Closer Look

MEMORANDUM

Bayer 2Q14 - Contour sales down 16% YOY; Bayer fares worst of Big Four in 2Q14; No plans for divestment - July 30, 2014

Executive Highlights

- Contour revenue totaled €165 million (~$226 million), declining 16% as reported and 14% operationally YOY.
- Management indicated that it has no plans for divesting the Diabetes Care business, as it is cash generating.
- Separately from Bayer's 2Q14 financial update, collaborator Regeneron announced today that the FDA has approved a diabetic macular edema (DME) indication for Eylea.

Early this morning, Bayer CEO Marjin Dekkers led the company's 2Q14 financial update. Bayer's Diabetes Care business was addressed briefly in both the prepared remarks and Q&A. Below, we enclose the top five financial and top three drug pipeline highlights of the call.

Financial Highlights

1. During Q&A, management suggested that divestment of the Diabetes Care business is unlikely: "...this is a business that requires very little cash investment...and is generating good cash flow. We are committed to this business, particularly because of the good cash flow that it continues to generate."

2. Revenue from Contour (Bayer's lead BGM franchise) totaled €165 million (~$226 million), declining 16% as reported and 14% operationally year-over-year (YOY); although we note that the comparison to 2Q13 was challenging, this is the steepest decline we have observed since we began reporting Contour's growth in 2008.

3. By our estimates, worldwide Diabetes Care revenue fell between 10-16% YOY on a reported basis, with sales totaling approximately €178- €204 million (~$244-$280 million); on a global basis, Bayer appears to have generated the weakest growth of the Big Four blood glucose monitoring companies (J&J, Abbott, Roche, and Bayer) in 2Q14 though their business is hard to analyze given absence of traditional reporting.

4. Combined revenue for the Big Four totaled ~$1.7 billion, an ~12-15% YOY reported decline; sequentially, combined revenue growth was relatively flat from 1Q14.

5. Management expects continued declines in Diabetes Care revenue in 2H14, and an uptick in sales is not expected despite the annualization of competitive bidding.

6. Management did not share any pipeline updates or plans for new BGM devices.

Drug Highlights

7. Although not mentioned on the call, Bayer and Regeneron announced today that the FDA has approved a diabetic macular edema (DME) indication for Eylea (VEGF Trap-Eye; intravitreal aflibercept).

8. Management included the MR antagonist finerenone, Bayer's investigational therapy for diabetic nephropathy, in its list of top phase 2 pipeline candidates.

9. Glucobay (acarbose) sales totaled €106 million (~$145 million) in 2Q14, down 2% as reported and up 4% operationally year-over-year (YOY). Management continued to report "significant growth in demand, especially in China" for Glucobay.

Table of Contents

FINANCIAL UPDATES

1. To start off highlights for 2Q14, we raise something notable from Q&A, namely, management suggested that divestment of the Diabetes Care business is unlikely, as the business is cash-generating. To answer a question on the potential for divesting the business, management acknowledged that the present BGM environment is challenging but commented, "...this is a business that requires very little cash investment...and is generating good cash flow. We are committed to this business, particularly because of the good cash flow that it continues to generate." The statement was similar with what Abbott said during its 2Q14 financial update - its Diabetes Care business remains profitable and is cash generating, and will continue to be run for cash. Although J&J did not comment on the cash-generation of its Diabetes Care business, the company also commented in its 2Q14 financial update that it "remains committed to its diabetes space." Although some wonder if the commitment of the Big Four (and their Boards of Directors) will remain if sales and profitability continue to decline as they have in the past year, we do think management was very clear about its plans at least in the next couple of years. While it would be easy enough to justify a change in course, management seems slightly more emphastic about its decision than it would be had it no commitment to the business.

2. Revenue from Contour (Bayer's lead CGM franchise) totaled €165 million (~$226 million), declining 16% as reported and 14% operationally year-over-year (YOY); this marks four straight quarters of declining Contour sales (two consecutive quarters of double digit declines) and the steepest decline we have seen since Bayer began breaking out this revenue back at the beginning of 2008. This was a particularly difficult comparison, as Contour revenue grew an impressive 13% as reported (15% operationally) in 2Q13 (although, the Contour brand has faced more challenging comparisons of 16%-21% growth in the past several years). Management did not comment on this volatility during prepared remarks or Q&A, though they did note that the Diabetes Care business continues to be "hampered" by reimbursement and pricing pressures, particularly in the US. Sequentially, Contour sales grew 13% as reported on an easy comparison to 1Q13, when sales of €146 million were the lowest since 2010.

