



Biotech Daily

Friday May 12, 2017

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: GI Dynamics

By TIM BOREHAM

ASX Code: GID

Market cap: \$36 million

Share price: 6.5 cents

Shares on issue: 558 million Chess depository instruments (CDIs)

President and chief executive officer: Scott Schorer

Board: Daniel Moore (chairman), Timothy Barberich, Scott Schorer, Graham Bradley, Michael Carusi, Anne Keating, Dr Oern Stuge

Financials (March 2017 quarter): revenue \$US54,000, operating cash outflow \$US2.96 million, cash on hand \$US5.4 million, estimated current quarter cash burn \$US3 million

Major shareholders: Crystal Amber Fund 40%, Medtronic 7%, Advanced Technology Ventures 5.8%, J&J Innovations 5%, Paul Cozzi 4.8%.

As Winston Churchill (sort of) said: "Never in the field of human endeavour has so much been lost by so few on one of the most promising medical device products".

The US annual filing of the Massachusetts-based GI Dynamics tells the story with the sort of bare honesty often lacking in local corporate disclosures: the company has accrued an accumulated deficit of \$US248 million (\$330 million) and has "incurred net losses in every year since inception".

While the Endobarrier weight-loss device has been approved in Europe and Australia since 2011 (as well as the Middle East and South America), the company has sold 3,500 units, generating underwhelming revenue of \$US7.8 million.

GI Dynamics listed its Chess depository instruments (CDIs) here in September 2011, at \$1.10 a piece in a \$US72 million raising.

Overall it has raised \$US232 million in equity and has little to show for it, except for some handy tax losses.

The premise of the company's Endobarrier product is as reliable as a gaffe from a bored Prince Phillip at the opening of a Morris dancing festival: beating obesity and type two diabetes.

Usually attributed to lifestyle factors, the incidence of type 2 diabetes is swelling in the Western world, with about 55 percent of patients adequately treated with current drug regimens and little global data available on treatment – if any – of obesity.

Insulin medication leads to higher resistance to diabetes and just exacerbates the problem. Globally, 415 million adults have from diabetes, 90 percent with type 2 diabetes, which some call type 1 obesity or the world's largest preventable epidemic.

Diabetes, if anyone needs reminding, is a leading cause of cardiovascular disease, kidney failure, blindness and lower limb amputation.

Endobarrier is a sleeve that sits in the upper intestine, just below the stomach. It is inserted endoscopically in a 20-minute procedure, with no surgery required.

After 12 months it is similarly painless removed from the hopefully lighter patient.

Crucible's gut feeling would have thought the world's first endoscopically delivered device therapy would have been a no brainer, but it's been no tea party for the Boston boys.

In the US, Endobarrier has only investigational device exemption (IDE) status, which means it can be used for research.

In March last year, the company terminated its 500-patient US trial after 325 patients were enrolled, with the trial failing to meet its primary and secondary endpoints. The stock fell as much as 60 percent on the day.

Seven of the patients suffered liver abscesses; an affliction attributed to the use of proton pump inhibitor drugs. As chief executive officer Scott Schorer noted, the alternative therapies – notably gastric bypass surgery or insulin – aren't without risk either.

In October 2014 European authorities ordered the halt of shipments, pending a review of the company's "reporting and vigilance systems".

Locally the TGA approved Endobarrier in 2011. But last October the authority banished Endobarrier from the Australian Register of Therapeutic Goods, citing compliance issues.

Note though, that no recall was ordered in relation to current users and a local trial of Endobarrier on type two diabetes and non-alcoholic steatohepatitis (NASH) continues.

The company has also re-engaged with the FDA to “address difficult legacy issues in multiple areas.”

Probably wisely, management’s commercialisation efforts have focused on securing reimbursement in Germany and the UK, bearing in mind the device is not fully reimbursed anywhere.

Financial weight loss:

Endobarrier procedure might not hurt at all, but probing GI Dynamic’s financials induces plenty of pain.

In the December half reported revenue of \$US500, 000 and a net loss of \$US13.1 million. The company’s cash balance stands at \$US8.3 million. The March quarterly report showed receipts of \$US54,000 and cash burn of just under \$US3 million, with a cash balance of \$US5.4 million.

In what non-executive director Anne Keating’s vaguely famous brother (St Paul of Balmain) would have dubbed the cost purge we had to have, last year management instituted measures including replacing every supplier with a “less expensive and more appropriate service provider”

Redundantly, the annual filing states: “We will need to raise capital in 2017.”

The GI Dynamics register includes healthcare giants Medtronic and J&J Innovations, who presumably would be willing to donate some small change when the hat is passed around.

But the real intrigue lies with the Crystal Amber Fund, which recently upped its stake by one percent to 40.7 percent. The Guernsey-based entity is described as an activist fund and evidently believes in the story. And if the company’s fortunes don’t turn for the best, presumably it is also willing to force changes.

Management declares Endobarrier remains ahead of the competition and has not lost its “first mover advantage”, which poses the question of how much lead the second movers have in their saddlebags.

GI Dynamics is pondering a listing on London’s Alternative Investment Market, to “synchronise” the company’s presence with its European commercial activities.

Management also hopes to confirm a new study design for a new Endobarrier obesity and diabetes trial this year.

Management promises to tell more in a so-called 10-Q form to the SEC, to be filed next week.

At the company's annual meeting this month, investors will be asked to vote on granting directors a swag of options, exercisable at either 2.025 cents per CDI or 6.2 cents.

Yep, they're currently in the money, but they don't vest for either 12 months or three years.

For those with the time, money and inclination, GI Dynamics' AGM will be held in Boston on May 22.

Endobarrier did win praise at this week's gathering of gastric heavyweights in Chicago at a function called Digestive Diseases Week.

Among the riveting papers was: "Augmentation of Meal-Related Symptoms Following Placement of Duodenal-jejunal Bypass Sleeve is a Potential Mechanism of Action Inducing Weight Loss".

Ah! To be there ...

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he would consider himself a heavyweight in the field of rambling prose.