



Diabetes Close Up, V2, #12
July 15, 2003

Greetings! It's a beautiful day in San Francisco – I hope this finds you all well. A few items on the diabetes docket that I thought might interest you:

- 1. JNJ/LifeScan 2Q03 results
 - 2. Medicare reform bill – early discussion/implications
 - 3. Upcoming earnings reports with implications for diabetes/obesity markets
 - 4. Upcoming diabetes/obesity – related conferences
 - 5. Review: This week's *US News and World Report* - “Diabetes Diet War: The Nutrition Advice Given to Most Diabetics Might be Killing Them”
- Appendix: More thoughts on MediCare

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1. **JNJ/LifeScan 2Q03 results:** I listened to the webcast of the J&J analyst meeting earlier today, where 2Q03 results were released and where the primary focus of the meeting was pharma (diagnostic results were not addressed in any depth). My comments below relate to LifeScan and J&J's progress on the obesity front.

- a. **As J&J had warned last quarter, this quarter for LifeScan was weak in the US**, contributing to a disappointing quarter for the franchise overall:
 - **US sales fell 27% to \$173 mm from \$236 mm a year ago**
 - **Int'l sales rose 35% (14% operationally) to \$157 mm from \$117 mm a year ago**
 - **Total sales fell 6% to \$330 mm from \$353 mm**
 - **The FX hit was larger than usual** – on a currency neutral basis, international sales rose 14% and total sales fell 12%.
- b. **J&J cited two factors as citing for 70% of the U.S. weakness** (19 of 27 points):
 - **Timing of price increases** – sounds like there was a price increase that went into effect a year ago (makes sense as this quarter is a particularly tough comparison) and there is a “mismatch” next year. My trusty San Francisco Castro Walgreen's sources¹ noted that prices haven't risen recently.
 - **Divestitures of Can Am and LXN** –
- c. **Competitive pressure is also an issue** – J&J did note that its market share has gone down modestly – the company estimated its share at the end of 2Q at 32.5% for meters and 36.8% for strips². JNJ also cited industry contraction, similar to last quarter; when other blood glucose manufacturers report this quarter, particularly Roche (July 23), which also has market share above 30%, we'll be able to give a better sense of overall industry health. Current 2003 estimate for LifeScan remains around \$1.4 billion.
- d. **Up next – 3Q has more positive vibe:** Seems like LifeScan is looking forward to 3Q – it promised that stronger results in the mail order segment and new products would aid results. Not sure whether new products are UltraSmart introductions or newer products that this meter – UltraSmart continues to garner praise for data management capabilities in particular.

¹ Reportedly the most profitable Walgreen's in America

² One factor contributing to the higher strip market share is that the average LifeScan user (compared to the average user) is a more intensively managed patient and likely uses a higher average number of strips per day. Intensive users are the most profitable users.

2. Topamax looks intriguing for diabetes/obesity:

- **JNJ spent some time on the call today discussing the use of Topamax, its blockbuster epilepsy drug, for diabetes and obesity.** JNJ has been a master at pharma lifecycle management³ – the company had been testing Topamax for obesity, though due to its side effect profile, the company decided to reformulate and start obesity trials early last year⁴.
- **This was the first update on these trials – it looks like J&J will now be seeking a diabetes indication as well.** We didn't receive full details, but the data looked positive – on average, in a 52-week study, A1C levels dropped 0.8 for those in the treated group, and remarkably, this group on average lost 24 pounds⁵. Exact baseline levels were not given, so the extent of the improvement is difficult to assess precisely, but the company did imply that the baseline A1C was decent – clearly a 0.8 drop from an 8.0 baseline is much more impressive than from an 11.0 baseline.
- **J&J noted that these results were better than currently marketed glitazones.** It has always surprised me that J&J hasn't been more active on the drug front with respect to diabetes; they did note at a 2002 analyst meeting that 25% of its NDAs related to diabetes/obesity, although investors don't tend to hear a lot regarding this early stage work. As more data is released, it will be very important to assess tolerability. One problem with insulin in particular and with many other Type 2 compounds has been weight gain associated with the drugs – this is clearly significant weight loss. I've heard that Topamax has been used off label for obesity (against label instructions); would be very interesting to see head to head Topamax vs. new GLP-1/GIP/DPP classes.
- **J&J used this opportunity to discuss obesity as a growing health crisis and noted intense public interest.** They shared CDC data that is compelling every time I see the maps⁶ – 11.1% obesity in 1991 has now risen above 20; likewise, diabetes prevalence has increased from under 5% in 1991 to 7.3% in 2000 – and climbing.
- **J&J's interest in obesity remains intense;** as a reminder, J&J acquired Swedish adjustable gastric band device company Obtech Medical last year at this time; although we haven't heard a recent update, no doubt exciting things are brewing at Ethicon Endo-Surgery on this front. This purchase reinforced the importance of the obesity market – which was also underscored by very positive presentations at the AACE this year on bariatric surgery.

