

DIABETES CLOSE UP

Diabetes Close Up, V2, #23
October 22, 2003

Greetings! TheraSense reported top 3Q results today¹...

1. **THER 3Q03 results – excellent top and bottom lines.** TheraSense announced robust sales of ~\$58 mm, excellent gross margins, and first profitable quarter ~
 2. **Pharma results: Pfizer, Lilly, and GlaxoSmithKline**
 3. **Media Update:** NYT's Freudenheim on consumer health insurance load
 4. **Upcoming earnings reports** with implications for diabetes/obesity markets
 5. **Upcoming diabetes/obesity – related conferences**
- Appendix: Roche clarification * FDA obesity meeting today**

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1. **THER 3Q03 results - 'O what a difference a year makes ~':**
 - a. **Continued strong financial performance amidst slower industry growth:**
 - i. Blood glucose monitoring sales totaled \$58.2 million, at high end of company forecast, up 49% from disappointing 3Q02 results.
 - ii. International revenue for 3Q came in at 19% of total revenue, similar to last quarter.
 - iii. Operating leverage continues to increase; while revenues grew 49%, COGS grew just 25% for the quarter. SG&A came in slightly higher than expected, likely due to Flash launch investment (based on Canada meeting last week, I already see a strong ROI on this front ~).
 - iv. Gross margin hit 61% versus 56% last quarter and 47% a year ago.
 - v. Profitability reigns! Net income hit \$2.7 million and earnings per share of \$0.06.
 - vi. TheraSense growing faster than market – see below.
 - b. **Positive meter/strip data: TheraSense had encouraging recent data from IMS and Neilson:**
 - i. 10.0% meter share (up 38% year over year) based on IMS NPA prescription data
 - ii. 6.7% strip share (up 35% year over year) based on IMS NPA prescription data
 - iii. 10.7% and 6.1% 90-day meter and strip share based on NSP data (wholesales/distributors)
 - iv. Neilson indicated 8.1% total category share, up 30% year over year and up from 7.8% last quarter and, importantly, from 0% in 2000.
 - b.c. Favorable balance sheet trends:**
 - i. TheraSense hit cash flow positive a quarter earlier than forecast in July by the Company and achieved operating cash flow positive for third straight quarter;
 - ii. Inventory fell by nearly 10% relative to last quarter, which was down 25%;
 - iii. Days sales outstanding (unweighted) reduced to 65 from 66 and 88 last two quarters; days sales outstanding on a weighted basis stayed below 60 as promised.
 - iv. Debt stood near nil, at \$2.2 million;

¹ During earnings season, DCU publishes multiple separate issues as well as monthly digests. If you prefer the latter, please send a message stating preference to info@closeconcerns.com.

- v. Cash balance is ~\$83.5 million, above expectations – nice directional movement!

Guidance:

- vi. Revenue of \$60-\$63 million for 4Q was forecast, which would bring total revenue to \$210-\$213 million for 2003, within the forecast range;
 - vii. 2004 revenue forecast articulated for first time - \$255-\$265 million, which would bring annual growth to 20% - 26%;
 - viii. 2004 international revenue forecast at 20% of total sales – this is at the lower end of previous ranges for percent of total revenue.
- d. **Growth vehicles come in strong: Managed care contracts and Flash clearly represent growth vehicles in the second half.**
- i. Managed Care: Management announced an agreement with Advance PCS that will get FreeStyle and Flash on an “equal – pay” basis for 70 million covered lives. This is important because 1) it’s big; and 2) TheraSense was previously disadvantaged when patients were asked to pay a higher co-pay (see media update on related *NYT* article).
 - ii. New products update:
 - 1. Great reception continues at recent meetings Flash, THER’s new glucose monitor:
 - a. So this is called Mini in Canada, due to some trademark issues. Doctors LOVED the meter there. It’s cool and small and fun – doctors interviewed repeatedly described it as, well, ‘slick.’ That’s definitely a compliment. This slick new meter is now on the market, and said to be rolling out in Rite-Aid, CVS, and Walgreens (though the 24-hour Castro Walgreen’s down the street doesn’t have it yet ...)
 - b. The meter is small and fast and will appeal to the ‘on the go’ demographic in particular, due to the faster time and sweet wicking² action. This customer segment offers the best ROI as it tests the most and likely uses the least support.
 - c. It’s great in my view that all TheraSense products use the same strip – one SKU seems like a great idea. I’ve always been surprised Roche uses so many different strips, as do some other competitors. Shelf space is tough enough ~
 - 2. Management noted that regulatory plans still call for the Navigator, TheraSense’s continuous monitor, to be submitted to the FDA in the second half.
- e. **Market growth disputed:** TheraSense management noted its belief that the market is actually growing closer to 8-10% in the US, while competitors LifeScan and Roche suggested lower rates, well below 5%. Almost everyone somehow maintains they are growing faster than the market – clearly it’s easier to do so at lower base revenues, but there seems no question that TheraSense is growing faster than the somewhat subdued market. Note on mail orders: since TheraSense has already been playing in the mail order market, the movement toward mail order for the market hasn’t been as noticeable for them. Translated – they’ve probably had lower ASPs historically than larger competitors, which may have hurt in the past, but now is serving as a buffer. In fact, ASPs actually increased slightly this quarter. TheraSense expects to be a price follower and forecasts at least a slight price increase in 2004.

