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Despite efforts, new molecules elude Indian pharma

Pallavi Ail
Mumbai, June 1

INDIAN pharma firms have tried for more than a decade now to develop new molecules but they've had little luck so far. Over the last 15 years or so, several of them, including Glenmark, Biocon Cadila Healthcare, Dr Reddy's Laboratories, have put in the time and resources to try and discover some blockbuster drug or other but their efforts haven't paid off.

At least four of Glenmark's experimental drugs were returned or abandoned by partners, according HSBC analysts. Apart from Crofelemer—a treatment for HIV-related diarrhoea and in-licensed from San Francisco-based Napo Pharmaceuticals — none of its pipeline drugs has fructified into marketable products.

Oglemilast, a drug meant to target asthma and chronic obstructive pulmonary disorder (COPD), for which Glenmark partnered with Teijin Pharma for marketing rights in Japan and Forest Laboratories for US rights, was abandoned after the drug failed to meet the main goals of a mid-stage study in 2009.

Similarly, other out-licensed molecules such as melogliptin, an anti-diabetic licensed to Merck, and GRC8211, a potential painkiller with Eli Lilly as the licensing partner, were also junked after statistically insignificant results.

Others too have met with little success. Dr Reddy's Laboratories scrapped its promising anti-diabetic experimental drug, Balaglitazone, around 2011 after the drug failed to yield the requisite results. It had an out-licensing agreement with Swedish drugmaker Novo Nordisk.

Earlier in 2002, Ranbaxy had licensed out a prostate research molecule to Schwarz Pharma. Yet, the deal hit a roadblock in November 2004, after the German company terminated clinical trials due to unclear pre-clinical findings.

Sujay Shetty, ED and leader - pharma life sciences, Pricewaterhouse Coopers, notes that NCE-styled research can be very difficult and takes years to be perfected. "So there is no shame with some molecules being junked," he says. Nevertheles, out-licensing products guarantees milestone-based payments, a revenue model which yields returns even if the product does not materialise in the end. Analysts agree that Mumbai's Glenmark has successfully monetised its NCE programme in this manner.

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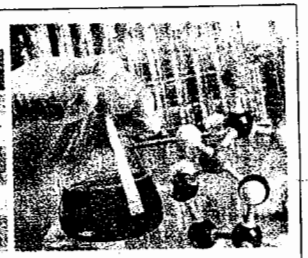
DISSIPATING BEFORE HALF-LIFE

Company	Compound	Indication	Out-licensed to	Milestone payment ($ m)	Year
Glenmark Pharma	GRC 3886 (Oglemilast)	Asthma, COPD	Teijin Pharma - Japan	6	FY06
Glenmark Pharma	GRC 3886 (Oglemilast)	Asthma, COPD	Forest Labs - NA	15	FY04
Glenmark Pharma	GRC 8200	DPPIV inhibitor for Type II diabetes	Merck	31	FY07
Dr Reddy's Labs	Balaglitazone	Type II diabetes	Novo Nordisk	NA	
Ranbaxy Labs	RBx-2258	Benign prostate hyperplasia	Schwarz Pharma	42	FY03



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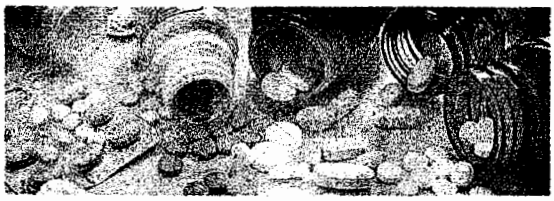
Pharma...



programme – where novel drugs are engineered from biological products such as proteins, antibodies, viruses and vaccines.

An out-licensing strategy is one where the licensee assumes control over development of the drug or a new chemical entity (NCE) with the benefit of marketing rights to some geographies as a reward if the product is approved. It's not just the expertise which makes Indian companies reach out to their older peers. Funds play an important part. "Even the biggest balance sheet in the Indian pharmaceutical industry today cannot support a robust NCE programme," Murali Nair, partner, EY, observes. He adds that globally too, the ratio of the success of developing a marketable drug from a promising molecule is very low. "Indian companies are developing only a handful of molecules," he points out.

Glenmark gets a steady flow of milestone-based payments from various out-licensing agreements it has signed with drug majors. JP Morgan analysts peg the revenues at about $232 million till date.

Glen Saldanha, CMD, Glenmark Pharmaceuticals, says his firm has moved up the innovation and drug discovery value chain. "For NCEs, we are looking at out-licensing at the phase 2 stage while for NBEs, we are looking at out-licensing opportunities in the pre-clinical phase itself," Saldanha told FE. He added that the firm has three R&D facilities, in India, the United Kingdom and Switzerland, employing over 500 scientists dedicated primarily to drug discovery and not just generics research.

"Indian companies can manage development by themselves up to Phase – I or sometimes Phase – II of clinical trials. After that point, you need to conduct global studies, for which a partner is essential," said Alok Dalal, pharma sector analyst with Motilal Oswal Financial Services.

The company also has a new biological entity (NBE)

Contd.