MEDRx（4586） TSE Mothers

Achieving the American dream with topical tape

Yuya Okamura, Analyst

Company profile	
Location	Higashikagawa-shi, Kagawa
Representative	Masayoshi Matsumura
Established	January 2002
Capital	¥4,560 million
Listing	February 2013
URL	http://www.medrx.co.jp/index.html
Sector	Medicine

Stock price data （closing price on February 22）	
Stock price	¥457
Outstanding shares	6,689,700 shares
Trade unit	100shares
Market cap	¥3.19billion
PER (est.)	-
EPS (est.)	-
PBR (actual)	1.16x

■Striving to become the first topical tape supplier in the U.S. market

MEDRx is a venture company that was established in Higashi-Kagawa-shi, Kagawa in January, 2002. Utilizing ILTS, its proprietary technologies that use ionic liquid, the company launched development of adhesive skin patches. The second stage of the clinical trials commenced in December 2013. Presently the company is conducting an additional test (DOMS test) based on a new test model. The results of the first test are expected to be known in the first half of 2016, and the results of the second one in the second half of 2016. The company intends to submit the application for approval in the first half of 2017, and has concluded a contract with KOWA, its business partner, which will be selling the product, that entitles MEDRx to a milestone income of 1,050 million yen when the application is submitted. The company is simultaneously conducting development of other pipelines, and the development portfolio has become quite large and diverse.

■Red figures increase in this term due to simultaneous development

For this term ending December, 2016, the company expects net sales of 29 million yen (a 20.3% decrease compared with the previous term), ordinary loss of 2,102 million yen (an increase of deficit), and net loss of 2,080 million yen (an increase of deficit). Including ‘ETOREAT’, the leading pipeline, the company is concurrently advancing with four development pipelines. With just these projects, MEDRx is expecting the research and development expenses of a little more than 1,500 million yen for the term, double of the previous term, and the reason for this massive deficit is the company’s forward-looking stance regarding developmental advances.

■Need for a long-term planning stance based on a thorough grasp of results to be achieved in the first half of 2017

As in this term, MEDRx is simultaneously conducting four clinical tests, the research and development expenses are expected to reach a little more than 1,500 million yen, double of the previous term. However, as of the end of December of the previous term, the company had a cash equivalent of 2,060 million yen, and also issued a stock purchase warrant in December of last year. MEDRx thus has no problems with financing. The purpose for capital investment is to achieve the American dream as the company envisages it, and the plan is to do it in the first half of 2017 when MEDRx intends to submit its application for approval of the ‘ETOREAT’. From the point of view of investors, the company’s current position can be also perceived as a merit as it is possible to make the entry at the record low since MEDRx has been listed.

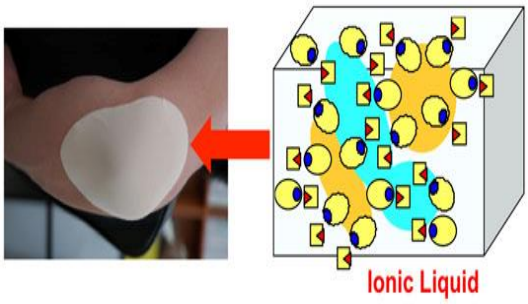
Point summary (1)

●What kind of company is MEDRx?

MEDRx is a venture company established in January, 2002 in Higashi-Kagawa-shi, Kagawa. Masayoshi Matsumura, the founder and the current President of the company, served as vice president at the Teikoku Seiyaku Co., Ltd. until 2000. Capitalizing on 'ILTS', MEDRx's proprietary technologies using ionic liquids, the company developed a number of adhesive skin patches and is currently trying to create the first topical tape product for the U.S., country boasting an enormous pain-relief market. In February, 2013, MEDRx was the first bioventure from Shikoku to achieve an IPO at the Mothers of the Tokyo Stock Exchange.

●What sort of technology is 'ILTS', the proprietary technology of MEDRx?

