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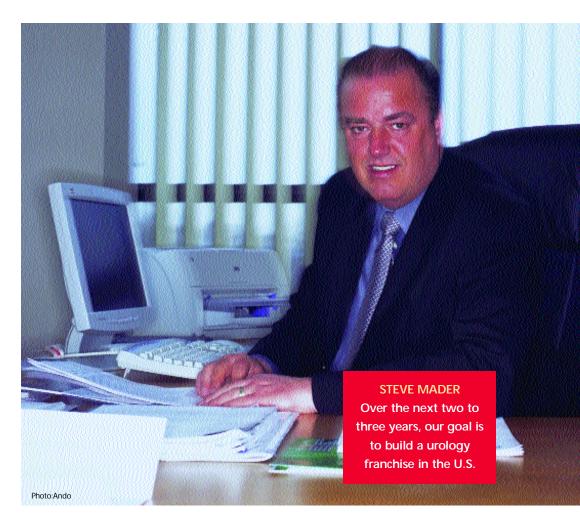
Japanese pharmaceutical companies are gaining a foothold in the highly competitive U.S. market thanks to a carefully conceived, and targeted approach

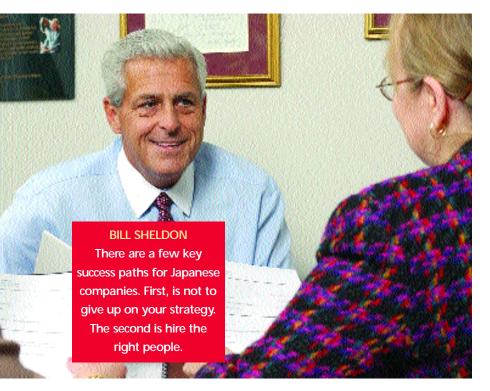
For years,

the pharmaceutical powerhouses have either been U.S. or European companies, and all have extensive operations in the U.S. Of the top 10 pharmaceutical companies, six are U.S.-based companies, the remaining four have their headquarters either in the United Kingdom or continental Europe, according to data from IMS Health. There are no Japanese companies in the top 10, despite that market's status as the second largest in the world. However, several Japanese companies are making inroads in the U.S. market, relying less on alliances and more on building their own marketing infrastructure and R&D operations.

According to Mikihiko Obayashi, Ph.D., who leads the Japan International Desk — a division of Quintiles Transnational Corp. that offers consulting services to Japanese pharmaceutical companies wishing to enter or expand in overseas markets — there are currently between 40 and 50 Japanese companies conducting clinical trials in the U.S.

"Of those, about 10 plan to register products on their own and the others will license their compound to a local company for Phase III trials or commercial development," Dr.





Obayashi says. For Japanese pharmaceutical companies to realize bottom-line growth, it is essential for them to diversify into different markets, and in particular into the huge North American market.

According to IMS Health's study Pharma Prognosis International 2001-2005 (PPI), which forecasts pharmaceutical sales in the 10 major markets of the world — the U.S., Japan, Germany, France, the United Kingdom, Italy, Spain, Canada, Australia, and Belgium — an innovation-driven U.S. will be the engine for growth in the global pharmaceutical market between 2001 and 2005. As a result, the U.S. will increase its dominance of the global market, with its 53% share of the PPI region forecast to increase to more than 60% in 2005.

PPI forecasts that the U.S. market will grow by almost 12% per year between 2000 and 2005, a rate similar to the annual growth recorded between 1995 and 2000. This growth is matched by no other developed market. Of the major European markets, only Spain will approach double-digit growth during this period, while Japan is forecast to record just 2% annual growth (See chart on page 42).

The widening of the gap between the U.S. and the rest of the world will continue a trend that has prevailed throughout the 1990s. IMS Health data show that the U.S. pharmaceutical market was roughly the same size as the European market at the start of the 1990s, but has since grown to twice the size of the European market. According to PPI, this trend looks set to continue, unless there are moves toward price deregulation in Europe and Japan. The data show that growth in the U.S. tends to be driven by value (price) rather than volume, due in part to the launch of innovative, premium-priced products. Europe and Japan have been unable to innovate to the same extent as the U.S., and as a result have fallen behind.

