MEDRx Co., Ltd

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FISCO Ltd. Analyst
Yuzuru Sato

A Drug Discovery Venture That is the First in the World to Develop ILTS® Using Ionic Liquid

MEDRx Co., Ltd. <4586> is a drug discovery venture that has lead the world in developing a transdermal drug delivery technology using ionic liquid called ILTS® (Ionic Liquid Transdermal System). Use of ionic liquid enables the development of transdermal drug delivery formulations for substances that have previously presented difficulty for transdermal delivery, such as drugs with low solubility or high molecular compounds (peptides, nucleic acids). The Company is aiming to launch transdermal drugs using ILTS® in the US. It is also advancing development of drug formulations using advanced technologies such as microneedles and nano colloids.

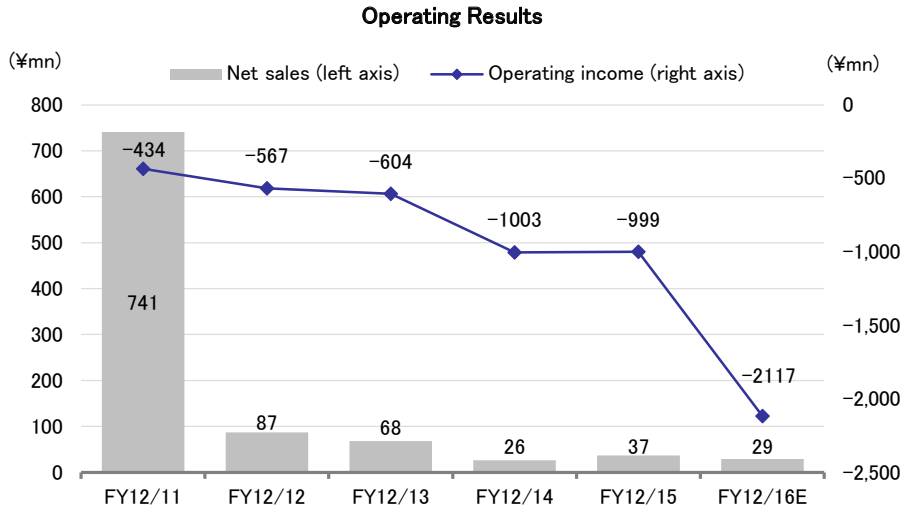
ETOREAT®, a topical patch for alleviating pain caused by inflammation, is the product that is closest to market launch. Additional Phase III clinical trials are planned for 2016, and if they proceed smoothly, the Company expects to file for manufacturing and marketing approval in early 2017, and to receive approval in 2018. The Company expects to receive milestone revenue of ¥1.05bn from sales and marketing alliance partner Kowa Company Ltd. when the approval application is filed, with a further ¥1.5bn to be received when approval is granted. The market for topical patches for inflammation pain relief in the US is worth around US$1bn, but only includes poultices (aqueous formulation). Since ETOREAT® is a tape (non-aqueous formulation), it has the potential to quickly capture market share if it is launched there, due to its high convenience. If oral formulations are included, then the potential market scale expands to around US$2-3bn, and the future direction of the Company in this regard will bear watching.

Another of the Company's powerful pipeline drugs is MRX-1OXT, a topical patch for relieving moderate to severe pain. MRX-1OXT uses ILTS® technology to create a tape formulation of oxycodone, a drug which makes up more than 50% of the US opioid (narcotic-based analgesic) market. Preclinical trials of MRX-1OXT started in November 2015, and the Company plans to move to Phase I clinical trials as early as the end of 2016. The US oxycodone market is large at approximately US$2.3bn, and there are no transdermal patch formulations yet. If it can be launched as a tape formulation, there should therefore be plenty of room to expand sales.

Other pipeline drugs that are scheduled to start clinical trials in the US from 2016 onwards include MRX-4TZT, a drug for alleviating spastic paralysis, and MRX-5LBT, a drug for alleviating nerve pain. This is expected to significantly increase R&D expenses for FY12/16 by 2.6 times compared with FY12/15 to ¥1,878mn. Operating loss is also expected to expand from ¥999mn in FY12/15 to ¥2,117mn in FY12/16. The Company is currently in its development stage and therefore continues to record operating losses. However, if ETOREAT® clinical trials proceed steadily and market launch is achieved, the Company should see its earnings transition to the growth stage.

