

# DIABETES CLOSE UP

Diabetes Close Up, V2, #22  
October 16, 2003

Greetings. I just arrived in Canada and have listened to the most info-packed earnings call from Roche I can remember in awhile. Read on for their 3Q results<sup>1</sup>...

1. **Roche – Top Ten Points of Interest about the 3Q03 Earnings Call:**

- a. **Roche's diabetes business grew 5%** to 1,954 mm CHF for the first nine months of the year and as near as I can figure, grew 8% in the quarter. Excluding the Disetronic acquisition (which added nothing in the US this quarter), I'd peg nine and three month operational growth at closer to low- and mid-single digits.
  - b. **US growth hit 8%**, very respectable.
  - c. **Compact sales are doing the best**, up 293%, though from a small base. Workhorse Advantage meter saw flat sales, a cause for concern.
  - d. **Depressing blood glucose monitoring markets:** To his credit, Head of Diagnostics von Prondzynski was very candid about the troubled state of the market. It was harder to tell if he was more down about the US or Europe though I think the Americans win that sad prize due to unwelcome convergence / divergence trends described below. *It was stated explicitly that Roche could not see signs of recovery in either the US or Europe.* Period.
  - e. **Mail order – geez, look out.** Again, to his credit, von Prondzynski discussed pricing at some length. He raised the points that convergence of high-priced channels to low-priced channels in the US had taken Roche (and one would guess, the industry) by surprise. According to Roche, mail order represented 9% of total US market in 2002 and is now up to 22-23% of the US market.
  - f. **Type 1s said to be testing less:** The company also made an explicit point of noting that Type 1 testing is plateau-ing. Unfortunately, they didn't review sources here - market data, their own data, Roper data, anecdotal data? It's a believable point, but I'm curious.
  - g. **Channel divergence** wasn't discussed in depth, but after months of informal talk of this in the industry, it was nice to see it acknowledged in the call. To understate the obvious, this also doesn't sound like an easy problem to solve.
  - h. **Lots of detail on new products:** New product discussion represented a bright light on the call. von Prondzynski gave a very detailed overview of Roche's pipeline plans:
    - i. **First generation continuous** "physician" monitor, a la Medtronic's Guardian, will begin testing late this year.
    - ii. Given the timing of the physician monitor, it seems unlikely that a real-time continuous monitor isn't in the wings, though clearly there is big focus on this at Roche. Although they were vague on timing, they were explicit about intent.
    - iii. **Minitron** pump should be out next year.
    - iv. **Go coming soon.** Go will be 2/3 size of Active - almost the same shape, smaller, and more, well, sexy.
2. **NAASO tidbits:** Much ado about bariatric surgery.
  3. **FDA Meeting on Obesity next week:** On October 23, there will be an FDA open meeting on obesity that will take place at the NIH in Bethesda. See more below.
  4. **Media Follow up**
  5. **Upcoming company reports of note**
  6. **Upcoming conferences of note**

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<sup>1</sup> A logistical note – during earnings season, you receive multiple e-mails from me; I also do monthly digests, so please let me know if you prefer that to separate as-real-time-as-I-can-make-it messages.

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## 1. Roche: More Improvement Seen

