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Generic Formulators Position for Profits. By: Sauer, Pamela. Chemical Market Reporter. 8/13/2001, Vol. 260 Issue 7, pFR12. 2p. Abstract: Focuses on the growth potential of generic drug formulators in the pharmaceutical industry. Competition faced by formulators; Importance of drug delivery technology on the success of generic companies; Top generic manufacturers in the market. (*AN: 6040608*)

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GENERIC FORMULATORS POSITION FOR PROFITS

A spate of drugs is scheduled to come off patent over the next several years, but is a generics feast enough to sustain profitability?

Roughly $50 billion in branded drugs in the US will lose patent protection between now and 2005, providing generic formulators a rich opportunity. However, despite the huge potential of this market, analysts emphasize that differentiation will be key for formulators to realize gains.

Although the generic drags macro environment appears favorable, this high growth potential is matched by an equally competitive market. "As a general rule, we favor companies that have evolved beyond broad-based generics and either have a major niche presence in the $25 billion controlled release/delayed release generic drug segment or have a proven ability to receive FDA approval on successful brand drags that are internally developed," says UBS Warburg analyst Steven Valiquette. "The companies that fit this criteria are likely to generate the most rapid eearnings per share growth and are equally likely to sustain this higher-than-industry-average growth for a longer period of time because of longer product life cycles and fewer competitors resulting from the technological barriers to entry."

Drug delivery technology is one key element for generic companies for differentiation. "We favor companies with proprietary controlled-release drug technology to develop both branded and generic drags. These companies ultimately face less competition and thus more sustainable profit growth," says Mr. Valiquette. Key companies in this area, according to the analyst are Andrx and Biovail, as well as Impax Labs.

The other key means of differentiation is to diversify portfolios with branded drags. "Following the 1996-1997 bloodbath of the generic drag industry, many generic drug companies decided to no longer focus exclusively on multisource pharmaceuticals, but to instead accelerate and hopefully generate more consistent earnings growth and expand profit margins through the development, manufacture, and sale of branded pharmaceuticals," says Mr. Valiquette. "Among the hybrid generic drug companies, we favor those with a proven ability to internally develop and market branded drugs as a means for generating more consistent profit growth and margin expansion."

Companies that fit this bill are Teva, Watson and Ivax. "Teva has Copaxone; Ivax has its Easi-breathe respiratory franchise, and Watson has four major branded drags expected to contribute

meaningfully to the bottom line during the next several years--Ferrelict, Aslera, Unithroid and oxybutynin patch," points out the UBS Warburg analyst.

He notes that there is less investor enthusiasm for broad-based generics companies. "We have a less bullish view about the companies that have not evolved with the group and are still considered more plain vanilla broad-based generic companies or for which the respective diversification strategies have not worked successfully."

Alpharma, along with Mylan, were two companies cited by the analyst earlier this year for not having a strong enough diversification strategy. Alpharma is seeking to change that in part, through a pending three-part deal between the health care and logistics company Mayne Nickless Ltd., Alpharma and Teva Pharmaceuticals.

Last month, Mayne Nickless moved closer to its goal of acquiring the Australian-based pharmaceuticals company F.H. Faulding & Co. following a recommendation by Faulding's board of management last month to accept an improved bid by Mayne Nickels. If the merger is approved (still pending as of press time), Mayne will sell Faulding's genetic oral solid dose pharmaceuticals business to Alpharma Inc. for $660 million and will offer Teva Pharmaceuticals Industries Ltd. an exclusive opportunity to purchase Faulding's injectable business for $365 million. Included in the oral solid dose pharmaceuticals business sold to Alpharma would be Purepac Pharmaceuticals and Faulding Laboratories in the US and Foshan Faulding Pharmaceutical in China. These businesses have sales of roughly $200 million.

In speaking of Alpharma's bid to buy the Faulding generic oral solid dose pharmaceutical business, Banc of America Securities analyst Jerry Treppel says, "We believe it would be a transforming acquisition that heretofore the company has not had--a highly visible US business with rapid growth and potentially a homerun product in generic Neurontin."

Purepac has the first-to-file status on the '476 patent on Pfizer's Neurontin tablets and capsules, the subject of litigation between the two companies. "Figuratively and literally, generic Neurontin would be to Alpharma what generic Prozac would be to Barr. The potential financial impact could be expected to be similar," says Mr. Treppel.