² People sometimes ask me what “wicking” means. It’s hard to explain but easy to show. You may remember the term from high school chemistry – it basically represents the action of how liquids are ‘slurped up,’ so to speak, on absorbent materials. Great wicking action on a strip helps the process go faster and typically ensures that the blood drop size is large enough.

2. **Pharma results:**

a. **Pfizer:** On the diabetes front ...

- i. Sales for Glucotrol XL came in very strong, to \$92 million worldwide, up 25%, and to \$86 million in the U.S., up 26%.

- ii. Inhaled insulin:

1. We received an update on Pfizer's clinical trials with inhaled insulin, Exubera – talk of this seems to be reaching a bit of a frenzy in certain parts of the industry.
 - a. So initial phase three trials are complete and Exubera has demonstrated blood glucose lowering equivalent to insulin injections. This makes sense to me due to likely improved compliance; I had wondered whether dosing differences would reduce efficacy of Exubera and it hasn't seemed to.
 - b. When used alone or in tandem with oral agents, Exubera improves glycemic control more than oral agents used exclusively. 2,000 patients have been through phase two and phase three trials with the drug and some have been on Exubera for over five years.
2. The big question on the trials has been the side effect profile. Early lung function decline has been a red flag but Pfizer maintains that their data shows lung function stabilizing to rates normally seen with patient aging. Additional pulmonary safety tests continue, however. I'm not sure I've seen such extreme views voiced within the diabetes community, well, ever.
 - a. Camp A: *I wouldn't touch pulmonary insulin with a 10-foot pole. You're going to put insulin in the most delicate tissue in the body? When you don't have 10-year data?*
 - b. Camp B: *Are you kidding? Your lung tissue is the size of a tennis court. Insulin concentrations are so low there's not a chance of fibrosis.*
 - c. Camp A: *Either way. No way is this product going to get reimbursement. It's a convenience item!*
 - d. Camp B: *Okay, it's a convenience item. How many Type 2 patients with A1Cs of 9 that refuse to inject insulin do you have in your practice? If outcomes improve – and look at UKPDS to see what a 1 point drop in A1C does to complications – I think reimbursement is well within the potential to happen!*
 - e. Camp A: *Yeah, well, won't this be so pricey to make reimbursement impossible anyway?*
 - f. Camp B: *Tell me again – how much are your patients on metformin/TZD/secretagogues spending per day? \$6, \$8, \$10 in some cases!? Bioavailability doesn't have to be that high to stay under that ...*
3. We'll stay tuned for more news on this front.

b. **Lilly:**

- i. Worldwide diabetes products reached \$589 million, up 3%. In the U.S., diabetes care revenue dropped 2%, while it increased 10% internationally.
- ii. Humalog achieves double digit growth while Humulin lags: Lilly's two major insulin brands, Humulin and Humalog experienced 3% and 12% revenue increases respectively, over the same quarter last year. Nice result for Humalog, which is experiencing still competition from Novalog, Novo's short-acting analog – though according to a close industry watcher analyst contact, sounds like price is what's driving growth, not units, which have been flattish. Humalog price increases on the other hand have been huge – 20% in 2002 and 10% in 2003. On the long-acting insulin side, Humulin is suffering conversion to Lantus. On the Actos front, revenue was down 18% for Actos – as usual, according to Lilly, the revenue sharing agreement with Takeda Pharmaceuticals makes comparisons between quarters tough

to call. I often am asked whether this is a convenient excuse – dunno, but TZD scripts seem pretty strong to me.