The Future is Now

Japanese companies have acknowledged the limitations they face by not diversifying into world markets. In the same year that Takeda set up its Takeda Pharmaceuticals North America operations, 1998, it published a report stating that measures by the Japanese government to contain healthcare costs had placed significant downward pressure on volume and pricing for domestic pharmaceutical manufacturers. Because of

discouraging prospects for growth in the Japanese pharmaceutical market, the company had decided to create a global operating structure that would enable Takeda to compete effectively with leading overseas pharmaceutical companies.

"For Japanese companies to survive, it is critical that they have a global presence," says Dr. Obayashi, who has more than 30 years of pharmaceutical industry experience. "The Japan market is large but not growing like other markets. In addition, their home market is becoming more and more competitive as major foreign companies expand their business into Japan. To have the return on research investment, Japanese pharmaceutical companies need to add value to their assets and their products in the major pharmaceutical markets."

Even with a large parent company in Japan providing its U.S. subsidiary with support, the prospect of establishing credentials, getting product recognition, and winning over the U.S. physician audience can be daunting.

"It is not easy for Japanese companies to work in a totally new environment," Dr. Obayashi says. "The culture, social system, and regulations are different from Japan. One of the most important factors when entering the U.S. market is the interaction with the FDA. Most Japanese companies do not have that direct experience and rely on alliances, consultants, or outside help from CROs."

The Payoff

With five to 10 years of U.S.-based operational experience under their belts, a few Japanese companies are starting to see their patience, perseverance, and focused strategy pay off.

"The larger companies — Takeda, Sankyo Eisai, Fujisawa — have been established for more than 10 years and are now beginning to develop and launch their products themselves in the U.S.," Dr. Obayashi says. Traditionally, Japanese pharmaceutical companies out-licensed their compounds to U.S.-based companies for marketing or entered into joint-promotional agreements with U.S. pharmaceutical companies to manage their products.

In Japan, large drug companies have an extensive list of products spanning not only the ethical pharmaceutical market, but also over-the-counter medications and other related products. However, those Japanese companies that have been successful in the U.S. market have done so by focusing on a small, select group of products.

"Fujisawa has taken a very targeted approach, focusing on marketshare growth, which has delivered to us solid bottom-line results with regard to sales," says Kurt Lewis, senior VP of marketing and sales at Fujisawa Healthcare Inc. "Fujisawa is a niche-market company, focused on the areas of transplantation, with Prograf; on nuclear cardiology, with Adenoscan; on dermatology, with Protopic, which was launched in February 2001; and on anti-infectives, with Ambisome."

With increased sales in 2001, Mr. Lewis says Fujisawa is well on the way to its goal of being a \$1 billion pharmaceutical company by 2005. Prograf, which competes against Novartis Pharmaceutical's Neoral, has been a tremendous asset for Fujisawa.

"Fujisawa is a small company in comparison to Novartis, and Prograf has become the leading immunosuppressive drug on the market," says John Schroeter, president of The Synapse Group, which handles the professional advertising for Prograf, Ambisome, and micafungin, an antifungal compound in development. "This is pretty remarkable considering the company's relative size and resources. Fujisawa has been able to take the leadership role from a very large, very well-entrenched company. If you wanted a report card of the company's ability to adapt to the North American market, particularly in highly specialized medicine, I would give Fujisawa an A. It's taken time, obviously, but the company has adapted

well. We honed in on the core differentiating benefits of Prograf and focused on specific patient populations. Fujisawa was meticulous assembling supportive clinical data, which enabled us to generate evidence-based communications. These helped erode Neoral's market share through the steady accumulation of outstanding clinical data, a focused message, and a strong sales organization."

Another major Japanese pharmaceutical company Eisai Inc., which for the year ending March 2002, exceeded \$1 billion in sales, echoes the keep-it-focused strategy.

"Eisai has about 30 products in Japan, but when the company decided to globalize the business, it picked two of the best products," says Bill Sheldon, president and chief operating officer at Eisai Inc., which has been operating in the U.S. market for 10 years. "That meant we were trying to penetrate a new market with products of superior quality. Those two products turned out to be very good indeed. Aricept is a market leader and the gold standard for Alzheimer's disease, and Aciphex is growing very rapidly and is a good PPI (proton pump inhibitor.)"