Purepac markets a full line of generic and solid oral dosage forms in immediate release and extended release formulation to national and regional retail chains, drag wholesales, drug distributors, mail-order houses and managed care facilities in the US. The company manufacturers roughly 2 billion tablets and capsules each year at its plant in Elizabeth, N.J., and it recently purchased an additional facility at Piscataway, N.J., to increase its product development and manufacturing capacity.

"While Purepac's focus is in anti-infectives, cardiovascular, anti-inflammatories, analgesics, anti-depressants and tranquilizers, the company is most well known for being one of three players in the generic Cardizem market," says Mr. Treppel. Purepac currently retains a roughly 20 percent share of the market, which is estimated at roughly $50 million to $60 million.

The other pieces that would be gained by Alpharma are Faulding Laboratories and Foshan. Faulding Labs is a small pharmaceutical business that develops and markets branded proprietary products in niche therapeutic areas. "Its lead products include Kadian, an oral sustained release morphine for pain, and Serax, used to treat anxiety," with 2000 sales of $7.5 million and $5 million, respectively, according to IMS Health, a Plymouth Meeting, Pa.-based healthcare market research firm. The company's strength is in the development of modified release products and its history includes Eryc, an antibiotic, and Doryx, an antibiotic.

Faulding's facility in China manufacturers and supplies the Chinese market with generic oral pharmaceutical products along with a range of traditional Chinese medicines. The facility, located in Foshan in Guangdong Province, is a joint venture 90 percent owned by Faulding and 10 percent by Foshan City.

The other side of the Mayne's deal with Faulding would allow Teva Pharmaceuticals to purchase Faulding's generic injectable business for $365 million in cash. "Overall, we believe the acquisition of Faulding's generic injectables business will be a positive move for Teva. We continue to believe that Teva is in a class by itself in the generics industry and with this new agreement, along with recent alliances with Impax for controlled release genetic products, the distance continues to widen," says Banc of Securities analyst Jerry Treppel.

The analyst points out that the acquisition would fit well with Teva's existing business and provide opportunities for growth. Teva has a generic injectables business in Europe through the acquisition of the Dutch firm Pharmachemie in 1998, but it has no presence in the US, and Faulding is a competitor in Europe. "Most of the other competitors are local players, none with the global presence of a Teva or a Faulding. Thus, with this acquisition, Teva will be able to broaden its product line, expand into other regions in Europe, and achieve much greater penetration into the entire European market," says Mr. Treppel. He adds that this combination would also position Teva as the global market leader in generic oncology products.

The analyst also points out that the Faulding deal allows Teva to expand into a less competitive segment of the generics market. "The production of injectable products is a highly capital intensive business that requires dedicated sterile manufacturing facilities and must meet stringent FDA requirements. Because of the barrier to entry, competition tends to be relatively limited," says Mr. Treppel.

A Faulding acquisition also provides a growth platform for Teva's active pharmaceutical ingredients (API) business. "Teva, through its API business, already supplies many of the raw materials in generic injectable products. This acquisition will allow Teva to become vertically integrated in the injectable business just as it has in the oral solid dose business. This strategy has proven to been extremely successful in the oral solid dose business, as evidenced by the leading market shares of Teva's vertically integrated products. We see no reason why that would not be repeated in the injectable business," says Mr. Treppel.

Another opportunity for Teva from the acquisition of Faulding's injectables business is entry into generic biologics. "Pan of this strategy has involved an alliance with Bio-Technology General (BTG)

for several genetic biotech products to be developed and manufactured by BTG and marketed by Teva. The acquisition of Faulding's injectables business with its manufacturing capabilities and technology may pave the way for Teva to develop these products on its own. Although the opportunity in generic biologics may be a bit further down the line given that a regulatory pathway has not been established, we believe the potential is enormous," says Mr. Treppel.

Other generic players are also positioning themselves in the generics biologics arena. In April, Ivax Corp. acquired the remaining 70 percent of India Protein Technologies (IPT), which specializes in using recombinant technology to develop peptide-based pharmaceuticals. Ivax had acquired a 30-percent share interest in IPT in 1999. In addition to the Teva/BTG collaboration, Barr Laboratories is working on one biotech drag and Sicor has a facility in Mexico for biologics and announced another acquisition to beef up its biologics manufacturing capacity.

