

## Impact of Microneedle Business

### Proprietary technology in a niche market

MEDRx is in the business of developing transdermal absorption formulations based on the active ingredients of existing oral and injection drugs. Its business model is based on the collection of licensing payments and milestone payments from pharmaceutical companies to whom it has licensed out products and, after the drugs go to market, the collection of income from royalties.

Unlike most other companies developing new drugs, MEDRx uses the active ingredients of existing drugs, thus ensuring a higher probability of success. Since this is a niche business there are relatively few competitors, in addition to which the company's proprietary ILTS® technology gives it a distinctive edge.

### Getting ready to build a microneedle array plant for attachable vaccinations

The company has been working for the past 15 years on R&D for microneedle technology and on April 10 2018 announced a plan to build a production facility funded by the issue of a third-party allotment of new share warrants. The vaccine business has the desirable attributes of high-volume and stable-supply but the mega-pharma companies themselves have little interest in developing medical devices. They are happy to develop vaccines in-house but are unlikely to develop and produce the microneedles themselves. While MEDRx has introduced its microneedle technology to several Japanese and overseas companies with a view to establishing a collaboration or tie-up, it appears to have received a strong indication of interest from a major foreign vaccine maker. Hence the decision to announce the construction of a facility and an increase in capital to finance it to realize a collaboration with vaccine makers.

### Further increases in capital unlikely for the time being

The stock market has responded negatively to the news, since the construction of a factory represents a risky departure from the company's current business model. However, modelling the profitability of the microneedle business posits a maximum cost of just over JPY50 million, meaning that the investment could possibly be recouped by 2025-2026. Even allowing for continued high levels of R&D expenditure, reflecting the company's enthusiasm for R&D activities, the licensing-out revenue of the oxycodone tape preparation, which we assume in 2019, would bring in a sufficient lump sum payment to ensure the company's first operating profit since listing. This we surmise would put it on a more lasting profit trajectory. A further capital increase would be unlikely for the near-future. We regard the recent decision as an opportunity to endow the company with an operational scale which can propel it well beyond what is possible with its current business model.

### Follow-up Report

Fair Research Inc.

Tsuyoshi Suzuki

### Company Information

Location	Kagawa Prefecture
President	Yonehiro Matsumura
Established	Jan. 2002
Capital	JPY5,298 mil
Listed	Feb.2013
URL	www.medrx.co.jp
Industry	Pharmaceuticals
No. of employees	23 (consol. basis)

### Key Indicators (as of May 17 2018)

Share Price	1081
Year High	2060
Year Low	662
Shares Outstanding	10,061,400
Trading Unit	100 shares
Market Cap	10,876 mil.
Dividend (est)	0
EPS (est)	-116.98JPY
Forecast PER	na
BPS (actual)	287.44 JPY
PBR (actual)	3.76X

Note: calculated on the basis of total shares outstanding, excluding treasury shares

Results	Revenue JPY mil	YoY %	OP Income JPY mil	YoY %	RP Income JPY mil	YoY %	Net Income JPY mil	YoY %	EPS JPY	Share Price	
										High	Low
Dec-14 Actual	26	-61.7	-1,003	na	-1,012	na	-1,016	na	-152.0	2,518	785
Dec-15 Actual	37	43.1	-999	na	-990	na	-878	na	-131.2	1,446	500
Dec-16 Actual	22	-40.6	-1,342	na	-1,301	na	-1,259	na	-155.5	1,455	341
Dec-17 Actual	198	787.2	-983	na	-988	na	-884	na	-103.2	1,345	453
1H 2018 forecast	0	-100.0	-811	na	-809	na	-793	na	-84.3		
Dec-18 forecast	698	252.2	-1,120	na	-1,115	na	-1,100	na	-116.9		

## Company outline – management philosophy

A venture company in the business of developing transdermal absorption formulations.

The company has a proprietary technology, giving its products a higher probability of success than other new drug discovery businesses.

In broad terms the company's business model is based on developing transdermal absorption formulations based on the active ingredients of existing oral and injection drugs. It then out-licenses the formulations to pharmaceutical companies from whom it collects milestone payments and, after commercialization, royalty payments.

