

# DIABETES CLOSE UP

Diabetes Close Up, V2, #24  
November 10, 2003

**Greetings!** There's been so much happening! BD results, Novo results, fabulous press releases – Animas and THER, and meetings abounding (on last two topics, see separate reports). Let me dig in ~...

1. **BD F4Q03 results**
2. **Novo 3Q03 results**
3. **News Update: New Animas pump approved**
4. **Media Update: [Diagnosis: Wider Net for Diabetic Disorder](#), *New York Times***
5. **Upcoming earnings reports** with implications for diabetes/obesity markets
6. **Upcoming diabetes/obesity – related conferences**

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1. **BD F4Q03 results:**
  - a. **BD reported November 6.** Blood glucose monitor sales totaled \$5.4 million and \$15 million for the year.
  - b. **Guidance of \$50 million** offered for 2004.
  - c. **Despite not yet being on more formularies, the radiofrequency and monitor connected to the pump is getting positive reports** from the handful of people I know that have them.
  - d. **BD said it planned for 2004 investment levels to mirror those of 2003** – around \$35 million, I believe.
  - e. **A high percentage of doctors are adopting BD's product, relative to goals.** It is estimated that over 50% of Paradigm 512 pump wearers are using BD. The company noted that it is seeing signs of strength that give confidence - Paradigm 512 customer pull-through said to be consistently increasing (at least among those that share the info). The products are said to be performing "*exceptionally well*" in market place, and the company is making traction on managed care and DME (durable medical goods) contracts.
  - f. **BD is investing at a higher level** to build strong and sustainable position and will invest particularly heavily in the first quarter, so as to enable the best opportunity for return. The interim goal 10% US market share in first five years remains unchanged.
  - g. **Management allowed that it was too ambitious initially** with its 2003 goal; since then, it has made progress on the managed care (Tier 2) accounts in particular.
  - h. **The main patient focus centers on those taking insulin**, namely pump users and frequent insulin injectors, who BD says represent 60% of strip market - "*and this are the part of the market that is still growing*" and, importantly, where the company has the most access.
2. **Novo 3Q03 results:**
  - a. **Novo reported October 29. Nine-month sales** for Novo's diabetes franchise grew 4%.
  - b. **Insulin and delivery systems rose 7% worldwide**, while sales of oral anti-diabetic drugs fell 15%. US sales were brisk, up 18%, driven by strength of analogs. See more below on results.

- c. **Regarding Detemir**, not much new news on Novo's recent approvable letter<sup>1</sup> from the FDA and likely approval time is tough to bracket at present: While we do know certain clinical issues need to be addressed, we didn't learn much about the issues. Likely implications for US approval based on the approvable letter:
  - i. **Best-case scenario**: Novo can use data collected since submission to take care of new requirements and the process can proceed – in this scenario, approval could happen in a number of months.
  - ii. **Worst case**: New studies needed, which would depress expected sales, depress the sales force, cost a lot of money, and take a lot of time.
- d. **On the international approval front**, in Europe Novo looks for a CPMP decision close to year-end. In Japan, Detemir trials are in Phase 3 and a launch sounds two years away at best. Stay tuned for more information on the US and Europe when Novo announces full year 2003 results.
  - i. **Some approval stats**:
    - 1. Average FDA approvals are said to be taking 19-23 months;
    - 2. Notably, this is not actually all that much better than in Europe, where decisions take 16-17 months on average.
    - 3. Then again – for a billion dollar drug (let's think big), three to six months represents \$250 - \$330 million in sales.
- e. **Elsewhere on the development front – NN414 discontinued**:
  - i. **NN 414 was beta cell selective compound for treatment of type 1 and type 2 diabetes**; it has been discontinued due to the finding of reversibly elevated liver enzymes in a few patients, all after more than 1 week treatment. The mechanism underlying adverse liver effect has not been “clarified” but is being studied. My super smart pharma contacts tell me NN 414 was an orally active beta-cell-selective regulator of insulin release, for the treatment of type 1 and type 2 diabetes. Although Novo's news on this drug was disappointing, my contact sagely pointed out to me that there are a huge number of early Phase 2 drugs I probably never hear about<sup>2</sup>.
- f. **No new news on**:
  - i. **NN1998** - AERx inhaled insulin – Phase 3
  - ii. **NN2211** – Liraglutide (GLP-1 analog) – Phase 2
  - iii. **NN2344** – Balaglitazone (oral agent – insulin sensitizer) – Phase 2
  - iv. **NN344** – insulin – Phase 1
  - v. **NN2501** – oral agent – Phase 1
- g. **Interesting market, market share, and growth estimates**:
  - i. **Novo has 30% of the US market** for diabetes drugs
  - ii. **Novo has 11% US share** for insulin analogs
  - iii. **Novo's worldwide share for insulin analogs** – “increasing steadily”
  - iv. **Insulin market growing** at 5%
  - v. **27% of market for insulin** now comprised of insulin analogs
  - vi. **Novo accounts for 14% of insulin sales worldwide** – in the US, for nearly one third. US launch of premixed analog adding to market share gains.
  - vii. **Novolog and Novolog mix** driving growth and market share increases
- h. **Although Novo isn't talking about this during their conference calls**, they have a small footnote that explains they are working on “next generation” insulin pumps. I really believe that pump penetration will grow with the advent of the newer pumps and particularly when real-time continuous monitoring emerges.
- i. **New premix launch to come in Japan**: Novo will be launching the first premixed analog mix in Japan shortly, following recent approval; one would think that the introduction of Lantus there would stem growth, but the mixes have been popular

