DIABETES CLOSE UP

Diabetes Close Up, V2, #20
October 9, 2003

Greetings. Abbott reported this morning; details are below, along with a couple of industry comments.

1. **Abbott reported this morning – worldwide reported MediSense sales increased approximately 8% year over year, a nice sequential uptick over last quarter's 3% year over year growth – over 90% of the quarter's growth stems from international sales**. Industry slowdown persists.
2. **Industry update:**
   - **Cygnus: Cygnus announced a Sankyo pull out earlier this week** and a 60% workforce reduction today.
   - **Novo: Novo announced that it received an approvable letter for Detemir, the "basal" insulin challenger to Lantus.** Launch will be later than expected, an obvious positive for Aventis, which has achieved a home run by any definition with Lantus.
3. **Upcoming earnings reports with implications for diabetes/obesity markets.**
4. **Upcoming diabetes/obesity-related conferences.**

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1. **More Abbott details**:
   a. **Abbott MediSense sales reached $145 million in the third quarter (following two quarters of $128 million), up ~8% on a reported basis.**
      i. **US sales rose 1.5% to $53 million and reported int'l sales rose nearly 12%** to $92 million (including FX benefit, int'l sales rose 23%).
      ii. **Year over year growth this quarter came in five percentage points higher than last quarter** and bolster's management's comment last quarter that product availability was an issue. Backorder on G2 strips had modest impact in 3Q but should not be a factor next quarter.
      iii. **Hospitals represented a key area of strength for MediSense** – it is said to have 25% market share here.
      iv. **Look for stronger 4Q growth** (likely largely stemming from typical year-end strength related to sales force compensation, flexible benefits, etc.) Will be interesting to see how typically lumpy international growth comes in; management sounds confident. I think 4Q should be better for the industry all around, after an anemic year to date for many players. New product entries such as TheraSense's *Flash* will be very interesting to watch, given positive clinician/CDE response at summer meetings.
   b. **MediSense cited slowness in the industry as a barrier to stronger sales.** I'm trying to figure this puzzle out – while industry sales have slowed, IMS numbers don't reflect weakness to the same degree. Of course, IMS doesn't represent all scripts.
      i. **Pricing?** Would be interesting to see profitability figures for the industry. Appears that that some of the industry slowdown relates to pricing; while I haven't seen retail pricing cuts, and don't expect to for the top players,
         1. some of the lower-cost strips are doing better (e.g., Roche Active)/new ones have been introduced;
         2. lower-cost mail order sales have been strong; and
         3. managed care is continuing to add pressure.

ii. **It's also still the economy**: From speaking to clinicians and CDEs, it also sounds like the economy is still impacting patients, who may be using this as an excuse to test less (if only hyperglycemia were painful – outcomes would be much better – it's easy for many patients to bury head in sand). From all the analysis I've seen on post-prandial testing, it seems clear to me that more testing is far better, since excursions become fewer in overall number and overall time spent in the state.

iii. **Offsetting the economy's impact on testing is the trend toward using insulin** sooner, for T2's – many will make insulin-dosing decisions based on blood glucose scores. Then again, blind blousing is always an issue. One of my queries for clinicians/CDEs at the Canadian Diabetes Meeting is whether they are seeing more or less of this.

c. **Although Abbott didn't show new products at IDF, I would still look for continued strip innovation.**

2. **Industry news**:

a. **Cygnus – what next, after the Sankyo pullout?**

i. **Without Sankyo support, hard to see how Cygnus will be able to survive**, particularly given its high debt level. It is said to have two years of inventory. Unclear what happens to customer service.

ii. **Reimbursement woes**: Although Glucowatch achieved product improvements w/G2, difficulties persisted, with reimbursement likely representing the biggest.

iii. **I view the patient (especially parent) interest in Glucowatch, though it was not a perfect product, as a positive harbinger for continuous monitoring**.

iv. **If production stops, they'll also undoubtedly have many patient complaints** – I met two parents the other morning at a UCSF symposium on pediatric diabetes that had just purchased a Glucowatch for ~$700[1].

b. **Detemir:**

i. **Ouch, Novo received an approvable letter** rather than an approval.

ii. **Why the delay?** We'll have more information on Novo's call on the 29th and after next week's visit to Ottawa. Sounds like launch could be delayed til 2005? Will be interesting to see what is required before we see approval.

1. For now, I can only imagine the FDA want to make triple-sure that everything is in check before this release.

2. Remember that the therapeutic index for insulin is very low – i.e., an overdose of insulin is probably more dangerous than almost any other drug (a few exceptions exist, such a coumadin). While it takes about 200x a typical Penicillin dose to post a truly dangerous threat, a dose of 2x a normal insulin dose – or even less – can cause a serious reaction.

iii. **One product benefit that may help Detemir significantly**, despite Aventis' jump on the market with Lantus, is that patients can mix Detemir with shorter-acting insulins – this isn't possible at present with Lantus.

3. **Upcoming earnings reports with implications for diabetes/obesity markets**

a. **JNJ – Tuesday, October 14,** 8:30 am EST – 3Q03 results www.jnj.com

b. **Roche – Thursday, October 16,** 1:00 am EST – 3Q03 results www.roche.com

c. **BDX – TBD; likely week of October 13** – F2Q03 results www.bdx.com

d. **PFE – TBD; likely the week of October 13**

e. **LLY - Wednesday, October 22,** 5:00 pm EST www.lilly.com. Note new info.

f. **THER – Wednesday, October 22,** 5 pm EST. www.therasense.com

g. **AVE** – Details TBD, likely week of Oct 27. www.aventis.com

h. **Novo** – **Wednesday, October 29**, 9:00 am EST www.novonordisk.com Note new info.

i. **IMDC –** Details TBD; www.inamed.com

j. **AMLN** – Details TBD; www.amylin.com.

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[1] This was a fantastic patient seminar – UCSF makes a major commitment to diabetes research. If you are interested in learning more or receiving news on UCSF's stellar diabetes program, see www.diabetes.ucsf.edu.

4. Upcoming diabetes/obesity-related conferences. Tonight, I'm attending an obesity seminar in Boston; if you would like to join me, please e-mail me at kclose@closeconcerns.com.

a. **October 11-15, NAASO Annual Scientific Meeting**: Ft Lauderdale www.naaso.org
b. **October 15 – 18, Canadian Diabetes Association**: Ottawa, Canada. www.diabetes.ca
c. **October 25, Diabetes Research Institute, 4th Annual Conference,** New York 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.diabetestechnology.org
f. **November 8, American Heart Association**: Diabetes symposium led by the esteemed Dr. Steve Marso. Orlando 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 51st Annual Postgraduate Course. San Francisco, CA http://www.diabetes.org/main/professional/conferences/default.jsp

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