- a. **Total reported growth diabetes care sales for the first nine months of 2003** rose 5% to 1,954 million CHF from 1858 CHF; local growth was 12%. This is pretty similar to the forecast of 12-13% given a year ago.
  - i. Interestingly, Roche gives all results in “year-to-date” figures and doesn’t actually even report quarterly figures per se.
  - ii. But when I do the math, it seems that for the quarter itself, Roche diabetes actually rose 8% - a positive trend, above the first and second quarter growth results of 4% and 3%, respectively, and in line with Abbott’s 3Q result although lower than LifeScan’s 11% 3Q worldwide growth.
  - iii. YTD growth excluding the gain from Disetronic was 9% locally and likely ~ 3% overall.
- b. **Excluding the favorable impact of Disetronic for Roche and the unfavorable divestiture impact for LifeScan, seems to me that Roche is growing the fastest of those that have reported**, though it’s hard to compare apples to apples because sales outside the US are sometimes reported in local currency and sometimes not. We still have yet to hear from TheraSense and Bayer.
- c. **Growth by product:**
  - i. Worldwide, sales were flat for the Advantage, the traditional “workhorse” meter, which I would guess must prompt some concern, though Roche has clearly been at work, as evidence by the pipeline described shortly.
  - ii. Sales for the Active brand (low-priced 5-second meter/strips) rose 5%
  - iii. From the smallest base, Compact sales grew nearly 300%. While Compact has clearly been a real success – this is the “drum” meter that obviates the need to touch every strip.
  - iv. Pump sales weren’t broken out but growth rates of 12% in Europe and 5% worldwide were noted. Obviously the US has been hit by FDA issues in the US.
- b. **Growth by Geography:**
  - i. Roche’s US growth hit 8% year-to-date. In the US, Roche estimates the following growth year to date growth for selected competitors: 1) LifeScan down 7% (including, I think, the impact of the Can-Am and LXXN divestitures); 2) Bayer down 3%; and 3) Abbott up 1%.
- c. **Industry comparison:** Once the FX benefit is removed as well as the Disetronic lift, sounds like Roche’s quarterly growth came in lower than the operational 7% growth seen by LifeScan and 8% seen at Abbott. But they clearly are primed to compete ...
- d. **Notes on the market:**
  - i. Head of diagnostics Heino von Prondzynski noted Roche’s belief that the worldwide blood glucose market is growing at 5% (compares to 9-11% over the last 4-5 years) and that the US blood glucose market is growing at 2.7%<sup>2</sup> - this low US estimate mirrors the 3% suggested by LifeScan a couple of days ago. It cited the economy and channel divergence as the primary drivers.
  - ii. Notably, Roche stated explicitly that it could not see signs of recovery in either the US or Europe.
  - iii. Roche also noted that the number of tests performed by Type 1 patients is plateau-ing or actually declining, while the number of tests by Type 2s is also going down, sometimes from 1 - 2 times per week going down to virtually none.
  - iv. I’ve been hearing about divergence for awhile, though this is the first time a company has cited it openly that I know of. What I am curious about is whether it is divergence among countries internationally or divergence to the US from overseas. My guess is that the latter is harder to accomplish, but I’m not sure it’s impossible.

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<sup>2</sup> Reflects Roche’s estimate of the first seven months of the year

- v. To its credit, Roche addressed the pricing issues we've been discussing in some detail, acknowledging that convergence of high priced channel to low priced channels in the US has been much higher than expected. The company noted that mail order represented 9% of total US market - now up to 22-23% of US market. This convergence (the quote says it all - "*a year ago we couldn't spell that word*") has clearly impacted the market unfavorably.
- vi. On the international side, Roche notes although it is still #2 in the US, it is the undisputed #1 player in Japan and that Germany offers a big opportunity, based on some recent goings-on related to EC legislation (on which I have lobbied in a question, as I wasn't familiar with this).
- e. **New Roche/Disetronic products coming:** Roche showed a terrific slide illustrating its diabetes pipeline, which offered more detail that I'd ever seen for Roche's diabetes business. The main differentiating factor for Roche is its plans for convergence between blood glucose monitoring and its new Disetronic pump – they have a long way to go, but clearly this is the direction of choice—definitely needs close monitoring, so to speak. This pipeline is illustrated in Slide 41 on the presentation at [www.roche.com](http://www.roche.com). The line up:
  - i. **New Active meter, the Active S,** will be launched at the end of '03. The bigger news in the Active portfolio is plans for a product called Go. When I talked to the company after the call, they weren't offering significant detail here, but it sounded like the Go will be 2/3 size of Active - almost the same shape, smaller, and more, well, trendy-looking. Sounds like they are going after the 'on the go' crowd with this one, similar to TheraSense's strategy with Flash. Flash feedback over the summer meetings was very strong, a point Roche likely didn't fail to note. The real question is when Roche will launch Go – in the product pipeline it looks like 2004 but in the Appendix, it's listed as a 4Q03 product. My guess is the former.
  - ii. **Compact:** "Superfast" strip coming in the next couple of quarters. Roche introduced a new 8-second strip earlier this year, and I'm wondering how fast is super-fast<sup>3</sup>. A next-generation Compact II is planned for 2004.
  - iii. **Guardian-style monitor – Trial start late 2003:** By the end of 2003, Roche plans to have in trials what they are terming the "first version" of their continuous monitor, i.e., the "physician" version that sounds similar to the Guardian. They will put in professional use clinical trials in selected sites, likely half Europe and half US. This does not show real-time data but is downloadable at the physician office. Although I doubt Medtronic has made significant revenue or profits from this product (this is very difficult for continuous products not labeled as substitutes, of which there are none to date), the learning from the product has been valuable as I imagine it will be for Disetronic. It'll be interesting to see the "hassle factor" with this product – Medtronic's initial product had significant issues, though the current CGMS gold works very well given its relatively limited purposes.
  - iv. **Pump – Introduction planned for 2H04:** Roche is clearly very motivated to create a product that combines insulin delivery and blood glucose testing. The company noted that a pump and meter that can "talk" with each other should be available in the second half of next year. In terms of an *integrated* pump and meter as one device, the timelines appear under review due to the Disetronic