<sup>1</sup> [Novo received a setback with an approvable letter from the FDA for Detemir. As a reminder, detemir is a “flat” basal insulin analog that will compete with Lantus; it has neutral pH, prolonging action based on albumin binding.](#)

<sup>2</sup> [So true. At NAASO, we learned that over the last 20 years, 114 obesity drugs had been developed and only four marketed – to boot, only two remain on the market today.](#)

(premixed insulin is ~50% of the total Japanese market); will be interesting to see how Lantus does in Japan, since it's pretty well exploded in the US – amazing textbook launch.

3. **News Update: New Animas pump approved**
    - a. The IR 1200 is the smallest, full-feature insulin pump available today. It's got all the smart features like bolus calculator, unused insulin calculator, which sound straightforward to teach and learn – an Animas hallmark. Other new features include CarbSmart. Look for launch in the next several months.
  4. **Media Update: [Diagnosis: Wider Net for Diabetic Disorder](#), *New York Times*.** See copy of article in appendix. This new way to define pre-diabetes should result in more diagnoses of both pre-diabetes as well as diabetes. Visibility continues to increase ~ we applaud it. Next up: exercise prescriptions?
  5. **Upcoming earnings reports** with potential implications for diabetes/obesity markets
    - a. MDT – November 12, 4:30 pm EST. [www.medtronic.com](http://www.medtronic.com)
  6. **Upcoming diabetes/obesity-related conferences**
    - a. **November 14, Designing an Accelerated Cure for Type 1 Diabetes: Integrating Biology with Bioengineering.** Symposium at Sunsun, Santa Barbara.
    - b. **February 6-8, 2004, ADA 51<sup>st</sup> Annual Postgraduate Course.** San Francisco, CA  
<http://www.diabetes.org/main/professional/conferences/default.jsp>
    - c. **April 28 – May 2: AACE,** Boston, MA.
    - d. **May 1-4, 2004: Pediatric meeting,** San Francisco, CA.
    - e. **June 4-8, 2004: ADA,** Orlando, FL.
    - f. **August 11-14, 2004: AADE,** Indianapolis, IN.
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**Appendix 1: New York Times - October 28, 2003, Tuesday.**

**VITAL SIGNS: DIAGNOSIS; Wider Net for Diabetic Disorder**

**By ERIC NAGOURNEY**

Millions of Americans who may once have been given a clean bill of health will now qualify for a diagnosis of a condition known as prediabetes.

Late last week, the American Diabetes Association released new guidelines for doctors to use when looking for the problem. They appear in the journal *Diabetes Care*.

There are two main methods to assess whether a person has prediabetes. With one, patients fast overnight and then their blood is drawn in the morning and the glucose levels are tested. With the other method, patients are given the morning test and are retested after drinking a sugar solution.

The new guidelines lower the acceptable level of blood glucose, to 100 milligrams a deciliter from 110.

Prediabetes, which often causes no symptoms, is considered a serious condition because almost everyone who develops diabetes has it first, the diabetes association said. Moreover, it said, recent research has shown that even before full-scale diabetes occurs, prediabetics may be suffering damage to the heart and circulatory system.

Under the old definition, at least 16 million Americans ages 40 to 74 were believed to have prediabetes.

The new guidelines are important, experts said, because after doctors know their patients are prediabetic, they can take steps to prevent the condition from worsening, usually with diet and exercise.

*Diabetes Close Up* is a newsletter highlighting notable information and events related to selected companies with diabetes/obesity businesses. This newsletter is put forth as an unbiased commentary on the industry. If you have any suggestions or comments regarding content, please contact [info@closeconcerns.com](mailto:info@closeconcerns.com). If you would like to 1) unsubscribe; 2) receive a monthly digest rather than real-time updates; 3) add a name to the DCU mailing list; or 4) offer any suggestions or comments regarding content, please contact [info@closeconcerns.com](mailto:info@closeconcerns.com).

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