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Novo needs new blood despite earnings relief

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Novo Nordisk's better-than-expected first quarter raised hopes that its new chief executive Lars Fruergaard Jørgensen has begun to turn things around, sending its shares up 7% yesterday. But there is still a long road ahead for Novo, which is more exposed than most to the harsh US diabetes pricing environment.

The group's absence from the SGLT-2 inhibitor class is now looking like a misstep, and the company will need something to plug this gap. Questions about M&A were strangely absent from the analyst call, but after speculation earlier this year that Novo was interested in Global Blood Therapeutics more rumours of this kind will surely emerge.

Once-weekly

Management was keen to highlight several upcoming events for its pipeline, the most important of which is an FDA decision on its once-weekly GLP-1 agonist semaglutide, due in December.

Approval should help shore up its GLP-1 franchise: Novo's once-daily Victoza, facing stiff competition from once-weekly products like Lilly's Trulicity, has seen its US market share decline to 48% from over 60% in 2014, the company said on its earnings call yesterday.

Semaglutide has already shown a cardiovascular benefit, something that Trulicity has yet to do, which could help Novo claw back market share – at least until results from Trulicity's Rewind cardiovascular outcomes study come out next year (*Semaglutide heart data spice up once-weekly GLP-1 race, April 28, 2016*).

Novo has taken the bold step of evaluating semaglutide head-to-head against Trulicity in the Sustain 7 trial, results of which are due in the third quarter. It is also trialling an oral version of semaglutide in the phase III Pioneer programme.

Phase II data with subcutaneous semaglutide in obesity are also due in the third quarter. In this indication, the company will likely need to carry out a phase III study in around 3,500 patients for at least a year in order to gain approval.

As for earlier-stage candidates, Novo highlighted six projects in phase I that it says have innovative modes of action. These includes NN9423 for obesity, which chief science officer Mads Krogsgaard Thomsen described as the first G protein-coupled receptor tri-agonist.

But near-term challenges remain for Novo, not least the increasingly cost-conscious US diabetes market. And in spite of the positive first quarter, things look set to get more difficult as the year goes on. The company's bottom line was helped by improved cost control, which will not be maintained as Novo steps up R&D investment, Berenberg analysts noted.

Poxel promise

If Novo is looking for diabetes white space to move into, there are still some novel candidates around – one of which, Poxel's imeglimin, has just posted promising interim results from a Japanese phase IIb study.

The product, a mitochondrial bioenergetics enhancer, aims to address the dysfunction in mitochondria seen in diabetes and could target the two main defects in the disease: decreases in insulin secretion and insulin sensitivity.

Bryan Garnier analysts describe the approach as "very innovative" and believe that Poxel could attract the attention of other diabetes players. It plans to develop imeglimin alone in Japan, where a phase III programme is set to begin by the end of this year, but will need a partner for US and European trials, chief executive Thomas Kuhn told *EP Vantage*.

Investors sent Poxel's stock up 37% this morning.

There is no suggestion – yet – that potential suitors could include Novo. And the company has been reticent historically to buy in innovation. But with its first-quarter results looking more like a temporary reprieve than a

return to the good times, the Danish company might need to start looking elsewhere for growth.

Project	Trial	ID
Trulicity	Rewind CV outcomes trial	NCT01394952
Semaglutide	Sustain 7 trial vs Trulicity	NCT02648204
Semaglutide	Phase II obesity trial	NCT02453711
NN9423	Phase I obesity trial	NCT03095807

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