a driver of share-price performance.

Valuation

We set our mid 2014 price target at £19 based on a 2014E forward multiple of 14x (vs. a 2014E multiple of 13.7x) in line with the current sector forward multiple. This price target represents a 20% premium to our EmV/ SOTP value of £15.81 that excludes most of the company's pipeline. Key pipeline events in 2H'13 could be Darapladib phase III data (worth up to 140p per share/ 7%) for CV risk reduction and Vercinon phase III data (worth up to 30p/ 2%) for Crohns disease.

Risks to Rating and Price Target

1. Earnings could remain disappointing, as the near-term opportunity for operating leverage remains modest, with S&M spend required for new launches.
2. Buy-backs may be closer to the £1bn than the £2bn mark, and thus potentially result in a lower boost to net income growth from buybacks
3. Key swing factor is the pipeline with scope for both, positive and negative surprises: (A) GSK may fail to get US Anoro approval as a once daily therapy (B) Other assets, such as Darapladib or MAGE-A3 could fail, having only a very limited impact on earnings estimates, but a bigger dent to sentiment.

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J.P.Morgan CAZENOVE

JPM Q-Profile

GlaxoSmithKline PLC (BRITAIN / Health Care)

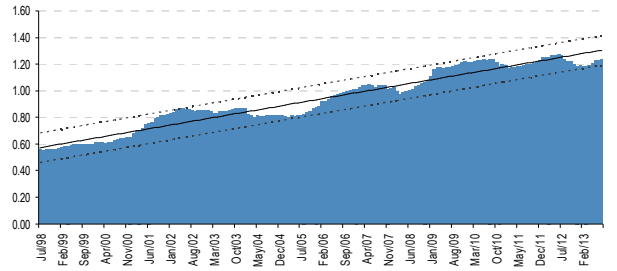
As Of: 08-Aug-2013

Global Equity Quantitative Analysis

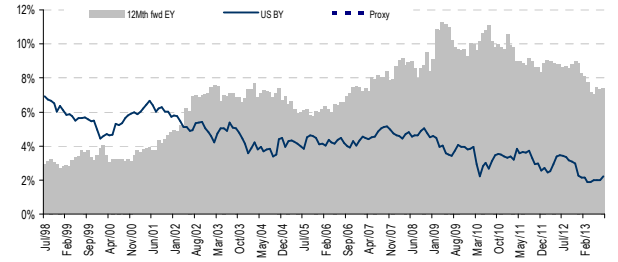
Quant_Strategy@jpmorgan.com

Local Share Price Current: 16.70

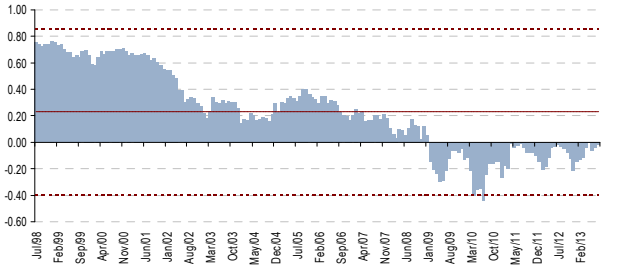
12 Mth Forward EPS Current: 1.23



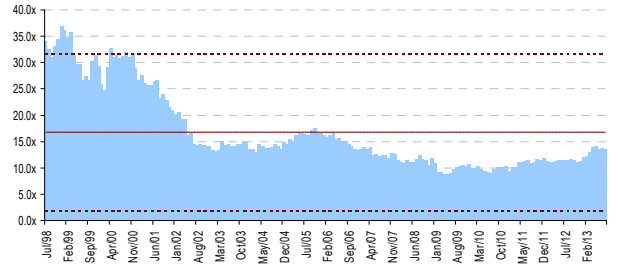
Earnings Yield (& local bond Yield) Current: 7%



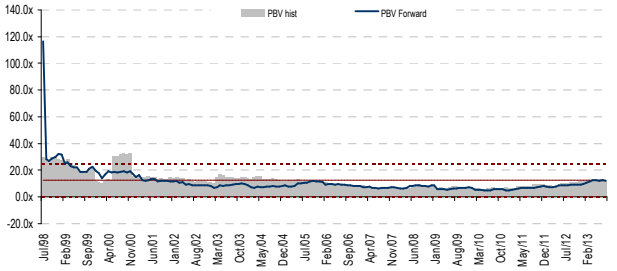
Implied Value Of Growth* Current: -2.23%



