Closer Look

MEMORANDUM

Bayer 3Q14 - Contour revenue declines 5%; Sales of Eylea more than double year-over-year - October 31, 2014

Executive Highlights

- Contour sales totaled €167 million (~$222 million), declining 5% year-over-year (YOY) as reported and operationally against an easy comparison to 3Q13 (revenue declined 7% as reported, 4% operationally.
- We estimate that combined worldwide revenue for the Big Four totaled ~$1.8 billion, growing ~1-3% YOY in 3Q14. Bayer was the only one of the Big Four to experience a worldwide YOY decline in 3Q14.
- Management believes that it has a "very, very strong" value proposition for diabetic macular edema and will not engage in price concessions following the DME indication for Eylea.

Early Thursday morning, Bayer CEO Mr. Marijn Dekker led the company's 3Q14 financial update. Sales of Contour continue to experience weakness due to reimbursement pressure in the US and lower demand in Germany. On the drug side, the eye medication Eylea (afilbercept) is experiencing rapid growth, with sales more than doubling year-over-year. Below, we have enclosed our top device and drug highlights from the call.

Device Highlights

1. Contour sales totaled €167 million (~$222 million), falling 5% year-over-year (YOY) as reported and operationally against an easy comparison to 3Q13 (when revenue declined 7% as reported, 4% operationally).

2. By our estimates, Bayer's worldwide Diabetes Care revenue declined ~5-7% YOY against an easy comparison (revenue declined by over 7% in 3Q13). Weakness reflected "reimbursement pressure and lower prices" in the US and lower demand in Germany.

3. Combined revenue for the Big Four totaled ~$1.8 billion in 3Q14, growing ~1-3% YOY compared to pooled revenue in 3Q13. Bayer was the only one of the Big Four to experience a YOY decline in global revenue in 3Q14.

4. Management did not share any pipeline updates. The last we heard of the company's novel CGM was in 2012. We are unaware of any plans to develop a next-generation meter.

Drug Highlights

5. Eylea revenue totaled €189 million (~$251 million) in 3Q14, growing 122% as reported and operationally from a low base (€89 million) in 3Q13. The company said the product is doing particularly well, especially in Europe.

6. Regarding a diabetic macular edema (DME) indication for Eylea (afilbercept), management believes that it has a "very, very strong" value proposition. Bayer does not plan to engage in price concessions following the FDA approval of a DME indication in July 2014.

7. Management was "very excited" by the findings of an NIH-sponsored comparative effectiveness study that demonstrated benefits of Eylea treatment in comparison to Novartis' Lucentis (ranibizumab) and Genentech's Avastin (bevacizumab) in patients with DME.

8. The call did not mention finerenone, Bayer's mineralocorticoid receptor (MR) antagonist for diabetic nephropathy; a phase 2 trial (ARTS-DN) has now been completed (ClinicalTrials.gov Identifier: NCT01874431).

9. Sales of Glucobay (Bayer's alpha-glucosidase inhibitor) totaled €102 million (~$135 million), remaining flat as reported and growing 1.4% operationally. The drug was Bayer's tenth best selling pharmaceutical product in 3Q14.

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DEVICE HIGHLIGHTS

1. Revenue from Bayer's Contour BGM franchise totaled €167 million (~$222 million), falling 5% year-over-year (YOY) as reported and operationally against a particularly easy comparison to 3Q13 (down 7% as reported, 4% operationally). This marks the fifth consecutive quarter of declines in the Contour business - however, 3Q14's decline of 5% was the most modest observed in this period. The 3Q14 performance also represents a significant improvement relative to the double-digit declines observed in 1Q14 (-16%) and 2Q14 (-16%), though those quarters had harder comparisons to 2013. Sequentially, Contour sales grew 1% relative to 2Q14, a significant improvement over the 11% decline observed between 2Q13 and 3Q13. Contour revenue makes up ~70% of Bayer's overall Diabetes Care business

Table 1: Contour Revenue (3Q13-3Q14)

	3Q13	4Q13	2013	1Q14	2Q14	3Q14
Revenue in millions of EUR (USD)	€176 ($189)	€179 ($244)	**€722 ($959)**	€146 ($200)	€165 ($226)	€167 ($222)
YOY Reported Growth	-7%	-7%	**0.0%**	-14%	-16%	-5%
YOY Operational Growth	-4%	-4%	**2.2%**	-12%	-14%	-5%

Currency conversions are based on average exchange rates from start to end of the quarter on oanda.com (e.g., 1.3266 USD per EUR for 3Q14, July 1-September 30, 2014).

