COMPANY RESEARCH AND ANALYSIS REPORT

ReqMed Company, Ltd.

17-Sep.-2026

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https://www.fisco.co.jp

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Summary

Pharmaceutical company which succeeded in developing and launching two products

ReqMed Company, Ltd. (hereafter, also "the Company") is a pharmaceutical development/sales company established in 1998 by utilizing the internal venture system of Kyowa Hakko Kogyo Co., Ltd. (currently Kyowa Kirin Co., Ltd. <4151>). The Company became independent in 1999 and has a track record of developing and launching two products to date. Currently, the Company is advancing domestic Phase III clinical trial of pentosan polysulfate sodium (hereafter, NaPPS) for the indication of knee osteoarthritis. In pharmaceutical sales business area, it sells Orphacol Capsules 50mg (generic name: cholic acid), a treatment for congenital bile acid metabolism disorders*.

> * Congenital bile acid metabolism disorders are diseases caused by a hereditary deficiency of any one of the enzymes involved in the biosynthetic pathway from cholesterol to bile acids in liver, resulting in hepatic dysfunction due to the accumulation of intermediate metabolites (bile acid precursors) within hepatocytes. They are progressive diseases, and if left untreated, there is a risk of death due to cirrhosis or liver failure. They are designated as target diseases under Japan's pediatric chronic specific disease program and are extremely rare hereditary diseases with a very small number of patients.

1. Development status of NaPPS

Since December 2024, the Company has been conducting domestic Phase III clinical trial of NaPPS for the indication of knee osteoarthritis. It is a double-blind comparative trial against a placebo group with total 160 cases planned. The trial involves administration once a week for a total of eight doses (subcutaneous injection), with the primary endpoint being the change in pain score from pre-administration to eight weeks after administration. As of the end of June 2026, the subject enrollment rate exceeded 50%. If the progress continues as planned, subject enrollment is scheduled to be completed by March 2027, the trial (including treatment and observation periods) is expected to be completed around August 2027, and if the results are favorable, the Company aims to apply for marketing approval by March 2028. The number of patients with knee osteoarthritis is on the rise as the Japanese population is aging. Currently, anti-inflammatory analgesics and hyaluronic acid injections are generally used, and joint replacement surgery is also performed for severe patients. The Company is targeting mild to moderate patients and estimates the number of such patients at approximately 8 million in Japan. Of these, the number of patients using hyaluronic acid injections is estimated at approximately 2.5 million, and the Company has formulated its business plan with 500,000 patients (20% of the patients using hyaluronic acid injections) as the bottom line for the target patient population. Sales on the scale of several tens of billions of yen* can be expected. The drug price of NaPPS is expected to be higher than that of hyaluronic acid injections and similar drugs; efficacy (cost effectiveness) will be the key to gaining market share.

> * The Company anticipates that the Ministry of Health, Labour and Welfare will calculate the drug price by the cost accounting method as there are no similar drugs. The drug cost for one course of treatment (eight administrations) is estimated at approximately ¥80,000.

2. Financial results

In the FY3/26 results, net sales decreased 7.6% year on year (YoY) to ¥443mn, and the operating loss was ¥785mn (compared with a loss of ¥112mn in the previous fiscal year). While net sales in the pharmaceutical sales business increased ¥187mn, the absence of ¥200mn in milestone income from a partner related to the sale of NaPPS (for knee osteoarthritis) recorded in the previous fiscal year in the pharmaceutical development business was the factor in the decline in sales. In terms of profits, in addition to the absence of the milestone income, R&D expenses increased from ¥285mn in the previous fiscal year to ¥778mn due to the start of the Phase III clinical trial, leading to a widening loss. For FY3/27, the Company forecasts net sales of ¥532mn (up 20.1%) and an operating loss of ¥1,067mn. Increase in the number of patients is the main factor for the increase in sales; nevertheless the operating loss is also expected to widen due to the clinical trial costs for NaPPS pushing up R&D expenses. Cash on hand at the end of FY3/26 stood at ¥1,480mn, and the Company is expected to raise business funds through equity financing.

