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GNI Group Ltd

Pharma & biotech

7 October 2014

Price	¥354
Market cap	¥40bn

Poised for the next phase

GNI is close to advancing its lead product Etuary (pirfenidone) into pivotal clinical studies in radiation pneumonitis, diabetic nephropathy and other fibrotic diseases. Etuary is commercialised in China for idiopathic pulmonary fibrosis (IPF). The company has global patents for Etuary, and for F351, its improved chemical entity, which is due to move into Phase II for liver fibrosis and potentially chronic kidney disease (CKD), both of which are prevalent in global populations. As GNI moves further forward, the scope to out-license these products in other territories, including the US, should improve.

From IND to NDA

To date, GNI has focused on the Chinese market, taking anti-fibrotic Etuary into orphan indications where few other clinical treatment options exist. GNI is advancing the product into Phase III studies in radiation pneumonitis initially for the Chinese market; it also holds global rights. GNI took Etuary, the only marketed therapy in China for IPF, from investigational new drug (IND) through to new drug application (NDA), one of few companies in China to complete the process. GNI also submitted an IND for the small molecule to the CFDA for diabetic nephropathy, the primary cause of mortality in young diabetics, targeting a direct move to Phase II.

Intercontinental growth potential

Having validated its capabilities, GNI is positioned for a new phase and it has CFDA approval to take F351, an improved chemical derivative of Etuary, into Phase II for liver fibrosis (the company estimates Chinese prevalence of c 18 million people). Subsequently it will develop F351 in CKD, initially in China but with options on global rights in these wider indications. GNI appears well placed to expand, both through growth in China and by forming international deals.

Multiple streams of revenue

Total H114 revenue increased 93.4% y-o-y to $1.3m, including $0.5m from Etuary sales launched in March plus CRO, licensing and manufacturing revenues. GNI had R&D expenses of c $0.5m in H114. At the end of the period it held c $45m cash and c $3m in long-term convertible debt.

Valuation: Pharmaceutical style upside

GNI shares trade c 40% below the 12-month high despite a rebound triggered in late August by the reclassification of the company as a pharmaceutical rather than a services company. Potential medium-term catalysts, including the start of the approved Phase II trial of F351, granting of an import licence for Tamibarotene or clinical and commercial progress with Etuary, could drive a further re-rating.

Historic financials

Year end	Revenue ($m)	PBT ($m)	EPS ($)	DPS ($)	P/E (x)	Yield (%)
12/12	2.0	(6.8)	(0.06)	0.0	N/A	N/A
12/13	1.9	(8.5)	(0.07)	0.0	N/A	N/A

Source: Bloomberg. Note: Converted from reported currency Japanese yen.

Share price graph

Share details

Code	2160
Listing	Tokyo Stock Exchange
Shares in issue	112.7m

Business description

GNI Group is a Japanese bio pharmaceutical company, with China-based drug discovery, development and manufacturing sites. Its pipeline includes proprietary anti-fibrotic Etuary and its derivative F351, in-licensed Tamibarotene (acute promyelocytic leukemia) and small molecule F573 (liver failure). GNI is expanding its pipeline, launching products initially for the Asian markets and with a view to seeking global deals.

Bull

- Track record of successful clinical development and commercialisation.
- Participation in emerging growth in non-traditional pharmaceutical market through a Japanese investment vehicle.
- Global out-licensing potential and broad pipeline.

Bear

- Relatively low profile outside Asia.
- Negative reputation of Chinese pharmaceutical industry.
- Chinese drug pricing is low and Chinese traditional medicine is still widespread.

Analysts

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