2. **Medicare reform bill – early discussion/implications.** See appendix for our report on what's happening in DC and resulting implications.

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

- a. **THER** – Thursday, July 24, 5:00 pm EST
- b. **BDX** – Thursday, July 24, 8:30 am EST
- c. **Roche** – Tuesday, July 23, 8:00 am CET (central European time – 2 am EST)
- d. **AMLN** – August, date/time TBD
- e. **IMDC** – July 30, 4:30 pm EST
- f. **MDT** – Week of August 11 (estimated); annual meeting occurs August 28

4. Upcoming diabetes/obesity – related conferences:

- a. **AADE:** August 5-9, Salt Lake, www.aadenet.org.
- b. **EASD/IDF:** August 24-29, Paris, www.easd.org.

³ Topamax was submitted to the FDA in 2002 for migraines; it had also been tested (and not pursued) for diabetic neuropathy and bipolar disorder. For more information on the obesity reformulation, see “Clinical Development for Topiramate for Obesity Extended to Simplify Dosing, Improve Tolerability” from February 2002.

⁴ Interesting related article in this morning's *New York Times* by John O'Neil “Treatments: When Drugs Do Double Duty” – the piece described a piece in today's *Annals of Internal Medicine*, which showed positive results from ACE inhibitors on kidney health, in addition to blood pressure levels. <http://www.nytimes.com/2003/07/15/health/15TREA.html?ntemail0> (registration required)

⁵ The chart cited looked closer to 11, but units were not cited, and 24 pounds was articulated on the call.

⁶ Lots of clinicians use the CDC stats in their presentations – you see a series of U.S. maps, starting in 1980 or so, when most of the states are white, indicating low percentages of obesity among the population, and there start to be a few states in blue – indicating more serious levels of obesity. By the time they fly through the 1990s, the maps are mostly blue, with some darker color blue in a few states, indicating morbid obesity. It's surreal.

- c. **NAASO Annual Scientific Meeting:** October 11 – 15, Ft Lauderdale, www.naaso.org/meetings/
- d. **Canadian Diabetes Association:** October 15-18, Ottawa, Canada. www.diabetes.ca
- e. **American Heart Association:** Diabetes symposium led by the great Dr. Steve Marso: November 9, Orlando – www.scientificsessions.org.
- f. **Diabetes Technology:** November 6-8, San Francisco. www.diabetestechology.org

5. Of note to diabetes patients and families and anyone following the diet craze in the U.S.:

Appearing in this week's *US News and World Report* is an interesting article by Dara Mayers, entitled "Diabetes Diet War: The Nutrition Advice Given to Most Diabetics Might be Killing Them." The article focuses on the current debate amongst doctors, nutritionists and diabetics as to whether or not a low-carbohydrate, Atkin's-style diet is healthy or unhealthy for diabetics. One nutritionist called the ADA's nutrition advice, which urges much higher carb intake vis a vis Atkin's tantamount to "malpractice." The article features a number of patients with diabetes that manage their blood glucose levels far more successfully with a reduced carbohydrate intake (I concur). There appears to be an enormous gulf among the ADA, low carb diets, and Atkin's (which I believe basically bans most carbs, including fruits). Other doctors maintain that Atkin's-inspired nutrition places too much strain on the cardiovascular and renal systems and could be especially dangerous for diabetes patients. Richard Bernstein, a noted diabetes doctor (also a T1 patient) and author of the nutrition book *Diabetes Solution* suggests a small steak (4-6 oz.), broccoli and salad with dressing for a healthy meal, while the ADA suggests pasta with a vinaigrette dressing, a small piece of fish, a granola bar and a banana for a diabetes-friendly meal. According to Mayers, the ADA is open to revising their nutrition advice should low-carbohydrate diets be proven healthy for both the heart and kidneys.