Check Point

- MRX-1OXT licensing contract concluded for sales in the US as early as 2017
- Four pipeline drugs for the US market currently in development
- In-house product Iodocoat ® Ointment 0.9% contributing to increased sales



■ Company Profile

Established in 2002 with the objective of developing transdermal drug delivery formulations

(1) Company history

The Company was founded by its current President & CEO, Masayoshi Matsumura, in Kagawa Prefecture in 2002 as a drug discovery venture company for developing transdermal delivery formulations. Prior to establishing the Company, Masayoshi Matsumura spent many years working at Teikoku Seiyaku Co., Ltd. where he contributed to the development of poultices (aqueous formulation).

After its establishment, the Company continued to develop new drugs, launching Iodocoat ® Ointment 0.9%, a treatment for bed sores and skin ulcers, in August 2005 in Japan. Subsequently, the Company has been promoting operations with the basic strategy of focusing on development of pharmaceutical products using ILTS®, a transdermal drug delivery technology using ionic liquid, aiming to launch it in the US. In 2007, the Company established the subsidiary IL Pharma Inc. as a base for conducting clinical trials in the US. (IL Pharma Inc. was absorbed by merger with the newly established MEDRx USA INC. in 2015). Then, in 2009 the Company formed a joint venture, KM Transderm Ltd. (49.0% equity stake), with KANEKA CORPORATION <4118> with the goal of mass producing the transdermal drug delivery formulation ETOREAT®, a topical patch for alleviating pain caused by inflammation developed in-house.

ETOREAT® is a tape-type transdermal formulation for pain relief from mild to moderate inflammation. Clinical trials in the US started in 2010, and in 2011 exclusive US marketing rights were licensed to Kowa Company Ltd. Phase III clinical trials were completed in May 2014, but the US Food and Drug Administration (FDA) requested further trials. In a statistical analysis of a trial group (PP: per protocol) of 211 subjects who were administered the drug according to the protocol (clinical trial plan), a statistically significant difference was recognized for effectiveness in the cumulative pain score, which was the main evaluation point, compared with a placebo group. Nevertheless, in a statistical analysis of a group all of the 225 subjects who participated in the trial (ITT: intention to treat), the difference was slightly below the level for recognition as a statistically significant difference. This prompted the request for additional trials. As a result, the Company is currently in discussion with the FDA regarding a protocol for conducting two additional trials in 2016.

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Moreover, in December 2015, the Company concluded a manufacturing agreement with US company The Tapemark Company (hereinafter "Tapemark") to start clinical trials of MRX-1OXT (oxycodone* tape) in the US. Tapemark is a contract development and manufacturing organization providing manufacturing for drugs and medical devices. It has over 60 years' experience in the development and manufacture of transdermal topical patches. The Company will transfer the MRX-1OXT manufacturing technology to Tapemark and proceed with Phase I clinical trials.

To promote smooth clinical trials in the US, in October 2015 the Company concluded consulting contracts with three experts in the field of pharmaceutical development. The consultants' previous experience includes positions such as a former director of the anesthetic, analgesic, and toxic drugs department of the FDA, a former FDA advisory committee chair, and a former chair of the expert subcommittee on clinical trials for the American Pain Society. Their various advice is expected to enable smooth progress in future clinical trials in the US for the development pipeline.

Company History

Date	Main events in the Company's history
January 2002	MEDRx Co., Ltd. established in Higashi Kagawa City, Kagawa Prefecture, with the objective of developing transdermal drug delivery products
August 2005	Launched sales of Iodocoat ® Ointment 0.9% for treatment of bed sores and skin ulcers
October 2007	Established IL Pharma Inc. in the US as a subsidiary for clinical development in the US Absorbed by merger with MEDRx USA INC. in September 2015)
September 2009	Established a new joint venture company, KM Transderm Ltd., with KANEKA CORPORATION. in Osaka
July 2010	Start of clinical trial in the US of ETOREAT ® topical patch for alleviating pain caused by inflammation
March 2011	Conclusion of exclusive license agreement with Kowa Company Ltd. for marketing ETOREAT® topical patch for alleviating pain caused by inflammation in the US
February 2013	Listed on Tokyo Stock Exchange Mothers Index
December 2013	Start of Phase III clinical trial in the United States of ETOREAT® topical patch for alleviating pain caused by inflammation (completed in May 2014)
April 2015	Established MEDRx USA INC. as a subsidiary for developing ethical pharmaceutical products in the US
October 2015	Concluded consulting agreements with three experts to promote development of pharmaceutical products at US subsidiary
December 2015	Concluded manufacturing agreement for MRX-1OXT with US company The Tapemark Company

Source: Created by FISCO based on securities reports and MEDRx's published materials