Transdermal absorption formulations constitute a growing medium to long-term pharmaceutical segment. Among their attributes are maximization of pharmaceutical effect, reduced side effects and enhanced quality of life for the patient. These attributes are achieved by the following:

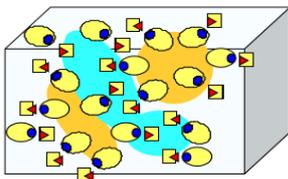
- ① Providing a consistent and sustained release of active ingredients to maintain a constant level of the drug in the bloodstream.
- ② Little or no first-pass effect: while the efficacy of oral drugs can be reduced to 10-20% as they pass through the liver, this is not an issue with transdermal absorption formulations.
- ③ Better medication compliance: suitable for patients who find it difficult to take oral drugs due to a problem in swallowing, and also reduces the problem of forgetting to medicate.
- ④ Unlike drug delivery by injection transdermal delivery is painless.
- ⑤ Transdermal delivery lends itself to a wide range of conditions.

The MEDRx business model is also distinctive in two ways:

- (a) It is low risk (i.e. high probability of success) because it does not involve the discovery or development of new active ingredients.
- (b) The company has its own transdermal absorption technology using ionic liquids (ILTS®: Ionic Liquid Transdermal System), which distinguishes it from other companies.

Note: Ionic liquids are salts in liquid form at room temperature composed of ions which are resistant to crystalization. They are non-volatile, non-flammable and electric conductive. In recent years these properties have led to applications in lithium battery electrolysis and elsewhere. With ILTS®, MEDRx was the first to develop the technology for the transdermal absorption of ionic liquids, thus facilitating the administration of drugs which are normally difficult to administer transdermally. With existing technology, transdermal absorption was difficult in the case of nucleic acid or macromolecular formulations, but ILTS® has made it much easier.

● ILTS® Breakthrough



➤ The use of ionic liquid facilitates transdermal absorption of drugs previously unsuited to this type of delivery, such as macromolecules like nucleic acid and peptides.

Source: Analyst meeting materials produced by MEDRx

Another interesting feature of MEDRx is that it has built high barriers to entry. It has a library of several hundred ionic liquids formed from combinations of compounds with a track record of use on human subjects as pharmaceuticals and additives. It also has extensive know-how on selecting optimum ionic liquids for

particular drug properties, and formulation expertise on maintaining and improving ionic liquids.

The company's primary target is the US market for transdermal absorption formulations. This strategy is mainly based on the potential size of the US market for tape-type formulations.

By basing its activities in the US on existing formulations, the clinical trials required to acquire FDA approval are simpler than for new drugs (although not true in all cases, after Phase 1 Phase 2 can be skipped and the process moves straight to Phase 3). Also worth bearing in mind is the fact that patch-type drugs tend to command higher prices in the US than in Japan.

Major Current Pipeline

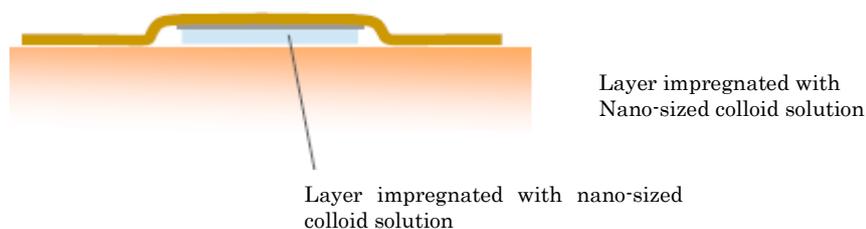
Product name Development Code	Drug Formulation Development	Pre clinical	Ph- I	Ph- II	Ph- III	NDA	Launch
CPN-101(MRX-4TZT) Spasticity (Tizanidine, transdermal, ILTS®)	[Progress bar from Drug Formulation Development to Ph-I]			worldwide licensing agreement (except for East Asia) with Cipla USA Inc. in April 2017 Phase 1a' has got result in January 2018			
MRX-1OXT Moderate-Severe pain (Oxycodone, transdermal, ILTS®)	[Progress bar from Drug Formulation Development to Ph-I]			Phase 1 has got result in February 2018			
MRX-5LBT Neuropathic Pain (Lidocaine, topical, ILTS®)	[Progress bar from Drug Formulation Development to Ph-I]			Phase 1 has got result in May 2016			
MRX-5DML Alzheimer's Disease (Donepezil / Memantine, transdermal, NCTS®)	[Progress bar from Drug Formulation Development to Pre clinical]			Pre clinical to be prepared			
Co-development with DAIICHI SANKYO (NCTS®)	Undisclosed (API, indication etc.)						