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APPENDIX

More on Medicare

Medicare reform bill – early discussion/implications:

- **On June 27th both the House of Representatives and the Senate passed Medicare reform bills. Key provisions in the bills provide some prescription drug benefits** to senior citizens and lower-income individuals and families. To date, although supplies have been covered⁷ (and more recently, diabetes education), no drugs or insulin delivery devices have been covered. Bodes well for manufactures of insulin, oral drugs, and syringes/pens.
- **What next?** The two bills now move to conference featuring mostly centrist Senators and more conservative House members. Two of the most influential conference members, Senator Charles Grassley (R-IA) and Speaker Dennis Hastert (R-IL) were commended by the ADA for their efforts to include coverage for insulin syringes and diabetic diagnostic screening tests in the bills. Currently, there are an estimated five million-plus undiagnosed patients with diabetes in the U.S. – clearly there is a push to increase diagnoses and treat patients earlier, with the hope of preventing some longer-term complications, which are very costly⁸.
- **Important differences exist between the two pieces of legislation with possible significant impacts on diabetes-related companies in the universe we follow.**
 - The Senate Bill, S.1.ES., provides for the importation of more inexpensive, price-controlled prescription drugs from Canada.
 - The same bill also mandates that the government cover prescription drugs directly in any rural areas lacking adequate private sector coverage (though such private coverage in the end will be backed by the government, the root of the drug benefit).
 - Insulin syringes are covered in both the House and Senate bills, as are measures encouraging competition between generic and brand name prescription drugs.
 - Notably, while the House bill, H.R.2469, providing funding for some diabetes diagnostic supplies, the Senate bill does not.

⁷ Coverage of blood glucose strips has generally been good; patients in many cases can request multiple strips per day (even though on average patients with Type 2 not on insulin test less than once per day.)

⁸ See Diabetes Close Up, V2, #5 supplement for more information on estimated costs of diabetes in the U.S.

- Also in the bill are tax breaks for Medical Savings Accounts (MSA's), encouraging people to save money to withdraw tax-free in the future to help cover medical expenses.
- **Both patients with T1 and T2 diabetes that are Medicare recipients stand to benefit from the new legislation as they would face lower costs for certain medication and supplies.** If MSA's are included in the compromise bill, this would be a positive for companies as consumers would likely spend money on treatments not covered by their insurance company or Medicare⁹. Other implications for pharmaceutical companies appear murkier:
 - **While a number of companies would likely benefit from increased purchases of prescription drugs and other supplies, the provision for rural-area coverage is being viewed skeptically by some,** who are worried the government's direct participation in the purchasing and dispensing of prescription drugs could lead to price controls in the future.
 - **On the positive side,** companies like Lilly, Aventis, Novo (and others with non-diabetes-related injectable drugs like J&J, Abbott, Amgen, and Wyeth) will finally have Medicare coverage for prescription self-injectable drugs. This also bodes well for Amylin, which has two injectable drugs, Symlin and Exenatide, in its pipeline.
 - **Medical device makers may also benefit in that the process to grant Medicare coverage to new devices and supplies promises to be streamlined** under both the House and Senate versions – this will have to be seen to be believed, in my view.
- **One of the more radical sections of the Senate bill provides for the importation of more inexpensive, price-controlled drugs from Canada.** However the Bush Administration and DHHS Chairman Tommy Thompson must certify the safety of re-imported drugs and plan to use this loophole to protect the current prescription drug market should the unlikely happen and re-importation is included in the compromise bill. Both bills contain measures promoting competition between generics and brand-name drugs, potentially depressing money available for research and development.
- **More to follow in September:** It promises to be a very interesting fall for the healthcare sector. If the White House and Republican leaders in the House have their way, a compromise bill would be up for a vote in early September. However, the House bill passed by just one vote and the Senate version has many detractors (many of whom voted for it nonetheless). News coming out of conference as well as the Sunday morning rhetoric may provide clues on whether the final bill will be more or less populist and hostile to pharmaceuticals producing brand-name drugs. Expect the White House to press for a final version much closer to the House of Representatives'. President Bush appears committed to MSA's and staunchly opposed to direct governmental coverage in rural areas.

Diabetes Close Up is an occasional newsletter that highlights notable goings-on related to selected companies with diabetes/obesity businesses. This newsletter is put forward as an unbiased commentary on the industry. If you have any suggestions that you think should be included, please contact info@closeconcerns.com. Many thanks!

Disclosure: Kelly L. Close is a specialized consultant to the medical technology/pharmaceutical industries. Companies 1) in which Kelly Close has a personal investment; 2) that are clients of Close Concerns, Inc.; and/or 3) on which Kelly Close serves on a speaker's bureau include Abbott, Animas, Amylin, Aventis, Johnson & Johnson, SimpleChoice, and TheraSense. All observations expressed are Kelly's opinions alone and should not be viewed as recommendations to investors on any companies in the industry. If you prefer not to be included on Diabetes Close Up mailings, or if you know others who would like to be on the mailing list for future occasional observations, please contact info@closeconcerns.com.

⁹ On the blood glucose supplies side, it's currently estimated that 30% of total revenue from these items stems from those covering costs out-of-pocket.