# R-Tech Ueno

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FISCO Ltd. Analyst Yuzuru Sato

# ■Revenue contribution from new drugs to commence, towards a new growth phase

R-Tech Ueno (RTU) is a pharmaceutical venture business that specializes in ophthalmology and dermatology. Its operations, the manufacture and sale of glaucoma and ocular hypertension treatment drug Rescula © Eye Drops, and contract manufacturing of AMITIZA © capsules for the treatment of constipation, are already profitable. A distinguishing feature of RTU is that it has already established the earnings power and a financial position capable of sustaining development costs for new drug discovery and delivering stable dividends. Further, as its underlying development philosophy RTU focuses targets medicines for which there is a strong need from a doctor's perspective, seeking high return on middle risk.

RTU's cumulative H1 FY3/14 operating results (Apr-Sep) showed significant gains of 52.5% YoY in revenues and 150.2% YoY in recurring profit. The reason behind this was that AMITIZA sales grew strongly 77.9% YoY due to changes in the delivery price in North America and the contribution from domestic sales. The full-year FY3/14 results outlook also calls for double-digit increases in revenue and earnings, with revenues up 16.6% and recurring profit up 47.7% as a result of growth in AMITIZA.

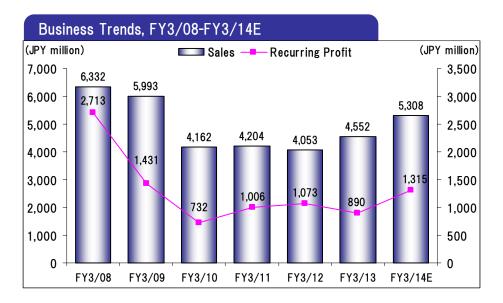
The development schedules for both the retinitis pigmentosa treatment drug Unoprostone eye drops (development code UF-021), and the world first dry eye treatment by way of biological medicine, recombinant human serum albumin eye drops (development code RU-101), which are expected to be the earnings drivers going forward are progressing satisfactorily. UF-021 has completed third phase clinical trial case registration, with the approval application now in sight in fiscal 2014. Further, in respect of RU-101, 1st phase clinical trials has been completed, and case registration for second phase clinical trials has commenced. It is anticipated that these new drugs will start to contribute to earnings from FY3/15, with the expectation that RTU's operating results also will enter a growth phase.

# **■Check Points**

- A pharmaceutical venture with the earnings power and financial position to continue to deliver stable dividends
- Significant revenue & earnings growth from successful rising of the AMITIZA® unit sales price
- H1 outperformance will lead to full-year results also being revised further upwardly



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# ■Corporate Overview

# A pharmaceutical venture with the earnings power and financial position to continue to deliver stable dividends

#### **Business Outline**

RTU is a pharmaceutical venture business that specializes in ophthalmology and dermatology, possessing medical products that are already profitable, a distinguishing characteristic being that it has already established the earnings power and a financial position capable of not only of sustaining development costs for new drug discovery, but also able to deliver stable dividends.

The current flagship product Rescula® is sold domestically as a glaucoma and ocular hypertension treatment drug by alliance partner Santen Pharmaceutical Co., Ltd. (4536). For overseas sales, in April 2009 a marketing tie-up was entered into with Sucampo Pharma Americas, LLC for the North American region, achieving a re-entry into the market from FY3/13. This pharmaceutical product has been sold domestically for 19 years since 1994 making it a long-seller. As a result, its market penetration is almost complete, with a trend, albeit gradual, for decline in sales volumes. Further, given that declines associated with drug price revisions, going forward also the outlook in respect of domestic sales is for this trend to decline to continue. As such, to what extent North American sales grow is a key point when examining sales trends for this product.

Further, in contract manufacturing services undertaken for the constipation treatment drug AMITIZA®, RTU produces them down to the active ingredients at its Sanda facility, outsourcing the capsulation and bottling processes. In the US market, marketing is through a local subsidiary of the Takeda Pharmaceutical Company Limited (4502), with marketing in the Japanese market, where approval was granted in June 2012, undertaken by Abbott via Sucampo Pharma Americas, LLC respectively. Moreover, in Sucampo Pharma Europe Ltd., the developer in Switzerland and the UK, has obtained marketing approval, however, a marketing alliance partner has not yet been decided on. Given that RTU has the exclusive global production and distribution rights, when a marketing alliance partner can be decided on for Europe, a contribution may be expected from European sales.



■Corporate Overview

#### Rescula®

## **AMITIZA®**





Source: Company

Also, in the FY3/13 composition of revenues, Rescula® accounted for 40% and AMITIZA® 57%. The remaining 3% represents pharmaceutical R&D support and contract manufacturing services, including a variety of services that span from R&D cooperation in the non-clinical phases (evaluation, investigation and testing) to obtaining and preparing data for approval applications. Looking at gross profit margins, Rescula® eye drop manufacturing and sales operations are the highest at around 70%, with AMITIZA® next at around 50%. In contract manufacturing services a level of 50% is high within the industry, however, one reason for this is that RTU has undertaken R&D support until the drug came to market.

