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Revision of Forecast of Financial Results for FY2015 and Extraordinary Loss Estimated to Be Recognized

The Company hereby announces that we have revised our forecast of financial results for FY2015 (May 1, 2015 to April 30, 2016) which was previously announced on June 12, 2015 and that we expect to recognize an extraordinary loss.

1. Revision of forecast of financial results for FY2015 (May 1, 2015 to April 30, 2016)

[Consolidated] (Millions of yen, %)

	Business revenue	Operating income (loss)	Ordinary income (loss)	Net income (loss)	Net income(loss) per share
					Yen
Forecast announced previously (A)	783 ~2,877	(1,996) ~24	(2,004) ~16	(2,005) ~11	(93.54) ~0.56
Revised forecast (B)	135	(1,858)	(1,862)	(2,385)	(111.13)
Change (B-A)	(648) ~(2,742)	137 ~(1,883)	141 ~(1,879)	(380) ~(2,397)	—
Change (%)	(83) ~(95)	—	—	—	—
Reference: Previous year results (FY2014)	99	(1,903)	(1,795)	(1,994)	(94.89)

Note: The changed amount and percentage from the previous forecast to the revised forecast shows the difference from the previous forecast with a range .

2. Reasons of revision

The initial forecast of the Company's group for FY2015 has a range between the upper limit and the lower limit in consideration of expecting to recognize product sales and milestone payments income of the absorbable local hemostat (the "hemostat") as business revenue. The Company, however, revised the forecast mainly due to major factors as stated below.

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ significantly from the forecast due to various subsequent factors.

In the initial forecast, business revenue from milestone payment income associated with the execution of sales partnership agreement for the hemostat of ¥176~¥2,175 million and product sales of ¥582~¥675 million (Asia and Latin America: ¥266 million, Europe: ¥316~409 million) was projected. In this revision, business revenue is amended to milestone payment income associated with concluding sales partnership for the hemostat of ¥30 million and overseas product sales of ¥71 million (Asia and Latin America: ¥51 million, Europe: ¥20 million)

(1) Delay of execution of sales partnership agreement for the hemostat

We were expecting to execute a sales partnership agreement by the end of Q3 FY2015 with a distributor chosen from three candidate distributors which have sales promotion potential across Europe. However, the agreement has not been executed and is unlikely to be concluded by the end of FY2015 in the course of reevaluation of the progress until Q3. Hence, the forecast of the Company's business revenue was revised since milestone payment income and product sales, in total of ¥2,094 million, is not expected to be recognized within FY2015. As milestone payment income for FY2015, the initial payment income from Daewoong Pharmaceutical Co., Ltd. in Korea according to the execution of sales partnership in ASEAN region (Thailand, Vietnam, Philippines) in Q1 is only recognized.

(2) Product sale plan of the hemostat changed

Product sale was planned to major hospitals through local agents in each country in Europe and in the other areas where CE Marking can be leveraged such as Asia (mainly Indonesia and Malaysia) and Latin America (Colombia, Chile, Mexico, etc.). In Europe, the hemostat has launched in Germany, France, UK, Switzerland, and Spain. Product registration for marketing approval completed in Indonesia, Singapore, Malaysia, Hong Kong, Thailand, Australia in Asia-Oceania region, and in Brazil, Colombia, Chile in Latin America. The product sale in Asia has been progressed as expected, but the sales in Europe and Latin America delayed during Q2 and Q3 FY2015 due to reasons below.

Marketing activities in Europe launched under contract with local agent in each country (one agent in Germany, one in France, one in Switzerland, two in Italy, one in Spain, one in Northern Europe) and many clinical uses were made jointly with such agents. However, the product sale has not increased as expected because (i) hospitals are reluctant to add new products to their inventory due to their budget system, (ii) it has taken longer than expected to prepare our sales partners for their maximum promotion potential, (iii) despite enthusiasm for our product from surgeons, many hospitals' purchasing departments took several months to follow through with purchasing, resulting in sales delays. Such time lag upon introduction of a new product was not reflected to the initial forecast. Furthermore, more than one agent were planned to be set in major markets, Germany, France, and UK but choosing new agents has taken longer time due to medium to large sized candidate agents merged in recent years. Therefore, the initial forecast of product sale in Europe is unlikely to be achieved despite of expanding marketing resources in Q2 and Q3.