Source: MEDRx

The 3 main products using this ILTS® technology and now under development (at the clinical trial stage) consist of the oxycodone tape formulation (MRX-1OXT), the tizanidine tape formulation (CPN-101, MRX-4TZT), which was successfully out-licensed to Cipla USA, and the lidocaine tape formulation (MRX-5LBT). Of the three, the oxycodone tape formulation is expected to achieve blockbuster sales and is presently the company's most promising pipeline product (see our report dated March 13 2018).

In addition, the company is alone in the field to have microneedle array technology and the technology to deliver using nano-sized colloids (NCTS®: Nano-sized Colloid Transdermal System). As noted later, on April 10 2018 MEDRx announced its decision to build a production facility for its micro-needle array operations. At the end of February it announced the development of a new preparation using NCTS® jointly with Daiichi-Sankyo.

NCTS®: Nano-sized Colloid Transdermal System - Image



Source: MEDRx analyst meeting materials

When the company announced its plans the stock market was surprised at the size of the capital increase.

Involves piercing the epithelium of the skin with very fine needles and thereby transmitting the medicine into the skin

This “vaccine application” technique makes vaccinations painless

Unlike injection preparations the procedure can be administered by the patient and the vaccine can be stored at room temperature, thus making it suitable for use in pandemic-type situations in developing countries with limited medical facilities.

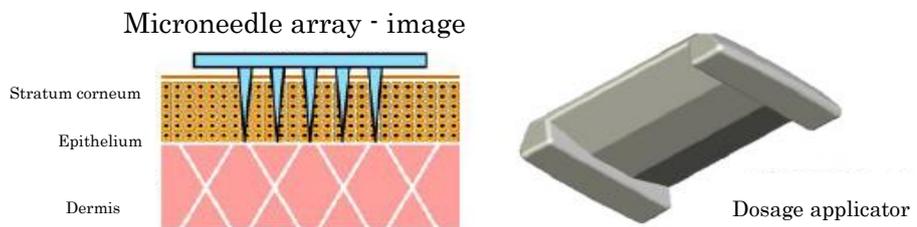
**Announcement of plan to build its own micro-needle facility**

On April 10th 2018, the company announced it was issuing a third-party allotment of warrants (representing 2.5 million shares and dilution of 24.8%) to finance a microneedle production facility and bring to fruition the research and development on micro-needle technology it had been working on for 15 years. Since investor interest so far had been concentrated on the oxycodone tape formulation and because there had been little disclosure to date on the micro-needle business, the announcement of a capital increase to finance a micro-needle factory came as a surprise to the market, which quickly marked the share price down significantly. The market was worried that a further capital increase might be necessary for microneedle clinical test facilities and building commercial plants, in addition to a number of products in the pipeline, such as oxycodone tape. Below we look in turn at the scope of micro-needles, at the profit potential for this business segment, and at the implications for MEDRx as a whole.

**Microneedle Technology**

In addition to providing a physical barrier preventing the intrusion of foreign matter into the body, the skin also has the immunological function of expelling foreign matter. Antigen presenting cells, which are present in the epithelium under the stratum corneum as Langerhans cells, and under the dermis as dermal dendritic cells, play an important role in defensive reactions in the body. A powerful immune response can be elicited by efficiently transferring vaccine to these antigen-presenting cells.

However, when the vaccine is applied it cannot penetrate into the skin because of the barrier presented by the stratum corneum. Very fine microneedles, however, puncture the epithelium, allowing the transmission of the vaccine into the skin. Since microneedles are less than 1mm in length they pierce the skin without reaching the nerves, making painless vaccinations possible. This technique is therefore a sort of “vaccination attachment”.



Source: MEDRx IR Materials

Currently, most vaccinations are injections, so medical staff are necessary for inoculation. In addition, the vaccines must be kept at consistently low temperatures (cold chain control) in the manufacturing, transportation and storage stages. The vaccinations using microneedle technology are not only painless (minimally invasive), but can be administered without medical staff (self-administration). Furthermore, the application of a solid vaccine antigen to a microneedle represents a promising technique for tackling pandemics in developing countries where room temperature storage is the norm, transportation and preservation is rudimentary, and the medical environment is inadequate. An analogy can be made with the way televisions evolved from the cathode ray tube type to the liquid crystal display type. In much the same way, microneedles may replace the standard injection.