# Business Trends by Divisions (JPY million) □ Rescula □ AMITIZA □ Medical R&D Development Support Services 4,000 3.500 3.000 2,500 2,000 1,500 1,000 500 FY3/08 FY3/13 FY3/09 FY3/10 FY3/11 FY3/12

# Promoting development while tackling market needs for orphan & other drugs

#### **Fundamental Development Strategies**

RTU's fundamental development strategies target "pharmaceuticals with actual needs from a doctor's perspective", or in other words "unmet medical needs" (areas or treatment where, despite actual needs on the medical front, there is no satisfactory treatment method), "orphan drugs" (this refers to pharmaceuticals for the treatment of rare diseases where despite strong needs at treatment facilities for these intractable and other diseases, the products would have low profitability even if developed), and "Anti-aging" (life enhancing drugs).



■Corporate Overview

Also, another distinctive feature is that it undertakes development that focuses on localized diseases (ophthalmological, dermatological etc.) where development costs can be relatively constrained. Within the current development pipeline, drugs that are expected to be profitable include retinitis pigmentosa treatment drug Unoprostone eye drops (development code UF-021) and a world first dry eye treatment by way of biological medicine, recombinant human serum albumin eye drops (development code RU-101).

As a pharmaceutical venture, RTU's business model is to out license the new drugs it develops to major pharmaceutical companies and derive income from license fees and royalties. This is because the financial burden of marketing and mass-producing them itself would be onerous. As an example of this, RTU licenses out Rescula ® to Santen Pharmaceuticals domestically. Licensing out income, in addition to a one-off payment at the time of entering into a contract, includes milestone payments that are obtained at certain progress points in the business schedule, such as the status of progress in clinical trials, when manufacturing approval is obtained, after product sales commence, and when sales reach prescribed targets. Further, royalty income obtained from the licensed partner, and is a fixed amount of sales after the commencement of product sales.

Currently, within the under-development pipeline also, by licensing out in this fashion, RTU is able to secure licensing fees and royalty income. Of course, it holds that unless the new drug under development is attractive and shows prospects of being marketable, contractual partners will not emerge, and from this perspective also, RTU's development policy is to promote development targeting areas where there are market needs such as "orphan drugs" and "anti-aging (products)".

# Results Overview

# Significant revenue & earnings growth from successful raising of the AMITIZA ® unit sales price

#### (1) Cumulative H1 FY3/14 Results

RTU's cumulative H1 FY3/14 operating results showed significant gains in revenues and earnings with revenues up 52.5% YoY to JPY2.794 billion, operating profit up 132.7% YoY to JPY713 million, recurring profit up 150.2% YoY to JPY756 million, and quarterly net profit up 153.0% YoY to JPY533 million. A major factor behind this was the 77.9% YoY increase in AMITIZA sales, including a rise in the North American unit sales price. Further, while there was also an upward revision versus the plan at the beginning of the term, the major reason for this was a greater than expected rise in the North American AMITIZA unit sales price. Also, another factor in the surplus was that RTU recorded a JPY39 million non-operating foreign exchange gains, given that the exchange rate shifted towards yen depreciation during the term.

The operating profit margin rose 8.8% YoY to 25.5%. While the decline in RTU's ratio of costs-to-sales was restricted to 0.4%, as the percentage of overall revenues from AMITIZA® which has a relatively low gross margin ratio rose, due to impact of increased revenues, the SG&A ratio declined 8.4%. Moreover, R&D costs rose JPY163 million YoY to JPY647 million due to increased clinical testing costs including those for RTU's retinitis pigmentosa treatment drug and dry eye treatment drug.



■Results Overview

## H1 FY3/14 Results

(Unit: JPY million)

|                              | H1 FY  | 3/13           | H1 FY3/14 |        |                |        |                    |
|------------------------------|--------|----------------|-----------|--------|----------------|--------|--------------------|
|                              | Result | Ratio to sales | Estimate  | Result | Ratio to sales | YoY    | Change in estimate |
| Sales                        | 1,833  | -              | 2,669     | 2,794  | -              | 52.5%  | 4.7%               |
| COGs                         | 671    | 36.6%          | -         | 1,014  | 36.3%          | 51.0%  | -                  |
| SG&A                         | 854    | 46.6%          | -         | 1,066  | 38.2%          | 24.8%  | -                  |
| Operating profit             | 306    | 16.7%          | 647       | 713    | 25.5%          | 132.7% | 10.2%              |
| Recurring profit             | 302    | 16.5%          | 676       | 756    | 27.1%          | 150.2% | 11.7%              |
| Extraordinary gains & losses | 0      | -              | -         | 0      | -              | -      | -                  |
| Net profit                   | 210    | 11.5%          | 439       | 533    | 19.1%          | 153.0% | 21.3%              |

Revenue trends by region for RTU's main products are as per the following graph, with Japanese revenues from Rescula rising by JPY39 million from JPY657 million to JPY696 million. We do not feel that this is not because ultimate demand is growing, but rather that revenues rose due to the timing of Santen Pharmaceutical selivery dates. On the other hand, shipments to North America started in the Jan-Mar 2013 period, with actual cumulative H1 results of JPY101 million. On a quarterly basis, JPY101 million in revenues were recorded in Q1 (Apr-Jun), with the initial shipment to Sucampo Pharma Americas, LLC being completed in Q1. In the next shipment, it is expected that 2 years worth of inventory will be allowed for, with the company side seeing little likelihood of North American orders until FY3/15 (depending on local sales circumstances, there is the possibility of shipments in FY3/15).

