MEMORANDUM

GI Dynamics 2Q13 - EndoBarrier offered at 42 centers internationally; REVISE- Diabesity trial begins- September 19, 2013

Executive Highlights

- GI Dynamics' French study, ENDOMETAB, is expected to begin in 4Q13.
- The first patients have received treatment in the REVISE-Diabesity trial in the UK.
- The EndoBarrier Gastrointestinal Liner was available at 42 centers in 10 countries at the end of 2Q13.

CEO Stuart Randle led GI Dynamics' 2Q13 financial update on July 31. GI Dynamics continues to advance its US pivotal trial, ENDO, of the EndoBarrier Gastrointestinal Liner for obese patients with uncontrolled type 2 diabetes. As a reminder, the EndoBarrier is a flexible, tube-shaped liner that excludes the duodenum and proximal jejunum from nutrient flow. At the time of the call, 17 sites were enrolling patients, up from seven at the end of 1Q13. GI Dynamics' enrollment goal is ~500 patients at 25 sites. While no specific enrollment numbers were given, GI Dynamics still expects to complete enrollment in 2H14 with overall study completion in June 2015. The company hopes to use US based specialty healthcare funds, or funds used only for healthcare businesses, to support the study. GI Dynamics also noted that the first patients were treated in the REVISE-Diabesity trial, which is aimed at demonstrating a reduction in weight and A1c levels with the use of EndoBarrier. GI Dynamics also noted that ENDOMETAB, the two-year clinical study of EndoBarrier in France, is expected to begin in 4Q13 and to enroll 174 people.

At the end of 2Q13, EndoBarrier was available at 42 centers in 10 countries, up from 37 centers at the end of 1Q13. Management noted that the number of centers has expanded in Germany, Spain, and Switzerland within the last six months, with the majority of the growth in Germany. The company also noted that it has made inroads at centers in the Netherlands, which management remarked provide an "excellent model" for how the reimbursement process could look in future centers throughout the Netherlands. Turning to Australia, although launch delays occurred at the five new centers in 2Q13, all centers were trained and screening patients at the time of the call. Management also remarked that it would continue to focus on Australia, select markets in Europe, the Middle East (Saudi Arabia, UAE, and Qatar), and South America. EndoBarrier has also been approved in Columbia, and management believes that centers in the country can begin training as early as 4Q13. Looking ahead, GI Dynamics also hopes to gain regulatory approval in Brazil and India (regulatory approval is expected in 2014 for Brazil).

EndoBarrier sales totaled ~$700,000 in 1H13, which management noted is almost equivalent to all sales in 2012. However, sales in 2Q13 were less than the company expected, at ~$300,000 (down from ~$400,000 in 1Q13 and up from ~$100,000 in 2Q12). Management attributed the less-than-expected revenue to launch delays at centers in Australia. GI Dynamics attributes the high revenue 1H13 to traction in key self-pay areas, such as Chile, as well as investments from European centers in Germany and the Netherlands where reimbursement for the EndoBarrier continues to expand. GI Dynamics ended 2Q13 with ~$22 million, down from ~$42 million at the end of 2012. Management also attributed this decrease to the delay in the opening of centers in Australia. Research and development was similarly up from 2Q12, totaling ~$3.5 million in 2Q13, up from ~$2.5 million in 2Q12, which GI Dynamics attributed to the active enrollment in the US pivotal trial. Sales and marketing were ~$3 million for 2Q13, up from ~$2 million in 2Q12 due to building infrastructure in the US, Europe, and Australia. General and administrative expenses were ~$2.3 million for 2Q13, relatively similar to ~$2.2 million in 2Q12.