3. Future development strategy

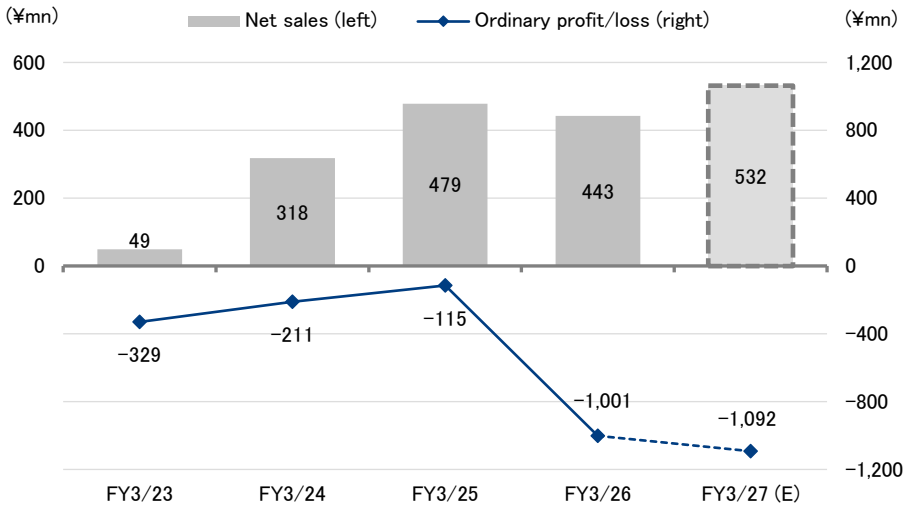
As its future development strategy, the Company first aims to obtain marketing approval of NaPPS for the indication of knee osteoarthritis in Japan. Thereafter it aims to expand the indications for NaPPS to osteoarthritis of the hand and hip, the rare hereditary disease mucopolysaccharidosis, and rare diseases HTLV-1-associated myelopathy.

As for eltoprazine, another product under development for the indication of Parkinson's disease, Phase IIa clinical trial has been completed overseas, and the Company will proceed with discussions on development strategy with key opinion leaders (KOLs) related to Parkinson's disease in Japan.

Key Points

- The Company aims to submit application for approval of NaPPS for the indication of knee osteoarthritis during FY3/28
- In FY3/26, the amount of loss widened due to R&D expenses increase
- The Company will continue focusing on the domestic Phase III clinical trial of NaPPS in FY3/27

Business performance



Source: Prepared by FISCO from the Company's financial results and the securities registration statement for the issuance of new shares and secondary offering of shares

Company profile

A biotech venture established utilizing the internal venture system of Kyowa Hakko

1. History

The Company is a pharmaceutical development/sales company established in 1998 by Tadashi Matsumoto, the current Representative Director and President, utilizing the internal venture system of Kyowa Hakko Kogyo (currently Kyowa Kirin). The ownership ratio was 51% for Kyowa Hakko Kogyo and 49% for Matsumoto, but later, when starting an investment fund management business for biotech ventures*, Matsumoto used his retirement benefits to purchase all of Kyowa Hakko Kogyo's shares and became independent upon discussions with Kyowa Hakko Kogyo.

* The investment fund management business ended in 2013.

While participating in Japanese and international biotech conferences to search for investee biotech ventures and seeds for drug discovery, the Company concluded a joint development agreement with the US biotech company PsychoGenics, Inc. (currently PGI Drug Discovery LLC) regarding eltoprazine and started its pharmaceutical development business in 2003. Around the same time, a professor at Nagasaki University Hospital asked the Company to procure NaPPS manufactured by the German company bene pharmaChem GmbH & Co. KG (hereafter, bene) for Creutzfeldt-Jakob disease* research purposes. The professor also recommended developing NaPPS as a treatment for knee osteoarthritis, and the Company concluded a joint development agreement with bene for Japan in 2004.

* A type of prion disease which is a degenerative disease of the central nervous system characterized by involuntary movements throughout the body and rapidly progressing dementia. There is currently no curative treatment, and the average life expectancy from first symptom is approximately 1.2 years.

Phase I clinical trial began in 2007, and development and sales license agreement for Japan was concluded jointly with bene for Asahi Kasei Pharma Corporation (currently Asahi Kasei Therapeutics Corporation) in 2008. Subsequently, Asahi Kasei conducted Phase IIa clinical trial for the indication of knee osteoarthritis but could not achieve the primary endpoint. The license agreement was terminated in 2012 and the Company decided in-house development. Subsequently the Company conducted Phase IIb clinical trials changing the dosage, administration method, administration period, and other factors, and found a dosage and administration period in which efficacy was confirmed. It entered a sales license agreement with Teikoku Seiyaku Co., Ltd. in 2024 and is conducting Phase III clinical trial from December 2024.

The drug lag (time gap between pharmaceuticals approved overseas and delay in development and approval in Japan) became problematic around 2010 and the Ministry of Health, Labour and Welfare launched project supporting unapproved drug development. The Company applied for the project selecting betaine for the indication of homocystinuria*, and was chosen as developer in Japan. Phase III clinical trial began in 2012 using subsidies from the Japanese government, and the Company obtained marketing approval, resulting in sales from 2014. The Company shifted its development strategy from license-out model to in-house development model since then. It continued to enjoy the sales of betaine until the overseas licensor established a local subsidiary in Japan and the sales rights were transferred upon the expiration of the license agreement period in 2022.

> * A type of congenital amino acid metabolism disorder, a rare hereditary disease caused by the accumulation of homocystine, a metabolite of methionine, in the blood. Neurological disorders and thrombosis are symptoms, and skeletal abnormalities, ocular symptoms, and blood abnormalities may also emerge depending on the disease type. It has been designated as an intractable disease under Intractable Diseases Act.