Different uses for ILTS® and NCTS® technologies, promoting new drug development

(2) Businesses outline

The Company is developing patch and ointment formulations based on the conventional active ingredients of oral and injected medicines, using its proprietary transdermal drug delivery technologies. Transdermal drug delivery formulations have several characteristics: i) it achieves the sustained release and continuity of the active ingredient; ii) the drug is not affected by the first pass effect (oral drugs have a higher risk of reduced efficacy after passing through the liver and side effects); iii) transdermal drug delivery also increases compliance (enables administration to patients who are unable to swallow, prevents people from forgetting to take their medicine, etc.); and iv) it is also painless. The Company aims to develop new drugs that can provide new added value in areas that capitalize on these characteristics (maximizing drug efficacy, reducing side effects, improving patient quality of life (QOL), and enhancing convenience for medical professionals). Target fields of application for transdermal are mainly centered on pain; however, pharmaceutical products have also been marketed in the fields of Alzheimer's disease, Parkinson's disease, depression, hyperactivity disorder, and overactive bladder. The Company is also targeting these fields for development.

As a business model, the Company's process for bringing its pipeline candidate drug formulations to market includes forming agreements for development, sale, and manufacture with pharmaceutical companies and so forth, and receiving one-time contract payments, milestone revenue in accordance with development progress, and product sales and royalty revenue after the product has been launched. The Company's basic policy is to conduct clinical trials itself, and although this incurs initial R&D expenses, the return on products that are launched is amplified.

* Oxycodone is a type of central analgesic (acts on the central nerves in the brain and the spinal cord to relieve pain) and is a designated ethical drug. It is used for relieving severe acute pain, chronic pain, and cancer pain. Since it is an ethical drug, imports in the US are banned, making it necessary to secure a manufacturing site in the US to conduct clinical trials and so forth.

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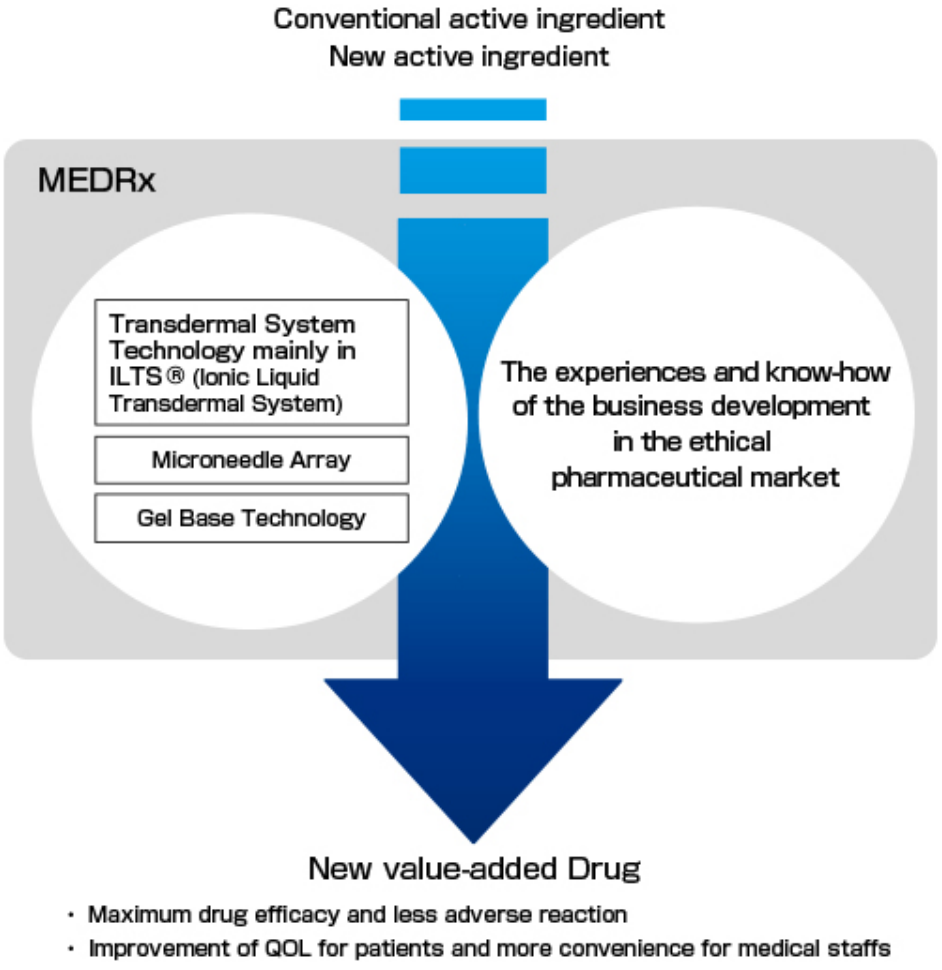
Business Outline



Source: Company HP

The Company's main drug formulation technologies are transdermal drug delivery technology using ILTS®, transdermal drug delivery using nano colloids (NCTS®), and microneedle arrays.