- **Though competitive bidding went into effect on July 1, 2013, Contour sales continue to be hampered by pricing pressure**. The US continues to be a challenging region for the Big Four blood glucose monitoring companies. For context, Abbott fell 16% YOY and Roche fell 2% YOY in 3Q14; J&J grew just 3%. It's hard to know at this point what the new "normal" will be or when the pressures will abate; we expect ongoing growth challenges in the US.

2. By our estimates, worldwide Diabetes Care revenue declined ~5-7% YOY on sales of ~€217-243 million (~$288-322 million). This came on a particularly easy comparison, as revenue declined by at least 7% in 3Q13. According to management, weakness reflected "reimbursement pressure and lower prices" in the US and lower demand in Germany. This characterization was consistent with company guidance in 2Q14, when management anticipated continued declines driven by these regions. The call's commentary did not bring further optimism for the foreseeable future either: management expects "diabetes care market weakening" to drive shrinkage in its Medical Care business going forward.

- **Key Assumptions**: Bearing in mind the limited information Bayer provides about its Diabetes Care business (only Contour revenues), we stress that these numbers are all estimates. Bayer is the only one of the Big Four BGM companies (Abbott, J&J, Roche) that does not report full results for its Diabetes Care business, which making pooled estimates challenging.
    - **Upper Bound**: Considering that Contour revenue makes up ~70% of Bayer's overall Diabetes Care business (which includes the Elite and Breeze meters), we assume that overall revenue largely follows Contour's sales. Bayer management alluded to a "weak market environment" for global Diabetes Care, leading us to believe that overall performance could not have exceeded that of Contour (i.e., best case scenario of a 5% decline).
    - **Lower Bound:** Considering a hypothetical scenario in which non-Contour revenue declined 10% (much weaker than the Contour business' 5% decline), this results in a ~7% decline in global Diabetes Care.

3. Combined revenue for the Big Four totaled ~$1.8 billion, growing ~1-3% YOY compared to pooled revenue in 3Q13. It's possible that the declines associated with competitive bidding are tapering, though comparisons to 3Q13 were easy (a year ago, pooled revenues declined ~3-4%).

- **Notably, Bayer was the only one of the Big Four to experience a YOY decline in global revenue in 3Q14** - this is the second consecutive quarter in which the company's worldwide sales have been the weakest of the Big Four. The trend is concerning for Bayer, considering no major pipeline products (that we are aware of) and an expectation for a weakening market moving forward. By comparison, there was slightly more optimism from Abbott in particular - management raised its global sales guidance to mid-single-digit operational decline for 4Q14 and shared that pricing pressures in the US are abating. Of course, we expect Abbott's recent launch of FreeStyle Libre to be a major growth driver in the quarters ahead.
- **Despite the "weak" Diabetes Care performance, Bayer's estimated market share grew roughly two percentage points relative to 3Q13.** Bayer may be winning market share more than anticipated by cutting price. Abbott's estimated market share fell ~1-2 percentage points, while Roche and J&J maintained their share.

Table 2: Estimated Market Share Worldwide (by sales) - 3Q14 vs. 3Q13

	3Q13	*3Q14*
Abbott	*~18%*	*~16-17%*
J&J	*~31-32%*	*~31%*
Roche	*~35%*	*~35-36%*
Bayer	*~14-16%*	*~16-18%*

- **Direct comparisons between J&J, Abbott, Roche, and Bayer are difficult because each company's Diabetes Care business includes a fraction of non-BGM revenue.** J&J and Roche have global insulin delivery, and Abbott has continuous glucose monitoring outside of the US. In addition, Roche only reports North America revenue, which bundles US and Canada. Additionally, the values for Bayer Worldwide Diabetes Care stem from our estimations, with assumptions outlined above.

Table 3: Big Four 3Q14 Diabetes Care Revenue Comparison

Company	Worldwide	US/North America	International

	3Q14 Revenue in Millions	*Reported (Operational) Growth from 3Q13*	*3Q14 Revenue in Millions*	*Reported (Operational) Growth from 3Q13*	*3Q14 Revenue in Millions*	*Reported (Operational) Growth from 3Q13*
J&J	*$558*	*0.2% (1%)*	*$244*	*3% (3%)*	*$314*	*-2% (-2%)*
Roche	*$636*	*1% (4.0%)*	*$120*	*-2%*	*$516*	*2%*
Abbott	*$300*	*6% (5%)*	*$102*	*-16%*	*$198*	*0.5% (2%)*
Bayer	*$288-322*	*-7% to -5%*	*--*	*--*	*--*	*--*

Currency conversion for Roche is based on the average exchange rate on oanda.com (e.g., 1.0948 USD per CHF for July 1 - September 30). Different results are possible with different currency conversion. Roche does not report revenues for an international category, and the international value we report includes the company's EMEA and RoW categories; as such, operational growth is not available. We also note that Roche's US value is slightly inflated, as it includes revenue from Canada ("North America" sales).

