

generic fondaparinux

Fondaparinux is the active ingredient in the drug Arixtra® currently marketed by GlaxoSmithKline. Alchemia has developed a cost effective synthesis for fondaparinux. Patent protection covering Arixtra® has expired, enabling Alchemia's partner Dr Reddy's to file an ANDA with the FDA for approval. Alchemia's fondaparinux is expected to be the sole generic version of Arixtra®, and as such, not subject to heavy price discounting common with other generics.

Progress over the last year

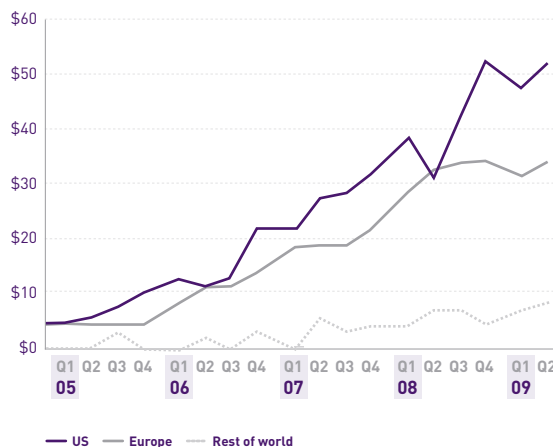
Bringing generic fondaparinux to market continues to be Alchemia's primary focus. In March, 2009, Alchemia's global manufacturing and US marketing partner Dr Reddy's Laboratories submitted the Abbreviated New Drug Application (ANDA) to the US Food and Drug Administration (FDA). The ANDA was accepted for review by the FDA in May 2009.

Fondaparinux is a difficult molecule to synthesise and production on an industrial scale presented some challenges. These technical risks have now been overcome and only the regulatory risk remains, which we consider to be low. We anticipate a regulatory review to be finalised during Q4 of CY 2009, according to the FDA's first generics policy. When launched, the generic version is expected to take market share from the branded drug Arixtra®.

Fondaparinux – a growing market

The patented version of fondaparinux is GlaxoSmithKline's Arixtra®, global sales of which for CY 2008 were up by 58% to \$315m (\$200m in 2007; GSK figures). Data from both GSK and IMS health (commissioned by Alchemia) show a strong trend in sales growth in Europe and the US.

Quarterly Sales of Arixtra®, US\$ millions



Source: IMS data

In June 2008 Alchemia received notice from IP Australia that two of the Company's patents, in the "synthetic heparin oligosaccharide" family of patents, had been granted. Corresponding applications in other jurisdictions are currently being examined. The patent family provides legal protection of Alchemia's industrial fondaparinux synthesis until 2021.

Dr Reddy's Laboratories Limited

– A world class manufacturing and marketing partner



- A global pharmaceutical company headquartered in India and listed on the NYSE (Symbol RDY).
- The Company has synthesised active pharmaceutical ingredient (API) for some of the world's largest pharmaceutical companies and is now manufacturing fondaparinux API for Alchemia.
- Currently, Dr Reddy's holds number three position in the US for number of approved DMFs and number five position in the US for ANDAs filed.
- As at July 2009 Dr Reddy's had filed 139 ANDAs in the US and 355 drug master files globally.
- Dr. Reddy's has a strong presence in the North American and European generics market.

Under the terms of the 2007 License Agreement between Alchemia and Dr Reddy's, profits from US sales of generic fondaparinux will be divided in an agreed proportion between the partners, with Alchemia receiving between 50 – 60% of the profits. Dr Reddy's also has a right of first refusal to market generic fondaparinux in Europe once data exclusivity expires in 2012.

Abbreviated approval route

In 1984 The Drug Price Competition and Patent Term Restoration Act (so called "Hatch-Waxman" Act) was introduced in the USA. Part of this act addressed the onerous and costly approval route for generic drugs. A new section (505(j)) of the Federal Food, Drug and Cosmetics Act was created, establishing an abbreviated new drug application (ANDA) route for generic versions of brand-name drugs. Under such legislation, generic drugs would not have to repeat the lengthy and expensive clinical trials of the brand-name drug.

As part of an ANDA filing, generic companies must include one of four certifications with regard to the brand-name drug:

- i. that the patent has not been filed
- ii. that the patent has expired
- iii. the date the patent will expire
- iv. that the patent is invalid or will not be infringed.

These patent certifications are usually referred to as paragraph I, II, III or IV certifications.

The patent for GlaxoSmithKline's Arixtra[®] expired in 2002, therefore Alchemia was able to lodge a Paragraph II certification with the FDA.

FDA's GIVE Initiative – accelerating approval times for first generics

In October 2007, in response to the increasing number of generics being filed, the FDA announced the GIVE (Generic Initiative for Value and Efficiency) initiative to streamline the generic drug approval process. One feature of the initiative is to apply a priority review process to the first generic, of a brand-name drug, submitted to the FDA. This priority review process has the goal of a 6 month review process and applies so long as there are no blocking patents or exclusivity protections. Alchemia's generic fondaparinux is this first generic version of GSK's Arixtra[®]. The US patent for GSK's drug expired in 2002 and market exclusivity expired in 2007, therefore Alchemia's fondaparinux has been able to take advantage of the FDA's GIVE initiative.

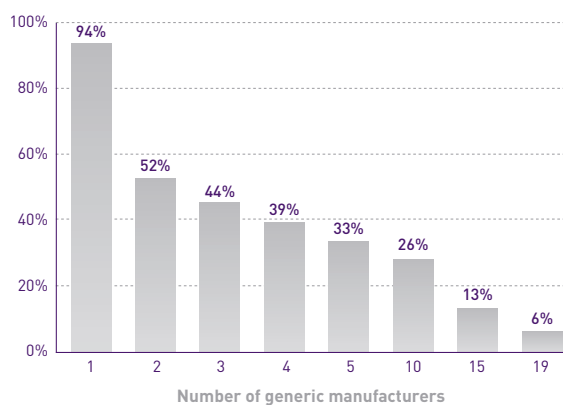
Single generic - high margin

A very high barrier to entry for other competitors exists due to the complexity of the synthesis and Alchemia's patent protection for its process. It's for this reason that Alchemia fully expects the fondaparinux market to be limited to just one

generic drug for the foreseeable future – Alchemia's generic fondaparinux. As the graph illustrates there is little price erosion when only one generic drug enters the market. This is in contrast to a typical scenario where multiple generic companies enter the market causing the price to collapse, for example, five generic entrants yield a price that is 33% of the brand-name drug price.

Average generic price per dose relative to brand-name drug

Source: FDA analysis of IMS Health data



Outlook – complex synthesis will deter competition

In regulatory terms Alchemia's generic fondaparinux:

- was submitted to the FDA under an ANDA filing with paragraph II certification (i.e. certification stating the Arixtra[®] patent expired in 2002) in March 2009
- was granted an expedited review, estimated at 6 months, under the FDA's GIVE initiative, in May 2009.

Furthermore, generic fondaparinux:

- is the generic equivalent of GSK's Arixtra[®] (global sales up 58% in CY 2008 to \$315m)
- will compete in the multi-billion dollar heparin-drug market
- has a superior safety and efficacy profile to other heparin drugs
- benefits from complexity of manufacture and broad IP protection which present a high barrier to entry for potential competitors
- has a process of synthesis that is patent protected until 2021
- is expected to be a sole generic and therefore not subject to significant price discounting.