- **Unfortunately, Bayer did not share specific growth figures for its global Diabetes Care business, as it did in its 1Q14 financial update when sales declined a relatively modest ~6% YOY** (it was not clear whether this was as reported or operationally) and a striking ~40% in the US. The 1Q14 call represented the first time since 2008 that we had heard a more detailed breakout of Bayer's overall Diabetes Care business - Bayer typically has the hardest financials to unpack since it reports so little and currency also plays a role; indeed, it is challenging to even put these values from 1Q14 into context since the company has not offered relatively little insight into the Diabetes Care business in past and current years.

Table 2: Contour Revenue (2Q13-2Q14)

	2Q13	3Q13	4Q13	2013	1Q14	2Q14
Revenue in millions of EUR (USD)	€197 ($257)	€176 ($189)	€179 ($244)	**€722 ($959)**	€146 ($200)	€165 ($226)
YOY Reported Growth	13.2%	-6.9%	-7.3%	**0.0%**	-14.1%	-16.2%

YOY Operational Growth	15%	-3.5%	-4.1%	**2.2%**	-11.5%	-13.9%

Currency conversions are based on average exchange rates from start to end of the quarter on oanda.com (e.g., 1.3715 USD per EUR for 2Q14, April 30-July 1, 2014).

3. By our estimates, worldwide Diabetes Care revenue fell ~10-16% YOY on a reported basis, with sales totaling approximately €221-264 million (~$303-362 million). This came on a moderately challenging comparison, as we estimated overall Diabetes Care revenue grew ~8-10% in 2Q13. The 2Q14 decline can be largely attributed to the steep 16% drop in Contour sales (see above) and to a lesser extent, to the discontinuation of A1c Now, which was a small business.

- **Key Assumptions:** Baring in mind the limited information Bayer provides about its Diabetes Care business, we stress that these numbers are all estimates. Bayer is the only one of the Big Four BGM companies that does not report full results for its Diabetes Care business, which makes estimations very challenging:
    - **Lower Bound:** Bayer said that Contour revenue fell 16% YOY on a reported basis. We assumed that the overall Diabetes Care business may have performed better than Contour alone, as was the case in 1Q14; management also commented: "The diabetes care business in the United States continued to be held back by reimbursement pressure and price declines, particularly for our Contour line of blood glucose meters" - this led us to use the 16% decline YOY as a conservative lower bound for our estimate of global Diabetes Care sales.
    - **Upper Bound:** To find the upper bound of the estimate, we assumed that revenue from Diabetes Care outside of Contour also declined (the company noted that there was a "weak" Diabetes Care market). Since non-Contour revenue makes up a much smaller portion of the overall Diabetes Care revenue (including the Elite and Breeze meters), we assumed a moderate decline of 5% YOY - this approximates to an estimated 13% YOY decline in global Diabetes Care sales as an upper bound (assuming these other meters make up ~30% of the market). However, to maintain a conservative outlook, we have chosen to use a general 10% decline YOY as our upper bound for our estimate of global Diabetes Care sales..

4. Combined Big Four revenue of ~$1.8-1.9 billion declined ~4-9% YOY on a reported basis. This was not a challenging comparison, as pooled revenue dropped ~4-5% on a reported basis in 2Q13. This steep decline is indicative of the challenges the industry continues to face as reimbursement challenges and pricing pressures press on in the US - the story is starting to sound repetitive at this point, although we may have expected a sort of "annualization" at this juncture since competitive bidding began last July 1, 2013. At this point, it doesn't seem likely that will be happening soon based on comments in the Big Four financial updates. Even at these lower revenue numbers, it seems that these businesses are still profitable and cash-generating, suggesting that even the new normal is still a viable business. That may change if private payers follow CMS and margins drop further.

- **Among the Big Four, we estimate that Roche had the highest market share by sales in 2Q14 (~37%), followed by J&J (~30%), Bayer (~18%), and Abbott (~16%).** Compared to 1Q14, Roche gained approximately one percentage point of share, J&J maintained its share, and Abbott lost one percentage point of share. Our estimate suggests Bayer's maintained its share, but it's impossible to know precisely.