Although the microneedle concept has existed since the mid-1970's, research had been bedeviled by problems in production technology and in terms of cost effectiveness. However, with the development of micro-fabrication technology since the 1990's there have been advances in microneedle development.

The methodology being pursued by MEDRx involves coating microneedles made of biodegradable biopolymers with vaccine in a dried state.

The type of applicator on which the microneedle array is mounted also comes in different versions.

Nipro already leads the pack in Japan (investigational drug plant now operating)

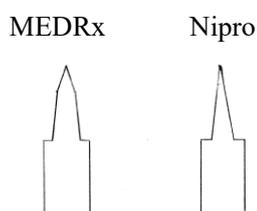
Given the large number of vaccine types and the size of the market it seems unlikely that a single company will dominate.

There are four main types of microneedle. One, developed in Japan by ASTI Corporation, is the hollow microneedle. Like the standard injection needle it has a hollow cavity into which the antigen solution is inserted before being administered. Another involves the use of solid microneedles in an array to puncture the skin, following which the needles are removed and the vaccine antigen is applied. Since these two methods use a liquid containing the vaccine antigen, they require cold chain storage in the same way as the standard vaccine formulation and this has stymied widespread usage. The third methodology involves the use of a microneedle array, the surface of which has been coated with dried vaccine to puncture the skin. Since the vaccine is not in solution but in a dry state it is highly stable and amenable to use with live vaccines. This is the methodology being developed by MEDRx and Nipro Pharma and, overseas, by 3M. To improve safety (i.e. in the event of a broken needle remaining in the body) efforts are being made to make microneedles using biodegradable biopolymers or some such material. The products of these companies seem to differ in terms of the shape of the needles, the density of the needles per unit area of skin, and the coating solution. In the fourth methodology, being developed by Fuji Film, the vaccine antigen is kneaded into the microneedle, the biopolymer needle point in the skin then decomposes and the antigen is released.

A further differentiating point between different methodologies seems to be in the use of an applicator, which ensures that the microneedles are accurately inserted directly into the skin. MEDRx’s applicator can be inserted using only hand strength, while the 3M and Nipro versions seem to use springs in the applicator. The 3M version requires a force of 1 joule, as compared with the 0.4 joules or so required by the MEDRx applicator. This means the latter is less likely to cause momentary impact pain. In addition, MEDRx reports that there have been difficulties controlling the puncture depth in the case of spring-type applicators. The cost difference is also an issue. Having said which, however, it is at present difficult to judge relative superiority because of insufficient disclosure from the companies involved.

Domestically, it appears that Nipro now leads in terms of development. In April 2017, it introduced an investigational drug production line at its Ise factory, which went operational in October of the same year, probably to conduct trials jointly with a vaccine maker. Details on the type of vaccine and the schedule going forward have not as yet been disclosed. MEDRx itself undertook joint research with Daiichi-Sankyo and Teijin between 2012 and 2015 but, just prior to the start of pre-clinical tests, Teijin withdrew for reasons of business strategy and the development was halted. Fair Research believes that, given the number of vaccine types and the size of the market, it is unlikely that any one company will have a monopoly on the microneedle market, and that the market is big enough to accommodate multiple participants.

Reference: Two different microneedle shapes



Note: The diagram is an image showing the general configuration only and is not intended to be accurate.

MEDRx has stated that in the case of its own device, when the preparation is coated on the needles it spreads evenly rather than ‘beading’ at the needle tips.

