

Notice of Recording of Impairment Loss and Revision of Full-Year Earnings Forecasts

Santen Pharmaceutical Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Shigeo Taniuchi; hereinafter “Santen”) announced that it expects to record an impairment loss on intangible assets related to STN2000100 (DE-128, hereinafter “DE-128”) in the fourth quarter (January 1, 2021 to March 31, 2021) of the fiscal year ended March 31, 2021. Santen also announced the revision to its forecasts of consolidated financial results for the year ended March 31, 2021, previously announced on May 8, 2020.

1. Recording of impairment loss

(1) Reasons for impairment loss

Santen has been in discussions with the U.S. Food and Drug Administration (FDA) since the end of February 2021 when it received notification from the FDA regarding DE-128, for which Santen submitted a Premarket Approval (PMA) application for the U.S. in June 2020. Due to the possibility that discussions will be prolonged, Santen has decided to record an impairment loss as a result of reviewing the value of this asset based on the assumption that the approval date in the U.S., which was assumed to be the first half of fiscal year 2021 will be delayed.

(2) Description of impairment loss

Currently, Santen has recorded 53.4 billion yen in intangible assets (goodwill and development, manufacturing and sales rights) related to InnFocus, Inc. (U.S.), developer of DE-128. Although Santen expects to record a total impairment loss of 40.5 billion yen (US\$ 382 million), consisting of the full 15.7 billion yen in goodwill and 24.8 billion yen in development, manufacturing and sales rights as a result of reviewing the value of this asset, it also expects to record a gain on reversal of change in fair value of contingent consideration of 14.9 billion yen (US\$141 million).

2. Revision of forecasts of consolidated financial results

(1) Revision of the forecasts of consolidated financial results for the year ended March 31, 2021 (April 1, 2020 to March 31, 2021)

Core basis

	Revenue	Core operating profit	Core net profit for the year	Basic core earnings per share
Forecast announced on May 8, 2020 (A)	JPY millions 235,000	JPY millions 52,000	JPY millions 38,700	Yen 97.67
Revised forecast (B)	249,000	51,000	38,000	95.13
Increase/decrease (B-A)	14,000	-1,000	-700	
Increase/decrease (%)	+6.0	-1.9	-1.8	
(Ref.) Consolidated results for the year ended March 31, 2020	241,555	50,023	35,894	90.00

IFRS basis

	Revenue	Operating profit	Profit before tax	Net profit for the year	Basic earnings per share
Forecast announced on May 8, 2020 (A)	JPY millions 235,000	JPY millions 35,000	JPY millions 34,000	JPY millions 23,000	Yen 58.35
Revised forecast (B)	249,000	14,500	14,000	7,000	18.27
Increase/decrease (B-A)	14,000	-20,500	-20,000	-16,000	
Increase/decrease (%)	+6.0	-58.6	-58.8	-69.6	
(Ref.) Consolidated results for the year ended March 31, 2020	241,555	33,535	32,091	21,714	59.16

(2) Reason for revision

Revenue has remained steady amid the COVID-19 outbreak, centered mainly on Santen's core prescription pharmaceuticals business. In the fourth quarter, however, revenue is expected to increase by 6.0% to 249.0 billion yen, exceeding the previously announced forecast of 235.0 billion yen, as a result of steady growth of mainstay products such as *Alesion LX* in Japan as well as steady sales in China primarily to private hospitals despite the impact of value-based purchasing. Although operating profit on a core basis is expected to total 51.0 billion yen, operating profit, profit before tax, and net profit for the year on an IFRS basis are expected to fall well below the previous forecast mainly due to the recording of an impairment loss related to DE-128.

*The earnings forecasts contained in this disclosure are based on information currently available to Santen as of the date of this release. Actual results may differ from these forecasts due to various factors.

*The core basis is calculated by adjusting the following income and expense items, which are deducted from IFRS results, and the related income tax expense.

- Amortization of intangible assets associated with products
- Other income
- Other expenses
- Finance income
- Finance expenses
- Share of (profit) loss of investments accounted for using equity method
- One-time expenses related to acquisitions of companies included in SG&A

3. Impact of impairment loss on the business

Discussions with the U.S. Food and Drug Administration (FDA) in the U.S. regarding DE-128 have been continuing as mentioned above. Santen does not anticipate any impact on its European business, where the surgical device has already received a CE mark and is currently marketed, or on the current regulatory process in Asian countries. Santen will continue to contribute to helping treat glaucoma patients with DE-128 as one of the treatment options.

In the U.S. business, Santen will continue to aim for steady sales and profit growth mainly in its prescription pharmaceuticals business by utilizing sales channels of Eyevance Pharmaceuticals Holdings Inc. (U.S.), which Santen acquired in September 2020, while continuing to expand its pipeline.

Santen will explain its future measures and strategies in its Medium-term Plan, which is currently being refined, including the impact of the impairment loss.

About STN2000100 (DE-128)

In the United States, STN2000100 (DE-128) is an investigational, ab-externo, minimally-invasive surgical glaucoma implant designed to help drain eye fluid and reduce intraocular pressure (IOP) in primary open-angle glaucoma patients whose IOP is not controlled when using maximum tolerated glaucoma medications. IOP reduction is the most effective means of preventing the progression of glaucoma and vision loss. Made of a proprietary, biocompatible material called SIBS [poly (styrene-block-isobutylene-block-styrene)], STN2000100 (DE-128) is a flexible, 8.5-mm-long tube with planar fins to help fixate the device in tissue and prevent leakage and migration.

About Santen

As a specialized company dedicated to ophthalmology, Santen carries out research, development, marketing, and sales of pharmaceuticals, over-the-counter products, and medical devices. Santen is the market leader for prescription ophthalmic pharmaceuticals in Japan and its products now reach patients in over 60 countries. With scientific knowledge and organizational capabilities nurtured over a 130-year history, Santen provides products and services to contribute to the well-being of patients, their loved ones and consequently to society. For more information, please visit Santen's website (www.santen.com).

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