○ **ILTS® (Ionic Liquid Transdermal System)**
ILTS® has been developed by the Company and is a transdermal drug delivery technology that uses ionic liquid. Ionic liquid refers to salts that keep liquid form at temperatures of 100°C or below, and generally has various features such as low melting point, high ionic conductivity, high polarity, and non-combustibility. Currently, its main application is as a raw material for industrial products such as solar cells and lithium-ion batteries. The Company focused on the properties of such ionic liquid and succeeded in utilizing them for drug formulation technologies in pharmaceutical products. Converting a drug into an ionic liquid, or dissolving a drug in ionic liquid, enables a dramatic improvement in the drug's transdermal absorbability. As a result, high polymers such as nucleic acid and peptides, which have traditionally been difficult to absorb via the skin due to their low solubility, can now be delivered transdermally by converting them to ionic liquid. There are also a wide range of drug candidates for development as new drugs.

The Company has an ionic liquid library consisting of between 100 and 200 types of with proven performance in use on the human body. It also has know-how for designing ionic liquid preparations so that the absorbability of the drug is improved, and know-how for transforming ionic liquids containing drugs into the preferred preparation forms (e.g., topical patches and ointments) while retaining the drug properties. The Company has obtained drug patents for each of the items it has developed.

The Company's main current development pipelines are ETOREAT®, MRX-1OXT (a central analgesic), MRX-5LBT (a drug for alleviating nerve pain associated with shingles), and MRX-4TZT (a drug for alleviating spastic paralysis).

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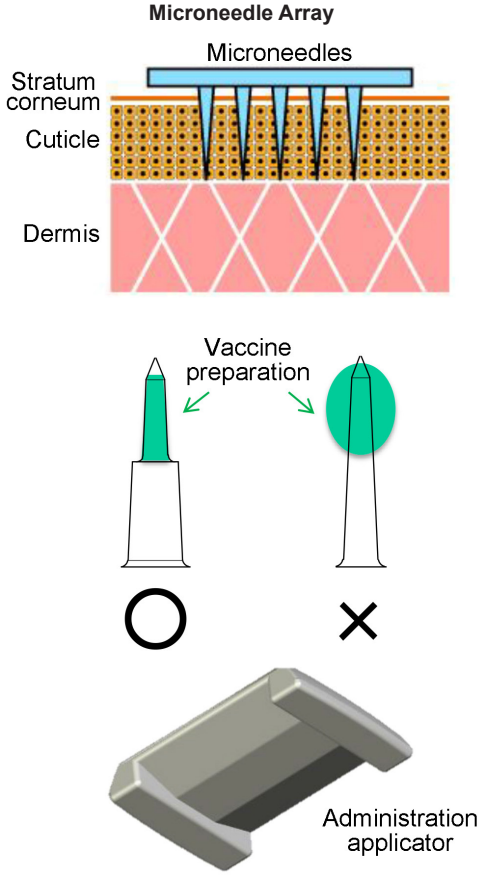
○ **NCTS®（Nano Colloid Transdermal System）**
NCTS® is a transdermal drug delivery technology that uses nano colloids. Nano colloids are formed by ultra-refining particles to around 100 nanometers in diameter so that they become liquid. Converting a drug into a nano colloid has two characteristics: 1) it enables high transdermal absorption and 2) preparing the liquid as a topical patch should enable it to take effect immediately.

The current development pipeline includes' MRX-4MIGL (a migraine treatment), and MRX-5DML (an Alzheimer's disease treatment). The migraine treatment was adopted as a supported project for the Fiscal 2013 Innovation Commercialization Venture Support Project of the New Energy and Industrial Technology Development Organization (NEDO) in fiscal 2013, and has been developed with grant funding (support period: May 2014 to Feb 2015; grant funding recorded as extraordinary income in FY12/15). The Alzheimer's disease treatment is currently being developed based on a drug marketed by Pfizer Inc. Preclinical trails are to be held later, but animal experiments have confirmed the transdermal absorption action of the drug formulation.

The Company's policy is to separate application of the two technologies, ILTS® and NCTS®, in accordance with the properties of the drugs, as it proceeds with development of new drugs.