Conversely, in respect of AMITIZA® there was significant growth in the main North American sales channel from JPY1.08 billion to JPY1.564 billion. This was impacted significantly by the fact that there was a clause in the contract with Takeda Pharmaceuticals that the delivery price would be reviewed after a certain period, and the delivery price rose 20% from April 2013. Moreover, in April 2013 AMITIZA® obtained an additional new drug approval (see note) for opioid-induced constipation, and while new demand may be expected from those sufferers, at present Takeda Pharmaceuticals have not altered their sales forecasts, and sales volumes are progressing almost in line with the initial plan.

In respect of Japanese AMITIZA © sales, given that sales commenced in Q3 FY3/13 (Oct-Dec) there were no actual results in the preceding year, with H1 FY3/14 revenues of JPY358 million contributing in full to the increase in revenues. Here also sales volumes progressed in line with the initial plan, and are expanding steadily.

## Business Trends by Region □ Rescula for Japan □ Rescula for North America (JPY million) □ AMITIZA for Japan □ AMITIZA for North America 3,500 3,000 2,500 2,000 1,500 1,000 500 0 01-02 03-04 Q1-Q2 FY3/13 FY3/13 FY3/14

Note: Opioid-induced Constipation is common adverse effect of chronic opioid use. Binding of opioids to peripheral opioid receptors in the gastrointestinal tract results in absorption of electrolytes, such as chloride, and subsequent reduction in small intestinal fluid. In addition, activation of enteric opioid receptors results in abnormal GI motility. Together, these processes result in OIC. which is characterized by infrequent and incomplete evacuation of stool, hard stool consistency, and straining associated with bowel movements.



■Results Overview

# Shareholders' equity ratio rises, RTU continues to maintain a sound financial position

#### (2) Financial Position

RTU's financial position at the end of September 2013 is, as described in the following table, and shows an increase in total assets of JPY93 million to JPY10.013 billion. Within this the major factors that changed were, despite a decline of JPY679 million in accounts receivable within current assets, cash on hand and at banks increased JPY472 million and inventories increased JPY107 million. Further, current liabilities decreased due to a JPY187 million decline in accounts payable, while net assets grew JPY259 million due to gains from profits. As a result, amongst management indices, RTU's shareholders' equity ratio rose from 82.3% to 83.9%, indicating that it continues to maintain a sound financial position.

## **Balance Sheet**

(Unit: JPY million)

|                            | 3/10   | 3/11   | 3/12    | 3/13   | 9/13    |
|----------------------------|--------|--------|---------|--------|---------|
| Current assets             | 5,371  | 6,878  | 7,235   | 7,799  | 7,873   |
| (cash & near cash)         | 3,196  | 4,741  | 5,209   | 5,119  | 5,592   |
| (Inventory)                | 1,601  | 1,441  | 1,296   | 1,282  | 1,390   |
| Tangible fixed assets      | 657    | 565    | 421     | 400    | 451     |
| Intangible fixed assets    | 146    | 114    | 86      | 117    | 101     |
| Investment & other         | 868    | 935    | 1,586   | 1,602  | 1,586   |
| Total Assets               | 7,043  | 8,493  | 9,329   | 9,919  | 10,013  |
| Current Liabilities        | 741    | 890    | 705     | 973    | 785     |
| Fixed Liabilities          | 143    | 367    | 529     | 755    | 777     |
| (Interest-bearing debt)    | 0      | 0      | 0       | 246    | 246     |
| Total Liabilities          | 884    | 1,257  | 1,234   | 1,728  | 1,563   |
| Total Net Assets           | 6,159  | 7,235  | 8,095   | 8,191  | 8,450   |
| (Reliability)              |        |        |         |        |         |
| Current ratio              | 724.7% | 772.3% | 1025.6% | 801.3% | 1001.9% |
| Shareholders' equity ratio | 87.4%  | 85.2%  | 86.6%   | 82.3%  | 83.9%   |
| D/E ratio                  | 0.0%   | 0.0%   | 0.0%    | 3.4%   | 3.3%    |
| (Profitability)            |        |        |         |        |         |
| ROA                        | 10.3%  | 11.8%  | 11.4%   | 7.9%   | -       |
| ROE                        | 11.7%  | 18.5%  | 9.5%    | 7.8%   | -       |
| Profit margin on sales     | 17.5%  | 23.8%  | 26.2%   | 16.7%  | 25.5%   |