Table 4: Estimated Big Four Worldwide Market Share by Sales for 2Q14

	Roche	**J&J**	**Abbott**	**Bayer**

Percent of 2Q14 Pooled Revenue (worldwide)	~37%	~30%	~16%	~18%

- **In 2Q14, Bayer's estimated worldwide ~10-16% decline in sales was the worst of the Big Four.** Though all four companies reported declines for overall Diabetes Care - J&J revenue fell 5% as reported and operationally YOY; Abbott global revenue declined 10% as reported and operationally YOY; and Roche Diabetes Care revenue fell 10% as reported and 4% operationally YOY.

Table 3: 2Q14 Big Four Diabetes Revenue Comparison

Company	Worldwide		US/North America		International	
	2Q14 Revenue in Millions	*Reported (Operational) Growth from 2Q13*	*2Q14 Revenue in Millions*	*Reported Growth from 2Q13*	*2Q14 Revenue in Millions*	*Reported (Operational) Growth from 2Q13*
Roche	$677	-10% (-4%)	$124	-24%	$554	-6%
J&J	$558	-5% (-5%)	$222	-14%	$336	2% (2%)
Abbott	$294	-10% (-10%)	$98	-27%	$196	3% (2%)
Bayer	$303-362	-10% to -16%	-	-	-	-

Currency conversion for Roche is based on the average exchange rate on oanda.com (e.g., 1.1247 USD per CHF for April 1 - June 31). 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). Reported growth for Roche is calculated based on CHF.

Currency Conversion for Bayer is based on average exchange rate on oanda.com (e.g., 1.3715 USD per Euro for April 1 - June 31). Different results are possible with different currency conversion. We emphasize that worldwide Diabetes Care revenue is based on our own estimation (see above).

- **We emphasize that 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, so Roche's US revenue includes sales from Canada. Additionally, the values from Bayer Diabetes Care stem from our estimations, with assumptions outlined above.

5. Management highlighted "weaker-than-anticipated" Diabetes Care revenue, attributing the sales deficit largely to the fallout from competitive bidding and associated pricing pressures in the US. This is a common refrain we have heard from Abbott, Roche, and J&J in each of their 2Q14 reports, as well as previous reports dating back to 2Q13 when competitive bidding went into effect. Of more concern, management noted in Q&A that it does not expect annualization of competitive bidding to contribute to an uptick in revenue; instead, the company still "[plans] to see a decline in Diabetes Care" in 2H14 driven by the US and Germany. This gloomy forecast does not bode well for any of the Big Four, and the fact that sales are still declining YOY suggests that the market has not bottomed yet.

6. Management did not share any pipeline updates or plans for new BGM devices. We would note that Abbott, Roche, and J&J seem to moving ahead on the new product front, despite the reimbursement

challenges. We are particularly looking forward to seeing how the launch of Abbott's FreeStyle Libre goes, which is slated to kick off at EASD 2014.

Table 1. Big Four Near-term Pipeline updates

Company	Device Name	Device Type	Timeline
Abbott	FreeStyle Libre	Flash Glucose Monitoring	2H14 EU launch
Roche	Accu-Chek Connect (BGM with Bluetooth connectivity to smart App and cloud)	BGM	2014 EU launch
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 ~22 months Under FDA review (submitted in April 2013)
Bayer	-	Novel CGM	Last update at ATTD 2012

DRUG PIPELINE UPDATES

7. Although it was not mentioned during the call, Bayer and Regeneron announced today that the FDA has approved a diabetic macular edema (DME) indication for Eylea (VEGF Trap-Eye; intravitreal aflibercept) - this approval is in line with the previous estimation of an August 2014 approval. The label recommends a 2 mg dose of Eylea every two months following five initial monthly injections. This approval puts Eylea just about two years behind the release of Novartis' Lucentis (ranibixumab), which was approved by the FDA for a DME indication in August 2012. Eylea received a positive opinion from the EMA's Committee for Medicinal Products for Human Use (CHMP) for a DME indication in June, suggesting that European approval could occur within the next two to three months. Bayer/Regeneron have also submitted Eylea for regulatory approval of a DME indication in Japan and other Asian and Latin American countries. As a reminder, Eylea is currently marketed for wet age-related macular degeneration (wet AMD); the drug has been approved in the US since 2011 and in the EU since 2012 for that indication.