Eisai's partnership with Pfizer for Aricept has proven to be very successful, and has allowed Eisai to gain invaluable experience in the U.S. "Eisai has always taken a very active role," says Cameron Munro, senior VP, account group supervisor at Lyons Lavey

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Nickel Swift Inc., the healthcare advertising agency that is responsible for the Aricept account. "From the start, that was one of the parameters of the partnership. It's not a junior partnership situation. Obviously, Eisai teamed with Pfizer because it is such an important player in the U.S., but Eisai wanted to be equal partners and have an equal say in what happens and what goes on."

Another entrant to the U.S. market, Yamanouchi America Inc. currently is not involved in direct sales of its products. The company, through its clinical development arm Yamanouchi U.S.A., has a treatment for overactive bladder, YM905, which is in Phase III trials and is building a marketing and sales

Western Eyes on Eastern Markets

ultinational pharmaceutical companies are implementing strategies aggressively to expand their presence in Japan. Some of the biggest names in the industry, including Pfizer, AstraZeneca, Aventis and Eli Lilly, recently have made clear their intent to target the world's second-largest drug market. Their interest is being driven by the huge potential gains the companies hope to realize if they can extend their global market share in the Japanese market. This could translate into billions of dollars in additional revenue. The task is becoming more readily achievable as regulations overseeing drug development are harmonized between Japan, the U.S., and Europe.

Aventis has stated that it aims to more than double its sales in the Japanese market within the next five years, via increased sales of its biggest global products such as the allergy medication Allegra (fex-

ofenadine) and the cancer treatment Taxotere (docetaxel).

Eli Lilly and Co. intends to substantially increase its presence in the Japanese market, with a view to entering the top 25 companies by 2005 and the top 10 by 2010. The company currently is outside the top 50 in Japan, despite its global position at No. 11. Lilly plans to increase its Japanese salesforce to about 600 by 2003.

AstraZeneca also has signalled its intention to expand its presence in the Japanese market, with a pledge to become

one of the country's top 10 pharmaceutical companies by 2005. The company is currently at No. 21 with less than 1.5% of the market, compared with its global No. 4 position and 4.5% market share. In March 2001, AstraZeneca announced plans to invest almost \$50 million in expanding its Japanese manufacturing and distribution facilities in Shiga prefecture.

AstraZeneca intends to launch up to 20 new products in Japan in the next five years. The breast cancer agent,

Arimidex (anastrozole), was launched in Japan in January 2001, and the migraine treatment Zomig (zolmitriptan) received marketing approval

in June 2001. Arimidex was one of the first drugs to be launched in Japan with clinical-trial data mostly collected outside the country.

There is probably no company more intent on conquering the Japanese market than Pfizer Inc. The president of the company's Japanese operation, Alan Bootes, stated toward the end of 2000 that Pfizer's global market share of more than 7% was a "reasonable target for Pfizer's business in Japan." To achieve this goal, Pfizer probably would need to become the largest player in the Japanese pharmaceutical market, which currently is topped by local companies Takeda and Sankyo, both with market shares of just more than 5%.

In Japan, Pfizer rose to seventh place in 2000 from ninth place in 1999, with dollar sales growth of 25%, according to IMS Health's World Review; Pfizer now holds more than 3% of the Japanese market. Pfizer has become a formidable power in Japan

since its merger with Warner-Lambert — the integration of the two companies' salesforces has given the combined company a total of From 1996 to 2000, the proportion of the Japanese market held by foreign companies increased from 20% to almost 28%.

1,700 sales reps in Japan. Pfizer intends to increase this number by 500 to 600 as it rolls out as many as 10 new drugs over the next few years, giving it the largest salesforce in Japan.

This assault on the Japanese market has been gaining momentum in the past few years as regulatory changes have

begun to alter the operating environment in Japan for foreign pharmaceutical companies.

