Biotech Daily
Marc Sinatra's Bioguide

October 2, 2008

PHOSPHAGENICS' VERY DEEP VITAMIN E PIPELINE

Overview: Phosphagenics is a Melbourne-based company, primarily focused on exploiting the properties of their proprietary phosphorylated vitamin E compounds.

Phosphorylated vitamin E is thought to be the biologically active form of vitamin E and it also demonstrates unique properties when applied to the skin. This has led Phosphagenics to seek multiple applications in a wide range of areas, including nutraceuticals, drug delivery and as enhancers of existing drugs. Nutraceuticals include food additives, dietary supplements and some cosmetics enhancers.

This raises the question of whether Phosphagenics is trying to do too much and, if so, on which projects should they be focused?

Financials: Market cap: $46 million; cash: $16 million; last half cash burn: $4 million.

Directors: Non-executive chairman, Prof Andrew Vizard; president and chief executive officer, Harry Rosen; executive vice-president, Dr Esra Ogru; non-executive directors Prof John Mills, Jonathan Addison and Michael Ashton.

Phosphagenics' board is quite strong and suits its wide ranging activities.

Products in Development:
1) Phospha E (supplement): Previously sold in the US under the brand name Ester-E by Zila Nutraceuticals, generating $2 million a year in royalties for Phosphagenics. The licence with Zila was not renewed and Phosphagenics looks likely to take this product to market.
2) Phospha E (food additive): Subject of a research agreement with Nestlé. A worldwide licence has been negotiated and is likely to be signed after completion of a phase 2 study for metabolic syndrome due at the end of 2008.
3) Phospha E (cosmetics): A material transfer agreement was signed with a major cosmetics company in 2006. Any commercial outcome should be known in 2009.
4) Oxycodone-TPM: A transdermal system to deliver oxycodone. A phase I trial has been completed. The product may be refined before phase II trials or out-licencing.
5) Morphine–TPM: A patch for the delivery of morphine. Phase Ia and Ib studies have been completed. Its future will become clearer after its current phase IIa trial.
6) Lidocaine-TPM: A system to enhance delivery of lidocaine to the skin. A phase I trial commenced last month.

7) Diclofenac-TPM: A system to enhance the delivery of the non-steroidal anti-inflammatory Diclofenac to the skin. Currently in pre-clinical testing.
8) Insulin–TPM: A transdermal system to deliver insulin. Phase Ia and Ib trials have been completed. Results from its phase II study are due at the end of 2008.
9) Retinoic Acid–TPM: A system to efficiently deliver retinoic acid (vitamin A) to the skin. It has completed a phase I trial.
10) APA-01: An enhanced form of Vitamin E for use with a statin or cholesterol-lowering drug. Preclinical work is complete and the project is available for out-licencing.
11) GTP-0805: An anticancer agent intended for combination use. Preclinical work is complete and the project is available for out-licencing.

Significant Product Markets: Nutraceutical sales are marketing driven, quite competitive and dominated by big brands.

Supplemental vitamin E sales in the US were $US400 million in 2006. Sales have been falling since 2000, as papers questioning vitamin E's benefits have surfaced.

The worldwide opioid analgesics market was worth $US7.7 billion in 2007. The long-acting opioid segment was worth $US3.0 billion. A 2008 Datamonitor report found "the topical market represents an opportunity for companies to enter a comparatively underserved market". Fentanyl is the only opioid that is currently delivered transdermally. Sales of the first Fentanyl patch, Duragesic, were $US1.2 billion 2007, despite increasing generic competition.

Worldwide insulin sales were $US7 billion in 2007.

In 2005, Pfizer launched, Exubera, an inhalable form of insulin. Sales were poor and Exubera was discontinued earlier this year. There were product specific issues with Exubera (such as being a cumbersome device as well as safety), but it also appears diabetics aren't too worried by the injections. Several companies have since discontinued new insulin delivery projects.

Phosphagenics puts the US topical retinoids market at $US340 million. Retinoids mainly target the acne market, which is crowded and the subject of much research.

Lidoderm Patch, a leading lidocaine product, had worldwide sales of $US748 million in 2006. Development of topical lidocaine products is focused on dysmenorrhea.

Opinion: Both Phosphagenics' nutraceutical and drug delivery arms have significant merit.

Earning $2 million a year in royalties, Phospha E clearly has some appeal to consumers, despite the negative image of standard vitamin E. Whether this demand will stay with Phospha E if it is launched under a Phosphagenics brand is another question, given the marketing and brand driven nature of nutraceuticals. Successfully striking a deal with Nestlé could do wonders for the Phospha E brand.

A licencing agreement is needed to validate the drug delivery technology, but it does look good for opioid analgesic delivery where the market need is clear. The retinoic acid and lidocaine products will probably need to demonstrate clear superiority over the market leaders to garner significant sales. Given the fate and fallout from Exubera, the insulin product has a very tough task in front of it.

Phosphagenics is probably doing too much and I would like them to choose a subset of projects and truly back them. In the future, it may be worth splitting the nutraceutical and drug delivery arms into two companies given their different foci.

Nonetheless, Phosphagenics has some gems and, as such, I have given it a valuation based on comparables of $0.12 per share.

Phosphagenics closed down 0.2 cents or 2.86 percent at 6.8 cents.

Marc Sinatra's Bioguides
marc@biotechdaily.com.au