MEMORANDUM

# Bayer 4Q13 - Contour sales down 7% in 4Q13, up 2% in 2013; Big Four down 5-7% in 2013, driven by challenging US marketplace - March 7, 2014

**Executive Highlights**

- Contour (Bayer's leading BGM franchise) revenue totaled €179 million (~$244 million) in 4Q13, down 7% year-over-year (YOY); for 2013, Contour sales of €722 million (~$959 million) were flat as reported and up 2% operationally from 2012.
- The Big Four BGM companies (J&J, Abbott, Roche, and Bayer) brought in a pooled worldwide Diabetes Care revenue of ~$2.0 billion in 4Q13, a 6-8% decline (YOY). In the US, pooled 4Q13 sales for J&J, Abbott, and Roche were down a pooled 23% YOY.

*Bayer CEO Mr. Marjin Dekkers recently led the company's 4Q13 and full year financial update. Diabetes Care was not mentioned during the prepared comments, although management did comment on the "shrinking overall market" and the company's expansion into "attractive segments" of the market in its 2013 Annual Report. Our top five learnings from the call include (i) financial results for Contour; (ii) a 4Q13 and 2013 sales comparison among the Big Four blood glucose monitoring companies (see our 4Q13 reports from J&J, Abbott, and Roche); (iii) remarks on the future of Bayer Diabetes Care; and (iv) drug updates on Glucobay (acarbose) and (v) Eylea (intravitreal afibercept).*

*Bayer's 4Q13 financial results call rounds out a challenging 2013 for the Big Four BGM companies: pooled sales totaled ~$7.5-$7.7 billion, falling ~5%-7% as reported from 2012. This was actually a lower drop than we had expected though we imagine the profitability drop was certainly in the double digits. The Big Four story in 2013 was shaped by geography, as modest international growth (ranging from 0.5%-5%) bolstered the steep sales declines in the US (ranging from -9% to -24%). The year-end results reinforced, of course, just how challenging the US marketplace has become following the start of CMS' competitive bidding program on July 1. However, it's still encouraging to see signs in innovation and clear intentions to evolve: J&J's OneTouch VerioSync (launched in the US in January), Abbott's Flash Glucose Monitoring system development (CE Mark expected in 2H14), Roche's Bluetooth BGM and smartphone app (EU launch in 2014), and as noted in #2 below, Bayer's efforts to develop new blood glucose meters and expand into (unspecified) "attractive segments of the diabetes market."*

## TOP FIVE HIGHLIGHTS

**1. Revenue from Contour (Bayer's lead BGM franchise) totaled €179 million (~$244 million) in 4Q13, declining 7% year-over-year (YOY) as reported and 4% operationally YOY; sales for the 2013 full year totaled €722 million (~$959 million), remaining flat as reported from 2012 and up 2% operationally**. This was a particularly challenging comparison for both 4Q13 as the full year; sales grew 14% as reported and 11% operationally YOY in 4Q12, while sales for the full year 2012 grew 13% as reported and 9% operationally YOY (2012 also faced a challenging comparison, with sales growing 6% as reported and 8% operationally in 2011 YOY). Sequentially, Contour sales grew 2% from 3Q13; the lowest sequential growth since we began reporting Contour revenue in 2007. This now marks two straight quarters of negative YOY growth for the Contour franchise, a trend we have not seen since mid-2010. The call attributed the 2013 operational growth for Contour products, in part, to the launch of the Contour Next.

**Table 1: Contour Revenue (4Q12-4Q13)**

| | 4Q12 | 2012 | 1Q13 | 2Q13 | 3Q13 | 4Q13 | 2013 |
|---|---|---|---|---|---|---|---|
| **Revenue in millions of EUR (USD)** | €193 ($250) | **€722 ($959)** | €170 ($225) | €197 ($257) | €176 ($189) | €179 ($244) | **€722 ($959)** |
| **YOY Reported Growth** | 13.5% | **12.8%** | 2.4% | 13.2% | -6.9% | -7.3% | **0.0%** |
| **YOY Operational Growth** | 10.7% | **8.5%** | 2.6% | 15% | -3.5% | -4.1% | **2.2%** |

Currency conversions are based on average exchange rates from start to end of the quarter or year on oanda.com (e.g., 1.3609 USD per EUR in 4Q13, and 1.3280 from year start to year end in 2013).