With the conventional percutaneous absorption technology, there are many drugs which do not easily penetrate through the skin. MEDRx is striving to utilize its technology using ionic liquid to pave the way for adhesive skin patches with drugs, which so far were not available for this kind of application. The key features of ionic liquid are its low melting point (100 degrees and below), that it remains liquid at room temperature, and that its (equilibrium) vapor pressure is virtually zero. Furthermore it is incombustible, and boasts excellent solubility. This technology has already been commercially exploited by various industries in areas such as lithium-ion and solar cells, but MEDRx is the first company in the world that has ever tried to use it for medication.



●What are the special advantages of adhesive skin patches in the first place?

The best known kind of adhesive skin patch in Japan is surely the anti-inflammatory analgesic plaster. There are many kinds of drugs including oral medicine, injection drugs, ointments, etc., but the adhesive skin patches including anti-inflammatory analgesic plasters have four major advantages.

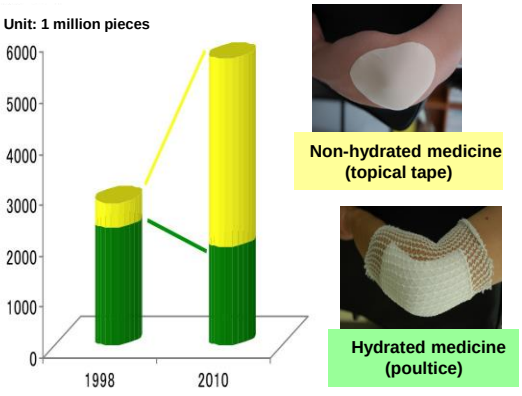
(1) The first is that the pharmacologically effective agent is released gradually. Because the medicine comes out slowly, it is easier for the benefits of the drug to be continuously maintained.

(2) The second is that as the medicine does not have to pass through the liver unlike orally taken medicine, it does not remain there. Side effects are thus less likely to emerge.

(3) Risk of forgetting to take medication can be eliminated. One can even apply the patches to the backs and other parts of the body of infants and young children where they won't be seen.

(4) There is no pain like with injected pharmaceuticals.

Point summary (2)



●What are successful examples of adhesive skin patches?

One example is the Mohrus Tape made by Hisamitsu Pharmaceutical. Today, the annual sales of the entire range of the Mohrus Tape products are running at just under ￥80.0 billion making this a major, revenue-generative product. Formerly, the only kind of anti-inflammatory analgesic patches available was the hydrated type - plasters containing water. As the cooling effect of such plasters was caused by evaporation of moisture content, they gave the user a pleasant, cooling feeling when applied to the skin. Hisamitsu Pharmaceutical, on the other hand, succeeded in developing their Mohrus Tape – a topical tape that did not contain any water. Their products do not come off easily so they can also be used in sports just as they are. Also, they do not dry out like the hydrated type plasters, which need to be changed several times a day as the water evaporates, and thus save the user time and effort. Hydrated type patches have already lost in market share to the non-hydrated ones in the Japanese market.

●What are the attractions of the U.S., the intended market?

Simply put, the U.S. people are a ‘population that is prone to pain’. Americans, who tend to be more affected by pain than Japanese, administer most of the drugs orally, and mostly use very strong analgesic drugs - morphine and other opioids.

The market for adhesive skin patches to treat mild and moderate severity pain has been expanding since 2008. ‘Flector’, which is manufactured by Teikoku Seiyaku (where the current MEDRx President Matsumura formerly held the position of Vice President), was first marketed in 2007, and Pfizer's marketing muscle ensured that it became a big hit. ‘Lidoderm’ was another major hit and between them these two drugs (both of hydrated type) now account for annual sales of around ￥100.0 billion. There is thus already a well-established track for selling adhesive skin patches in the U.S., and the market has been also expanding ever since with new medicine being developed for depression, ADHD, Parkinson, Alzheimer, and other diseases. The unit prices per single patch for these adhesive skin patches are worthy of special mention in this regard. In Japan, 1 Mohrus Tape sells for around ￥40 a piece, but the same item is sold for approximately ￥800 a piece in the U.S. Now, this can be held up as simply a textbook example of the operation of the price setting system in the U.S. but it also illustrates the scale of the fat profits that are to be hoped for if MEDRx manages to become the first topical tape supplier in the U.S. This would be, in all truth, an American dream.