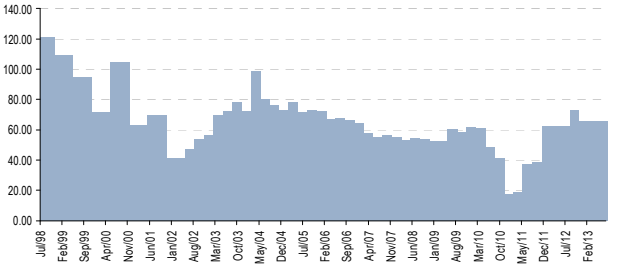
PE (1Yr Forward) Current: 13.5x



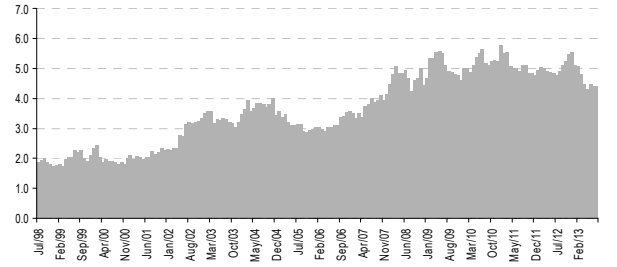
Price/Book Value Current: 12.6x



ROE (Trailing) Current: 65.96



Dividend Yield (Trailing) Current: 4.39



Summary

GlaxoSmithKline PLC								As Of:	8-Aug-13
BRITAIN	SEDOL	0925288						Local Price:	16.70
Health Care								EPS:	1.23

	Latest	Min	Max	Median	Average	2 S.D.+	2 S.D. -	% to Min	% to Max	% to Med	% to Avg
12mth Forward PE	**13.53x**	8.91	36.92	14.01	16.74	31.67	1.82	-34%	173%	4%	24%
P/BV (Trailing)	**12.62x**	5.63	32.69	11.30	12.42	24.98	-0.15	-55%	159%	-10%	-2%
Dividend Yield (Trailing)	**4.39**	1.73	5.76	3.53	3.65	6.06	1.24	-61%	31%	-20%	-17%
ROE (Trailing)	**65.96**	17.30	120.60	65.96	66.50	107.91	25.10	-74%	83%	0%	1%
Implied Value of Growth	**-2.2%**	-0.44	0.76	0.22	0.23	0.85	-0.39	-1896%	3515%	1067%	1135%

Source: Bloomberg, Reuters Global Fundamentals, IBES CONSENSUS, J.P. Morgan Calcs ** Implied Value Of Growth = (1 - EY/Cost of equity) where cost of equity =Bond Yield + 5.0% (ERP)*

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GlaxoSmithKline: Summary of Financials

Profit and Loss statement					
£ in millions	FY12A	FY13E	FY14E	FY15E	FY16E
Revenue	26,431	27,027	27,105	28,029	28,705
% change Y/Y	(3.5%)	2.3%	0.3%	3.4%	2.4%
COGS	(7,925)	(7,981)	(7,922)	(8,064)	(8,148)
Core COGS	(7,109)	(7,540)	(7,480)	(7,623)	(7,706)
Gross Profit	18,506	19,046	19,183	19,964	20,557
Core Gross Profit	19,322	19,482	19,571	20,285	20,807
SG&A	(8,789)	(8,468)	(8,402)	(8,457)	(8,570)
Core SG&A	(7,905)	(8,016)	(8,120)	(8,257)	(8,370)
R&D	(3,979)	(3,748)	(3,761)	(3,799)	(3,841)
Core R&D	(3,485)	(3,536)	(3,572)	(3,610)	(3,652)
Operating Profit	7,300	8,874	7,437	8,127	8,568
Core Operating Profit	8,238	8,268	8,194	8,737	9,107
Profit before Tax	6,600	8,290	6,799	7,511	7,881
Core Profit before Tax	7,543	7,666	7,610	8,241	8,612
Tax	(1,922)	(2,053)	(1,563)	(1,676)	(1,724)
Core Tax	(1,838)	(1,832)	(1,781)	(1,887)	(1,929)
Net Profit	4,499	6,017	5,017	5,611	5,939
Core Net Profit	5,470	5,614	5,611	6,130	6,465
Diluted EPS	90.18	124.10	105.36	119.72	128.65
Core Diluted EPS	111.36	117.66	119.76	132.98	142.40

Cash flow statement					
£ in millions	FY12A	FY13E	FY14E	FY15E	FY16E
EBIT	7,329	8,972	7,509	8,203	8,648
Depreciation & amortisation	2,199	1,609	1,638	1,664	1,687
Change in working capital	397	(503)	(5)	(57)	(42)
Taxes	(1,673)	(2,053)	(1,563)	(1,676)	(1,724)
Cash flow from operating activities	11,313	12,322	10,896	11,564	12,052
Capex	(1,051)	(1,165)	(1,165)	(1,165)	(1,165)
Disposals/ (purchase)	(1,679)	(82)	0	0	0
Net Interest	749	677	657	572	575
Free cash flow	10,262	11,157	9,731	10,399	10,887
Equity raised/(repaid)	414	184	70	77	85
Debt raised/repaid	3,614	2,000	0	0	0
Other	(910)	(1,300)	(694)	(605)	(605)
Dividends paid	(3,939)	(3,990)	(4,154)	(4,327)	(4,486)
Beginning cash	5,467	3,768	5,222	4,467	4,094
Ending cash	3,768	5,222	4,467	4,094	3,887
DPS	74.00	79.00	84.00	89.00	94.00