- **By our estimates, overall Diabetes Care (Contour, Breeze, Elite, A1c Now) revenue totaled between €246-273 million (~$334-371 million) in 4Q13 (a ~7-13% decline).** For the full year 2013, we estimate that sales reached €0.9-1.1 billion (~$1.2-1.4 billion), falling somewhere between flat growth and a 12% decline relative to 2012. Management commented that 2013 Diabetes Care performed "at around the previous year's level," which we took to assume that growth was flat year-over year. As a reminder, Bayer only breaks out Contour sales and does not present total Diabetes Care revenue - we would emphasize that these numbers are estimates.
    - **Key assumptions:** We assumed that overall Diabetes Care would decline more than Contour sales, placing Contour's 7% drop in revenue as our upper limit for 4Q13. The lower limit was defined by J&J's worldwide Diabetes Care decline (13% for 4Q13), since that is the steepest drop in sales seen for a BGM company in 4Q13. To estimate 4Q13 revenue, we applied these guidelines to our estimated 4Q12 revenue range. Our estimated 2013 revenue range assumed flat growth from our 2012 estimate.
- **Management commented on the challenging marketplace, noting that a weaker Diabetes Care market contributed to the "slight downturn" in the company's Medical Care business segment.** The call also highlighted that Diabetes Care performance performed similarly to how it did last year, despite a "shrinking overall market."

**2. In Bayer's 2013 Annual Report, the company noted that it would "focus on strengthening product lines and expanding into further attractive segments of the diabetes market."** While we have no further details on what areas those may be, we continue to wonder if Bayer is still working on the CGM front - the company last publicly discussed its CGM two years ago at ATTD 2012. The 4Q13 call highlighted several ways that Bayer has attempted to bring innovative products to key markets in 2013: the launch of the Contour Next and Contour Link BGM in the EU, as well as the Contour Plus platform in parts of the EU, Africa, and the Middle East. Even with the increasingly challenging reimbursement landscape, it's encouraging to see that the Big Four are still pursuing new products:

- **J&J**, which reported 4Q13 results on January 21, has reorganized its Diabetes Care business and effectively given its LifeScan sales force to Janssen, manufacturer of the SGLT-2 inhibitor Invokana. The division continues to launch new products, most recently the LifeScan OneTouch VerioSync in mid-January. Additionally, Insulet said in its recent 4Q13 financial update that it had filed for FDA 510(k) clearance of a LifeScan OneTouch Verio-integrated OmniPod (a J&J-Insulet partnership announced in April 2012).
- **Abbott**, who reported 4Q13 financial results on January 22, renewed its commitment to expanding in emerging markets. Additionally, the company is also developing the new Flash Glucose Monitoring System - per the last update at ATTD 2014, a CE Mark is still expected in 2H14. Abbott is also conducting two European multi-center, multi-country, randomized controlled trials to demonstrate improved glycemic control in type 1 and type 2 diabetes. The trials are intended to

show real clinical outcomes, and we imagine would help drive data to support reimbursement in Europe.

- **Roche** reported 4Q13 results on January 30 and highlighted the 2014 EU launches of the Accu-Chek Insight (next-gen pump + meter remote) and Accu-Chek Connect (meter with Bluetooth connectivity to a smartphone app and the cloud).

**3. Combined 4Q13 worldwide diabetes care revenue for J&J, Abbott, Roche and Bayer totaled ~$2.0 billion, representing a decline between 6% and 8% from pooled revenue reported in 4Q12.** This range is similar to the decline we saw in 3Q13 (5-10% YOY), indicating sustained US marketplace pressures. For the full year, pooled sales for J&J, Abbott, Roche, and Bayer totaled ~$7.5-7.7 billion in 2013, falling 5%-7% as reported from 2012, with the decline driven by pricing pressure in the US market. Pooled US revenue for J&J, Abbott, and Roche totaled $494 million in 4Q13, down 23% YOY (Bayer does not break out US Diabetes Care sales). The massive drop in US sales underscores the impact competitive bidding has had on industry in 2H13.

- **For 2013 overall, J&J experienced the steepest decline in worldwide sales (-12%), driven by a 24% decline in the US** (on a positive note, the international business grew 2% operationally). This trend was similar for Roche (-17% in the US, +1% internationally, -7% overall) and Abbott (-9% in the US, +5% internationally, -2% overall). We estimate that Bayer's overall 2013 business was flat year-over-year best-case scenario, and assume the declines in the US were helped by modest international growth. See table #3 below for detailed information.
- **Among the Big Four, we estimate that Roche had the highest market share by sales in 4Q13 (~37%), followed by J&J (~28%), Bayer (~17%), and Abbott (~17%).** The split was relatively similar for the full year. See table four below for more details.