○ **Microneedle array**
The microneedle array is a body of microneedles of length 500-600μm and diameter 10-30μm made from biodegradable plastic. It is a device for painlessly administering via the skin vaccines, nucleic acid medical drugs and protein medical drugs that can only be administered by injection today. They are also being developed by NIPRO CORPORATION <8086>, FUJIFILM Corporation <4901>, and 3M Company, among others; however, there are no practical applications in the pharmaceutical field as yet. The challenges are application of the drug to the needles and reliable puncturing of the skin surface. Puncturing requires pointing of the needles inn a perpendicular direction to the skin surface, and this challenge has yet to be overcome.

The Company has approached this challenge by designing the needle shape and developing an applicator for pointing the needles perpendicular to the skin surface. In this way, the challenge has already been overcome technically. However, the joint development partner, Teijin Pharma Limited <3401>, dissolved the collaborative alliance in October 2015 for reasons of business strategy. The Company is therefore currently seeking a new alliance partner in Japan, and having narrowed the field to several candidate companies, now plans to proceed with negotiations.



■ Development Pipeline Direction

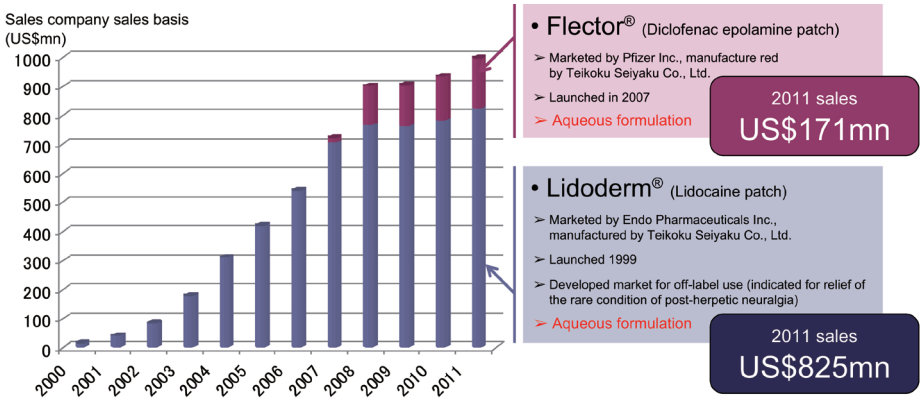
Later non-aqueous formulation (tape) extends share

(1) ETOREAT® (Etodolac tape)

Etodolac is a non-steroidal anti-inflammatory drug (NSAID) that is used extensively worldwide as an oral treatment for pain and inflammation. MEDRx's ETOREAT® is the world's first version commercialized for use as a topical patch. As mentioned above, currently the Company is currently in discussion with the FDA regarding protocols for additional Phase III trials. A trial method that has currently been agreed on involves inducing delayed onset muscle soreness in healthy test subjects by artificially creating stress on muscles. The effectiveness of ETOREAT® will then be checked by monitoring any reduction in pain in comparison with a placebo. The number of cases is still under discussion and has yet to be determined; however, if a statistically significant difference is recognized in the first additional trial to be held in the first half of 2016, and the second additional trial, to be held in the second half, then the Company plans to file for manufacturing and marketing approval from the FDA in the first half of 2017. The expenses for the additional trials are currently in flux as the number of cases has not yet been determined; however, the two trials combined are expected to run to around ¥1bn.

The US market for topical patch treatments for mild to moderate pain due to inflammation was approximately US$1.0bn as of 2012, and the potential market including oral medicines and so forth appears to be worth around US$2.0bn-3.0bn. Topical patch formulations currently available in the US included Lidoderm® (marketed by Endo Pharmaceuticals Inc.) and Flector® (marketed by Pfizer Inc.). Since both are poultices (aqueous formulations) the tape ETOREAT® (non-aqueous formulation), if approved, would have ample scope for sales expansion. The reason is that tape offers greater convenience compared with poultices, superior adhesion performance, even in joint areas, and requiring only one application per day (poultices require two applications per day), for example. Looking at the case of Japan, in 1998 the lion's share of the topical patch market was held by poultices, but by 2010 tape had become the mainstream, accounting for just under 70% of the market by volume, and appears to be taking the lead role in the market. In the US, the sale price of poultices is around US$6.00 each, which is significantly higher than Japan (¥20-30). In this sense too, the US market represents an attractive market with plenty of scope for the Company to enter.