Similarly, the Company was chosen under the same project as developer in Japan for cholic acid (indication: congenital bile acid metabolism disorders*), obtained marketing approval and has been selling the product (product name: Orphacol Capsules 50mg) since June 2023.

> * A condition caused by a hereditary deficiency of any enzyme involved in the biosynthetic pathway from cholesterol to bile acids in the liver. It is a rare disease that causes hepatic dysfunction due to the accumulation of intermediate metabolites (abnormal bile acids or bile alcohols) within hepatocytes and is designated as a pediatric chronic specific disease in Japan.

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Company profile

History

Month/year	Major milestones
May 1998	Established as the first company under the internal venture system of Kyowa Hakko Kogyo Co., Ltd. (currently Kyowa Kirin Co., Ltd.)
June 1999	Representative Director Matsumoto purchased all equity held by Kyowa Hakko Kogyo Co., Ltd. (51%), and the company became fully independent
February 2000	Established the Life Science Investment Business Partnership jointly with MBL Venture Capital Co., Ltd. (currently Life Science Venture Capital Co., Ltd.), and started investment fund management business
August 2003	Entered joint development agreement for eltoprazine with PsychoGenics, Inc. (currently PGI Drug Discovery LLC) and started the pharmaceutical development business
May 2004	Entered joint development agreement for NaPPS with bene pharmaChem GmbH & Co. KG
September 2005	Started clinical research on NaPPS (indication: knee osteoarthritis) at Nagasaki University Hospital
January 2007	Started Phase I clinical trial of NaPPS in Japan
June 2008	Entered domestic development and sales license grant agreement to Asahi Kasei Pharma Corporation (currently Asahi Kasei Therapeutics Corporation) on NaPPS jointly with bene pharmaChem GmbH & Co. KG
March 2009	Started pharmacokinetic study of eltoprazine with Japanese participants in the United States
April 2010	Started Phase IIa clinical trial of NaPPS in Japan for knee osteoarthritis by Asahi Kasei Pharma Corporation
September 2010	Entered development and sales license grant agreement in South Korea to Chong Kun Dang Pharmaceutical Corp. on NaPPS jointly with bene pharmaChem GmbH & Co. KG
June 2011	Selected as the development company for betaine under the Ministry of Health, Labour and Welfare's project supporting unapproved drug development
September 2011	Entered exclusive development and sales license agreement for betaine in Japan with Orphan Europe SARL (currently Recordati Rare Diseases SARL)
March 2012	Started Phase III clinical trial in Japan of betaine for the indication of homocystinuria
June 2012	Phase IIa clinical trial of NaPPS conducted by Asahi Kasei Pharma Corporation ended. Further development was abandoned as the primary endpoint was not achieved. Subsequently the license agreement in Japan was terminated
April 2013	Obtained Type 1 pharmaceutical manufacturing and marketing business license
May 2014	Launched betaine (product name: Cystadane Powder) and started pharmaceutical sales business
October 2014	Started Phase IIa clinical trial of NaPPS for the indication of HTLV-1-associated myelopathy (HAM)
November 2015	Started Phase II clinical trial of NaPPS for the indication of pediatric mucopolysaccharidosis
October 2019	Selected as the development company for cholic acid under the Ministry of Health, Labour and Welfare's project supporting unapproved drug development
April 2020	Entered joint development agreement with Laboratories CTRS (currently THERAVIA SAS) on development and sales of cholic acid in Japan
May 2020	Started Phase III clinical trial in Japan of cholic acid
November 2021	Started Phase IIb clinical trial of NaPPS for the indication of knee osteoarthritis
January 2022	Transferred betaine sales to Recordati Rare Diseases Japan Co., Ltd. (Recordati Rare Diseases' Japanese subsidiary) upon termination of the license agreement
June 2023	Launched cholic acid (product name: Orphacol Capsules 50mg)
September 2024	Entered basic sales agreement regarding NaPPS with Teikoku Seiyaku Co., Ltd.
December 2024	Started Phase III clinical trial of NaPPS for the indication of knee osteoarthritis
October 2025	Entered Data Sharing and License Agreement for eltoprazine with PGI Drug Discovery LLC

Source: Prepared by FISCO from the securities registration statement for the issuance of new shares and secondary offering of shares

Expanding pharmaceutical development and sales as two pillars

2. Business description

(1) Characteristics of the Company

Since its establishment, the Company has been engaged in the development of "Required Medicine for all who request it." In particular, key characteristics are: the Company identifies drug seeds with significant unmet medical needs* through broad network spanning Japanese and international biotech ventures and academia as well as academic societies and patient associations, takes the lead in formulating research and development strategies, and advances development utilizing contract research organizations (CROs) and other parties.

* Unmet medical needs refer to medical needs that have not yet been satisfied and for which no effective treatment methods currently exist.

Other characteristics include the fact that the Company understands the properties of development compounds, constructs clinical trial designs in-house, and possesses the know-how and track record to conduct everything from Phase I to Phase III clinical trials through to marketing approval applications, as well as having obtained authorization as a Type 1 pharmaceutical manufacturing and marketing business operator. Based on this know-how, the Company has a track record of launching two products to date through in-house development.

