In conversation with **Tim Clover**, *Rayner CEO*

Why **European Medical Device Regulation** is still a threat, why **cataract market contraction** could hurt clinics, and could **new tech** transform the market?

Tim Clover, CEO of UK-based ophthalmic medtech firm Rayner, is excited about new tech, concerned about regulation, and pleased with the way the market is growing. Candesic caught up with him this week to find out more.

Based on the south coast of England in Worthing, Rayner has played its part in the development of the sector, pioneering the first intraocular lens in 1949. It is now very much an international player, active across the globe with offices across Europe, India and the USA.

With revenue comfortably over £200m, and an EBITDA margin exceeding 30%, Rayner is doing well. Clover is acutely aware of Rayner’s position in the market – a step or two behind the largest players like Johnson & Johnson (J&J) or Alcon, but ahead of the chasing pack. He explains this feels like a sweet spot, and while conceding he “won’t be buying J&J any time soon” he adds: “If you think about the guys bigger than us, they all have very internalised R&D structures and most of the things that they launch are initiated internally.

“We're a little bit out on our own in the market, as the groups behind us are quite small and have neither the impact. We are small enough to care about an innovation that might generate, say, £50 million worth of revenue, but we're big enough to make quite a significant impact with those products globally.”

Well-backed by Luxembourg-based PE firm CVC Capital Partners, Rayner is not lacking in financial support either. Clover says money has not been spent rashly, however: “Over a very long period, debt was extraordinarily low, and some groups extended to the point where their cash flow was consumed by debt repayments. It was a huge gamble – in the medium-term interest rates were always going to go up. We kept our debts relatively modest.”

Boosted by a post-Covid bounce-back, Clover says the cataract market has been busy: “The cataract market has been extremely healthy. It has been disproportionately served by the private sector. That has not been especially positive for suppliers like Rayner as in these circumstances, operators tend to go for large volumes of low-cost lenses and that’s not us.”

The increasing involvement of the private sector is changing the market, he adds: “If you look at the number of ophthalmic operating rooms that have opened in the UK alone over the last three years, it must be between 30 and 50. NHS theatres are dealing more and more with the private cases the independent sector doesn’t touch – it leaves those to go through the NHS referral path and that has real implications for surgeon training. If this continues, how do you train new surgeons, let alone manage the cost inefficiencies of having underutilised NHS theatres?

“There has been a cataract feeding frenzy. When the market returns to its steady state, what will happen to that excess supply which was built to deal with the Covid backlog?”

Rayner continues to grow internationally, and that is partly down to cost, partly to boost innovation. Clover explains: “We’re continuing to expand, recently moving into France, Poland, Brazil and Australia. If you work with a distributor, you pay quite a big margin. Distributers can operate with a 50-100% markup depending on whether they deal with regulatory affairs, have a large sales team, and invest in marketing.”

There is aways a lead in time in entering any new country and operating in an unfamiliar environment – Clover says the first 12-18 months are “wobbly” – but it is

worth it. When Rayner does need to rely on a distributer, Clover prefers having an exclusive partner which isn't promoting rival products.

He explains: "If you don't commit to us, we won't commit to you. In those instances, we tend to launch our own company and terminate the distributor and start from zero. In other markets where we already have an exclusive partner, we tend to acquire them."

Being in a country also lets you build relationships and get closer to surgeons, he adds, explaining "that leads to conversations and clever innovations and before you know it, the next generation of products".

What are the most appealing markets? Clover says looking internationally, China (which recently went through a national tendering process), India and the US are particularly interesting when it comes to growth potential, adding: "In the US, it is really unconsolidated. Operators are about 35% owned by private equity, which is lower than you would see in some other markets, UK included. The level of reimbursement and the prices that you can obtain in the US and the speed of adoption make it an extremely attractive market provided you've got the scale to put up the $10 million to go through the FDA."

Closer to home, France and Poland are of interest to Clover because of their long tradition of patients going to independent providers. He says: "We're positioning ourselves more in this private or copay market where people pay for improved outcomes – about 50% of our revenue comes from 'premium' technology products".

Turning to legislation, he has strong feelings about the European Medical Device Regulation (MDR) which was meant to have already come into effect, requiring more stringent clinical evidence and follow ups for approval. He says: "The EU bottled it and gave a stay of execution until 2028. The regulations were very clear, very well communicated. We put the resources in place and the investment in place to meet those regulations. And at the 11th hour, they just extended it - because virtually no other companies had done the same.

"It is still coming. To launch a new technology, you'll need a clinical study as defined by ISO and not dissimilar to what the FDA requires in the USA. But not for a while. At present, only around 15% of medical devices have (the new) MDR approval and without it, when the regulations come in, your device is off the market. There will be a bloodbath of smaller and historic products which surgeons have been using that will no longer be available in three to four years and we're already seeing people withdraw products now because they know they're not going to be able to take them through MDR."

Looking forward, Clover believes the lens premium market is interesting. "Next generation" lenses, including accommodating IOLs and Spiral IOLs which give a full range of vison with no dysphotopsia (glare/light streaks) are being developed by the likes of Rayner.

He explains: "We've tested this in patients in Brazil, it works in a real life clinical setting. We're taking it through reg. affairs and are hoping to launch in the near term.

It will be unlike anything on the market today and has the potential to accelerate premium lens adoption by improving outcome reliability."