Source: Prepared by Fair Research using various materials

<p>Vaccine operations require the provision of large volumes and stable supplies, but drug makers are not particularly interested in developing medical devices.</p> <p>MEDRx has released a plan to itself produce microneedles in volume and thereby demonstrated its intention to expand into this business. In order to measure the risks we have conducted a simulation of prospective profitability in this business.</p> <p>We are assuming a two-stage launch of this business, involving a clinical trial facility and a small-scale production plant and have modelled the profitability for the clinical trial facility alone and for the entire project.</p>	<p style="text-align: center;"><b>Modelling the profitability of microneedle production operations</b></p> <p>The vaccine business is one which needs high volumes and stable supplies. The pharmaceutical majors have the funds but are not interested in developing medical devices. They are happy to develop vaccines in house but are unlikely to develop or manufacture the microneedles themselves.</p> <p>Meanwhile, MEDRx has introduced its own microneedle technology to several major domestic and overseas vaccine makers with a view to a collaboration or a tie-up, and appears to have received a strong indication of interest from a foreign producer. Detailed plans have been made to produce needle array devices on a commercial level and, in order to promote the possibility of a tie-up, MEDRx has announced a capital expenditure plan supported by an increase in capital via the issue of warrants (No. 13) to fund this capex. We can infer from this move by MEDRx that the company feels there is a strong possibility of a collaboration or tie up-being realised.</p> <p>MEDRx has conventionally been regarded as a developer of transdermal absorption formulations based on the active ingredients of existing drugs delivered orally or by injection. Under its business model those preparations have then been licensed out to pharmaceuticals companies from whom MEDRx collects milestone payments and, after commercialisation, royalty payments. However, while still producing transdermal formulations using existing drugs the company is now proposing to build a facility in the entirely new field of microneedles. This move into an area external to, and riskier than, that of its conventional business model was something the market found difficult to accept. Here we will look at the profitability of the microneedles business and evaluate the level of risk.</p> <p>In fact MEDRx is thinking of a two-stage capex plan involving an investigational drug facility and a commercial scale production plant. Fair Research is positing introduction of the investigational drug production line in 2018 for operations to start in 2019 for the beginning of clinical trials with a vaccine maker. If the partnership and cooperation with the vaccine maker goes well during clinical trials (Phase 1/2) the ideal scenario would be for the feasibility of mass production and supply stability of the vaccine preparation to be demonstrated at the mass production level. Capital investment in the factory would begin in 2020 with start-up scheduled for the second half of the same year and the shipment of output for Phase 3 from 2021. Mass production would then begin in 2023. We undertook profitability trend modelling of the clinical trial facility and the mass production plant in line with this schedule.</p> <p>&lt;Main preconditions&gt;</p> <p>Clinical trial facility (phase1/2:test drug plant) Capex amount: JPY400-500 million</p> <p>Commercial-scale production plant (Phase 3+ commercial-scale plant) Capex for relatively small-scale output: around JPY3.5 billion</p> <p>On the assumption of a stock price prevailing at the level of mid-May 2018, the warrants would be exercised at the minimum exercise price and would not generate the proceeds initially envisaged by the company. To take account of this eventuality we modelled a relatively small-scale plant for microneedle commercial production.</p>
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The clinical trial facility considered in isolation would be producing a profit in 2020 and by 2021 would have recovered the investment outlay.

Including the commercial-scale factory in our modelling suggests a peak individual-year loss of around JPY50 million before turning positive in 2021, with investment outlays being recovered by 2025.

It is apparent from the simulation that a relatively small-scale commercial production factory would present limited risk. MEDRx itself appears to be contemplating vaccines requiring small scale production.

Given the interim outlook for the company a whole, and in order to evaluate the possibility of further capital raising activity, we should look at the trend in the company's cash position

#### <Results of the simulation>

Looking at the individual-year profitability of the test drug facility in isolation, we would model a loss of around JPY30 million in 2018 due to capital investment, and a further loss of JPY40 million in 2019 after one year of operations before generating a profit in 2020, the second year of operations. We believe that cumulative cash flow will turn positive (recovery of investment) in 2021.

Modelling the profitability of the total project on an individual-year basis yields a peak loss of around JPY50 million in 2020 and a slight profit in 2021, which then expands going forward. We project cumulative cash flow turning positive (recovery of investment) in 2025.

#### Profit & loss simulation for the microneedle facilities

		Unit: JPY100 million									
		2018	2019	2020	2021	2022	2023	2024	2025	2026	
<b>Sales</b>	Total – both facilities	0.0	1.0	2.0	6.5	6.5	12.0	12.0	12.0	12.0	
	Test drug plant only		1.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	
<b>Investment</b>	Total – both facilities	0.3	1.4	2.5	6.3	5.3	6.4	5.9	5.9	3.0	
	Test drug plant only	0.3	1.4	1.0	1.0	1.0	1.0	0.5	0.5	0.0	
<b>Return</b>	Total – both facilities	-0.3	-0.4	-0.5	0.2	1.2	5.6	6.1	6.1	8.1	
	Test drug plant only	-0.3	-0.4	1.0	1.0	1.0	1.0	1.5	1.5	1.0	
<b>Cash flow</b>	Total – both facilities	-2.3	-19.8	-8.9	4.2	5.2	9.6	9.6	9.6	9.6	
	Test drug plant only	-2.3	0.2	1.6	1.6	1.6	1.6	1.6	1.6	1.6	
<b>Cum. cash flow</b>	Total – both facilities	-2.3	-22.1	-31.0	-26.8	-21.6	-12.0	-2.4	7.2	16.0	
	Test drug plant only	-2.3	-2.1	-0.5	1.1	2.7	4.3	5.9	7.5	9.1	

Assumptions Test drug facility for Phase 1/2  
Commercial-scale factory for Phase 3 and large-scale output

Source: Compiled by Fair Research Inc.