Current Status of the US Market for Topical Patches to Treat Mild to Moderate Pain



• Visible market: US$1bn → Potential market: US$2bn – 3bn (FISCO estimate)

Source: Company materials

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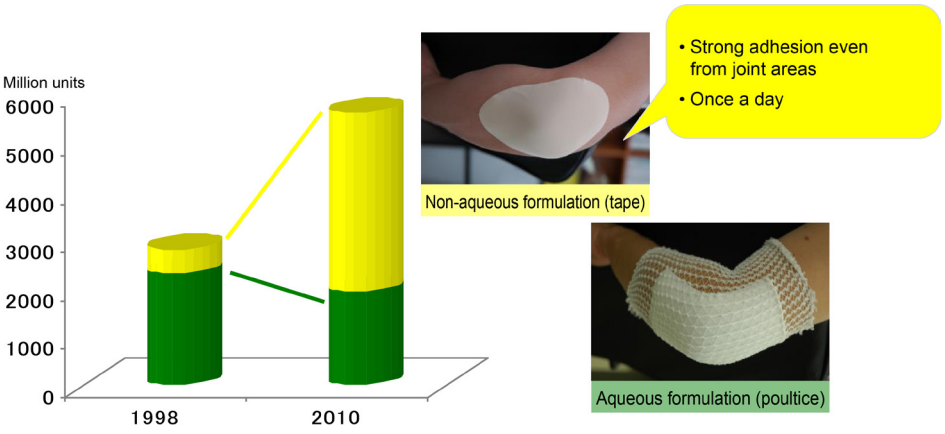
Japanese Market Changes – Tape vs. Poultices



Later non-aqueous formulations (tape) have increased share as the market expanded

Source: Company materials

Looking ahead, the milestone revenue to be received from marketing alliance partner Kowa Company Ltd. under the agreement is ¥1.05bn on filing for approval, ¥1.5bn on obtaining approval, and 5% of annual net sales if they reach a predetermined amount. In addition, the Company is also to receive royalty income from Kowa Company Ltd. on product sales. With regard to manufacture, the agreement stipulates that Yutoku Pharmaceutical Ind. Co., Ltd. is to produce up to 50 million units per year, with any portion in excess of 50 million units to be manufactured by the Company's equity method affiliate, KM Transderm Ltd.

Licensing contract concluded for sales in the US as early as 2017

(2) MRX-1OXT (Oxycodone tape)

MRX-1OXT (central analgesic) is an oxycodone tape-type transdermal patch formulation. Through ILTS®, the Company has succeeded in dramatically increasing the poor transdermal absorbability of oxycodone and developed a formulation. Preclinical trials began in the US in November 2015 and the Company plans to start Phase I clinical trials as early as the end of 2016. Having established safety for the human body, the presence of any side effects, and proof of concept (POC)* through these trials, the Company plans to conduct sales licensing activities. Therefore, if the Company makes steady progress, it is possible that the Company could also conclude a sales licensing agreement in the US in 2017 as well.

The clinical trial of MRX-1OXT appears to have proceeded smoothly compared to ETOREAT®, since the drug efficacy of ETOREAT® is confirmed by the subjective judgement of the subjects (whether the pain subsided or not), while for MRX-1OXT the drug efficacy is determined objectively by the blood levels of oxycodone. Another positive factor this time is receiving the advice from a clinical development expert in the field of pain who was newly contracted in the US.

The US market for pain relief is valued at more than ¥1.0tn each year. Within this, opioid analgesics, which are used for moderate to severe pain such as during and after surgery or cancer pain, accounts for ¥447.0bn or approximately 39%, and within this, OxyContin®, which uses oxycodone as the drug agent, accounts for ¥240.0bn. Other than oxycodone, there are morphine and fentanyl, of which only fentanyl is marketed as a patch formulation (market scale of around ¥100.0bn). Since the efficacy of each drug varies by patient, they are segregated.

* POC: Proving the envisaged effect of a drug in foundational research through trial administration to actual animals or people.

The oxycodone oral medicines require twice daily administration whereas the tape formulation needs to be administered only once every 1 to 3 days. Moreover, since it is a formulation that accords with the proposed guidance on prevention of opioid overuse announced by the FDA in January 2013 (a formulation from which the narcotic component cannot be extracted for use in other purposes), and since it provides increased convenience as a topical patch formulation, MRX-1OXT is expected to find significant demand if it is marketed, and its development status will be of interest going forward.