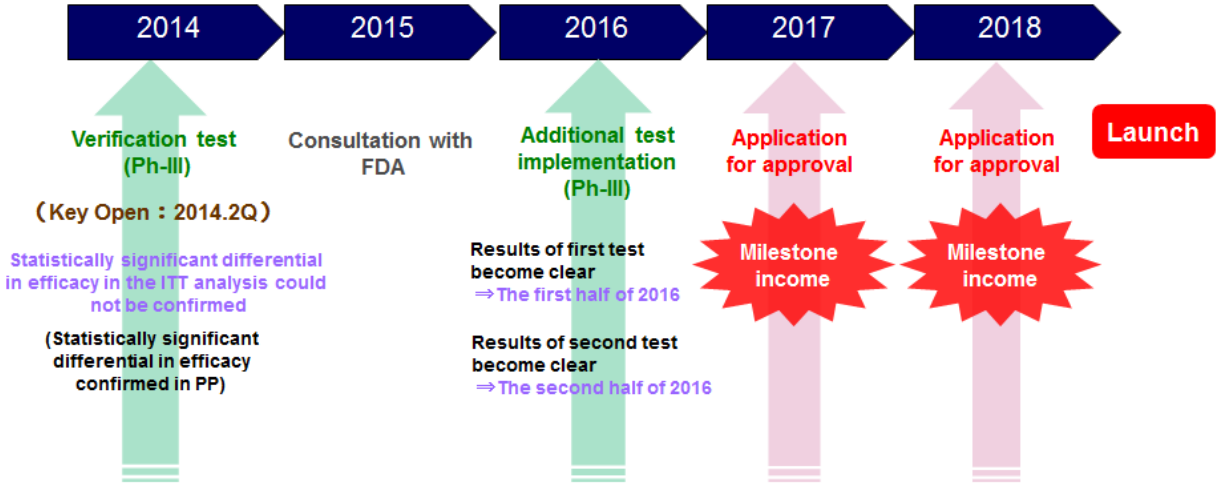
Development pipeline: present conditions and prospects (1)

① 'ETOREAT'

The company is striving to become the first topical tape supplier in the U.S. with 'ETOREAT', an anti-inflammatory, pain-relief patch that is its most advanced pipeline prospect. Japan's major drug manufacturers have tried but abandoned the U.S. market, while MEDRx has already entered the second stage of the clinical trials with 'ETOREAT'.

The first stage of clinical trials was completed in 4Q 2012, even before the company was listed. In phases II/III, placebo (drugs not containing any active/effective elements) comparison tests have already established a statistically significant differential in efficacy in comparison to the placebos.

The second stage of the clinical trials commenced in December 2013 and two years have passed since. MEDRx is having a rough passage with the second stage of the clinical trials because there is still an obstacle to be overcome with the FDA (Food and Drug Administration), the U.S. regulatory agency. During the second stage of clinical trials conducted in 2Q 2014, there was no statistically significant differential in efficacy in the ITT analysis, which also included subjects, who used the patch just once and gave up after that. However, the PP analysis of subjects, who used the medicine according to the plan of the clinical trial, showed the opposite result - a statistically significant differential. For that reason, the U.S. FDA required an additional clinical test.



For this additional clinical test, the FDA gave the company a new test model comprised of two tests for DOMS (delayed onset muscle soreness). Delayed onset muscle soreness is a condition experienced by people who get sore muscles after exercising for the first time in a long time. The trials will induce DOMS in healthy test subjects by artificially creating stress on muscles with one day of training, and the effectiveness will then be checked by monitoring any reduction in pain. I believe that with this format of clinical trials it is easier to get the results and get them quickly.