Currency Conversion for Bayer is based on average exchange rate on oanda.com (e.g., 1.3266 USD per Euro for July 1 - September 30). Different results are possible with different currency conversion. We emphasize that worldwide Diabetes Care revenue is based on our own estimation (see above).

4. Management did not share any pipeline updates. We're not sure if Bayer continues to work on a novel CGM; it has been over two years since our last update on the product (ATTD 2012). We recognize that the challenging market conditions do not lend themselves to innovation, though other members of the Big Four are moving ahead on the new product front. As a reminder, Abbott debuted its novel FreeStyle Libre at EASD 2014 and is in the process of launching the device in seven EU markets. Roche has launched three products this year, including the Accu-Chek Insight (next generation insulin pump and BGM system), Connect (standalone meter + smartphone app + web portal) and Aviva Expert (meter with built-in bolus advisor).

Table 4: Big Four Near-term Pipeline updates

Company	Device Name	Device Type	Timeline
Abbott	FreeStyle Libre	Flash Glucose Monitoring	Launched
Roche	Accu-Chek Connect (standalone meter + smartphone app + web portal) Accu-Chek Insight (next-gen pump + BGM system) Accu-Chek Aviva Expert (meter + built-in bolus advisor) Solo MicroPump	BGM Pump + BGM System BGM Patch Pump	September 2014 launch in SA, Italy, Germany January 2014 EU launch 2Q14 US launch Still under development

J&J	Calibra Medical's Finesse (three-day, bolus-only, wearable insulin patch) Animas Vibe	Patch-pen Pump with Dexcom G4 Platinum integration	Launch within ~19 months Under FDA review (submitted in April 2013)
Bayer	-	Novel CGM	Last update at ATTD 2012

DRUG HIGHLIGHTS

5. Eylea (afilbercept) revenue totaled €189 million (~$251 million) in 3Q14, growing 122% as reported and operationally from a low base (€89 million) in 3Q13. The company said the product is doing 'very, very well...particularly in Europe." Eylea was characterized as a primary driver of growth for the Pharmaceutical segment and was #7 on Bayer's "Best Selling Pharmaceutical Products" list.

- **"We are very confident that you are going to see a development of our sales [for Eylea]..."** Management attributed its confidence to two recent and "important" indications for Eylea in diabetic macular edema (Europe) and myopic choroidal neovascularization (Japan). Both products launched recently in September, and management believes there is upside to these indications that has yet to be realized.
- **Management anticipates that Eylea revenue, in addition to four other recently launched products outside of diabetes, have a combined peak annual sales potential of at least €7.5 billion (~$9.9 billion).** In addition to Eylea, the products include the anticoagulant Xareito, the cancer drugs Stivarga and Xofigo, and the pulmonary hypertension drug Adempas. Together, they posted a combined revenue of €750 million (~$995 million) in 3Q14 (up from €407 million in 3Q13) - this puts them about 30% of the way to the annual peak projection. The company did not break down individual projections, so it is impossible to know what fraction of that growth is anticipated for Eylea. Regardless, enthusiasm and expectations are clearly sky high and the drug is trending in a positive direction.

6. Management believes that it has a "very, very strong" value proposition for Eylea's diabetic macular edema (DME) indication, and it will not engage in price concessions. As a reminder, Novartis engaged in a price-reduction strategy when it received its DME indication for Lucentis. In contrast, Bayer's intension is "not to lower our price at this point," though management acknowledged that it is typical to negotiate "country by country, payer by payer." In Germany, management highlighted that it has established a one-year offer for reimbursement at the same price as before the DME indication, though it remains to be seen how the drug will be reimbursed going forward. For patients and for Bayer, the reimbursement represents a huge win and we hope to see the value proposition recognized going forward as well.

