

BIOTECHNOLOGY-RELATED BUSINESS



On a Steady Path toward Profitability and the Expansion of the 5-ALA-related Business

Principal Companies

Intermediate Holding Company: SBI ALApharma

SBI Pharmaceuticals
SBI ALApromo
photonamic
NX Development Corp.
SBI Biotech
Quark Pharmaceuticals

Full-year Profit before Income Tax Expense of the Biotechnology-related Business (Based on IFRSs)

(Millions of yen)

	FY2017	FY2018
SBI Biotech	(432)	(166)
Quark Pharmaceuticals	(7,902)	(8,193)
5-ALA-related business		
SBI Pharmaceuticals	42	(1,395)
SBI ALApromo	40	263
photonamic	55	412

Note: Excluding impairment losses of drug pipeline, etc.

Principal Initiatives in FY2018 and Future Priority Measures

> SBI Biotech

- Losses narrowed owing to the receipt of the final year subsidy from Japan Agency for Medical Research and Development (AMED)
- Development of out-licensed pipeline products is proceeding at a healthy pace. Planning to achieve and sustain full-year profitability through the out-licensing of new pipeline technology

> Quark Pharmaceuticals

- U.S.-based Quark Pharmaceuticals continues its discussions with the FDA on moving a drug, which targets delayed graft function (DGF) in kidney transplants, to the new drug application (NDA) process. At the time the NDA is approved, an IPO, a partial or complete sale of its shares will be considered
- Phase III clinical trials continue for a drug pipeline product targeting acute kidney injury (AKI)

> 5-ALA-related Business

- U.S.-based NX Development Corp., a subsidiary of German-based photonamic, started U.S. sales of "Gleolan," an intraoperative diagnostic agent for brain tumors, in October 2018
- SBI ALApromo started sales of "ALA PLUS Fukai Nemuri (Deep Sleep)," a food with functional claims containing 5-ALA, in March 2019

5-ALA-related Products

Ethical drug



ALAGLIO®
Divided Granules 1.5g

Health foods and cosmetics



ALA PLUS
Tou (Sugar) Down



ALA PLUS Fukai Nemuri
(Deep Sleep)



ALA PLUS
Gold



ALA PLUS
Karada Shape



ALA PLUS
Sports High-performance



ALA PLUS
Cosmetic Series

Strong Progress in Drug Discovery for 5-ALA-related Pharmaceuticals

In the Biotechnology-related Business, profit expectations are high over the medium- to long-term for pharmaceuticals utilizing 5-Aminolevulinic Acid (5-ALA). Although, drug discovery and product commercialization requires time and sustained effort, in FY2018 various results indicated steady progress toward future profitability in the segment overall.

SBI Pharmaceuticals is a company that conducts R&D and the manufacturing of health foods and drugs containing 5-ALA. In September 2013, it started sales of “ALAGLIO® Oral 1.5g,” a photodynamic intraoperative diagnostic agent for malignant glioma (a type of brain tumor) treatment as its first pharmaceutical product. In December 2017, it commercialized “ALAGLIO® Divided Granules 1.5g,” a photodynamic intraoperative diagnostic agent for carcinoma vesicae (a type of bladder cancer). Chugai Pharmaceuticals was granted exclusive marketing rights in Japan for “ALAGLIO® Divided Granules 1.5g,” and is currently selling the product domestically.

SBI Pharmaceuticals is continuing its efforts with multiple drug discovery pipeline products. In December 2019, it expects to complete Phase III trials of an intraoperative diagnostic agent for peritoneal dissemination of gastric cancer, and in September 2020 it expects to complete Phase II trials for its drug treatment for cisplatin nephropathy protection. A drug to treat mitochondrial diseases is also expected to be completed in January 2021, and is currently entering Phase III with clinical trials being conducted at each stage on its path to approval. Also, Phase II preparations are underway for a drug to treat cardiac ischemia-reperfusion injury, and a drug for photodynamic therapy for brain tumors.

Note: For more details on the Biotechnology-related Business's drug discovery pipeline, please refer to the fact sheet on pages 56–57.

Commencement of U.S. Sales for an Intraoperative Diagnostic Agent for Brain Tumors Using 5-ALA

Strong sales continued for two core products of photonamic, a German company that in January 2016 became a wholly owned subsidiary of SBI ALApharma (an intermediate holding company in the 5-ALA-related business), and photonamic's profitability is also increasing steadily. The first product was “Gliolan®,” an intraoperative diagnostic agent for brain tumors, and the other was “Alacare,” a drug that treats actinic keratosis. Until now, photonamic has been predominantly engaged in the development and sales of products using 5-ALA, focusing on Germany, the U.K. and other European countries. In April 2018, it purchased its former partner, U.S.-based NX Development Corp., and started sales of “Gliolan” in October of the same year in the U.S. Favorable sales have produced a net sales amount of \$3.7 million over eight months. International expansion of “Gliolan®” is progressing in other regions with sales through local partners in over 40 countries, including South Korea and Australia.

Strong Sales of Foods with Functional Claims and Planning a Global Reorganization

Recently, increased interest in foods with functional claims has been taking place in Japan, and SBI ALApromo has accelerated its development of products that contain 5-ALA as a functional ingredient.

The sale of “ALA PLUS Tou (Sugar) Down” began in December 2015, and this popular food with functional claims product helps normalize high fasting glucose levels, as well as moderates the elevation of postprandial glucose levels. In November 2018, sales began for “ALA PLUS Tou (Sugar) Down Rich,” which contains a greater amount of 5-ALA. Then in March 2019, “ALA PLUS Fukai Nemuri (Deep Sleep),” with a function for improving the quality of sleep, was newly placed on sale, and helped enrich our product offerings.

In addition, “ALA PLUS Karada Active,” which helps improve the efficiency and function of physical exercise, is scheduled to be released in October 2019. SBI ALApromo is also participating in joint research with various universities, and is moving forward on the development of new foods with functional claims, such as those for alleviating fatigue and improving the effects of male menopause.

As a result of further global expansion, the 5-ALA-related Business is planning a structural reorganization. Specific goals include an IPO of SBI ALApharma, the Hong Kong-based intermediate holding company, within two to three years. In addition to this, the SBI Group intends to carry out an organizational restructuring to optimize management resources at the 5-ALA-related business for those affiliated with SBI ALApharma, such as the Japanese business under SBI Pharmaceuticals and SBI ALApromo, the European business under photonamic of Germany, and the U.S. business under NX Development Corp. In other regions, business bases may be added through M&A activities.

OTHER BUSINESSES

Digital Asset-related Business Targets Early Profitability

In the digital asset-related business, SBI VC Trade (formerly SBI Virtual Currencies) has been operating exchanges for crypto-assets since July 2018. By utilizing Group synergies, SBI VC Trade achieved profit before income tax expense of approximately ¥360 million in its first fiscal year (FY2018). After examining the company's services, including its leverage trading, SBI VC Trade underwent a segment change in July 2019, and will pursue sales activities under SBI SECURITIES, which runs the Type 1 Financial Instruments Businesses.

The Group is also actively mining crypto-assets. SBI Crypto, which is engaged in the mining of crypto-assets, operates highly efficient, reliable and sustainable mining businesses in cooperation with the SBI Group and its portfolio companies, and is building a comprehensive framework covering everything from hardware and software development, to the securing of locations and electric power. The laws, regulations and institutions related to crypto-assets are undergoing revisions and updates, and the SBI Group will take these revisions into account as it continues to provide services in response to various customer needs, and will make the preservation of customer assets its first priority.