



Biotech Daily

Marc Sinatra's Bioguide

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CELLESTIS – A QUIET ACHIEVER

Overview: Cellestis first caught my eye in 2001 when its share price surged six-fold on the news that the US Food and Drug Administration would expedite the review of its test for latent tuberculosis. Two months later, Chemeq's share price took off in a similar fashion when its antibiotic alternative received FDA fast-track status.

But that was where the similarities ended. Chemeq seemed to focus on its share price. It constantly made bullish statements about its future. It turned its back on the US to focus on quicker routes to market and built a huge factory to supply the expected massive demand. Cellestis quietly went about its business. It refined its products, supported extensive clinical research, gained endorsements from numerous groups and professional bodies, methodically gained regulatory approvals and built a sales and marketing network.

Chemeq went into administration in May 2007. Cellestis has just reported its first profitable half-year for the period ending December 2007. Having survived the temptations of being distracted by a rapidly rising share price, the immediate question for Cellestis is how does it increase sales?

Financials: Market cap: \$215 million; cash: \$12.2 million; half year profit: \$328,000.

Directors: Non-executive chairman, Ronald Pitcher; chief executive officer and managing director, Dr Anthony Radford; scientific director, Dr James Rothel; non-executive directors, Prof Antonino Catanzaro and John Bennetts. Cellestis' board is very strong in TB and TB diagnostics, but weak in the area of international sales and marketing of diagnostics.

Marketed Products: Cellestis has three products available on the market:

- 1) Quantiferon-TB Gold: An Elisa kit for diagnosing latent TB infection via the detection of interferon γ , produced by T-lymphocytes after incubation of the patient's blood with specific TB antigens. It is more specific, sensitive and less subjective than the Mantoux test and only requires one visit to the clinician's office.
- 2) Quantiferon-TB Gold In-Tube: Essentially the same as the standard gold version except the patient's blood is collected directly into a specialized tube that allows more flexibility in terms of transport and testing.
- 3) Quantiferon-CMI: A research test for studying the cell mediated immune (CMI) response of patients' T-lymphocytes to antigens supplied by the researcher.

Products in Development: Cellestis has two products in development:

- 1) Quantiferon-CMV: A test to determine the level of an immuno-compromised patient's CMI response to cytomegalovirus (CMV). It is expected to gain Conformité Européenne (CE) Marking this year. Patients with latent CMV whose CMI response declines are at risk of their infection becoming active. Clinical suspicion alone is not enough to justify treatment given the expense and side effects of the drugs to treat CMV.

2) Quantiferon – Leishmania: A test for leishmaniasis. A diagnostic is needed because, like CMV, clinical suspicion alone is insufficient to justify treatment. Numerous methods of detecting leishmaniasis exist, but all have problems.

Significant Product Markets: The market for latent TB testing is the largest target market for any of Cellestis' products by far. The costs associated with testing and treating latent TB means the market is limited to the developed world. A 2006 World Health Organisation report estimated 41 million requests for latent TB testing in the developed world. The market value of this testing is estimated at \$US339 million.

The T-Spot TB test is the only other marketed CMI response test for latent TB. It has not been studied as extensively as the Cellestis tests and is more rudimentary. Other tests are in development, but are largely aimed at diagnosing active TB infection.

Verdict: Cellestis is a quality company with highly responsible management and latent TB diagnostics that fit extremely well with a clear market need.

But I see two significant issues. The first is that Cellestis' core patents have expired in most countries, except in the US where they expire in 2011. This means that they are becoming increasingly dependent on more peripheral intellectual property, such as patents on other test components, to maintain their competitive advantage. As a result, they will need to actively identify and protect additional and potentially competing innovations.

The second and more important issue is increasing sales. This will involve replacing the Mantoux test in countries where it is widely used and increasing the market in countries where the number of false positives created by high rates of vaccination has rendered the Mantoux test ineffective - the Quantiferon TB tests are not affected by prior vaccination. Replacing the Mantoux test is likely to provide quicker revenues, but increasing the market in countries with high levels of vaccination may provide bigger revenues because of the lack of a useful alternative to the Quantiferon TB tests. Hence, extra marketing and sales expenditure in these countries may be prudent.

Marketing and sales strategies will be very important to increasing sales and these strategies will need to vary from country to country depending upon the nature of the healthcare system and the medical community's attitude and treatment of TB. Although Cellestis is making good headway in this area, given the complex nature of this task, it would be nice to see the inclusion of at least one person on the board with significant international diagnostic marketing and sales experience.

Valuing Cellestis is difficult and not just because of current market conditions. Unlike your usual high-risk Australian biotech, Cellestis has products that are likely to generate consistent long-term sales. On the other hand, Cellestis isn't a lower risk proven medical device company, such as Cochlear or Resmed, either. Consequently, I have used an intermediate discount rate to arrive at an estimated price per share of \$2.35.

Cellestis fell nine cents or 4.02 percent to \$2.15.

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