Current ratio (current assets/current liabilities)
Shareholders' equity ratio (shareholders' equity/total assets)
D/E ratio (interest-bearing liabilities/shareholders' equity)

ROA (Operating profit/total assets)
ROE (Net profit/shareholders' equity)



■Results Overview

# H1 outperformance will lead to full-year results also being revised further upwardly

#### (3) FY3/14 Results Outlook

The company forecasts for FY3/14 operating results anticipate revenues up 16.6% YoY to JPY5.308 billion, operating profit up 63.8% YoY to JPY1.285 billion, recurring profit up 47.7% YoY to JPY1.315 billion, and net profit up 52.2% YoY to JPY855 million. Given that cumulative H1 results exceeded the initial plan, full-year results also have been revised upward from the initial plan. On a volume basis, both Rescula  $\$ and AMITIZA  $\$ are in line with the initial plan, however, the difference in estimated price for AMITIZA  $\$ and the delivery price that was actually determined are reflected in the results outlook revision.

## Company forecast for FY3/14

(Unit: JPY million)

|   | FY3/12 | FY3/13 | FY3/14           |                  |        |
|---|--------|--------|------------------|------------------|--------|
|   | Result | Result | Initial estimate | Updated estimate | YoY    |
| Sales                                       | 4,053  | 4,552  | 4,991            | 5,308            | 16.6%  |
| Rescula                                     | 1,943  | 1,811  | 1,430            | 1,442            | -20.4% |
| AMITIZA                                     | 2,026  | 2,592  | 3,410            | 3,712            | 43.2%  |
| Medical R&D Development<br>Support Services | 83     | 148    | 150              | 152              | 25.0%  |
| Operating profit                            | 1,063  | 784    | 971              | 1,285            | 63.8%  |
| Recurring profit                            | 1,073  | 890    | 974              | 1,315            | 47.7%  |
| Net profit                                  | 680    | 561    | 633              | 855              | 52.2%  |
| EPS   | 15     | 15     | 20               | 20               | -      |

The outlook for sales by segment anticipates the underlying decline in Rescula to continue with a decrease of 20.4% YoY to JPY1.43 billion. By proactive marketing activities and new sales promotions in the domestic market it is expected to remain at levels unchanged YoY, however, there will be an impact from lower North American sales. Further, in respect of the FY3/15 outlook, there is the possibility of unit price reductions of around 5% associated with drug price revisions (April 2014), with declines in that order expect domestically. Conversely, with shipments having been completed for North America, as noted above, there is high likelihood of a temporary absence in revenues. As a result, it is forecast that Rescula® will decline in the order or 20% from the outlook for this term.

On the other hand, it is expected that AMITIZA® revenues this term will grow 43.2% to JPY3.712 billion. By region, it is expected that, with a full-year contribution in Japan there will be a significant rise from JPY264 million in the previous term to JPY808 million. Further, in respect of North America the outlook is for 25% growth from JPY2.327 billion to JPY2.904 billion. Moreover, it is expected that growth will continue in respect of domestic sales in FY3/15. This is because, given that this product is a new drug previously patients could only be prescribed for 2 weeks about once conventionally, however, as that limitation will be removed from December 2013, an increase is anticipated in amongst other things treatment periods and pharmacies handling it. Further, as recognition rises for it as a constipation treatment drug, it is expected that FY3/15 domestic sales meet or exceed JPY1.0 billion. Also, given that this product is manufactured for Sucampo Pharma Americas, LLC, essentially there will be no impact from drug price revisions. Further, with an increase in demand expected as a treatment drug for Opioid-induced Constipation in North America also, continued growth may be anticipated. From the above, growth in the teen percentages is expected in FY3/15 also.



■Results Overview

In respect of FY3/14 R&D costs, the plan calls for JPY1.278 billion, almost in line with the previous term, centered on clinical trial costs for RTU's retinitis pigmentosa and dry eye treatment drugs.

Further, the exchange rate assumption is for JPY90/USD1 in H2. Given that for each JPY1 of yen depreciation there is a JPY5 million gain in earnings, if the current exchange rate levels prevail it is expected that there will be a slight contribution to results.

# ■New Drug Development Trends

# Raised certainty that the retinitis pigmentosa treatment drug will come to market in FY3/16

## (1) Retinitis pigmentosa treatment drug Unoprostone eye drops (UF-021)

Retinitis pigmentosa is a progressive form of night blindness, being a genetic disorder with narrowing of the field of vision as its major symptom, and which may lead to blindness. In Japan it is the 3rd leading cause of visual impairment (and the leading cause for those over 60 years old). To date no effective method of treatment has been established using low molecular weight compounds, with sufferers in Japan being certified as having a specified intractable disease, making this arguably a new drug with strong social demand.

If it can be practically applied it will be, not only in Japan, but globally also a first in treatment drugs, with the potential to monopolize the market. It is estimated that there are approximately 30,000 sufferers domestically and over 1 million worldwide, placing it in the orphan drug category.