- **The value proposition for Eylea has been reinforced by the results of two, ongoing phase 3 pivotal trials: VISTA-DME in the US (ClinicalTrials.gov Identifier: NCT01363440) and VIVID-DME in Europe, Asia, and Australia (ClinicalTrials.gov Identifier: NCT01331681).** As a reminder, FDA approval for Eylea in DME (July 2014) was based on the one-year results of these phase 3 trials. Both studies have shown positive results for the use of Eylea with DME. Patients treated monthly or bi-monthly with Eylea 2 mg (after five initial injections) achieved greater improvements in best-corrected visual acuity from baseline compared to photocoagulation after one (VIVID-DME) and two years (VISTA-DME).
- **In total, four phase 3 trials investigating Eylea as a treatment for DME remain in progress:** (i) VISTA-DME in the US (ClinicalTrials.gov Identifier: NCT01363440) is currently ongoing but not recruiting participants (listed above); the completion date is listed as November 2014; (ii) VIVID-DME in Europe and Japan (ClinicalTrials.gov Identifier: NCT01331681) is currently ongoing but not recruiting participants (listed above); the completion date is listed as April

2015; (iii) VIVID-EAST in China and other Asian countries (ClinicalTrials.gov Identifier: NCT01783886) is ongoing and not currently recruiting participants; the primary completion and study completion date are July 2015; and (iv) VIVID-Japan study in Japan (ClinicalTrials.gov Identifier: NCT01512966) has been completed but has not posted results (the primary completion and study completion date is listed as September 2013).

7. Management was "very excited" by the findings of an NIH-sponsored comparative effectiveness study that compared Eylea treatment to Novartis' Lucentis (ranibizumab) and Genentech's Avastin (bevacizumab) in patients with DME. The study randomized 660 patients to receive Eylea 2 mg, bevacizumab 1.25 mg, or ranibizumab 0.3 mg. At 52 weeks, Eylea demonstrated "significantly" greater improvement in mean change in BCVA from baseline compared to both other drugs (p-value unreported). Rates of most adverse events were similar across the three study groups. However, the rates of arterial thrombiembolic events were found to be lower in the Eylea group (2%) relative to the bevacizumab group (4%) and ranibizumab group (5%). The data is presently being processed and verified prior to submission for publication.

- **Novartis fielded a question regarding this study during its recent 3Q14 financial update.** Management responded that more work will need to be done to reach more definitive conclusions - in particular, the dose used in the study was the US dose for DME, which is much lower than the EU dose. In addition, management called the study's definition of side effects "odd" and "un-validated" and not traditionally used in eye trials. It is hard to speculate on the validity of the study, though we imagine NIH had a strong hand in designing the study with experts.

8. Management did not mention finerenone, its mineralocorticoid receptor (MR) antagonist for diabetic nephropathy (and chronic heart failure), in its prepared remarks or during Q&A. The company characterized the drug as one of its top phase 2 pipeline candidates in 2Q14. According to ClinicalTrials.gov (Identifier: NCT01874431), the phase 2 ARTS-DN trial has now been completed. As a reminder, the double-blind trial enrolled 745 patients with type 2 diabetes and a clinical diagnosis of diabetic nephropathy who were randomized to receive one of seven doses of finerenone (ranging from 1.25 mg to 20 mg) or placebo once daily for 90 days. The primary outcome is change in urinary albumin-to-creatinine ratio (UACR) from baseline after 90 days; secondary outcomes include changes in serum potassium, renal function, and health-related quality of life, as well as the number of adverse events. At 2Q14, management noted that results would likely be available in the second half of this year - we are eagerly awaiting an update on this front.

- **AbbVie, AZ, Kyowa Hakko Kirin, Concert Pharmaceuticals, Lilly, Pfizer, J&J, Daiichi Sankyo, NephroGenex, Mitsubishi Tanabe Pharma Corporation, and Vascular Pharma are also investigating treatments for diabetic nephropathy.**

Table 5: Diabetic Nephropathy Competitive Landscape

Company	*Drug Name*	*Class*	*Status/ Timeline*	*Other Remarks*
AbbVie	Atrasentan	Endothelin-receptor antagonist	Phase 3	Primary completion expected 2017
AZ	Roxadustat	2-OG inhibitor	Phase 3	Recently entered phase 3
AZ	AZD1722	NHE3 inhibitor	Phase 2	Phase 3 expected in 2015