With regard to sales strategy, the Company adopts a strategy of maximizing profits by conducting everything from development to sales independently in rare disease areas with a small number of patients, while in disease areas with a large number of patients, it enters sales license agreements with pharmaceutical companies and deploys a business model that generates contract lump-sum payments, milestones, and royalty income based on sales amounts. As a general guideline, for therapeutic drugs targeting rare diseases with fewer than 200 patients and fewer than 100 medical facilities, the Company deploys them through in-house sales because sales costs do not become a burden, while for other drugs it enters sales license agreements and sells them through other pharmaceutical companies.

Criteria for distinguishing between in-house sales and sales partnerships

	In-house sales	Sales partnerships
Number of patients	Fewer than 200	200 or more
Number of facilities	Fewer than 100 facilities	100 facilities or more

Source: Prepared by FISCO from the securities registration statement for the issuance of new shares and secondary offering of shares

(2) Overview by business

The Company currently operates three businesses: the pharmaceutical development business, the pharmaceutical sales business, and the consulting business.

a) Pharmaceutical development business

In the pharmaceutical development business, the Company is primarily advancing the development of NaPPS for the indication of knee osteoarthritis, and has also positioned eltoprazine, which has the indication of levodopa-induced dyskinesia (LID)* in advanced Parkinson's disease patients, as a development candidate product.

* Phenomenon in which uncontrollable body movements occur when the therapeutic drug L-dopa is administered to patients with advanced Parkinson's disease.

NaPPS, the Company's main pipeline product, is a plant-derived semi-synthetic substance extracted from beech trees. It has a long history, having been developed as an antithrombotic agent in Europe in 1949, and has been approved and sold as a treatment for interstitial cystitis in the United States in 1996 and as a treatment for bladder pain syndrome in Europe in 2017. It is also sold as a veterinary drug as a treatment for osteoarthritis in dogs in Japan, Europe, and the United States, and as a treatment for arthritis in dogs and horses in Australia. Because the original developer, bene, deliberately did not file a patent application to keep the manufacturing method as internal know-how, the manufacturing process is still managed within bene, giving it an overwhelming advantage over other companies in terms of quality. As a result, the Company, which has entered a joint development agreement with bene, will also be able to secure a competitive advantage in business if it succeeds in developing NaPPS.

Furthermore, the Company has independently developed freeze-drying formulation technology to achieve long-term stability and has filed international patent applications. Patents have already been granted in Japan, Australia, and Europe (it is under review in the United States). Other companies developed liquid injectable formulations. In the case of long-term storage, the liquid injectable solution has a risk that it adheres to the inner surface of the glass vial and the glass membrane peels off. Freeze-dried formulations eliminate this risk and also have the advantage of allowing room-temperature storage. Consequently the Company imports the pharmaceutical ingredient from bene and produces freeze-dried formulation at a Japanese pharmaceutical manufacturing company for use at the clinical trial.

The expected effects of NaPPS include suppressing various types of chronic inflammation and normalizing biological functions. In osteoarthritis, it alleviates pain symptoms of the arthropathy through composite actions on joint tissues. In mucopolysaccharidosis, it suppresses bone and cartilage symptoms (particularly joint contractures) while suppressing systemic chronic inflammation caused by glycosaminoglycans*. In addition, in progressive myelitis caused by the virus responsible for adult T-cell leukemia/lymphoma (HTLV-1) (hereafter, HAM), it is expected to improve lower-limb functional impairments such as walking difficulties and urinary dysfunction caused by HAM.

* Long-chain polysaccharides which normally show no branching. They are universally present in all tissues, primarily in animal connective tissues. Mucopolysaccharides in a narrow sense.

Outside Japan, the Company jointly entered a development and sales license agreement with Chong Kun Dang Pharmaceutical Corp. of South Korea (hereafter, CKD) together with bene in September 2010. This agreement came into place through the Company's search for a development partner in South Korea, which was a part of the joint development with bene. CKD imports NaPPS pharmaceutical ingredient from bene and sells it as a treatment for interstitial cystitis. Under the license agreement, the Company receives a portion of the profit bene receives from CKD, and records this as net sales of the pharmaceutical development business (¥32mn in FY3/26).

b) Pharmaceutical sales business

In the pharmaceutical sales business, the Company entered a joint development agreement with Laboratories CTRS of France (currently THERAVIA SAS) in 2020 and started selling cholic acid (product name: Orphacol Capsules 50mg) from June 2023. Orphacol Capsules 50mg has also been designated as orphan drug* for congenital bile acid metabolism disorders treatment.

* Pharmaceuticals for intractable diseases for which treatment methods have not been established due to limited number of patients despite high medical necessity. Under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, pharmaceuticals whose number of subjects pertaining to their usage does not reach 50,000 are designated as orphan drugs. This designation enables developers to utilize smoother development systems such as obtaining development subsidies and prioritized consultations with regulatory authorities.