- **Eylea's FDA approval was based on one-year results (presented at this year's ADA) from two phase 3 trials: VISTA-DME in the US (ClinicalTrials.gov Identifier: NCT01363440) and VIVID-DME in Europe, Asia, and Australia (ClinicalTrials.gov Identifier: NCT01331681).** The two similarly designed trials randomized 872 patients with DME to receive either Eylea 2 mg every four weeks (2q4), Eylea 2 mg every eight weeks (2q8, following five initial monthly doses), or standard laser photocoagulation. The primary endpoint was mean change in best-corrected visual acuity (BCVA) from baseline at week 52; Eylea treatment led to a drastic improvement of +12.3 letters and +10.9 letters in the 2q4 and 2q8 groups, respectively, compared to an improvement of +1.1 letters with laser treatment ($p<0.0001$). There were no significant differences in the rate of adverse events across the three groups.
- **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; the completion date is listed as November 2014 (one-year results reported above); (ii) VIVID-DME in Europe and Japan (ClinicalTrials.gov Identifier: NCT01331681) is currently ongoing but not recruiting participants; the completion date is listed as April 2015 (one-

year results listed above); (iii) VIVID-EAST in China and other Asian countries (ClinicalTrials.gov Identifier: NCT01783886) is currently recruiting; 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).

- **Other treatments for diabetic macular edema on the market or in development include Novartis/Genentech's Lucentis and Alimera Sciences' Iluvien.** Both products exert their effects via the same anti-VEGF mechanism as Eylea. Lucentis is marketed by Genentech in the US and by Novartis elsewhere; Alimera submitted Iluvien to the FDA for the fourth time in April after receiving a complete response letter in October 2013 - the drug is approved in several European countries and is on the market in the UK and Germany. We wonder now that there are two approved treatments for a DME indication, whether off-label use of Genentech's much cheaper Avastin (bevacizumab) will decrease. That will depend on how Bayer prices Eylea for DME - if it offers Eylea at approximately the same cost as Lucentis, it could push some patients towards cheaper off-label options such as Avastin.

8. Management characterized finerenone, a mineralocorticoid receptor (MR) antagonist for diabetic nephropathy, as one of the top phase 2 candidates in Bayer's pipeline. We first learned about this drug at the beginning of 2Q14, although Bayer did not mention finerenone during its 1Q14 financial update. Additionally, this is the first time that we have heard details on the drug's phase 2 trial (detailed below).

- **The on-going, phase 2 ARTS-DN trial (ClinicalTrials.gov Identifier: NCT01874431), examining the safety and efficacy of different oral doses, has an estimated completion date of August 2014.** Management noted during Q&A that results will likely be available in the second half of this year. 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. This study is ongoing and not currently recruiting participants.
- **AbbVie, Kyowa Hakko Kirin, Concert Pharmaceuticals, Lilly, Pfizer, J&J, AZ, Daiichi Sankyo, NephroGenex, 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
J&J	Invokana (canagliflozin)	SGLT-2 inhibitor	Phase 3	Already marketed for type 2 diabetes; being investigated for diabetic nephropathy in CREDENCE trial

NephroGenex	Pyridorin	Oxidation inhibitor	Phase 3	Recently entered phase 3
AZ	Roxadustat	2-OG inhibitor	Phase 3	Recently entered phase 3
Bayer	Finerenone	MR (mineralcorticoid receptor) antagonist	Phase 2	Primary completion of safety/efficacy trial with different oral doses expected this month (Identifier: NCT01874431)
AZ	AZD1722	NHE3 inhibitor	Phase 2	Phase 3 expected in 2015
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
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
Lilly	LY2382770	TGF-beta monoclonal antibody	Phase 2	Primary completion expected this month (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)

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 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
Daiichi Sankyo	CS-3150	Oral MR antagonist	Phase 2	Expected to enter phase 3 by early 2015
Lilly	Undisclosed small molecule	Undisclosed	Phase 1	None