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<sup>3</sup> **Tangent on time:** New strips were launched earlier this year – timing moved from 15 to 8 seconds. Roche is clearly intent on fast innovation in terms of speed, as it has lagged the market in this area actually think once you get to the 5-7 second mark, it's as fast as one needs. That said, to the frequent user, faster is *always* better, assuming accuracy holds (and users always assume it does, though I have more questions here). When LifeScan's Ultra was launched, investors asked if this was a big deal, the 5 seconds, and I would always respond that, well, 15 seconds is good, especially compared to the 90 seconds I remember from the mid-80s. (Sub-tangent - at that time it also always seemed every fifth strip resulted in an error, wasting big time and money.) But 5 seconds versus 15 seconds for someone who tests 8x/day is a savings of eight hours over a year! Even those only checking a couple of times a day still save a couple of hours a year. Bear with me here: So, to move from 8 seconds to say 4 seconds would save another three hours for the hard-core 8x/day user – and still 48 minutes a year for the 2x/day user.

issues; my guess would be perhaps well beyond 2004. It would be great to be surprised here but patients don't hold their breath on this stuff anymore.

- v. **Continuous blood glucose monitor – 2005?** Although timing plans on continuous were not made explicit, with the acquisition of Disetronic, it's easy to see the company is focused on this. The timing chart doesn't pin Roche down to a specific quarter or even year – the “2004 and beyond” is comfortably vague, probably a smart strategy. I do think when the continuous monitor emerges, this will drive the entire pump industry – it will be far more clear the benefits of “physiologic” insulin and fewer excursions.
  - f. **More on Disetronic:**
    - i. Pump sales grew 12% in Europe and 5% worldwide, obviously impacted by FDA issues in the US.
    - ii. We didn't hear exact Disetronic revenue, but assuming it was not above the 31 mm CFH seen last quarter (seems safe bet in light of FDA trouble) – thus overall diabetes business “same store” sales would appear to be closer to very low single digits overall.
    - iii. Pumps are said to be gaining acceptance in Europe and Disetronic's major focus now is increasing pump penetration there. The company was proactive in going to regulators in France, Germany, and Italy to share their view that the FDA issues were not related to product quality. Reports from the US appear less clear on that front - it appears that two areas of major focus were inadequate testing and validation of changes and insufficient testing and validation of software.
  - g. **Other:**
    - i. **Advantage:** The Advantage III was launched mid-year – main new product feature is smaller size along with new faster-time Advantage strips
    - ii. **Safe T-Pro lancets:** These are disposable single use lancing devices coming soon with adjustable depth settings for professional use.
    - iii. **Pharma tangent:** For obesity market followers - *Xenical* sales hit 471 m CHR – down 13% “amidst an obesity drug slowdown.” While I don't sense a slowdown in demand for obesity treatments (quite the opposite), it's certainly true that there appears to be big-time unmet needs here.
2. **NAASO tidbit:** I learned a tremendous amount at NAASO, being a relative newcomer, though no earth-shattering news broke while I was there ~ for sure, the basic trends are unsettling enough. One quick theme - the increased attention on bariatric surgery at this meeting (according to those that have come for many years) mirrors the trend in the field toward huge increases in demand – sounds like there are not nearly enough docs to meet this demand. Thus, bariatric surgery waiting lists are said to be getting longer and longer. Controversy flies over who how to characterize the optimal patient.
3. **FDA Meeting on Obesity next week:** Next Thursday, October 23, there will be an FDA open meeting on obesity that will take place at the NIH in Bethesda. The meeting, sponsored by the FDA Obesity Working Group, chaired by FDA Deputy Commissioner Lester M. Crawford and vice chaired by Joseph A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition, will focus on six questions related to obesity. Should be mighty interesting to see the government's take on this one, as well as industry's (food, pharma, medical device, biotech) response to it.
- a. What is the available evidence on the effectiveness of various education campaigns to reduce obesity?
  - b. What are the top priorities for nutrition research to reduce obesity in children?
  - c. What is the available evidence that FDA can look to in order to guide rational, effective public efforts to prevent and treat obesity by behavioral or medical interventions, or combinations of both?
  - d. Are there changes needed to food labeling that could result in the development of healthier, lower calorie foods by industry and the selection of healthier, lower calorie foods by consumers?
  - e. What opportunities exist for the development of healthier foods/diets and what research might best support the development of healthier foods?