Congenital bile acid metabolism disorders are diseases in which a congenital genetic mutation causes abnormalities in the enzymes that biosynthesize cholic acid and chenodeoxycholic acid (components of bile) from cholesterol in the liver, causing biosynthesis to stop midway. As a result, harmful abnormal metabolites accumulate in the liver and induce hepatic disorders. These disorders are divided into 12 disease types depending on the type of enzyme that is impaired, and Orphacol Capsules 50mg are used for treatment in 3 of these disease types (cerebrotendinous xanthomatosis (hereafter, CTX)* and 2 other diseases).

* A disease in which the function of the enzymes deteriorates and hinders production of bile acids from cholesterol, resulting in accumulation of lipids such as cholestanol in the body (including cranial nerves). This leads to thickening of the Achilles tendon as well as intellectual decline, walking difficulties, and unsteadiness.

The mechanism of action is that the cholic acid contained in Orphacol Capsules 50mg, when taken as an oral agent, behaves in the same way as the cholic acid secreted from the gallbladder into the duodenum. This assists the absorption of fats and fat-soluble vitamins in the small intestine, and by circulating sufficient amount of bile acids in the body, the biosynthesis of highly toxic metabolic intermediates is suppressed, leading to recovery from hepatic disorders.

Currently, Orphacol Capsules 50mg is the only drug approved in Japan for congenital bile acid metabolism disorders other than CTX. As for CTX, Fujimoto Pharmaceutical Co., Ltd.'s Fujikenon 125mg granular tablets (generic name: chenodeoxycholic acid) obtained marketing approval and sales began in November 2025. Fujikenon 125mg granular tablets are recognized as the first-line drug for CTX. However some patients cannot take the first-line drug alone for safety reason; additional administration of Orphacol Capsules 50mg is expected in those cases. There also are cases in which Orphacol Capsules 50mg is prescribed from the perspective of side-effect risk.

The Company imports Orphacol Capsules 50mg in final product form from its joint development partner Theravia (under Norgine BV) and sells through Sano Co., Ltd., a pharmaceutical wholesaler. There is currently no impact from the depreciation of the yen as the settlements are conducted in yen; however there is a risk of future purchase price negotiation.

c) Consulting business

The Company provides consulting services in business alliance and drug discovery strategy planning to biotech ventures and academia throughout the world who wish to utilize the Company's expertise accumulated through many years of joint development with Japanese and international biotech ventures.

Development pipeline

Aims to submit NaPPS (indication of knee osteoarthritis) application during FY3/28

1. Development status of NaPPS

(1) Knee osteoarthritis

a) Symptoms, treatment methods, and patient population

The Company places its highest management priority on development of NaPPS with the indication of knee osteoarthritis. Knee osteoarthritis is a disease in which the cartilage of the knee loses elasticity due to aging and wears down, causing inflammation within the joint and resulting in pain. The incidence rate increases with age. It can also develop as a sequela of trauma such as fractures or injuries to ligaments and the meniscus, or of infections such as purulent arthritis. In the early stage, pain occurs when standing up or at the start of walking. In the middle stage, kneeling and climbing stairs become difficult. In the late stage, pain does not subside even at rest, the joint deforms, and walking becomes difficult.

Oral painkillers or anti-inflammatory analgesics are used in mild cases. When symptoms progress further, hyaluronic acid is injected into the knee joint. When symptoms become severe, surgical treatments such as total knee arthroplasty may be performed, and regenerative medicine technologies have also begun to emerge recently.

The prevalence among people aged 40 and over is said to be approximately 55% in Japan, of which the number of people with symptoms reaching 18 million. It has been pointed out that the risk of patients requiring long-term care in the future is approximately 6 times higher than that of healthy individuals. In Japan, where the elderly population will continue to increase, decreasing patients with knee osteoarthritis will also help curb the number of people requiring long-term care, and the significance of developing highly effective therapeutic drugs is substantial.

Unlike previous medications, NaPPS belongs to a new therapeutic category of drugs known as disease-modifying agents, which suppress the chronic inflammatory state of the knee that causes knee osteoarthritis and inhibit cartilage destruction within the knee joint. It does not act immediately like pain-relieving oral drugs and anti-inflammatory analgesics, but improves the condition of the knee joint and thus decreases pain. The target patients are all patients with knee osteoarthritis from mild to severe conditions. The Company currently performs Phase III clinical trial targeting patients with grades 2–3 (mild to moderate) under the KL classification*, a criterion determining severity. The Company estimates the number of grades 2–3 patients in Japan at approximately 8 million.

* The KL (Kellgren and Lawrence) classification is a four-grade classification of severity based on X-ray images according to the degree of reduction in articular cartilage, the extent of osteophytes, the size of the joint space, and other factors. Grade 1 indicates suspected knee osteoarthritis, grade 2 mild, grade 3 moderate, and grade 4 severe knee osteoarthritis.