From FY3/13 it has entered phase 3 clinical trials at 38 medical institutions nationwide, and in October 2013 completed case registration at a faster pace than initially scheduled (Case 180). Due to this it appears to be determined that phase 3 clinical trials will be completed by the end of 2014 at the latest. Given that the results of trials already implemented are satisfactory, the likelihood of realizing the initial plan for an application for approval of its manufacture and sales to be undertaken in fiscal 2015, and for it to be brought to market some time in fiscal 2016 have risen.

Given that Unoprostone is a medical product with strong social demand in the orphan drug area the likelihood of it obtaining a high drug price if approved is high. Further, given that, from a manufacturing perspective, it contains the same ingredients as Rescula®, with only slightly varied concentrations, it bears the merit that in starting mass production there is no need for new capital investment. Accordingly, there is arguably a strong possibility that from the commencement of sales it will attract a gross profit margin in excess of that of Rescula®, and that its impact on profits will be significant.



New Drug Development Trends

It is anticipated that in its peak revenue period domestically it will reach approximately JPY2.0 billion (assuming 100% domestic market share and being prescribed to 80% of sufferers). On the other hand, given that rights to develop and market Unoprostone overseas will be licensed to Sucampo (excluding Japan, Taiwan, China and Korea), it is dependent on its arrangements with Sucampo. It has already obtained orphan drug designation in Europe and America also, thus given that for a certain period it has gained exclusive marketing rights, in the mid-term significant growth is expected. RTU plans to apply for orphan drug status domestically by the end of FY3/14, and if certified it will attain exclusive marketing rights for a 10 year period. Further, this treatment drug also has the potential for its application to expand to be an age-related macular degeneration treatment drug, and if that occurs the market size will balloon.

# Estimated JPY150 Billion Global Market Size for Dry Eye Treatments Free From the Risk of Infection

## (2) Dry Eye Treatment Drug (RU-101)

After Unoprostone RTU's dry eye treatment drug is attracting attention as promising new drug. This treatment drug is a world first dry eye treatment by way of biological medicine, and because it is produced from recombinant human serum albumin there is the benefit that there is no risk of infection. Dry eye is estimated to have a global market size of JPY150 billion annually, with that market having doubled in the last 5 years, an annual growth of 10% per annum going forward also.

There are a number of approaches to dry eye treatment. These included instances of prescribing anti-inflammatory drugs (sales forecasts of the anti-inflammatory drug RESTASIS® by the US firm Allergan are USD870-900 million, it is yet to be approved in Europe and Japan), cases where moisturizing and rehydration agents are used (such as sodium hyaluronate and Methyl cellulose), and cases where mucin/water secretion promoting ophthalmic agents (only approved in Japan, 2 companies, clinical trials in progress in the United States also). In this setting RTU will seek market entry with its biological medicine produced from recombinant human serum albumin that carries no risk of infection. Benefits include hydration and the protective epithelium from mucin secretion, and use in conjunction with the anti-inflammatory RESTASIS® may also be considered. Further, it has a broad application for sufferers with severe to moderate cases of dry eye, and it is also under consideration that its application may be expanded to become a healing agent for corneal abrasion.

In relation to clinical testing, phase 1 and phase 2 clinical trials were commenced in the US from May 2013. In October 10 safety trials, which are phase 1 clinical trials, concluded, and case registration for phase 2 clinical trials that evaluate efficacy and safety were commenced. In the Autumn of 2014 phase 2 clinical trials are expected to conclude, at which stage RTU plans to grant a license to a major pharmaceutical company. The market scale for this treatment drug is large, and given that amount of investment required by RTU for mass production would be too great, RTU will act in line with its middle risk high return development strategy.



New Drug Development Trends

Note: DDS (Drug Delivery Systems) are technology for the effective and concentrated delivery of medication to the affected area being targeted (e.g. the internal organs and systems, specific cells, or pathogen), which not only enhances the efficacy of the medication, but also has the benefit that we may expect a decrease in side effects.

# side effects.



# Promotion underway of R&D with Hokkaido University for an atopic dermatitis treatment drug

## (3) Atopic Dermatitis Treatment Drug VAP-1inhibitor (RTU-1096)

Additionally, RTU is tackling the development of the VAP-1 inhibitor as an atopic dermatitis treatment drug. VAP-1 (Vascular adhesion protein-1) refers to a protein that exists in 2 forms with 2 differing function: a membrane bound form that exists in the vascular epithelium and soluble for that exists in the bloodstream. The former holds the molecular adhesion function between leukocytes and lymphocyte, and is linked to inflammation. The latter detoxifies via amino oxidase activation in vivo amino acids. In atopic dermatitis sufferers there is a mechanism whereby, via the activation of VAP-1, leukocytes migrate extravascularly, with activation causing inflammation. By medicating sufferers with an inhibitor that inhibits the activation of VAP-1 we may anticipate efficacy in inhibiting inflammation.