MEDRx expects the results for the first DOMS clinical test to come in the first half of 2016, for the second test in the second half of 2016, and application for approval to be submitted in the first half of 2017. There are no changes to the agreement that entitles the company as soon as the application for approval is submitted to the milestone income of 1,050 million yen from KOWA, a company well known for its 'Cabagin' and 'Vantelin'.

Furthermore, when the product is placed on the market, MEDRx will be able to use the sales network of KOWA with 250 MRs in the U.S., and, according to trial calculations, there is a potential market of a 200 billion yen - 300 billion yen scale waiting for the company there. As soon as the product is marketed and sales loyalties start coming from KOWA, MEDRx will be able to quickly collect the capital invested.

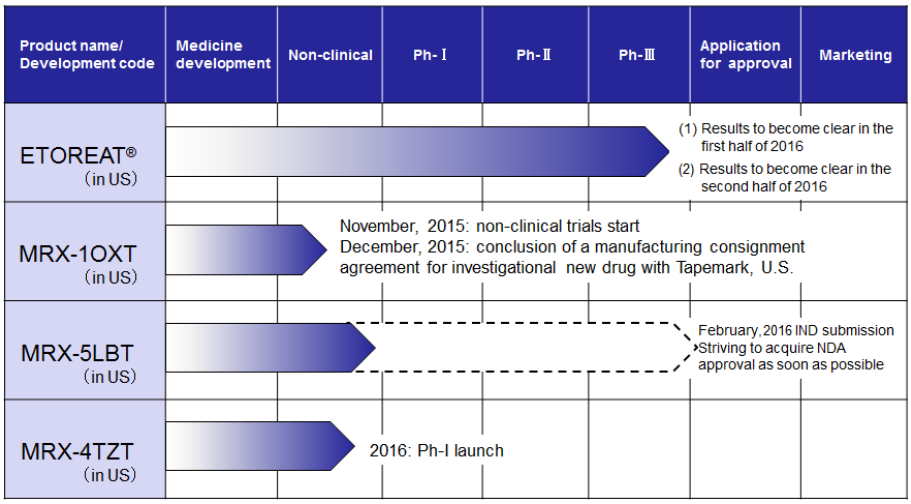
Development pipeline: present conditions and prospects (2)

②「MRX-1OXT」

'MRX-10XT' is a topical analgesic tape containing oxycodone, one of strong analgesics (opioids) such as morphine. This is a pipeline, with which MEDRx is trying to use its technologies that use ionic liquid to create a topical tape-type medicine containing oxycodone, which does not easily penetrate skin. With the pain-relief market in the U.S. alone worth some ￥1 trillion, and opioids holding a share of about half of the total, it is reasonable to believe that oxycodone holds about 40% of the opioid share (oxycodone accounts for around ￥200.0 billion of the market).

Non-clinical trials have been launched from November, 2015. Since oxycodone is classified as a "narcotic for medical use", manufacturing it in Japan and then exporting it is not allowed. For that reason, it is necessary to manufacture in the U.S. the investigational new drug for the phase I trials to be conducted there. MEDRx has outsourced this task to Tapemark, a manufacturer in Minnesota, U.S. with ample track record in development and manufacture of percutaneous absorption patches spanning over 60 years. Preparations to launch the phase I trials scheduled for 2016 are steadily being advanced.

Development pipeline



③「MRX-5LBT」

An adhesive skin patch with lidocain, a local analgesic. The product is developed to be used for alleviating acute nerve pain associated with shingles. An investigational new drug application was submitted to U.S. FDA in February, 2016.

One company has already scored a major hit with a lidocain adhesive skin patch in the U.S. The name of the product is 'Lidoderm', and in the peak period, the product brought the annual sales of 120 billion yen. As this precedent exists, it is possible to expect two points. First of all, by showing that the product made by MEDRx has the same qualities as Lidoderm, the company can possibly be let off with a simple test usually done for generic drugs. And the second point is that in addition to this possibility for the test being easy, MEDRx may be able to submit an application for approval of its drug as a new medicine. The difference between hydrated adhesive skin patch and non-hydrated topical tape is the key point here, and if everything goes as planned, this can prove to be a pipeline that will quickly take the company to the market with just a small amount of money invested.

