



Biotech Daily

Marc Sinatra's Bioguide

September 15, 2009

Genera Needs Right Paptyp Partner

Overview: Genera Biosystems was one of the few life sciences floats to get up in 2008 and, at 60 percent above the offer price, investors should be happy in a difficult market. While not the only application for its technologies, Genera is firmly focused on the human papilloma virus (HPV) testing segment of the cervical cancer screening market. This is a potential multi-billion dollar market segment that is developing quickly, but a significant number of players are already out there.

What does Genera need to do to succeed?

Financials: Market cap: \$48 million; cash: \$3.3 million; last quarter cash burn: \$726,000.

Directors: Non-executive chairman, Fernando Careri; chief executive officer, Dr Allen Bolland; non-executive directors Mel Bridges, Mr David Symons William Tapp; executive director, Dr Karl Poetter.

Genera's board is solid, without being spectacular. Mel Bridges is the shining light, but given his other commitments may be spread a bit thin.

Products in Development:

1. Paptyp: a diagnostic for the simultaneous detection and genotyping of HPV in cervical smear samples based on Genera's Ampasand Bead technology (described below). Paptyp identifies the 14 high risk and two low risk HPV genotypes. A recently completed retrospective study involving 894 abnormal Pap smear samples found a nine percent false negative rate for Paptyp compared to 21 percent for the market leading test, Qiagen's Hybrid Capture 2, results consistent with an earlier pilot study.

Genera expects to complete three further clinical studies of Paptyp during 2009, including one in a true screening population. The company also hopes to obtain Australian and EU marketing approval and complete a worldwide or regional licensing deal by the end of 2009. US FDA approval is penciled in for 2011-'12, but is likely to be the responsibility of a licensee.

2. Ampasand Bead Technology: this technology employs a standard flow cytometer to sort color and size-coded micro-beads that are coated with probes to specific analytes, so that a combination of beads mixed with a single sample can be used to test for multiple analytes at one time. After Paptyp, Genera intends to develop a test for the sexually transmitted diseases Chlamydia trachomatis and Neisseria gonorrhoea.

3. QSand: an optical detection system based on whispering gallery modes, whereby changes in the emission spectrum of probe coated translucent beads upon binding of an agent can be used to identify the agent. An important feature of this technology is that signal amplification is not required.

Significant Product Markets: The American Cancer Society estimates that there will be 11,270 new cases and 4,070 deaths from cervical cancer in the US this year. Worldwide these numbers are thought to be 473,000 and 253,500, respectively, 85 percent of which are in developing countries.

The National Cancer Institute estimates that 55 million Pap tests are performed per year in the US, with 3.5 million (6%) returning an abnormal result. Worldwide, it is thought about 120 million pap tests are done each year.

It is difficult to ascertain the current size of the HPV testing marketing, with global estimates ranging around \$US250-\$350 million.

There are several HPV tests already on the market. The most notable are Qiagen's Hybrid Capture 2 and Hologic's Cervista HPV HR. Both are FDA-approved for certain cervical cancer screenings. The Hybrid Capture 2 test garnered sales of \$US135 million for the first nine months of the 2007 financial year.

Opinion: Given the nature of the diagnostics industry, it seems likely that for Genera to be successful, Paptype must be successful.

On that note, there is an air of inevitability that HPV testing will continue to play an increasingly larger role in cervical cancer screening in years to come. HPV testing alone, however, is not a perfect screening tool and the area and how HPV testing is used in it, will continue to evolve.

If it evolves such that precise genotyping information is of major importance in cervical cancer screening, Genera's prospects would seem extremely good.

Given the present situation, however, I think it will be the quality of the partner that Genera attracts for Paptype that will be the biggest determinant of its success, rather than the relative advantages or disadvantages of Paptype compared to competitors.

A quality partner is required to give Paptype a foothold in what is likely to become an increasingly competitive environment, where no company has a knockout technology and marketing is a key.

Such a partner would also bode well for Genera, because once the market has accepted one product based on the Ampasand technology, acceptance of following products should be much easier.

Paptype is worthy of a licencing deal with a major player and the signing of any such deal would be a major value uplift point for the company.

For now, I see the company as pretty good buying and have given it a valuation of \$1.05 per share based on comparables.

Genera was up two cents or 2.5 percent to 82 cents.

Marc Sinatra's Bioguide
Email: marc@biotechdaily.com.au

www.biotechdaily.com.au