With atopic dermatitis, depending on the severity, in addition to external application of steroids, treatment by way of internal medication with immunosuppressants and steroids is undertaken, however, there is the risk of side effects, with calls for the development of safer medications from treatment facilities. Already, in animal testing using mice a degree of effect has been recognized. Currently, RTU is progressing R&D in respect of "Atopic dermatitis and eye complications" with Hokkaido University, with a view to commencing phase 1 clinical trials sometime in FY3/15.

In respect of the VAP-1 inhibitor, the scope of application outside atopic dermatitis is large also, including diseases of the internal organs and eye disorders, with RTU aiming to promote development while progressing joint research with the university. Moreover, as part of the industry-academia collaboration, RTU is promoting joint development of DDS via Unoprostone with Tohoku University.

## New Drug Development Pipeline

|             | Development Code                            | Disease Treated                  | Pre-clinical | Phase I | Phase II     |             | Phase III  |
|-------------|---|----------------------------------|--------------|---------|--------------|-------------|------------|
|             |   | Discase Il cateu                 |              |         | Initial Term | Latter Term | Filase III |
| 0           | UF-021 (Unoprostone)                        | Retinitis pigmentosa             |              |         |              |             |            |
| t<br>h      | RU-101 (Recombinant<br>human serum albumin) | Dry eye                          |              |         |              |             |            |
| a<br>m<br>o | RTU-007                                     | Diabetic cataract                |              |         |              |             |            |
| 0           |   | Diabetic retinopathy             |              |         |              |             |            |
| g<br>y      |   | Age-related macular degeneration |              |         |              |             |            |
| D           | RK-023                                      | Male pattern alopecia            |              |         |              |             |            |
| e<br>r<br>m |   | Hypotrichosis of the eyelashes   |              |         |              |             |            |
| a<br>t<br>o | RTU-1096<br>(VAP-1 inhibitor)               | Atopic dermatitus                |              |         |              |             |            |
| l<br>o<br>g |   | Contact Dermatitis               |              |         |              |             |            |
| ÿ           |   | Psoriasis                        |              |         |              |             |            |
| etc         |   | Diabetic neuropathy              |              |         |              |             |            |

Phase I: Testing the safety and action of the drug within the body using healthy volunteer subjects that have given their consent.

Phase II Initial Term: Testing the safety and action of the drug within the body for a patient group that has given its consent, and setting recommended clinical dosage criteria.

Phase II Latter Term: Determing efficient and safe dosages and medication methods for a patient group that has given its consent. Phase III: To confirm safety and prove the efficacy of the dosage and method of administering determined in Phase II using a larger number of target patients.

In cases of licensing out, development and commercialization rights for the compounds are assigned to global pharmaceutical companies in the Initial Term of Phase II.

Source: Prepared by FISCO from Company materials.

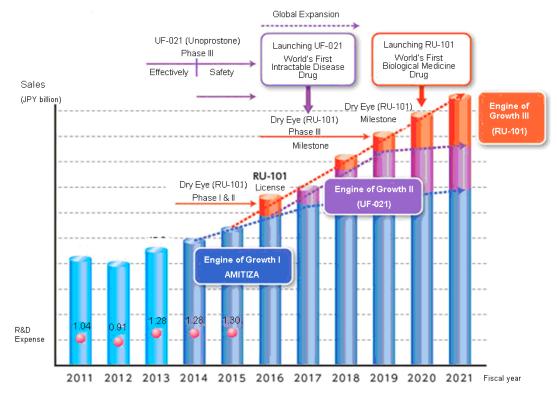
# ■Mid- to Long-term Outlook

# Outlook for results to expand steadily in the mid-term also

Given that it aims to maximize profit growth and shareholder value, as a midterm management index, RTU places emphasis on ROE as an indicator, having declared its aim to meet or exceed the 10% mark in FY3/16. However, in respect of this figure, given that current operating results are trending soundly, it is expected that it will clear this in FY3/14 (11% being forecast for FY3/14).

In respect of RTU's mid-term results outlook, as noted above, within its existing operations, while the decline in Rescula  $^{\odot}$  will continue, apart from growth in AMITIZA  $^{\odot}$  both domestically and overseas, in FY3/15 it is expected that its dry eye treatment drug will secure milestone income. Further, from FY3/17 revenue contribution from its retinitis pigmentosa treatment drug are expected. Thus, the outlook in the mid-term also is for results to expand steadily, with RTU feeling we may expect average growth rates over the 5-year period from FY3/15 to FY3/19 of 8% for revenues and 14% for operating profit. Further, this doesn't take into account the European market for AMITIZA  $^{\odot}$  or revenues from the overseas for the retinitis pigmentosa treatment drug, and if augmented by sales of these products the revenue growth potential is further enhanced.