- **The REVISE-Diabesity trial was approved by the National Health Service (NHS) and is funded by the Association of British Clinical Diabetologists (ABCD).** GI Dynamics noted that the approval is a great step toward making EndoBarrier Therapy mainstream within the NHS.
    - **REVISE-Diabesity will enroll 72 people with type 2 diabetes and obesity.** The study will enroll patients who have been treated with liraglutide for at least six months. One-third of participants (n=24) will be treated with EndoBarrier Therapy, one-third will be treated with a combination EndoBarrier therapy and liraglutide, and the final third will be treated with liraglutide only. The study duration will be 12 months with a 12- month follow-up. The trial's primary endpoints will be weight and A1c.
- **Other on-going clinical trials include the US pivotal trial ENDO and the French ENDOMETAB trial.**
    - **ENDO is a randomized, double blind, sham-controlled trial.** Key inclusion criteria are having a baseline A1c between 8-10% and a baseline BMI between 30-50 kg/ m2. The ENDO trial will assess changes in A1c over a 12-month intervention period. Secondary endpoints will include weight loss and change in cardiovascular risk factors, such as cholesterol and blood pressure (ClinicalTrials.gov Identifier: NCT01728116).
    - **ENDOMETAB will compare EndoBarrier Therapy to conventional treatment (dietary counseling, physical activity and lifestyle changes) across 12 months**. The study's aim to evaluate the impact and cost of both treatments. To do this, ENDOMETAB is to enroll 174 people at academic centers including sites in Lille, Toulouse, Lyon, Marseille, Montpellier, Paris, and Strasbourg. The study will include obsess patients both with and without type 2 diabetes. The French Ministry of Social Affairs and Health is funding ENDOMETAB for 1.16 million € (~$1.55 million). The study will be coordinated by the University Hospital of Lille.
- **Earlier in 3Q13, GI Dynamics launched its first-ever, comprehensive, national consumer marketing digital media and advertising campaign for screening patients in Australia.** The campaign targets obese people with type 2 diabetes. GI Dynamics expects an initial financial impact from this campaign in 3Q13 and a greater impact in 4Q13 and subsequent quarters.
- **Al-Nozha Medical Est. was named the distributor of EndoBarrier Therapy in select territories in the Middle East**, including centers in Saudi Arabia, Qatar, and UAE. Al-Nozha Medical is a leading distributor of medical devices in Saudi Arabia and the surrounding countries. GI Dynamics hopes to expand their presence in the Middle East through Al-Nozha.
- **GI Dynamics highlighted the two-prong development approach it continues to implement:** 1) expand self-pay centers to increase short-term growth; and 2) increase reimbursement for sustainable long-term growth. Management remarked that it is necessary to simultaneously invest in reimbursement, commercial expansion, regulatory approvals, and its US trial. GI Dynamics noted that although complex the US trial is complex, it is worth the resources for bringing the "game-changing" procedure, EndoBarrier therapy, to the US. For more information on GI Dynamic's commercialization strategy, please see page two of our coverage of GI Dynamics http://close.cx/GIDynamics2013AnnualMeeting.
- **We look forward to hearing the interim results of an EndoBarrier clinical trial on Wednesday September 25 at EASD 2013.** This oral presentation will give 12-month interim results from a post-market clinical trial in subjects with type 2 diabetes and/or obesity. Dr. Julian Teare will present results during OP14: "Technologies to transform diabetes" in the Ramón y Cajal Hall.

Questions and Answers

Q: Can your provide more details on the ENDO trial in the US? I know that there are 12 centers actively enrolling. Can I have details on how many people are enrolled so far and what the interest level is from the patients?

A: We have not released specifics in terms of enrollment. We are still early in process. Since David Maggs joined on May 1, he has used his experience at Amylin to educate us on the pace of enrollment in studies like this. As we open up a center, we start a recruiting campaign. It is a process to get through the recruiting campaign, and then the screening process, and then the prospective enrollment - that takes a few months. We do not have enough centers that have been engaged long enough to have a good sense of the timeline.

Q: Have there been any changes in the timeline?

A: We are still expecting to complete enrollment second half of next year.

Q: I understand that the adoption rate of EndoBarrier Therapy between self-pay vs. reimbursed centers is very different, but could you give me an idea of the activity in your highest volume center? How many implants are the physicians doing each month vs. the number that the new centers come in at?

A: We have not discussed center-specific numbers. We have talked in the past that when a center opens, they typically start with three to five patients in first day and then wait months to see how it goes. After that, the center does their next batch, and then they wait a month or six weeks. After that comes the third batch. Then the centers begin doing monthly implants, and then they move to doing implants twice a month. Centers in Holland that were involved in clinical trials and have some reimbursement typically schedule two days a month where they're doing implants. We expect, and they expect, to move to doing implants once a week. This will happen probably sometime next year.

Q: In terms of Columbia, can you give us a sense of what the opportunity would be like and whether this would be a direct vs. distributer market, assuming this is essentially self-pay?

A: We are approved in Columbia, and we have an executed agreement with the distribution logistics entity in Columbia. We expect to do cases there prior to the end of the year.

Q: In regards to Qatar, Saudi Arabia and the UAE markets, can you give us a sense of where you are in terms of the regulatory process?

A: With respect to the Middle East, we are currently approved in Qatar and Saudi Arabia to commercialize EndoBarrier Therapy and are in the process of readying centers to do cases in both of those markets. Thus far, we are not approved in UAE. That's in the future.

Q: When should we expect the launch in Qatar and Saudi Arabia? Would it be this financial year?

A: I would say it would be this calendar year. We have a newly assigned distributor there, and we are working to train his employees in those two geographies. We would expect that to occur in the back half of the year.

Q: The 2Q revenue was soft because of the delay in the Australia rollout. Once we get these centers up and running, Should we expect these revenues to go back to what we saw last year in the December quarter and first quarter this year? Or do we expect even further ramp up than what we saw in those months?

A: First of all, the change in revenue was very small, about $10,000, and a substantial portion was due to the delay that occurred in bringing up the Australian centers. To give you some additional details, because of revenue recognition requirements that occur because of GAAP [generally accepted accounting principles], we have to be paid before we recognize revenue. We find that our revenue can be quite lumpy. As a consequence, it can be, from quarter to quarter, one payment that dictates the difference between success and meaningful growth vs. not having that. I do want to note, and I think it's important to note, that we have gotten off to a very strong start in the third quarter this year. I think that gives us some comfort that we will, and we are, moving in the right direction.

-- Hannah Martin, Hannah Deming, and Kelly Close