- f. Based on the scientific evidence available today, what are the most important things that FDA could do that would make a significant difference in efforts to address the problem of overweight and obesity?
4. **Media Update:** So I don't want everyone to think I'm the *WSJ's* best friend. I'm not! Though I know I pass on a lot of stories related to diabetes/obesity. (By the way, I usually write the author to let them know and no one has appeared too worried about copyrights though ultimately we have to just provide links.)
  - a. ANYWAY. That said, I have a follow up comment on the story about the slight improvement noted in eating/obesity, etc. based on self-reported data. I probably should've emphasized the other day a bit more that the "self-reported" nature of the data that suggested Americans are eating a little better and are a little less obese than a year ago is certainly questionable as best. I sort of pointed to the piece as a public interest item, not as fact, but one fantastically smart reader dismissed the piece as irresponsible journalism – I don't disagree at all. This data is not necessarily grounded in *anything* – rather than suggesting this data reflected trend, I wondered in my notes whether Americans might be fibbing more these days because they are more aware of the negatives associated with obesity. At any rate, my reader pointed out that many studies exist that show whether diet, body weight, exercise, or alcohol, people have learned to report that which is less embarrassing, and not necessarily truthful.
  - b. There has apparently been a study shown where doctors asking their patients their weight via phone, then ask them to come in to be weighed. On average, the difference is said to be 10 (!) pounds, with the lower average clearly representing the self-reported figure, as opposed to the actual measured weight. Impossible to measure but I am thinking there might be something to the hypothesis that we're becoming slightly more delusional about weight in the US as media interest heightens and guilt grows! Carrot sticks, anyone?
5. **Upcoming earnings reports with implications for diabetes/obesity markets**
  - a. **PFE – TBD; likely the week of October 13**
  - b. **LLY - Wednesday, October 22, 5 pm EST** [www.lilly.com](http://www.lilly.com). Note new info.
  - c. **THER – Wednesday, October 22, 5 pm EST.** [www.therasense.com](http://www.therasense.com)
  - d. **AVE – Details TBD, likely week of Oct 27.** [www.aventis.com](http://www.aventis.com)
  - e. **Novo – Wednesday, October 29, 9:00 am EST** [www.novonordisk.com](http://www.novonordisk.com) Note new info.
  - f. **BDX – Thursday, November 6, 8:30 am EST** [www.bdx.com](http://www.bdx.com) Note new info.
  - g. **IMDC – Details TBD;** [www.inamed.com](http://www.inamed.com)
  - h. **AMLN – Details TBD;** [www.amylin.com](http://www.amylin.com).
6. **Upcoming diabetes/obesity-related conferences**
  - a. **October 15 – 18, Canadian Diabetes Association: Ottawa, Canada.** [www.diabetes.ca](http://www.diabetes.ca)
  - b. **October 23, FDA Meeting on Obesity, National Institutes of Health, Bethesda Md.** Sponsored by the FDA Obesity Working Group, chaired by FDA Deputy Commissioner Lester M. Crawford. The Vice Chair is Joseph A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition.
  - c. **October 25, Diabetes Research Institute, 4<sup>th</sup> Annual Conference, New York** [http://www.drinet.org/html/4th\\_annual\\_research\\_conference.htm](http://www.drinet.org/html/4th_annual_research_conference.htm)
  - d. **November 4-8, Rachmiel Levine Symposium: Advances in Diabetes Research: From Cell Biology to Cell Therapy.** Universal City <http://levinesymposium.coh.org>
  - e. **November 6-8, Diabetes Technology:** San Francisco [www.diabetestechology.org](http://www.diabetestechology.org)
  - f. **November 8, American Heart Association:** Diabetes symposium led by the esteemed Dr. Steve Marso. Orlando [www.scientificsessions.org](http://www.scientificsessions.org).
  - g. **November 14, Designing an Accelerated Cure for Type 1 Diabetes: Integrating Biology with Bioengineering.** Symposium at Sunsun, Santa Barbara.
  - h. **February 6-8, 2004, ADA 51<sup>st</sup> Annual Postgraduate Course.** San Francisco, CA <http://www.diabetes.org/main/professional/conferences/default.jsp>

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## Appendix

### Observations:

- I flew into Canada last night and attended one CDA session – I’ve never been to this conference before and I’m excited to see the differences and figure out what’s going on in Canada.
- The trees flying in looked absolutely glorious – brilliant colored leaves. Even though it started raining as I reached my destination, it was a truly beautiful day. My cab driver, called David, says that all the leaves will be gone by the end of the week, given the huge winds coming.
- Early this morning, I debated a stop at Tim Horton but new goals stemming from NAASO made me think twice and keep walking to the conference!
- Have a great rest of the week ~ I’ll be back with more from the rest of the market next week.

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