Last month, Sicor Inc. agreed to acquire Biotechna UAB, a Lithuania-based manufacturer of recombinant protein products. "The acquisition of Biotechna is an important milestone in Sicor's strategic initiative to develop and manufacture genetic biopharmaceuticals," says Michael Cannon, president, biotechnology division. "Biotechna currently manufactures products for several emerging countries and, with its new facility designed with the help of US consultants and constructed by a highly qualified Swedish firm, is expected to be fully compliant with the good manufacturing practice requirements of both the US and the European Union regulatory authorities. We believe that this facility will be the key factor to Sicor's entry into this high-growth market segment and could potentially put Sicor, well ahead of its competition."

"Through this acquisition, combined with our Mexican filling and finishing plant expected to be on line in early 2002, Sicor now has the means to develop and manufacture a broad menu of bio-engineered products with an estimated $10 billion worldwide market," says Carlo Salvi, president and chief executive officer. "These facilities will give Sicor the strength of the successful vertical integration model currently used by our traditional small molecule pharmaceutical operations, and provides us with the vehicle to execute our worldwide strategy of supplying biopharmaceutical products for, first, the emerging nations, followed by the EU and the US.

Other generic players are using distribution strategies. For example, Mylan, which recently received generic approval for various dosage forms of paclitaxel injection, is setting its target of nifedipine, the generic equivalent of Procardia XL. "Mylan has struck a unique distribution agreement with Pfizer for all three dosage strengths (30, 60 and 90 mg) that especially limits generic competition for nifedipine in the 30 mg strength, for which Mylan has first-to-file status. We have a great deal of respect for the management at Mylan in its successful implementation of such a strategic maneuver," says Mr. Valiquette. The company is in need of a positive outcome as it struggled in 2000 to generate positive year-over-year comparisons in light of price erosion on clorazepam and lorazepate as well as the delay in launching buspirone, the generic equivalent to Bristol Myers Squibb's $1 billion anxiety drug Buspar.

On the API front, Phytogen Life Sciences Inc., a Delta, British Columbia-based active pharmaceutical manufacturer, will supply Mylan Laboratories Inc. with paclitaxel. Last month, Phytogen reported its paclitaxel manufacturing process and facility underwent a successful

inspection by FDA in late June with no 483 observations. The inspection was the last step in the approval process for Mylan's product, paclitaxel injection, the generic equivalent to Bristol-Myers Squibb's Taxol. Phytogen operates a production facility in Delta, British Columbia. In addition to Mylan, the company supplies paclitaxel to Sinphar Pharmaceutical Co. Ltd., a Taiwan-based company. Drug Royalty Corp. Inc., a Canadian company that acquires royalty streams generated from pharmaceutical products, invested in Phytogen to fund expansion of its manufacturing platform in return for a 15-year royalty entitlement on all revenues.

However, paclitaxel is a key revenue driver for Ivax Corp., which saw its first half revenues for 2001 jump 52.6 percent to $561.7 million. Net sales of its paclitaxel product were more than $77 million in the second quarter following revenues of $50 million in the first quarter. In June, the company received a US patent for an oral formulation of paclitaxel. Merrill Lynch estimates $305 million in sales for Ivax generic paclitaxel in 2001 and $300 million in 2002. The company currently holds about 10 percent of the paclitaxel market, and an oral form could potentially boost that to one-third. Ivax is positioning itself in other markets. In July it completed the acquisition of Laboratorio Chile, the largest Chilean pharmaceutical company with 2000 revenues of $173 million.

Outside the US, generic competition is also coming from offshore producers. Last month, the Indian producer Dr. Reddy Laboratories (DRL) received FDA approval for generic versions of AstraZeneca's Prilosec (omeprazole) and Eli Lilly's Prozac (fluoxetine) in 40 mg capsules. The approvals come in the midst of patent litigation for the products.

DRL is setting up a sales and marketing organization in the US to market its 40 mg omeprazole capsules. In April, the company formed a profit-sharing deal with Pharmaceutical Resources Inc. (PRI) to co-market and develop 14 generic drugs, many scheduled to be launched in the 2002 or 2003. and which PRI's operating subsidiary, Par Pharmaceuticals Inc. will market.

DRL, which merged with Chem-inor Drug Limited in December, manufacturers bulk actives across six FDA-inspected facilities in India. DRL's generic finished dosage facility in Hyderabad, India, which has been commercially operational since 1997, will manufacture omeprazole. The facility produces oral dosage forms, hard gelatin capsules and soft gelatin capsules.

Leading Generic Manufacturers

Legend for Chart:

B - Generic Market Share 1999
C - Generic Market Share 2000E
D - Overall Market Share 1999
E - Overall Market Share 2000E

A	B	C	D	E
Mylan Labs	11.2	11.8	4.8	5.0

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