The investigational drug is a freeze-dried formulation for subcutaneous injection (hereafter, subcutaneous injection). By injecting it subcutaneously, the drug circulates throughout the body, and the Company expects that a single injection will effect both knees. While hyaluronic acid injections into the knee are performed by orthopedic surgeons, subcutaneous injections can be performed by internists as well as nurses, and in the future it may also become possible for patients themselves to administer the injection. This will ensure access to treatment even for patients who do not have an orthopedic surgeon nearby and are otherwise unable to receive it. Currently there are no other drugs that claim therapeutic effect on arthropathy via subcutaneous injection, and if development is successful, it may lead to a paradigm shift in the treatment of knee osteoarthritis.

b) Overview and progress of the Phase III clinical trial

Phase III clinical trial began in Japan in December 2024 (full enrollment started in July 2025), which is a double-blind comparative trial against the placebo group with a planned number of 160 cases. The subjects are patients aged 40–74 with KL classification grades 2–3 knee osteoarthritis. Subjects undergo provisional enrollment four weeks before the start of investigational drug administration, visit the facility once every two weeks to confirm the presence of pain, and drug administration starts after minimizing the placebo effect. The dosage is 2mg of NaPPS or placebo per kg of body weight, administered once a week for eight consecutive weeks. Subsequently subjects visit the facility 3 times at 4-week intervals (a total of 12 weeks) for follow-up observation. The primary endpoint is the change (degree of improvement) in the WOMAC-A score from baseline to Week 8 after administration, compared with the placebo group. WOMAC-A is the pain evaluation item among the WOMAC total index*.

* Index consisted of scores which the subjects assign to 24-item questionnaire on pain, stiffness, and difficulty in daily activities to evaluate symptoms related to osteoarthritis.

Phase III clinical trial design of NaPPS for knee osteoarthritis

Trial design	Placebo-controlled, randomized, double-blind, multicenter, parallel-group comparative trial
Target patients	Patients with knee osteoarthritis of KL classification grades 2–3 and age 40–74
Dosage	2mg/kg of the investigational drug or placebo administered subcutaneously once a week for eight weeks
Primary endpoint	Change in WOMAC-A score (pain score within 48 hours of administration) from baseline to Week 8 evaluation, compared with the placebo group
Number of cases	160 cases (80 cases for the investigational drug, 80 cases for placebo)

Source: Prepared by FISCO from the securities registration statement for the issuance of new shares and secondary offering of shares

In the Phase IIb clinical trial (number of cases: 12 in the active drug group, 11 in the placebo group), patients with KL grades 2–3 started to show difference in the degree of improvement in the WOMAC-A score between the placebo group and the active drug group from Week 6. It was confirmed that pain was reduced with a statistically significant difference at Week 8. If similar results are obtained in the current Phase III clinical trial, the Company will file an application for marketing approval.

The Company believes that favorable results were not obtained in the Phase IIa clinical trial conducted by Asahi Kasei Pharma because: the dosage was fixed at 100mg per administration regardless of body weight, the number of administrations and the period were short (four times over four weeks) and ended before the drug efficacy appeared, and the selection of subjects included patients with very mild symptoms. Patients with a VAS score (pain evaluation scale) of 2.5 to 7 on a 10-point scale were targeted at that Phase IIa clinical trial. 2.5 score corresponds to patients who experience pain only occasionally. In the current Phase III trial, patients with VAS score of 5 or higher are selected, making it more likely for patients to notice changes in pain.

As of June 2026, the progress of subject enrollment has exceeded 50%. The Company has expanded the number of trial sites from 25 to 28 to accelerate the enrollment pace and aims to complete full subject enrollment during FY3/27. If progress proceeds as planned, the clinical trial will be completed in August 2027, and if favorable results are obtained through data analysis, the Company will aim to apply for marketing approval during FY3/28. The review period is expected to take a little over one year; thus approval will likely be obtained in FY3/29 or later.

Regarding clinical trials of NaPPS with the indication of knee osteoarthritis, Paradigm Biopharmaceuticals is currently conducting Phase III clinical trial in Australia and plans to announce interim results in September 2026. The trial design is double-blind comparative trial in which a dosage of 2mg/kg is administered twice a week for six weeks, and its primary endpoint is set as the change in pain score two months after administration. Although the dosage and administration period differ slightly, the trial design is almost the same as that of the Company and attracts attention as a leading indicator.

CKD, currently selling NaPPS with the indication of interstitial cystitis, may consider development of knee osteoarthritis indication in South Korea after reviewing the results of the Phase III clinical trial in Japan. If the product is launched in South Korea, a certain percentage of the profit from the sale of the active pharmaceutical ingredient will go to the Company.

c) Potential market size

If development for knee osteoarthritis is successful, the scale of NaPPS sales is estimated to reach at least several tens of billions of yen based on drug prices. The drug price will be determined using the cost accounting method because there are no similar drugs in this field. According to the Company's estimates, approximately ¥80,000 is expected for eight administrations. The number of main target patients corresponding to KL classification grades 2 and 3 is approximately 8 million. However it will be difficult to replace hyaluronic acid preparations and anti-inflammatory analgesics as their prices are lower. The number of patients using hyaluronic acid preparations is estimated at approximately 2.5 million, and the Company has formulated its business plan using 500,000 patients (20% of that figure) as the bottom line expecting sales scale of several tens of billions of yen. Sufficient efficacy commensurate with the cost will be the key to gaining market share as the drug price will be higher than that of hyaluronic acid preparations and similar drugs*.