Having set up a partnership or tie-up at the testing stage it would be ideal if a major vaccine maker were to invest in a commercial-scale factory. Risk would be limited by a joint project covering a relatively small-scale commercial factory and a test-drug plant, although it should be noted that, depending on the type of vaccine, additional capacity might become necessary. It seems MEDRx plans to start out not with an influenza or like vaccine requiring large volumes, but a vaccine requiring relatively small volumes, and then expanding the business over time by adding vaccines or hormone preparations.

#### The company's cash position

The company's announcement of a plan to raise capital and expand its business into microneedle manufacturing came as a surprise to the market. MEDRx is clearly enthusiastic about expanding its business. It has 3 drug formulations under development, namely oxycodone tape (MRX-1OXT), tizanidine tape (MRX-4TZZ) and lidocaine tape (MRX-5LBT). In addition, it has microneedles and a number of other products under development. In order to discern the risk of a further capital increase in the future what is needed is an announcement by the company of its medium term outlook. This has not happened, so Fair Research has checked the trend in the company's cash position using a number of prior assumptions.

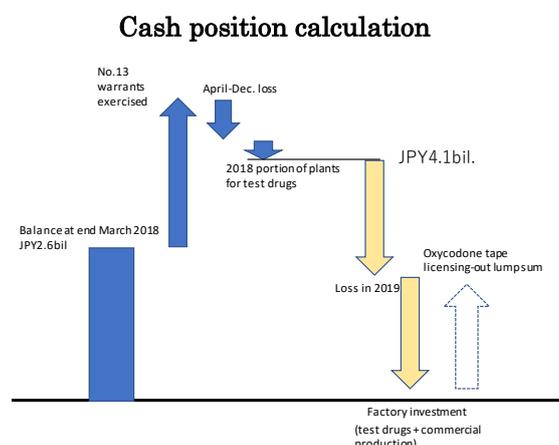
As of the end of March 2018, the company holds JPY2.6 billion in cash and deposits. If we were to assume that all the No. 13 warrants announced on April 10 were to be exercised at the minimum exercise price during the current year this would add JPY2.6 billion to the company's cash position. At the same time, the company forecasts a final loss in the April-December period of the current fiscal year of JPY800 million, while the commencement of capital expenditure for the facility to produce microneedle investigational drugs will lead to a cash outflow estimated at

The arrival of positive figures will depend on the timing of the licensing-out of the oxycodone tape preparation, and the amount of money received, but even excluding this, cash on the balance sheet will be sufficient to cover capital expenditure on the microneedle business.

around PY300 million. We see the above developments leading to a cash position at the end of December 2018 of JPY4.1 billion.

The company's earnings in 2019 will depend importantly on the successful licensing-out of the oxycodone tape preparation. However, omitting that from our calculation, there is also the fading effect of milestone income in 2018 from tizanidine tape, and a provisional loss on the microneedle operations, leaving a deficit of around JPY1.9 billion. In addition, for 2019 if we factor in a possible capital investment of JPY200 million for the test drugs production facility, and JPY1.5 billion for the commercial-scale factory (the remaining JPY2 billion expenditure falls in the following year) the total comes to JPY1.7 billion, leaving a positive cash position at the end of 2019 of roughly JPY500 million.

In 2019 we think it is very likely that the contract lump sum due from the licensing-out of the oxycodone tape formulation will be of a reasonable size, in which case operating profit will be positive and the cash balance at the end of 2019 should be at or above JPY2 billion. In 2020 if there is milestone income from oxycodone tape the company will have achieved a surplus at the operating level and a cash balance sufficient even with continued investment in the commercial-scale plant (JPY2 billion).



Source: Fair Research Inc.

Needless to say, there are risks, such as that posed by any delay in the lump-sum licensing-out contract payment for oxycodone tape, or an unexpected rise in R&D costs, or an increase in the scale of the microneedle commercial production plant. The accuracy of the above simulation will be much affected by these variables.