Bayer	Finerenone	MR (mineralcorticoid receptor) antagonist	Phase 2	Trial completed August 2014 (Identifier: NCT01874431)
Concert Pharmaceuticals	CTP-499	Inhibitor of inflammation, oxidation, and fibrosis to be used with standard CKD therapies	Phase 2	Positive 48-week phase 2 results
Daiichi Sankyo	CS-3150	Oral MR antagonist	Phase 2	Expected to enter phase 3 by early 2015
Kyowa Hakko Kirin	Bardoxolone methyl	Inhibitor of inflammation	Phase 2	Reata's phase 3 BEACON trial terminated due to safety concerns; Kyowa Hakko Kirin recently acquired the candidate
J&J	Invokana (canagliflozin)	SGLT-2 inhibitor	Phase 3	Already marketed for type 2 diabetes; being investigated for diabetic nephropathy in CREDENCE trial
Lilly	LY2382770	TGF-beta monoclonal antibody	Phase 2	Trial completed August 2014 (Identifier: NCT01113801)
Lilly	LY3016859	TGF-alpha/ epiregulin monoclonal antibody (inhibitor of two epidermal growth factor receptor ligands)	Phase 2	Currently recruiting, primary completion expected August 2015 (Identifier: NCT01774981)
Lilly	Undisclosed small molecule	Undisclosed	Phase 1	None
Mitsubishi Tanabe Pharma Corporation	MT-3995	Selective mineralocorticoid receptor antagonist	Phase 1 (US); Phase 2 (EU and Japan)	Four trials list as recruiting or ongoing on ClinicalTrials.gov

NephroGenex	Pyridorin	Oxidation inhibitor	Phase 3	Recently entered phase 3
Pfizer	PF-00489791	Phosphodiesterase inhibitor	Phase 2	Trial completed August 2013 (Identifier: NCT01200394); management mentioned "encouraging clinical performance" in 4Q13 update
Pfizer	PF-04634817	C-C chemokine receptor type 2/5 antagonist	Phase 2	Primary completion was expected September 2014 (Identifier: NCT01712061); also being investigated for diabetic macular edema
Vascular Pharma	VPI-2690B	Targets insulin-like growth factor-1 signaling pathway	Phase 2	Initiating phase 2 trial in September 2014, according to company website

- **As a reminder, AstraZeneca and Mitsubishi Tanabe Pharma Corporation announced the formation of a three-year research collaboration to develop novel therapies for diabetic nephropathy in September.** The partnership encompasses candidates from both companies' pipelines and all phases of the drug development process, from target selection to the delivery of small molecule drugs. Research will occur in parallel at MTPC's Japan-based facilities and at AZ's facility in Sweden. The agreement does not include any specific financial commitments - each company will contribute equal resources at its own cost.

9. Sales of Glucobay (Bayer's alpha-glucosidase inhibitor) totaled €102 million (~$135 million), remaining flat as reported and growing 1% operationally. The drug was Bayer's tenth best selling pharmaceutical product in 3Q14 (measured as a function of sales). Sequentially, revenue fell 4% -there is some rhythmicity to this market, as sequential revenue has alternated between growth and decline for five quarters now (perhaps due to supplier agreements).

QUESTIONS AND ANSWERS

Q: Could you touch on the ongoing dynamics in terms of pricing pressure with Eylea and Avastin?

A: On Eylea, you see that we've been sequentially going down by 3%. However, we did very, very well versus the previous quarter. The sales of Eylea are subjected to new indications - We did get two very important indications, the myopic choroidal neovascularization in Japan where there is a fair amount of prevalence of that disease, as you know. And we got DME in the European community very recently, as late as September and August for the DME in Europe. So the full benefit of those indications are still not there and we are very confident that you are going to see a development of our sales with those indications in the future.

Q: I believe that when Novartis introduced Lucentis in DME it had to give some price concessions in Europe on the labeling and, therefore, on the overall incentive. Did you have a similar experience or is your pricing absolutely identical to before with the DME indications?

A: We believe we have a very strong value proposition for DME. Our data from our pivotal trials have shown that patients should gain on average 11 letter of vision with a bimonthly dosing regimen if they follow five initial monthly injections. So our intention is not to lower our price at this point. I think our value proposition, again, is very, very strong. But of course, it's typical to negotiate country by country, payer by payer.

In Germany, for instance, we have a one-year of for generic reimbursement at the current price, during which we submit to the process and we'll probably get into negotiation afterwards. The value proposition has been reinforced by a comparative effectiveness study in patients with DME, where Eylea was compared to Lucentis and Avastin. Eylea came out significantly better when it comes to improvement on best corrective visual accuracy over 52 weeks. That's a very significant result, especially because safety results were very comparable between those three products. And when it comes to arterial thromembolic events, we were actually showing lower events in the group than the two other groups. So overall, the value proposition has been really confirmed in DME. We're very excited by those results.

-- by Varun Iyengar, Hannah Martin, Adam Brown, and Kelly Close