- **Japan-based Kyowa Hakko Kirin announced on July 4 that it will resume phase 2 development of bardoxolone methyl** (licensed from Reata Pharmaceuticals); a recent analysis of Reata's terminated BEACON trial suggested that excluding a subset of patients with certain baseline risk factors might have eliminated the worrisome increase in adverse events in the bardoxolone methyl arm.
- **J&J is investigating the potential of its SGLT-2 inhibitor Invokana (canagliflozin) to slow the progression of diabetic nephropathy.** The CREDENCE renal outcomes trial (ClinicalTrials.gov Identifier: NCT02065791) will enroll ~3,600 patients with type 2 diabetes and renal impairment, with an expected end date in 2019.
- **NephroGenex announced the initiation of patient enrollment in the first of two phase 3 studies examining the safety and efficacy of its diabetic nephropathy drug Pyridorin on June 18.** This is one of the relatively few agents we have seen enter phase 3 for diabetic nephropathy; notably, the FDA has granted Pyridorin fast-track status and approved a Special

Protocol Assessment for the PIONEER trial program. The study (ClinicalTrials.gov Identifier: NCT02156843) has an estimated primary completion date of December 2017.

9. Sales for Glucobay (acarbose), Bayer's alpha-glucosidase inhibitor, totaled €106 million (~$145 million) in 2Q14, down 2% as reported and up 4% operationally YOY. Sequentially, Glucobay revenue rose 4%. In the company's interim financial report, management said Glucobay had "registered significant growth in demand, especially in China" - these remarks are nearly identical to comments made in Bayer's 1Q14 financial update, and similar to those from the 4Q13; management also highlighted the drug's performance in China during the company's 1Q13 and 2Q13 financial updates. Once again, the drug made its way to Bayer's "Best-Selling Pharmaceutical Products" list.

Table 6: Glucobay Revenue (2Q13-2Q14)

	2Q13	3Q13	4Q13	2013	1Q14	2Q14
Revenue (EUR millions)	€108	€102	€112	€423	€102	€106
Revenue (USD millions)	$141	$109	$152	$562	$140	$145
YOY Growth, reported (operational)	4.9% (5.9%)	-16.4% (-13%)	13.1% (19.3%)	3.7% (6.6%)	1.0% (4.1%)	-1.9% (4.2)
Sequential Growth (reported)	6.9%	-5.6%	9.8%	-	-8.9%	3.9%

QUESTIONS AND ANSWERS

Q: Pricing pressures continue to affect the diabetes monitoring business. How are you thinking about this area going forward? Is Bayer planning to run it for cash or is divestment still a possibility?

A: Diabetes is a tough environment. In general, I would say that diagnostics businesses are tough, particularly in the US. However, as we have mentioned before, this is a business that requires very little cash investment from Bayer and is generating good cash flow. We are committed to the business, particularly because of the good cash flows that it continues to demonstrate.

Q: Competitors have been commenting they are beginning to see stabilization in revenues as last year's reimbursement pricing pressure annualizes. Are you seeing any stabilization or do you see your trends continuing in 2H14?

A: That's a pretty straight answer. The answer is yes. We are planning to see a continuous decline of our Diabetes Care, mainly driven by the US, as I mentioned, and in Europe, Germany. That is the main reason for the chance in guidance we have actually issued regarding Consumer Health in EBITDA for the full year. The two are very strongly related.

Q: Can you talk about the pipeline for your five phase 2 products?

A: Finerenone is a phase 2 study. As you know, we are looking for two different indications. One is in worsening chronic heart failure and the second in diabetic nephropathy, and we are expecting those results to be available during the second half of 2014.

Q: Can you clarify how data from phase 2 trials will be presented to the market? Will results be presented at conferences or reported through press releases?

A: Data publication or data release. Bayer typically goes to conferences and congresses for data release. We will continue to do that with the five assets we are talking about here.

Q: Regarding Eylea, I was wondering whether you are seeing any off-label use in DME already? Clearly it's not approved, but are you seeing that? Also do you think that there will be a boost in growth with the launch in a couple of months' time?

A: Eylea is doing very well and will continue to do well. We are counting on the DME indication [Editor's Note: as mentioned in the report, Eylea received FDA approval for a DME indication today]. I have no indications that the off-label use is actually happening - despite the fact that in this therapeutic area off-label use seems to be very prevalent. So I have no indication of that. However, as I said, DME is going to be a major indication for Eylea, and we're expecting positive news pretty soon now. Our data are very, very strong, showing a difference in vision with a bi-weekly dosing regimen. With that strong condition, we think DME will be very successful for Eylea. And in terms of revenue, it is estimated to represent approximately two-third of the Wet AMD market. That's what I can say on that.

Q: In terms of Eylea, can I check that all the growth was underlying and that there were no stocking impacts?

A: The answer is no.

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