From 1996 to 2000, the proportion of the Japanese market held by foreign companies increased from around 20% to almost 28%. Although this percentage is still low (in contrast, foreign companies account for more than 60% of the major European markets), it is significant that it has risen so dramatically in the last five years, after a long period of nongrowth. This is partly due to the multinational companies choosing to promote and market their drugs themselves in Japan, rather than license them to local companies. Currently, about 30% of the Japanese market consists of drugs of foreign origin marketed by local companies. As this proportion drops, the proportion of the market held by international pharmaceutical companies will grow.

AstraZeneca intends to launch up to 20 new products in Japan in the next five years. organization in preparation for the launch of that product. The company expects to submit the NDA for YM905 some time in 2004. Yamanouchi is following its Japanese peers into focused, specialty markets.

"We're going to start off in the urology field where Yamanouchi has experience," says Steve Mader, senior VP of sales and marketing at Yamanouchi America. "Over the next two to three years, our goal is to build a urology franchise in the U.S. We have already recruited, and will continue to recruit, people with U.S. pharmaceutical experience."

People Power

Regardless of the efficacious quality of the product, Japanese companies have little hope

of achieving penetration in the North American market without a focused business plan and workforce.

In addition to hiring quality staff, Dr. Obayashi says companies that globalize the development process also are likely to see a better return on their investments.

"By beginning Phase I with a global strategy, time and money can be saved," he says. "Studies then do not have to be duplicated and registrations in multiple geographic regions are possible if the plan is valid and properly implemented."

"There are a few key success paths for Japanese companies," Mr. Sheldon says. "The first is not to give up on your strategy, stay the course. The second is to hire the right people.

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To be a success, a company needs to have experienced people who care about creating a successful business. And because the business is small in the beginning, it is essential to have people who are willing to roll up their sleeves and get the job done.

"Eisai has hired people who are entrepreneurial, and who care about the outcome," Mr. Sheldon says. "Because we have such a small company compared with most pharmaceutical companies — we now have around 700 people on staff — our employees believe they can do something that will advance the business. And the truth is, they can. Because we have hired technically good people who care, we have found that we tend to get things right the first time around."

With the recent agreement on international harmonization of requirements for clinical-trial data, the presence of foreign companies in the Japanese market is likely to increase even further and more dramatically in the next few years, as multinationals find it easier to launch their products in Japan. One barometer of the changes taking place in the Japanese mar-

ket is the increasing presence of contract research and sales companies, which foreign companies are hiring to deal with the flood of new product approvals expected. Quintiles Transnational Corp., a contract pharmaceutical services organization, expects to increase its Japanese workforce to 1,200 in 2002 from 300 people in 1999.

Many industry experts believe that this increase in activity by international companies could lead to a realignment of the industry in Japan, with local companies being forced to merge

entry to the market. The relatively cheap valuations of Japanese companies and the steady unraveling of their complex cross-shareholding arrangements have begun to make them attractive acquisition targets. Some signs of such a realignment already are appearing, with foreign ownership of leading

or be acquired by foreign rivals seeking a quick

Japanese companies showing signs of increasing.

For example, foreign investors now hold more than

10% of Yamanouchi Pharmaceutical Co. Ltd. and Chugai Pharmaceutical Co.

40% of Yamanouchi Pharmaceutical Co. Ltd. and Chugai Pharmaceutical Co. Ltd., both of which are top 10 Japanese companies.

In October 2001, Nippon Boehringer Ingelheim Co. Ltd., the Japanese subsidiary of Boehringer Ingelheim GmbH, the world's largest privately held pharmaceutical company, announced that its equity stake in SSP Co. Ltd., a major listed Japanese pharmaceutical company, had exceeded 50.0%.

Schering AG's wholly owned Japanese subsidiary, Nihon Schering K.K., acquired all outstanding shares of the Japanese pharmaceutical company Mitsui Pharmaceuticals Inc. Similar to Schering AG's therapeutics business segments, Mitsui Pharmaceuticals is focusing on the three main areas of oncology, cardiovascular and central nervous system.