- iii. On the R&D front, Lilly referenced previously announced positive results (with Amylin) for the first of three phase three clinical trials for exenatide. They plan to announce the results for the remaining two trials at the end of the fourth quarter. Mid-2004 remains the target for FDA submission.
- iv. The FDA is now requiring class labeling for atypical anti-psychotics - Lilly's Zyprexa label will now include additional information on hyperglycemia and diabetes. Lilly has had a long-standing position that the risk for diabetes should be considered among patients with severe mental illness regardless of medication choice.
- c. **Glaxo Smith-Kline:**
 - i. Avandia and Avandamet, GSK's oral diabetes drugs, continue to perform strongly. Reported US sales growth of 60% to £197 million in the quarter benefited from a positive year-over-year comparison related to wholesaler stocking patterns. The estimated underlying growth of Avandia was 21%. Last quarter, Avandia sales reached £212 million
 - ii. International sales of Avandia grew by 66%, while European sales rose 78%. Look for European Avandamet launch in this quarter.
 - iii. Apparently, GSK will hold an R&D day in December – more to follow.
3. **Great article by Milt Freudenheim in today's New York Times on the increased burden consumers carry.** See www.nytimes.com. Of note:
 - a. **Health care costs appear headed into a fourth consecutive year of double-digit increases. Employers continue to shift cost onto consumers that use the most services.** More co-pays and higher deductibles.
 - b. **Almost two in three employers require patients to pay higher co-payments for drugs not on a preferred list.**
 - c. **On average, the annual out-of-pocket costs for employees of large companies have more than doubled since 1998, to \$2,126 this year, according to Hewitt Associates,** a benefits consulting firm. Hewitt is expecting a **22 percent jump** next year, to \$2,595.
 - d. **Employers contribution has slipped over the last five years, to 70 percent of total health care costs from 75 percent,** according to Hewitt's latest survey of 300 employers with 5,000 or more workers, released last week.
4. **Upcoming earnings reports with implications for diabetes/obesity medical device/pharma markets**
 - a. **BMS** – Thursday, October 23, 7:30 am EST. www.bms.com **Note new time**
 - b. **Novo** – Wednesday, October 29. www.novonordisk.com.
 - c. **IMDC** – Wednesday, October 29, 5:00 pm EST; www.inamed.com
 - d. **AVE** – Thursday, October 30. www.aventis.com
 - e. **BDX** – Thursday, November 6, 8:30 am EST www.bdx.com
5. **Upcoming diabetes/obesity-related conferences**
 - a. **October 15 – 18,** Canadian Diabetes Association: Ottawa, Canada. 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, 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. **ADA meeting**
 - f. **November 6-8, Diabetes Technology:** San Francisco www.diabetestechology.org
 - g. **November 8, American Heart Association:** Diabetes symposium led by the esteemed Dr. Steve Marso. Orlando www.scientificsessions.org.
 - h. **November 14, Designing an Accelerated Cure for Type 1 Diabetes: Integrating Biology with Bioengineering.** Symposium at Sunsun, Santa Barbara.

- i. **February 6-8, 2004**, ADA 51st Annual Postgraduate Course. San Francisco, CA
<http://www.diabetes.org/main/professional/conferences/default.jsp>

Appendix

- **Correction:** Roche had 76 CHF in pump sales from May – July. This suggests its 3-month and 9-month growth, excluding Disetronic, is closer to 1% than the 3% cited in the last letter.
- **FDA meeting on obesity takes place today – we’ll let you know how it goes end o’ the day.**

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