④「MRX-4TZT」

An adhesive skin patch containing tizanidine, a centrally acting muscle relaxant that is used in Japan to treat a number of symptoms including stiffness of the shoulders. Non-clinical trials are already under way and the product is scheduled to enter into phase I by the end of this year in the U.S.

Results of Operations

Performance（million yen, %）

Fiscal year end	Net sales	YoY	Ordinary income	YoY	Net income	YoY	EPS(¥)
December 2011	741	154%	-479	-	-433	-	-
December 2012	87	-88%	-578	-	-571	-	-
December 2013	68	-21%	-616	-	-621	-	-
December 2014	26	-61%	-1,012	-	-1,016	-	-
December 2015	37	43%	-990	-	-878	-	-
December 2016 (est.)	29	-20%	-2,102	-	-2,080	-	-

●In the last term (term ended December, 2015) the company posted net sales of 37 million yen (a 43.1% increase compared with the previous term), ordinary loss of 990 million yen (as against 1,012 million yen in previous term), and net loss of 878 million yen (as against 1,016 million in the previous term). The increase of revenue is due to the fact that MEDRx received more orders than expected for its iodine coating salves, etc., which is its sole income source. Selling, general and administrative expenses were 1,025 million yen, roughly the same as the previous term (research and development expenses were 716 million yen, other administrative expenses were 309 million yen).

●For this term (term ending December, 2016), MEDRx expects net sales of 29 million yen (a 20.3% decrease compared with the previous term), ordinary loss of 2,102 million yen (an increase of deficit), and net loss of 2,080 million yen (an increase of deficit). Including ‘ETOREAT’, the company’s leading pipeline, MEDRx is concurrently advancing with four development pipelines. With just these projects, MEDRx is expecting the research and development expenses of a little more than 1,500 million yen for the term, double of the previous term, and the reason for this massive deficit is the company’s forward-looking stance regarding developmental advances.

Investment appraisal

●Although the price of the company's shares is record low since it has been listed, there are no quantitative materials to back up the decision that now it is time to buy the company's shares. As is the case of all bioventures, it takes more time from the initial investment to the withdrawal, than in the case of an ordinary business model. Also, as in this term MEDRx is simultaneously conducting four clinical trials, the research and development expenses are expected to reach a little more than 1,500 million yen, double of the previous term. However, as of the end of December of the previous term, the company had a cash equivalent of 2,060 million yen, and also issued a stock purchase warrant (with articles of amendment of the exercise price) in December of last year. MEDRx is thus advancing with fund procurement from the capital market through exercise of right and has no problems with financing. For that reason, I believe that the present situation does not call for excessive caution regarding risks.

MEDRx expects its American dream to be achieved after the results of the additional test (the DOMS test) for 'ETOREAT' come in the second half of 2016 and the company submits the application for approval in the first half of 2017. Ever since the company was listed, the purpose for capital investment in its shares was to cash in on the application for approval (milestone income) of 'ETOREAT', and from the point of view of investors, the company's current position can be also perceived as a merit as it is possible to make the entry at the record low since MEDRx has been listed.

The current account deficit expanded due to concurrent clinical tests conducted during this term, but if we take into account the U.S. market size, which MEDRx will have access to after the product reaches the market, the range of the deficit is within acceptable limits. The reason for the deficit in the first place is that the company operates according to a business model different from ventures engaged in development of new drugs. MEDRx does not create new drugs from the stage of discovery or creation of new active substances, but is offering a new system for use of existing medicines in the form of topical tape. In this term, as the company is at the stage of phase III of clinical tests before application for approval, judging by quantitative information MEDRx may look like a high-risk venture. However, I believe that from a qualitative point of view there are no changes to the company's standing of a venture company of a 'medium risk/high return' business model.

(Okamura)

Stock Price (historical)	
Year high	¥1,446
Year low	¥341
Highest since the IPO	¥7,500
Lowest since the IPO	¥341

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