Nevertheless, analysts say it probably is too early to talk of a full-scale

wave of acquisitions of Japanese pharmaceutical companies. For many years, industry observers, in particular investment bankers, have talked up the need for consolidation within the Japanese pharma industry, and little has happened. The idea of a merger with a compatriot is anathema to many Japanese executives, never mind an acquisition by a foreign

company. Furthermore, although the profitability of Japanese pharmaceutical firms is poor by global standards, it is relatively healthy compared with other domestic industries, and Japanese pharmaceutical share prices continue to do well. Therefore, most Japanese companies believe there is no need to merge or be acquired.

In response to the intensified competition from multinational pharmaceutical companies, Japanese

companies have begun to form loose alliances. Chugai, for instance, has stated that it is ready to discuss a partnership with a foreign company to strengthen its technology, R&D, and marketing capabilities.

In July 2001, Shionogi & Co. Ltd. and GlaxoSmithKline signed a letter of intent to establish joint ventures to develop and market their compounds, such as new agents to fight against HIV and neurological disorders. The joint-venture company, Shionogi-GlaxoSmithKline Pharmaceuticals LLC, is engaged in arranging development, manufacture, and marketing in the U.S. This agreement is described as a move to increase Shionogi's globalization as opposed to GlaxoSmithKline's footing in Japan.

August 2001 —
Yamanouchi and Taisho
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In August 2001, Yamanouchi and Taisho Pharmaceutical Co. Ltd. announced an early-stage R&D alliance. The two companies are hoping that their pooling of talent and resources will result in faster, more efficient drug development. But this is as much a reaction to the likelihood that a soon-to-be revamped drug-pricing regime in Japan will reward innovative drugs with higher prices, as to try to match the threat of better-financed foreign drug development.

Source: IMS Health, Sept. 17,2001, World Review 2001

Fujisawa: on its way to \$1 billion



JOHN SCHROETER. If you wanted a report card of the company's ability to adapt to the North American market, particularly in highly specialized medicine, I would give Fujisawa an A. It's taken time, but the company has taken a very methodical approach and adapted well.



kurt Lewis. With increased sales in 2001, Fujisawa is well on the way to reaching its goal of being a \$1 billion pharmaceutical company by 2005.



PETER LABADIE. The fact that Fujisawa has had some very successful brand launches over the last eight years is testimony to the value that effective product branding brings to the success of the corporate brand.

Additionally, Eisai has hired and trained a large specialist salesforce. "We have the largest neurology salesforce in the U.S.," Mr. Sheldon says. "All of our reps are specialty reps and, given the importance of neurology to Aricept, having the largest neurology-specific salesforce in the country has certainly helped move the business forward."

Eisai has worked hard at building the company with the ultimate goal of becoming a fully integrated U.S. pharmaceutical company.

"Eisai is very close to achieving that goal," Mr. Munro says. "The company originally didn't do manufacturing in the U.S., but has since taken on that role. It's an incredible success story."

Mr. Sheldon credits the parent company in Japan for helping Eisai Inc. achieve success in the U.S. "There are a variety of reasons why we've made progress in becoming a fully integrated and successful pharmaceutical business in the U.S. One of them is we've had very strong support from the parent company. Eisai wanted to globalize about 15 years ago and believed the U.S. was the most important market to make that a reality. Therefore our parent company has given us a great deal of financial and psychological support along the way. Senior-level managers have been empowering and encouraging, which all of our staff here in America have appreciated a great deal.

They have been stalwart in their support, which has meant that we could set up a longer-term strategic plan.

"Finally, there is the mission of the company, human healthcare, which on the surface would seem very similar to every other pharmaceutical company, but is far different to us," Mr. Sheldon says. "It is not just about making good pharmaceuticals and selling them at a profit, it's about doing many things that we expect to make no money from. We do at least 20 free programs per year in service of healthcare that lead our employees to understand that Eisai is not just a money-making venture."

Fujisawa also is following a targeted approach to establishing a U.S presence. "We have a very targeted sales organization, with individuals who are highly trained," Mr. Lewis says. "We continuously train our reps on the latest clinical data to bring value to our customers."

As part of that focus, Fujisawa is actively involved in the promotion of its own products.