## Mid- to Long-term Outlook



Scource: Company

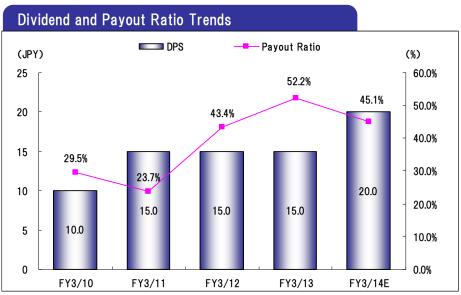


# ■Shareholder Reward Measures & Risk Factors

# As a pharmaceutical venture RTU rewards shareholders proactively

#### (1) Shareholder Reward Measures

With regard to shareholders reward measures, RTU's basic policy is to continue stable dividends over the mid- to long-term, comprehensively considering results and the dividend payout ratio, while retaining reserves in order to strengthen its management platform. In FY3/14 RTU plans to issue a dividend of JPY20 per share, or a payout ratio level of 45.1%. Arguably, for a pharmaceutical venture business this makes it proactive in rewarding shareholders. Given that it maintains a robust financial position, with amongst other things cash on hand and at banks in excess of JPY5.0 billion, and for the time being requires no significant capital investment, we feel it will continue to maintain a payout ratio above the 30% mark.



Note: On July 1, 2013 RTU plans to make a 200-for-1 stock split. DPS has been revised to reflect this in the past.

# Risk Factors in Reliance on Sucampo & Litigation in Relation to RTU's Rental Agreement

## (2) Risk Factors

In addition to the matters typical to the medical industry, such as uncertainty in new drug discovery and the impact of drug price revisions, the major operational risks peculiar to RTU are as noted below.

• Reliance on Sucampo Pharma Americas, LLC - within RTU's operations, the trading relationship with Sucampo includes the sales of Rescula® to the North American market, the contract manufacturing agreement for AMITIZA®, and the sale of the retinitis pigmentosa treatment drug overseas. Thus if there was a significant change from a management strategy perspective at Sucampo's there is the possibility of it impacting on RTU's results.



■Shareholder Reward Measures & Risk Factors

• Litigation in relation to the cancellation of the rental agreement on the factory site - litigation was filed in the Osaka District Court in August 2013 seeking amongst other things the removal of buildings from the site and surrender of the site by Ueno Fine Chemicals, which is the legal owner of the Sanda factory property, being RTU's sole factory. RTU expresses the opinion that "it has been using the factory site continuously since 2001, and that to ask for its surrender without a valid reason was unreasonable". From a legal perspective also, RTU's claim is correct, and we feel that the risk of being forced to surrender the site is extremely low. Coincidentally, Ueno Fine Chemicals is the founder of RTU, and the company is managed by a relative of the representative of the current Sucampo, Dr. Ueno.

## Income Statement for FY3/10-FY3/14E

(Unit: JPY million, %)