> * Among hyaluronic acid preparations, Seikagaku Corporation's <4548> ARTZ Dispo Joint Injection 25mg holds an overwhelming 80% share of the Japanese market (administered once a week for 5 consecutive weeks, and thereafter once a month). The drug price has been ¥663 per vial since April 2026, and when combined with the medical fee of ¥800 for intra-articular injection, the treatment cost for one knee is ¥1,463.

If the product is launched, it will be sold through the sales license partner Teikoku Seiyaku Co., Ltd.

d) Expansion of indications for osteoarthritis

If development for knee osteoarthritis ends successfully, the Company plans to expand the indications to similar diseases such as hand and hip osteoarthritis and proceed with development. The Company believes it will be possible to skip dose-setting trials by setting the same dosage as knee osteoarthritis and start from the Phase III clinical trial.

Hand osteoarthritis is a disease in which osteoarthritis primarily occurs in the first joints or the joints at the base of thumb, causing not only hand pain but also a decline in the quality of daily life due to reduced hand function. According to the Report on the Research Achievements of the Grants-in-Aid for Scientific Research published in 2022, the first epidemiological study conducted in Japan shows estimation that severe patients occur at a pace of approximately 700,000 per year and that approximately 1 million patients' symptoms worsen annually. Treatment methods consist of pain relief through oral drugs or anti-inflammatory analgesics, or surgical procedures. Hyaluronic acid preparations are not indicated for this condition partially because the joints of the hand are small and injection at the spot is difficult. NaPPS is expected to show efficacy in joints throughout the body via subcutaneous injection, and if knee osteoarthritis development succeeds, there is high possibility of similar success in hand osteoarthritis development.

Hip osteoarthritis is a disease in which the cartilage of the hip joint gradually wears down, causing pain during walking. If symptoms progress, it interferes with daily life, and in severe cases, replacement surgery with artificial joint is performed. It is estimated that there are approximately 1.2 million potential patients with hip osteoarthritis. Although hyaluronic acid preparations have been commercialized, there is strong unmet medical needs due to the risk of anaphylaxis and other side effects. NaPPS is expected to show efficacy in joints throughout the body via subcutaneous injection, and the Company intends to actively proceed with hip osteoarthritis development if knee osteoarthritis development is successful.

2. Development status of other pipelines

As for other pipelines, NaPPS Phase IIb clinical trial in Japan with the indications of mucopolysaccharidosis and mucolipidosis (improvement of bone and cartilage symptoms) has been completed and is currently under evaluation. In addition, NaPPS Phase IIa clinical trial in Japan with the indication of HTLV-1-associated myelopathy has similarly been completed and is under evaluation. However the Company places priority on the NaPPS development for osteoarthritis due to limited resources.

As for eltoprazine, the development partner PGI Drug Discovery of the United States has conducted pharmacokinetic study with Japanese residents in the United States. PGI Drug Discovery also conducted Phase IIa clinical trial in Europe with the indication of LID in patients with advanced Parkinson's disease. Going forward, the Company will search for contract manufacturers who will produce the active pharmaceutical ingredient toward the start of clinical trials for LID in Japan. It will also proceed with discussions on the development strategy with Parkinson's disease KOLs.

Results trends

In FY3/26, the amount of loss widened due to increase in R&D expenses

1. Overview of FY3/26 results

In FY3/26, net sales decreased 7.6% YoY to ¥443mn, the operating loss was ¥785mn (compared with a loss of ¥112mn in the previous fiscal year), the ordinary loss was ¥1,001mn (compared with a loss of ¥115mn), and the net loss was ¥1,002mn (compared with a loss of ¥120mn).

FY3/26 results

(¥mn)

	FY3/25	FY3/26	YoY	
			Change	Change (%)
Net sales	479	443	-36	-7.6%
Gross profit	369	238	-130	-35.4%
SG&A expenses	481	1,023	541	112.4%
R&D expenses	285	778	492	172.3%
Operating profit/loss	-112	-785	-672	-
Ordinary profit/loss	-115	-1,001	-885	-
Net profit/loss	-120	-1,002	-882	-

Source: Prepared by FISCO from the Company's financial results

The breakdown of net sales was ¥32mn for the pharmaceutical development business (down ¥219mn YoY), ¥407mn for the pharmaceutical sales business (up ¥187mn), and ¥4mn for the consulting business (down ¥4mn).

The pharmaceutical development business recorded a significant decrease in sales due to the absence of the ¥200mn milestone revenue from a partner recorded in the previous fiscal year under sales license agreement. In addition, the profit-sharing income from the NaPPS active pharmaceutical ingredient for the South Korean company also decreased from ¥51mn to ¥32mn.