Scale of the Pain Market

(¥bn)

2014	US	Japan	Europe
Pain Market	1131	379	511
Opioid Market	447	79	177
Opioid Market Share	39%	21%	35%
OxyContin® Sales	240	10	19
Share of the Opioid Market	54%	13%	11%

Source: Total Planning Center Osaka corp.
Forex rate: ¥105/US dollar, ¥140/euro

Off-label prescription demand expected after market launch

(3) MRX-5LBT (lidocaine tape)

MRX-5LBT is a product that uses ILTS® technology to prepare the local anesthetic lidocaine for transdermal delivery. It has the same properties as Lidoderm®, a drug for alleviating nerve pain associated with shingles, and is expected to improve convenience and safety when used. The Company has already obtained patents for the product in the US, and filed with the FDA for permission to begin clinical trials in February 2016.

Given the low number of target patients for a drug for alleviating nerve pain associated with shingles, annual demand is modest in the order of several hundred million yen. However, at its peak, Lidoderm® had considerable annual US sales of \120.0 bn. Most of these were due to off-label prescription use to treat mild to moderate pain associated with inflammation. Since MRX-5LBT has the same characteristics as Lidoderm®, it is expected to generate off-label prescription demand after its launch.

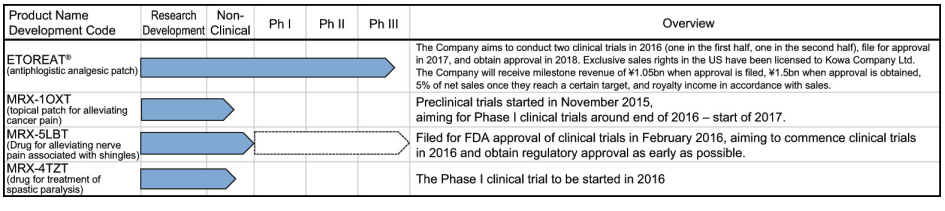
US tizanidine market valued at tens of billions of yen

(4) MRX-4TZT (tizanidine tape)

MRX-4TZT has been developed as a tape-type topical patch formulation of the central muscle relaxant tizanidine with ILTS® technology. Tizanidine is used to alleviate discomfort from shoulder stiffness, back problems, spastic paralysis, and post-operative muscle rehabilitation.

MRX-4TZT is currently undergoing preclinical trials with Phase I clinical trials expected to start in 2016. The US tizanidine market is valued at tens of billions of yen.

Development Pipeline



■ Earnings Trends

In-house product Iodocoat ® Ointment 0.9% contributing to higher sales

(1) Results for FY12/15

The Company's consolidated results for FY12/15 were announced on February 12, 2016. Net sales were ¥37mn, up 43.1% YoY, operating loss was ¥999mn (compared with operating loss of ¥1,003mn in the same period of the previous fiscal year). Sales were boosted by growth in sales volume of the Company's in-house products Iodocoat ® Ointment 0.9%, a treatment for bed sores and skin ulcers. However, the operating loss remained level YoY, due to a continued heavy burden for R&D expenses and fixed costs, mainly for ETOREAT®.

Extraordinary income in the period included a total of ¥116mn in public grants related to three research themes. Specifically, the Company received a grant of ¥79mn from NEDO for the research theme, "Development of a migraine treatment formulation through application of topical patch technology including nano colloid liquid;" ¥32mn from the Ministry of Economy, Trade and Industry's "Fiscal 2014 Strategic Foundation Technology Advancement Project" for the research theme, "Development of a biodegradable plastic microneedle array disposable mounting technology;" and ¥5mn from the Kagawa Industry Support Foundation's "Fiscal 2014 Kagawa SME Support Fund Project" for the research theme, "Development of a new topical patch treatment for osteoporosis using ionic liquid technology."

FY12/15 Consolidated Results

(¥mn)

	FY12/14		FY12/15			
	Actual	vs. Sales	Company plan	Actual	vs. Sales	YoY
Net sales	26	-	32	37	-	43.1%
Cost of sales	9	35.5%	-	12	32.2%	30.1%
SG&A expenses	1,020	3881.2%	-	1,025	2726.4%	0.5%
(R&D expenses)	718	2731.6%		716	1903.6%	-0.3%
Operating income	-1,003	-	-1,026	-999	-	-
Ordinary income	-1,012	-	-1,000	-990	-	-
Net extraordinary income (loss)	-	-	-	116	-	-
Net income	-1,016	-	-887	-878	-	-