In Latin America, a main reason of delay is that contracts with distribution agents have not executed by the end of Q3 FY2015, despite of the original forecast with starting the sale of the hemostat in Chie in Q2 and in Colombia in Q3. Sales agreement is still under discussion and expected to be finalized and the hemostat is to be launched in Chile and Mexico in Q4. The contract for marketing in Colombia is planned to be concluded in the first half of FY2016. Hence, the amount of product sale in Latin

America for FY2015 is forecasted to be small.

According to reevaluating the progress in Europe and Latin America until Q3 stated above, the forecast of business revenue was revised. This reevaluation can avoid similar roadblocks in the future.

(3) Amount of expense and profit in accordance with revising business revenue

The forecasted expense of the Company's group is calculated by accumulation of each project pipeline for R&D expense and by evaluating the past result for SGA. According to the revise of forecasted business revenue, cost of goods sold is expected to decrease. R&D expense of ¥300 million is reduced (expense for clinical trial of the hemostat in Japan, due to changing starting period from FY2015 to FY2016) and SGA of ¥200 million is reduced. Therefore, the initial forecast of profit/loss was revised downward, with operating loss of ¥1,858 million and ordinary loss of ¥1,862 million.

Since reevaluation of the non-current asset and booking impairment loss are now under discussion with auditors, an extraordinary loss of ¥569 million in total is estimated to be booked. As a result, the forecasted net loss was revised downward to ¥2,385 million. For details, please refer to "(5) Extraordinary loss expected to be recognized" stated below.

(4) Expectation of sales partnership agreement in Europe

The discussion of detailed conditions including milestone payment with three candidate distribution partners had proceeded after product evaluation. Since it took more time than expeceted for discussion with Distributor A and Distributor C and Distributor B had to spend their resources fo reorganization of their medical device department, the agreeement had not been concluded by the end of FY2014. In FY2015, the Company continues to negotiate with three candidate distributors. In discussion with Distributor A, marketing issues to be solved (need to make a database of feedback from doctors and characteristic features of product, to make marketing tools) are increasing. With Distributor B, the results of sales and clinical use in other areas are important issues to execute an agreemet, and it takes some time to evaluate the hemostat compared to existing products in discussion with Distributor C. Hence, the agreement has not been executed by Q3 FY2015 and is unlikely to be concluded by the end of FY2015 in the course of reevaluation of the progress until Q3.

Product evaluation by doctors has been progressing. More results of clinical use in Europe and the actual sales performance in other areas are able to solve the issues to Distributor A and Distributor B, and such results are able to respond the issues to Distributor C. The Company's group is going to focus on accumulating clinical use of the hemostat and product sales and continues to discuss with candidate partners in order to conclude the agreement in FY2016.

The Company expects that an exclusive sales parnership agreement for Europian area is going to be executed with one of those candidate distribution parners and existing product sales through local agents in each country is goig to be consolidated after the agreement. The Company's mid-term businss plan will be refleceted by a progress until the end of FY2015.

(5) Extraordinary loss expected to be recognized

The Company is evaluating an impairment loss of non-current assets during the term of Q1-Q3 FY2015 (May 1, 2015 to January 31, 2016).

Subjected non-current assets are ¥569 million (tangible non-current assets of ¥80 million, non-tangible non-current assets of ¥347 million (goodwill of a subsidiary in US of ¥134 million, patent

licenses of ¥213 million), long-term prepaid expenses for patents of ¥141 million), which are assets relating to medical product business including the hemostat and dental bone filler and recognized as one group. The Company's group calculates estimated revenue after FY2015, evaluates the book value and reestimated value of the subjected non-current assets and make discussions with auditors.

The amount of an impairment loss might be changed through discussion with auditors and be ¥569 million in total if all subjected non-current assets are recognized. Hence, the estimated amount is hereby informed and included to this reviseof the forecast. Final settlement of recognizing the impairment loss is going to be announced by the date when the Company's financial results for Q1-Q3 FY2015 (May 1, 2015 to January 31, 2016) is annouced.

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ significantly from the forecast due to various subsequent factors.