**Table 2: 4Q13 Big Four Diabetes Care Revenue Comparison**

| Company | Worldwide | | US | | International | |
|---|---|---|---|---|---|---|
| | *4Q13 Revenue in Millions* | *Reported (Operational) Growth from 4Q12* | *4Q13 Revenue in Millions* | *Reported (Operational) Growth from 4Q12* | *4Q13 Revenue in Millions* | *Reported (Operational) Growth from 4Q12* |
| *Abbott* | $346 | -4.4% (-3.6%) | $129 | -14.3% | $217 | 2.7% (4.1%) |
| *J&J* | $563 | -12.6 (-11.9%) | $219 | -25.9% | $344 | -1.3% (0.2%) |
| *Roche* | $750 | -7.0% | $146 | -26.7% | $604 | -0.5% |
| *Bayer* | $334 - $371 | -7% to -13% | -- | -- | -- | -- |

Currency conversion for Roche based on average exchange rate on oanda.com (e.g., 1.1068 USD per Euro for October 1 - December 30; 1.0790 USD per Euro for January 1, 2013 - December 30, 2013). 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., 1.3609 USD per Euro for October 1 - December 30; 1.3280 USD per Euro for January 1, 2013 - December 30, 2013). Different results are possible with different currency conversion. Bayer does not breakout US and International revenue.

**Table 3: 2013 Big Four Diabetes Care Revenue Comparison**

| Company | Worldwide | | US | | International | |
|---|---|---|---|---|---|---|
| | *2013 Revenue in Billions* | *Reported (Operational) Growth from 2012* | *2013 Revenue in Billions* | *Reported (Operational) Growth from 2012* | *2013 Revenue in Billions* | *Reported (Operational) Growth from 2012* |
| Abbott | $1.3 | -1.5% (-0.8%) | $0.5 | -8.6% | $0.8 | 5.0% (3.8%) |
| *J&J* | $2.3 | -11.7 (-11.2%) | $1.0 | -23.9% | $1.3 | 0.5% (1.6%) |
| *Roche* | $2.7 | -7.0% | $0.5 | -16.8% | $2.1 | 0.7% |
| *Bayer* | $1.2 - $1.4 | 0.0% | -- | -- | -- | -- |

**Table 4: Estimated Big Four Worldwide Market Share by Sales for 4Q13 and 2013**

| | J&J | Abbott | Roche | Bayer |
|---|---|---|---|---|
| **Percent of 4Q13 Pooled Revenue** | ~28% | ~17% | ~37% | ~17% |
| **Percent of 2013 Full Year Pooled Revenue** | ~30% | ~17% | ~35% | ~17% |

- **Direct comparison between J&J, Abbott, Roche, and Bayer is difficult because each company's Diabetes Care business includes a fraction of non-BGM revenue.** J&J and Roche have global insulin delivery, Abbott has continuous glucose monitoring outside of the US, and Bayer has A1c. In addition, Roche only reports North America revenue, so the US number includes sales from Canada, and Bayer only reports Contour revenue - that stems from a time when they changed their reporting structure so as to bury "other" diabetes revenue outside what was then (and still is) their strongest product.

**4. Sales for Glucobay (acarbose), Bayer's alpha-glucosidase inhibitor, totaled €112 million (~$152 million) in 4Q13, growing 13% as reported and 19% operationally YOY; for the full year, sales totaled €423 million (~$562 million), up 4% as reported and 7% operationally YOY**. Sequentially, sales rose 10% from 3Q13. Glucobay once again found its way onto Bayer's list of "Best Selling Pharmaceutical Products." In the company's 2013 Annual Report, management attributed Glucobay's success to growing demand from emerging markets - this is in line with remarks from 1Q13 and 2Q13, where remarks highlighted gains in China. In the company's 3Q13 call, management commented that sales were harmed by weaker demand in the Asia Pacific region.

