

BIOTECHNOLOGY-RELATED BUSINESS



Globally Expanding Both the Pharmaceuticals and the Health Foods Business toward Further Profit Growth in the 5-ALA-related Business, which Achieved Its First Full-year of Profitability

Principal Companies

Intermediate Holding Company: SBI ALApharma

SBI Pharmaceuticals
SBI ALApromo
photonamic
SBI Neopharma
SBI Biotech
Quark Pharmaceuticals

Principal Initiatives in FY2017 and Future Priority Measures

SBI Biotech, Quark Pharmaceuticals

- SBI Biotech is continuing the development of its drug discovery pipeline, and is seeking new out-licensing opportunities
- At Quark Pharmaceuticals, expenses rose as a result of the steady progress in clinical trials, including several of those in Phase III
- Quark Pharmaceuticals' pipeline candidate targeting acute kidney injury (AKI) has newly entered Phase III

5-ALA-related Business

- SBI Pharmaceuticals was profitable for the second consecutive year, owing to the start of sales of "ALAGLIO® Divided Granules 1.5g," which SBI Pharmaceuticals granted exclusive domestic marketing rights to Chugai Pharmaceutical, and received a milestone payment based on licensing agreements
- SBI ALApromo has achieved its first full-year profitability after increasing the number of outlets handling its health foods containing 5-ALA in Japan to 16,000 stores
- SBI ALApromo released "SBI Gingko Bilboa" to market as a new food with functional claims, and is accelerating its product development to expand the product offering of such foods

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

	(Millions of yen)	
	FY2016	FY2017
SBI Biotech	737	(432)
Quark Pharmaceuticals	(8,270)	(7,902)
5-ALA-related business	(298)	58
SBI Pharmaceuticals	91	42
SBI ALApromo	(233)	40
photonamic (consolidated in Jan. 2016)	(41)	55

*Excluding impairment losses of drug pipeline, etc.

5-ALA-related Products

Ethical drug



ALAGLIO®
Divided Granules 1.5g

Health foods and cosmetics



ALApplus
Gold



ALApplus
Body Shape



ALApplus
Sports High-performance



ALApplus
Tou (Sugar) Down



SBI Gingko Bilboa



ALApplus
Cosmetic Series

Global Expansion of 5-ALA-related Pharmaceuticals

In the SBI Group's Biotechnology-related Business, pharmaceuticals utilizing 5-ALA stand out as a promising field that will make major contributions to profit over the medium- to long-term. One such product is "Gliolan[®]," an intraoperative diagnostic agent using 5-ALA that was developed by photonamic, a wholly owned subsidiary of SBI ALApharma, which is an intermediate holding company of the 5-ALA-related business. After receiving approval from the European Medicines Agency (EMA) in 2007, "Gliolan[®]," through photonamic's sales partners, has accumulated a track record of sales in over 40 countries, including Germany and the U.K. In June 2017, photonamic also received approval of this pharmaceutical agent from the U.S. Food and Drug Administration (FDA), and expects to start sales in the U.S. in the second half of FY2018. The product will be sold under the name "Gleolan," and will be marketed through NX Development Corp., which became a subsidiary of photonamic in April 2018. In Japan, SBI Pharmaceuticals has been selling "ALAGLIO[®] Oral 1.5g" since 2013, as an application of intraoperative diagnostic agent for malignant glioma, a type of brain tumor. More recently, SBI Pharmaceuticals developed "ALAGLIO[®] Divided Granules 1.5g," for the purpose of visualizing tumor tissues during resection of bladder cancer. Its domestic sales were started in December 2017 by Chugai Pharmaceutical, which was granted exclusive marketing rights in Japan. Domestically, SBI Pharmaceuticals is proceeding with initiatives to expand the drug application.

Strengthening Overseas Sales of Drugs and Health Foods Using 5-ALA

In its objective to expand overseas sales of drugs and health foods using 5-ALA, SBI ALApharma jointly founded SBI Neopharma in Dubai in 2017. The partner in this joint venture, namely Neopharma, is one of the largest pharmaceutical distributors in the Middle East and North Africa region (MENA), and has built a business manufacturing generic drugs under license from 14 companies including global mega-pharmaceuticals, at 7 locations around the world. In May 2017, SBI Neopharma started Middle East sales of health foods containing 5-ALA. The company is currently undertaking registration procedures for selling health foods in over 80 countries. In FY2018, SBI Neopharma plans to start sales of the "NatuALA" health food in 20 or more countries. In the MENA and Indian regions, SBI Neopharma also plans to sell drugs using 5-ALA, including drugs for the treatment of diabetes and malaria, which are out-licensed to Neopharma, as well as "ALAGLIO[®] Divided Granules 1.5g."

Expanding Sales through Foods with Functional Claims

Since its start of business in 2012, SBI ALApromo, a company engaged in the domestic planning, manufacturing and sales of cosmetics and health foods containing 5-ALA, has steadily increased the number of outlets handling its product offerings. It

now conducts product sales through over 16,000 drugstores and pharmacies nationwide, as well as an official online shop and other channels. In particular, "ALApplus Tou (Sugar) Down," a food with functional claims, which started sales in December 2015, has been a big hit. By continually boosting sales, the product helped SBI ALApromo to increase its revenue in FY2017 by 29.6% year-on-year, and to achieve its first surplus in profit before income tax expense for the full-year since its establishment.

Furthermore, in steps toward expanding its product offering of health foods with functional claims, SBI ALApromo is developing products with functions for improvement in the exercise capacity and the quality of sleep, in addition to premium products with high 5-ALA content, and has completed its filings to the Consumer Affairs Agency. The company has also initiated R&D of products with functions for lessening daily fatigue, alleviating fatigue from physical activities and improving male menopause, and plans to complete the filings by the end of FY2018. Outside of this, SBI ALApromo is rolling out supplements using non-5-ALA components and general food products. In December 2017, it started sales of "SBI Gingko Bilboa," containing a ginkgo bilboa component that is reported to preserve memory. It has also started R&D and commercialization of germinated brown rice in FY2017, and plans to start sales of this new product offering in September 2018.

In a move towards creating a full offering of 5-ALA skincare products, SBI ALApromo sells a complete product offering of lotions and creams, with an addition of cleansing and facial wash, available through the Internet. It is also actively expanding OEM-branded health foods and cosmetics. Starting in FY2017, SBI ALApromo has also been making exclusive use of clinic sales channels to market "ALApplus 75," with high 5-ALA content. Through these types of initiatives, SBI ALApromo intends to further expand sales of its products, and to strive for the continuous profitability of the 5-ALA-related business.

"ALApplus Tou (Sugar) Down," a Food with Functional Claims Marketed by SBI ALApromo, was Awarded "The Storefront Hit Product" Award

In March 2018, "ALApplus Tou (Sugar) Down," a food with functional claims of SBI ALApromo, received "The Storefront Hit Product" Award at the Kinoushoku Awards 2018 (official name: Foods with Health Claims Market Creation Award) held by Health Business Magazine. These awards, which cover foods with health claims (foods with functional claims, foods for specified health uses and foods with nutrient function claims) encompass the needs of the time, and open up latent demand. The awards were established to recognize the products that will drive the future market. "The Storefront Hit Product" Award that SBI ALApromo received at this year's event is awarded to the product providing the greatest support to consumers through promotion and marketing at retail outlets from an "on-the-ground perspective at drugstores." The award was selected by the vote of the readers of the monthly magazine "H&B Retail."