"Fujisawa has a marketing staff that works with us daily to develop brand communications, whether it's salesforce communications, or mail, or advertising, or consumer promotion," says Peter Labadie, president of Williams-Labadie, the healthcare advertising agency assigned the professional promotional responsibilities for Protopic, Adenoscan, Ade-

nocard, and the consumer advertising for Prograf. "As Fujisawa has grown and expanded, it has added marketing staff accordingly, and the U.S. business is managed very skillfully."

Fujisawa, similar to other Japanese pharmaceutical companies, has overcome the initial obstacle of making its name known to a U.S. audience.

"Perhaps 10 years ago Japanese companies were concerned that they would be unknown, or that customers might not accept them readily in the U.S, but I don't think that is true any longer," Mr. Labadie says. "As more and more Japanese companies have globalized their marketing efforts and launched their own pharmaceutical products in the U.S. market, they've found the 'corporate' brand is less of a factor, if the 'product' branding job is done right. The fact that Fujisawa has had some very successful brand launches over the last eight years is testimony to the value that effective product branding brings to the success of the corporate brand."

According to Mr. Schroeter, Fujisawa's programs have become progressively more sophisticated, and that may be a manifestation of the company's growing comfort level in marketing to a U.S. audience.

'Fujisawa's programs for Prograf are unique in many ways," Mr. Schroeter says. "The traditional venues of journal advertising, while that's a component, are much less of a significant issue than in other markets. One of the things that Fujisawa did exceptionally well was to form a very effective medical science liaison group under Richard Miller. The group communicates directly with key decision makers, disseminating data, and facilitating clinical development. The sophistication of the company's programs has gone from fairly traditional to very innovative. We're working with the company now on a large-scale, 3,000-patient electronic chart review, using computer technology to rapidly collect large amounts of clinical data and perform online statistical analysis to develop peer-reviewed publications. The company also developed innovative DTC programs, which were a first in the transplantation market.'

Like their U.S. counterparts that are increasing the size of their field forces, Takeda Pharmaceuticals North America, another Japanese pharmaceutical company with a U.S. presence, announced in December 2001 that it plans to add 180 representatives to its salesforce bringing the total to 1,000 reps.

Yamanouchi, meanwhile, is starting to build its America operations and currently has around 50 employees at its Paramus, N.J., headquarters. "We have staff in the areas of clinical development, administration, and seven people in marketing and sales," Mr. Mader says. "We'll make strides to build the salesforce up this year to a higher number, around 20 or 30, and as we get closer to the

launch of YM905, we will build as the need arises."

Alliance Power

Helping to propel the growth of Japanese pharma companies in the U.S. market are the co-promotion partners with which they work. Even as Japanese companies continue to establish a marketing presence in the U.S., several continue to work in concert with established U.S.-based companies to promote their products.

One of the most highly visible alliances is the one between Abbott Laboratories and Takeda

Chemical Industries Ltd., which resulted in the formation in 1977 of TAP Pharmaceutical Products Inc., a "virtual" pharmaceutical company. At its inception, TAP acquired compounds solely from Takeda, but today TAP works with both Abbott and Takeda, and searches the world for in-licensing opportunities, focusing its efforts on rapid, high-quality drug development, and marketing and sales in North America. Meanwhile, to promote its first product on the U.S. market, Actos, Takeda Pharmaceuticals North America enlisted the help of Eli Lilly and Co.

Eisai, too, has turned to large U.S. and European pharmaceutical companies to jointly promote its products — Pfizer Inc. for Aricept and Janssen Pharmaceutica for Aciphex.

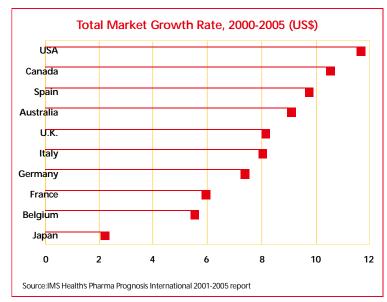
"Our co-promotion partners have helped us to sustain the launch of our products and continue our strong performance in the U.S.," Mr. Sheldon says. "Janssen has a long history in the gastrointestinal therapeutic area, and Pfizer has a significant presence in the CNS market-place."

One company that has broken away from the co-promotion strategy is Fujisawa.