| FY3/10  |                            |        |        |        | <u>*</u> | 1 11111110111, 707 |
|---|----------------------------|--------|--------|--------|----------|--------------------|
| COGs  | _                          | FY3/10 | FY3/11 | FY3/12 | FY3/13   | FY3/14E            |
| COGs  |                            | 4,162  | 4,204  | 4,053  | 4,552    | 5,308              |
| Ratio to sales   32.6   32.9   37.0   37.4  | YoY                        | -30.6  | 1.0    | -3.6   | 12.3     | 16.6               |
| SG&A   Ratio to sales   A9.8   A4.2   A1.1   A5.4   | )Gs                        | 1,358  | 1,349  | 1,324  | 1,703    | -                  |
| Ratio to sales   49.8   44.2   41.1   45.4  | Ratio to sales             | 32.6   | 32.9   | 37.0   | 37.4     | -                  |
| Operating profit         728         998         1,063         784           YoY         -50.4         37.0         6.5         -26.2           Ratio to sales         17.5         23.7         26.2         17.2           Recurring profit         732         1,006         1,073         890           YoY         -48.8         37.4         6.6         -17.0           Ratio to sales         17.6         23.9         26.5         19.6           Extraordinary gains         303         972         0         0           Extraordinary losses         19         6         51         4           EBIT         1,017         1,972         1,022         885           YoY         -28.2         94.0         -48.2         -13.4           Ratio to sales         24.4         46.9         25.2         19.5           Corporate income tax         350         724         342         323           Effective tax rate         34.4         36.7         33.4         36.5           Net profit         666         1,248         680         561           YoY         -28.8         87.2         -45.5         -17.4 | ì&A                        | 2,074  | 1,856  | 1,665  | 2,064    | -                  |
| YoY   | Ratio to sales             | 49.8   | 44.2   | 41.1   | 45.4     | -                  |
| Ratio to sales  | ing profit                 | 728    | 998    | 1,063  | 784      | 1,285              |
| Recurring profit  | YoY                        | -50.4  | 37.0   | 6.5    | -26.2    | 63.8               |
| YoY   Calcal Content  | Ratio to sales             | 17.5   | 23.7   | 26.2   | 17.2     | 24.2               |
| Ratio to sales   17.6   23.9   26.5   19.6  | ing profit                 | 732    | 1,006  | 1,073  | 890      | 1,315              |
| Extraordinary gains       303       972       0       0         Extraordinary losses       19       6       51       4         EBIT       1,017       1,972       1,022       885         YoY       -28.2       94.0       -48.2       -13.4         Ratio to sales       24.4       46.9       25.2       19.5         Corporate income tax       350       724       342       323         Effective tax rate       34.4       36.7       33.4       36.5         Net profit       666       1,248       680       561         YoY       -28.8       87.2       -45.5       -17.4         Ratio to sales       16.0       29.7       16.8       12.3         [Major indices]       1362       1040       917       1279         Ratio to sales       32.7       24.7       22.6       28.1  | YoY                        | -48.8  | 37.4   | 6.6    | -17.0    | 46.7               |
| Extraordinary losses 19 6 51 4  EBIT 1,017 1,972 1,022 885  YoY -28.2 94.0 -48.2 -13.4  Ratio to sales 24.4 46.9 25.2 19.5  Corporate income tax 350 724 342 323  Effective tax rate 34.4 36.7 33.4 36.5  Net profit 666 1,248 680 561  YoY -28.8 87.2 -45.5 -17.4  Ratio to sales 16.0 29.7 16.8 12.3  [Major indices]  R&D costs 1362 1040 917 1279  Ratio to sales 32.7 24.7 22.6 28.1   | Ratio to sales             | 17.6   | 23.9   | 26.5   | 19.6     | 24.8               |
| Test  | traordinary gains          | 303    | 972    | 0      | 0        | -                  |
| YoY   -28.2   94.0   -48.2   -13.4  | traordinary losses         | 19     | 6      | 51     | 4        | -                  |
| Ratio to sales         Corporate income tax       350       724       342       323         Effective tax rate       34.4       36.7       33.4       36.5         Net profit       666       1,248       680       561         YoY       -28.8       87.2       -45.5       -17.4         Ratio to sales       16.0       29.7       16.8       12.3         [Major indices]         R&D costs       1362       1040       917       1279         Ratio to sales       32.7       24.7       22.6       28.1   |                            | 1,017  | 1,972  | 1,022  | 885      | -                  |
| Corporate income tax         350         724         342         323           Effective tax rate         34.4         36.7         33.4         36.5           Net profit         666         1,248         680         561           YoY         -28.8         87.2         -45.5         -17.4           Ratio to sales         16.0         29.7         16.8         12.3           [Major indices]           R&D costs         1362         1040         917         1279           Ratio to sales         32.7         24.7         22.6         28.1  | YoY                        | -28.2  | 94.0   | -48.2  | -13.4    | -                  |
| Effective tax rate  | Ratio to sales             | 24.4   | 46.9   | 25.2   | 19.5     | -                  |
| Net profit         666         1,248         680         561           YoY         -28.8         87.2         -45.5         -17.4           Ratio to sales         16.0         29.7         16.8         12.3           [Major indices]           R&D costs         1362         1040         917         1279           Ratio to sales         32.7         24.7         22.6         28.1  | ate income tax             | 350    | 724    | 342    | 323      | -                  |
| YoY     -28.8     87.2     -45.5     -17.4       Ratio to sales     16.0     29.7     16.8     12.3       [Major indices]       R&D costs     1362     1040     917     1279       Ratio to sales     32.7     24.7     22.6     28.1   | Effective tax rate         | 34.4   | 36.7   | 33.4   | 36.5     | -                  |
| Ratio to sales     16.0     29.7     16.8     12.3       [Major indices]     R&D costs     1362     1040     917     1279       Ratio to sales     32.7     24.7     22.6     28.1  | ofit                       | 666    | 1,248  | 680    | 561      | 855                |
| [Major indices]  R&D costs  | YoY                        | -28.8  | 87.2   | -45.5  | -17.4    | 52.2               |
| R&D costs 1362 1040 917 1279 Ratio to sales 32.7 24.7 22.6 28.1   | Ratio to sales             | 16.0   | 29.7   | 16.8   | 12.3     | 16.1               |
| Ratio to sales 32.7 24.7 22.6 28.1  | indices]                   |        |        |        |          |                    |
|   | osts                       | 1362   | 1040   | 917    | 1279     | 1278               |
| Outstandinh shares (1000 shares)         19,688         19,688         19,688   | Ratio to sales             | 32.7   | 24.7   | 22.6   | 28.1     | 24.1               |
|   | ndinh shares (1000 shares) | •      | 19,688 | 19,688 | 19,290   | 19,290             |
| EPS (JPY) 33.86 63.39 34.55 28.73   | PY)                        | 33.86  | 63.39  | 34.55  | 28.73    | 44.32              |
| DPS (JPY) 10.00 15.00 15.00 15.00   | PY)                        | 10.00  | 15.00  | 15.00  | 15.00    | 20.00              |
| BPS (JPY) 312.82 367.50 411.15 423.33   | PY)                        | 312.82 | 367.50 | 411.15 | 423.33   | 438.00             |
| Payout ratio (%) 29.5 23.7 43.4 52.2  | ratio (%)                  | 29.5   | 23.7   | 43.4   | 52.2     | 45.1               |

Note: 200-for-1 stock split July 1, 2013. Per share data has been revised to reflect this in the past.



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