Note: The Company plan was announced in May 2015

Increase in R&D expenses set to widen operating loss

(2) Consolidated results forecasts for FY12/16

The Company's forecasts for FY12/16 are for net sales of ¥29mn, down 20.3% YoY, and an operating loss of ¥2,117mn, widening approximately two-fold from the previous fiscal year. With regard to net sales, there is the possibility of concluding licensing agreements for development pipelines, however, at this stage it is difficult to forecast, and these factors have not been included in the results forecast. Only sales of Iodocoat ® Ointment 0.9% have been planned. The widening of the operating loss is attributable to a significant increase in R&D expenses to ¥1,878mn, 2.6 times the level of the previous fiscal year. The main R&D expenses planned for FY12/16 are for the two additional trials of ETOREAT® (approximately ¥1.0bn), expenses for non-clinical trials of MRX-1OXT ahead of the start of clinical trials and transfer of manufacturing technology and so forth to Tapemark, expenses for clinical development of MRX-5LBT targeting early filing for new drug approval, and expenses for Phase I clinical trials of MRA-4TZT. In addition, the Company expected to receive grant income of ¥25mn as extraordinary income in FY12/16 as well.

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Results Outlook for FY12/16

(¥mn)

	FY12/15		FY12/16		
	Actual	vs. Sales	Company plan	vs. Sales	YoY
Net sales	37	-	29	-	-20.3%
Cost of sales	12	32.2%	11	29.2%	-9.3%
SG&A expenses	1,025	2726.4%	2,136	5679.0%	108.3%
(R&D expenses)	716	1903.6%	1,878	4993.1%	162.3%
Operating income	-999	-	-2,117	-	-
Ordinary income	-990	-	-2,102	-	-
Net extraordinary income (loss)	116	-	25	-	-
Net income	-878	-	-2,080	-	-

■ Financial Status and Risk Factors

Equity ratio over 90%

(1) Financial status

Looking at the Company's financial status at the end of FY12/15, total assets were ¥2,977mn, down ¥707mn YoY. The decline was mainly attributable to a ¥717mn decline in cash and deposits due to recording a net loss of ¥878mn and other factors. Liabilities finished the year at ¥205mn, up ¥34mn. This mainly reflected an increase of ¥31mn in accounts payable. Net assets were ¥2,772mn, down ¥741mn, reflecting a decrease in retained earnings due to the recording of a net loss.

Turning to management indicators, the equity ratio is over 90%, and with no interest-bearing debt, the Company appears to have no issues in terms of stability. However, an increase in R&D expenses for FY12/16 will generate a cash outflow of more than ¥2.0bn, and based on the current level of cash and deposits, the Company will need to procure funds. To secure R&D funding, the Company conducted a third-party allotment of warrants in December 2015. The allottee was Evolution Biotech Fund (an investment fund designed to invest in biotechnology-related companies). The exercise of the warrants will result in the issue of 1.6 million new shares (number of issued shares at the end of FY12/15: 6,889,000). Under the scheme, the warrants will be exercised in stages over a period of about 7.5 months. The Company issued 300,000 shares by the end of January 2016. The recent share price is below the minimum exercise price of ¥463, and the warrants will not continue to be exercised if the share prices continue to be weak. It therefore seems possible that the Company will consider a new fund procurement method. If the additional trials of ETOREAT® are successful, the Company will receive milestone revenue of ¥1.05bn upon filing for approval in FY12/17, and the progress of the additional trials is therefore an important focus from a financial strategy viewpoint as well.

Consolidated Balance Sheet

(¥mn)

	FY12/12	FY12/13	FY12/14	FY12/15	Change
Current assets	507	4,007	2,853	2,204	-649
(Cash and deposits)	465	3,937	2,780	2,062	-717
Non-current assets	279	722	831	773	-57
Total assets	786	4,729	3,685	2,977	-707
Liabilities	511	227	170	205	34
(Interest-bearing debt)	404	99	-	-	-
Net assets	275	4,502	3,514	2,772	-741
Management indicators					
(Safety indices)					
Current ratio	112.6%	2541.0%	3614.7%	2011.1%	
Equity ratio	35.0%	95.2%	94.9%	91.8%	
Interest-bearing debt ratio	51.5%	2.1%	-	-	

(2) Risks

The Company's operating results continue to reflect operating losses as it is currently in the drug discovery development stage. Risk factors for operating results going forward included uncertainty in the schedule for new drug development and the possibility of ILTS® competitive advantage being eroded by the appearance of new technology. In particular, the success or failure of the additional trials for ETOREAT® is highly likely to have a heavy impact on the Company's future operating results and financial status, and the progress of the trials will therefore be a focus. The Company is also expected to procure funds for future R&D expenses by issuing new shares, which could have a dilution effect on the shareholder value per share.

Finally, all or the Company' payments in the US are settled in US dollars. Currently, only expenses are being paid in advance, so that the yen's depreciation is a negative factor; however, once the Company begins to record sales, the yen's depreciation will become a positive factor.

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