"Fujisawa is really a pioneer among Japanese companies," Mr. Schroeter says. "The model always has been that the Japanese company would partner with a U.S. organization, provide the drugs, and sit behind the scenes. Fujisawa began that way — collaborating with SmithKline Beecham. But at any early point, the company decided it was going to fly under its own flag. In that regard, Fujisawa is very much a pioneer among Japanese pharmaceutical companies. It took a bold step to become a force unto itself in the U.S., and to carve out a market niche."

In February 2002, Fujisawa entered an agreement with Sucampo Pharmaceuticals Inc. giving Sucampo exclusive license to Fujisawa's flagship compound, tacrolimus, for ophthalmic use in the U.S., Europe, and much of the world, except Japan, Korea, Taiwan, and China.

Fujisawa markets tacrolimus in many countries as Prograf for the prevention of



organ graft rejection and as Protopic for the treatment of atopic dermatitis.

Opportunities of Their Own

As Japanese companies become more established in the U.S. market, a few are starting to field their own marketing opportunities. Last October, Fujisawa announced that Atrix Laboratories Inc. had granted Fujisawa North American marketing and distribution rights to Atrisone, a dermatological product currently in Phase III trials in the U.S. for the treatment of acne and in pilot studies for additional indications. Atrisone provides Fujisawa an opportunity to broaden its product offerings in dermatology by entering the \$500 million U.S. topical acne market.

"With the launch in February 2001 of Protopic, we established ourselves in the dermatological market," Mr. Lewis says. "We are looking at a number of other dermatological in-licensing and co-promotion opportunities."

Japanese pharma companies have started to build a strong manufacturing as well as R&D presence in the U.S. Eisai's manufacturing operations at Research Triangle Park, N.C., were expanded last May, and, Mr. Sheldon says operations will undergo another expansion this year.

"The longer-term plan has been for us to manufacture and package the products sold in the U.S. in the states, and we've been moving in that direction," he says. "We now produce all of Aricept in the U.S. and most of Aciphex."

The R&D division at Fujisawa consists of about 100 people working on Phase II, Phase III, and Phase IV studies.

In addition to its Yamanouchi America division, the company's U.S. operations include Yamanouchi Pharma Technologies Inc. in Palo Alto, Calif., and Manufacturing Center in Norman, Okla. YPT is principally involved in the development of the company's drug-delivery technologies. Central to that is Wowtab, which is an orally disintegrating tablet that is designed to be taken without water.

"The operations in California and Oklahoma are separate from Yamanouchi America — based in New Jersey," Mr. Mader says. "Our goal is to bring everybody into one company in America — Yamanouchi Pharma. We'll roll that in as we get ready to launch YM905."

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmalinx.com.

Experts on this topic

PETER LABADIE. President, Williams-Labadie, Chicago; Williams-Labadie is a full-service healthcare advertising agency KURT LEWIS. Senior VP, marketing and sales, Fujisawa Healthcare Inc., Deerfield, Ill., a subsidiary of Fujisawa Pharmaceutical Co. Ltd of Osaka, Japan; Fujisawa Pharmaceutical is a leading pharmaceutical manufacturer with operations in North America, Japan, Europe, and Asia

STEVE MADER. Senior VP, marketing and sales, Yamanouchi America Inc., Paramus, N.J., a subsidiary of Yamanouchi Pharmaceutical Co. Ltd.; Yamanouchi is the third-largest pharmaceutical company in Japan CAMERON MUNRO. Senior VP, account group supervisor, Lyons Lavey Nickel Swift

Inc., New York; Lyons Lavey Nickel Swift is a full-service healthcare advertising agency MIKIHIKO OBAYASHI, PH.D. President, Japan International Desk, Princeton, N.J.; JID is a division of Quintiles Transnational Corp, a leading provider of information, technology, and services to the healthcare industry JOHN SCHROETER. President of The Synapse Group, Burlington, Ontario; The Synapse Group is a full-service advertising agency

BILL SHELDON. President and chief operating officer, Eisai Inc., Teaneck, N.J.; Eisai Inc. is the U.S. pharmaceutical operations of Eisai Co. Ltd. of Japan, which discovers, develops, and markets products in more than 30 countries