**Table 5: Glucobay Revenue (4Q12-4Q13)**

| | 4Q12 | 2012 | 1Q13 | 2Q13 | 3Q13 | 4Q13 | 2013 |
|---|---|---|---|---|---|---|---|
| **Glucobay Revenue in EUR m (USD m)** | €99 ($128) | **€408 ($525)** | €101 ($133) | €108 ($141) | €102 ($109) | €112 ($152) | **€423 ($562)** |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Glucobay YOY Growth, Reported (Operational)** | 3.1% (-1.3%) | **12.7% (3.6%)** | 20.2% (20.3%) | 4.9% (5.9%) | -16.4% (-13%) | 13.1% (19.3%) | **3.7 % (6.6%)** |
| **Glucobay Sequential Growth, Reported** | -18.9% | - | 2.0% | 6.9% | -5.6% | 9.8% | - |

**5. Although not mentioned during the call, in December the FDA accepted the Biologics License Application (BLA) for a diabetic macular edema (DME) indication for Regeneron/ Bayer's Eylea (VEGF Trap-Eye; intravitreal afibercept);** this should likely place a decision in August 2014. This submission to the FDA comes approximately one year ahead of the previously announced schedule, putting Eylea about a year and a half behind the release of Novartis' Lucentis (ranibixumab), which secured FDA approval for a 0.3 mg dose for DME in August 2012. Bayer has also recently submitted a DME indication for Eylea in several other countries; the company submitted to the EMA on November 7, 2013, and, this week, the company announced that it had submitted the drug for a DME indication in Japan. As a reminder, Eylea is currently marketed for wet age-related macular degeneration (wAMD); the drug has been approved in the US since 2011 and in the EU since November 2012. Although the drug is still in phase 3 trials for a DME indication, two studies (VIVID-DME and VISTA-DME) have shown positive results for use of Eylea with DME. Patients treated monthly or bi-monthly with Eylea 2 mg (after five initial injections) achieved greater improvement in best-corrected visual acuity from baseline compared to photocoagulation after one year (VIVID-DME) and two years (VISTA-DME).

- **Regeneron/Bayer's phase 3 program includes four studies:** 1) VISTA-DME in the US (ClinicalTrials.gov Identifier: NCT01363440). This study is currently ongoing but not recruiting participants; primary completion point was in January 2013; 2) VIVID-DME in Europe and Japan (ClinicalTrials.gov Identifier: NCT01331681). This study is currently ongoing but not recruiting participants; primary completion is listed as June 2013; 3) VIVID-Japan in Japan (ClinicalTrials.gov Identifier: NCT01512966). This study is completed, although no results have been posted; and 4) VIVID-EAST in Russia, China, and other Asian countries (ClinicalTrials.gov Identifier: NCT01783886). This study is currently recruiting participants; the expected primary completion date is July 2015.

**Questions and Answers**

**Q: I had a question on the €2.8 billion revenue target for the novel launched products. That actually implies a healthy amount of acceleration throughout the year. I was wondering if you could say which product is going to be the biggest driver and whether the launch is driving that or it's just natural progression?**

A: Xarelto is going to be between around €1.4 billion, and Eylea will be between €500 million and €600 million. That gives you a pretty good understanding of what the acceleration will be. We're going to launch those products this year. We are actually in the launch mode in more than 100 cases. It's a combination of new indications and new countries, but a lot of those new products are actually not being launched. … We are also in the middle of the Eylea rollout, and have already obtained very significant results in four or five countries. It's already the market leader in that segment in Australia and Japan. We are between 20%-30% market share in Germany and France, so it's very successful there. We need to roll out a new indication for Eylea, CRVO but also DME.

**Q: Could you tell us, concerning Eylea, whether Novartis has started to fight back? You mentioned very strong early gains in both Japan and Australia, and Novartis said that they'd learned their mistakes and they were fighting back. If Novartis has actually learned from their**

**mistakes, are you seeing that now and is that making it more difficult to penetrate other markets due to Novartis' presence?**

A: We didn't notice that they were not competing. The product has been very, very well received. We think that the bi-monthly injection, after the first three months, is a real competitive advantage. Now in some countries, Lucentis is used more by way of on demand, not automatically going by the prescribed monthly injections, and that was what we used in our pivotal study. So we think that's a very strong advantage of our product. We're getting reports that in terms of efficacy, it's working better, and it's certainly working when Lucentis has not automatically made a great difference. That is the only thing that I can say at this point, and I confirm Australia at 51% market share and Japan at 46%.

**Q: We saw a nice uptake quarter-on-quarter of Eylea from Q3 to Q4. What is driving this? Is it specific reach in a particular country or is it just in the existing marketed regions where concentration is increasing? Should we expect this going forward?**

A: We launched in a few countries in the time between Q3 and Q4, and we've done specifically well in a couple of markets during those quarters - specifically Germany, the UK, and France. They have definitely been an important growth driver during the quarter. You can expect significant growth based on the launch execution and what I was describing earlier in terms of perception of the product profile in different markets since our guidance talked about this year about €500-600 million. So that's quite significant growth there.

*-- by Hannah Martin, Adam Brown, and Kelly Close*