Balance sheet					
£ in millions	FY12A	FY13E	FY14E	FY15E	FY16E
Cash and cash equivalents	4,184	5,638	4,795	4,333	4,087
Accounts receivable	5,242	5,531	5,547	5,736	5,874
Inventories	3,969	4,009	4,021	4,158	4,258
Others	216	166	166	166	166
Current assets	13,692	15,426	14,610	14,474	14,467
LT investments	1,366	1,366	1,366	1,366	1,366
Net fixed assets	8,776	9,067	9,329	9,566	9,778
Total Assets	41,475	42,765	41,476	40,841	40,312
Liabilities					
ST loans	3,631	3,631	3,631	3,631	3,631
Payables	8,054	7,880	7,903	8,172	8,370
Other current liabilities	2,130	1,372	1,225	1,259	1,273
Total current liabilities	13,815	12,883	12,759	13,062	13,274
Long term debt	14,671	16,107	15,565	14,820	14,105
Other liabilities	1,434	1,434	1,434	1,434	1,434
Total liabilities	34,728	35,325	34,755	34,412	34,010
Shareholders' equity	5,810	6,502	5,784	5,492	5,364
BVPS	137.36	155.92	143.45	139.48	138.80

Ratio Analysis					
£ in millions	FY12A	FY13E	FY14E	FY15E	FY16E
EBITDA Margin (%)	36.0%	39.0%	33.7%	35.2%	36.0%
Operating margin	27.7%	33.2%	27.7%	29.3%	30.1%
Net profit margin	17.0%	22.3%	18.5%	20.0%	20.7%
SG&A/Sales	33.3%	31.3%	31.0%	30.2%	29.9%
R&D/Sales	15.1%	13.9%	13.9%	13.6%	13.4%
Sales growth	(3.5%)	2.3%	0.3%	3.4%	2.4%
Net profit growth	(14.5%)	33.7%	(16.6%)	11.8%	5.9%
EPS growth	(12.6%)	37.6%	(15.1%)	13.6%	7.5%
Interest coverage	10.1	13.3	11.4	14.3	15.0
Dividend Coverage	123.8%	159.6%	127.5%	136.8%	139.2%
Net debt/equity	208.0%	188.4%	213.1%	218.3%	215.3%
Sales/assets	0.6	0.6	0.6	0.7	0.7
Assets/equity	6.0	6.8	6.9	7.3	7.5
ROCE	22.1%	26.9%	22.7%	26.1%	28.8%
ROE	79.0%	91.2%	91.3%	108.7%	119.1%

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

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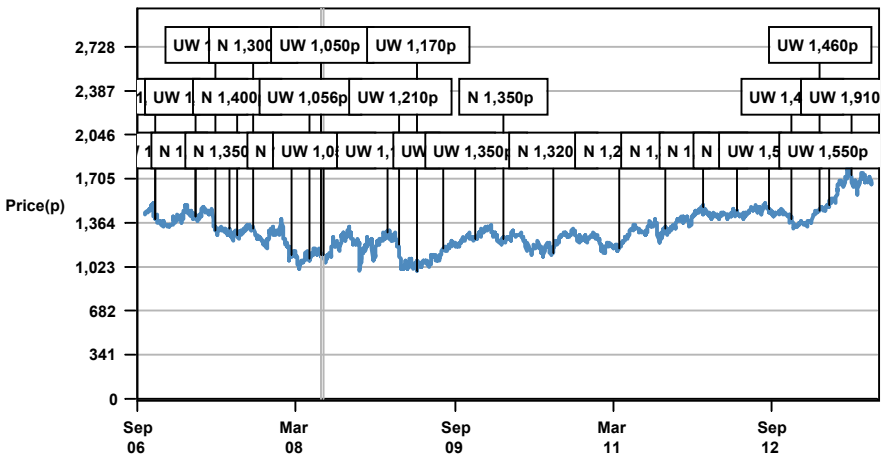
GlaxoSmithKline (GSK.L, GSK LN) Price Chart



Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Nov 01, 2006.

Date	Rating	Share Price (p)	Price Target (p)
01-Nov-06	UW	1392	1425
02-Nov-06	N	1392	1425
21-Mar-07	N	1413	1380
22-Mar-07	UW	1414	1380
30-May-07	UW	1306	1225
16-Jul-07	N	1310	1350
14-Aug-07	N	1262	1400
08-Oct-07	N	1317	1300
15-Feb-08	N	1112	1200
18-Apr-08	UW	1076	1056
29-May-08	UW	1108	1050
02-Jun-08	UW	1114	1050
09-Jan-09	UW	1285	1145
19-Feb-09	UW	1188	1210
23-Apr-09	UW	987	1170
27-Jul-09	UW	1163	1050
09-Nov-09	UW	1234	1350
15-Feb-10	N	1236	1350
05-Aug-10	N	1130	1320
22-Mar-11	N	1153	1280
01-Sep-11	N	1310	1350
05-Jan-12	N	1482	1540
04-May-12	N	1446	1470
22-Aug-12	UW	1466	1540
05-Nov-12	UW	1384	1450
11-Feb-13	UW	1453	1460
15-Mar-13	UW	1496	1550
30-May-13	UW	1726	1910

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