Sales of Orphacol Capsules 50mg expanded generally in line with the plan in the pharmaceutical sales business. Retaining expert physicians for CTX (one of the disease types of bile acid metabolism disorders) with advisor consignment contract, and the continuation of awareness-raising activities for healthcare professionals were effective in further recognition uncovering potential patients. Although the number of patients receiving administration is in the low teens as the number of CTX patients is estimated to be around 100, the Company believes there is potential to expand sales to ¥1.0bn or more by advancing awareness-raising activities.

In the consulting business, remuneration and other income were recorded as net sales including remuneration on the lecturer dispatch to educational and training programs organized by the Japan Bioindustry Association to nurture young generation in the biotech industry.

Cost of sales increased ¥94mn YoY to ¥204mn as purchase costs increased in line with the Orphacol Capsules 50mg sales increase. Gross profit decreased ¥130mn to ¥238mn due to the absence of the ¥200mn contract milestone income. SG&A expenses increased ¥541mn to ¥1,023mn. The main factor was the ¥492mn increase in R&D expenses to ¥778mn accompanying the start of the Phase III clinical trial in Japan of NaPPS. In addition, personnel expenses increased following increase of 5 employees from the end of the previous fiscal year to 23 employees. Non-operating income and expenses deteriorated by ¥213mn due to ¥225mn in equity issuance costs accompanying third-party allotment.

Policy of securing funds for business activities through equity financing

2. Financial position

Total assets at the end of FY3/26 increased ¥448mn from the end of the previous fiscal year to ¥1,847mn. In current assets, cash and deposits increased ¥237mn, and accounts receivable - trade increased ¥147mn. In non-current assets, property, plant and equipment increased ¥9mn and investments and other assets increased ¥6mn.

Total liabilities increased ¥123mn from the end of the previous fiscal year to ¥619mn. Accounts payable - other increased ¥102mn and accounts payable - trade increased ¥22mn. Total net assets increased ¥325mn to ¥1,227mn. While retained earnings decreased due to net loss of ¥1,002mn, capital surplus increased ¥1,327mn reflecting third-party allotment capital increase.

Although cash on hand stood at ¥1,480mn, the Company is expected to continue seeking fund procurement through equity financing because losses are expected to continue in FY3/27 due to R&D expenses increase.

Balance sheet

(¥mn)

	End of FY3/24	End of FY3/25	End of FY3/26	Change
Current assets	1,511	1,362	1,794	432
Cash and deposits	1,312	1,243	1,480	237
Accounts receivable - trade	184	66	213	147
Non-current assets	38	35	52	16
Total assets	1,550	1,398	1,847	448
Current liabilities	356	325	619	294
Long-term liabilities	171	171	-	-171
Total liabilities	527	496	619	123
Interest-bearing liabilities	251	171	171	-
Total net assets	1,022	902	1,227	325
[Safety]				
Equity ratio	66.0%	64.5%	66.4%	1.9pp
Interest-bearing debt ratio	24.5%	19.0%	13.9%	-5.1pp

Source: Prepared by FISCO from the Company's financial results and the securities registration statement for the issuance of new shares and secondary offering of shares

The Company will continue focusing on the NaPPS domestic Phase III clinical trial in FY3/27

3. FY3/27 forecasts

For FY3/27, the Company forecasts net sales of ¥532mn (up 20.1% YoY), operating loss of ¥1,067mn, ordinary loss of ¥1,092mn, and net loss of ¥1,093mn.

FY3/27 forecasts

(¥mn)

	FY3/26 Results	FY3/27 Forecast	YoY	
			Change	Change (%)
Net sales	443	532	88	20.1%
Gross profit	238	238	0	0.1%
SG&A expenses	1,023	1,360	336	32.9%
Operating profit/loss	-785	-1,067	-281	-
Ordinary profit/loss	-1,001	-1,092	-90	-
Net profit/loss	-1,002	-1,093	-90	-

Source: Prepared by FISCO from the Company's financial results

The breakdown of net sales is expected to be ¥55mn from the pharmaceutical development business (up ¥23mn YoY), ¥475mn from the pharmaceutical sales business (up ¥68mn), and ¥1mn from the consulting business (down ¥2mn). In the pharmaceutical development business, profit-sharing income related to the sale of the NaPPS active pharmaceutical ingredient for the South Korean company is expected to grow. In the pharmaceutical sales business, the Company aims to increase sales by strengthening promotional activities targeting healthcare professionals to expand sales of Orphacol Capsules 50mg for CTX patients.

While gross profit is expected to remain at approximately at the same level as ¥238mn in the previous fiscal year, ¥336mn increase in SG&A expenses centered on R&D expenses will be the factor behind the expansion of the operating loss. On the other hand, ordinary loss is expected to remain at approximately the same level as the previous fiscal year because the equity issuance costs recorded in the previous fiscal year will no longer be present in non-operating income and expenses.

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