By forming an alliance with a major vaccine maker at the test drug facility stage, the project would become an extension of MEDRx's existing business model. The company's involvement in commercial production would propel it to an entirely different stage.

## Conclusion

In broad terms, the company's business model has been based on developing transdermal absorption formulations based on the active ingredients of existing oral and injection drugs. It then out-licenses the formulations to pharmaceutical companies from whom it collects milestone payments and, after commercialization, royalty payments. The company's 'style', therefore, is to seek reasonable returns from a research outlay of a few hundred million yen. Given the quality of the company's balance sheet and its product development ability, the business model would seem to be optimally balanced.

The MEDRx's factory construction project for the new microneedle technology envisages the company working on the test drug facility alone, and then forming a production alliance with a major vaccine producer for the rest of the project. We believe this would be in line with the company's conventional business style, since

it again seeks returns from an investment of a few hundred million yen. However, this project does represent a major new departure for the company in that, since the vaccine market is huge and requires large volumes and stable supplies, and the vaccine makers themselves are averse to getting involved in the development of the necessary medical devices, MEDRx must show that it is ready to take on commercial production. Nevertheless, given the size of the worldwide vaccine market, the scale of the company's future business is an opportunity to move ahead of its conventional repetition of development followed by licensing-out.

Reference: The global vaccine market

Vaccine revenues in 2016		Five biggest sellers in 2016		
Unit USDmil.		Unit: USDmil.		
Company		Vaccine	Targeted condition	
GlaxoSmithKline	6,219	Prevnar13	Streptococcus pneumoniae	6,034
Merck & Co	6,750	Gardasil	HPV	2,488
Pfizer	6,071	Fluzone	Influenza	1,683
Sanofi	5,568	Pentacel	Hib polio	1,654
CSL	782	Bexsero	Neisseria meningitidis	528
Emergent BioSolutions	237			
Misubishi-Tanabe	360			
Astellas	319			
AstraZeneca	104			
Others	1,130			
<b>Total</b>	<b>27,540</b>			

Source: EvaluatePharma World Preview 2017

Our view is that the relatively small scale of commercial production contemplated in the foregoing simulation would not generate major costs, and that the recent capital increase will for the time being be sufficient to cover significant investments and R&D costs. We now look forward to the company forming a production alliance at the test drug facility stage or at the relatively small-scale commercial factory stage.

In our last report dated March 13, our calculations indicated a total value for the three main products in the company's pipeline at around JPY44.7 billion (pre-tax and adjusted for probability of success).

To calculate MEDRx's company value we need to take into account the value also of other products under development, and taxation. Since the microneedle business, and products aside from the three main preparations, are not yet at the clinical testing stage, we assume in our conservative modelling that revenues will only be sufficient to cover the recovery of capex and R&D outlays. On that basis, corporate value is found by deducting from the total value of the three product pipeline drugs (= JPY44.7 billion) the present value of annual expenses (basic R&D costs not earmarked for a specific pipeline product + miscellaneous general admin outlays = JPY300 million per year). We then deduct tax at a tax rate of 30%, arriving at a figure of around JPY29.5 billion. Of course, this is no more than a provisional figure based on a number of assumptions, and may be revised up if probability of success is raised by advances in development of products in the pipeline. On the other hand, there is also a risk of a downward revision in the event of an interruption to development or similar event. It is therefore important to bear in mind that the figures presented are, in the final analysis, the product of a simulation.

The sum of the current market cap of the company and the expected increase in market cap from the exercise of No. 13 warrants comes to JPY13.4 billion (assuming warrants exercised at minimum exercise price). Given the cash position analysis dealt with earlier we believe another capital increase is unlikely for the time being.

In our last report, we modelled the value of the three-product pipeline at JPY44.7 billion.

Microneedles and other operations, with the exception of the three main drug preparations, are not yet at the clinical testing stage. This being the case, corporate value comes to JPY29.5 billion on the assumption that only development costs and capex costs can be recouped, and after allowing for basic research costs, annual general administration expenses and tax.

While there is little concern currently for another capital increase, there is a gap between corporate value on the one hand and the sum of market cap and the amount scheduled from the recent capital increase on the other.

Investors should compare this JPY13.4 billion with the assumed value of the company, take into account any expectation of a capital increase, and calmly consider the undervalued status of MEDRx shares.

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