Business Report for the 18th Year
(Translation)

Nobelpharma Co., Ltd.

[From January 1, 2020 to December 31, 2020]

Business Report

(From January 1, 2020 to December 31, 2020)

1. Nobelpharma

1.1. Corporate Mission, Policies, Code of Conduct

Corporate Mission

Contribute to Society by Providing Critical but Neglected Pharmaceuticals and Medical Devices

Policies

1. General
   1) Give priority to legal and ethical compliance in the course of business--never prioritize loyalty to company over moral.
   2) Share our Mission, Policies and Code of Conduct among all stakeholders (employees, shareholders, officers)
   3) Pursue evolution of the Company, yet becoming larger is not our main goal
   4) Ensure transparency and disclosure
   5) Launch business overseas
2. Personnel
   1) Value employees and families, and respect self-development
   2) Employ the principle of "select few*," and create an environment where they can enjoy working
      * "Select few" = experienced experts passionately devoted to working, irrespective of gender, age, nationality, religion or preference
   3) Value suggestions and opinions from employees
3. Products
   1) Pursue high-quality products and data
   2) Ensure post-marketing safety
   3) Search for product seeds externally
4. Capital
   1) Profits are a result of and means of achieving the Mission
   2) Focus on higher return on sales/profits per employee
   3) Keep in mind the disadvantages of failure--not the assumption of success--when making investment decisions
   4) Profits are distributed to shareholders (dividends*), employees, and internal reserves
      * dividends: 1/3 of profits after tax
      * employees: up to dividends
   5) Invest asset only with a principal guarantee

Code of Conduct

1. Principle:

   When in doubt, the patient benefit takes priority
2. Our Challenges:
   1) YMWS: "Yatte Minakucha Wakaranai, shikashi Songiri wo tamerauna"
      = You never know how it will turn out unless you try, but do not hesitate to cut losses"
   2) ZY: "Zenrei ga nainara Yattemiru"

= Even if there is no precedent, be the first to try it

3. Speed:
   1) Never forget patients are waiting
   2) Be unafraid to buy time
   3) Set a specific deadline date at the beginning to pursue the goal without worrying about possible delays

      *Stay away from “approximately/around” and “early/late ~,” etc.
   4) If problems or mistakes occur, prevent their expansion first before preventing reoccurrence
   5) Speedy decisions by managers who have authority of million(s) yen projects*

      *3 million for Division Manager; 1 million for Department/Branch Manager/PM/PL
4. Cost/Efficiency:
   1) Never take or lead to wasteful actions
   2) No overtime is considered optimal
   3) Consider patient needs, scientific rationality and laws/regulations when pursuing higher quality in products/data
   4) Pursue cost reduction with the principle of multiple sources, while regarding providers as partners
5. Communications/Relationship:
   1) Embrace inter-departmental advice and cooperation—hiding in silos is a symptom of “Big Company” Disease
   2) Superiors to confidently entrust tasks to subordinates, but never leave unmanaged
   3) Hear anyone out--never interrupt in the middle
   4) Start with the conclusion/result when explaining/responding
   5) Greetings may seem small, but they are important

The Company will celebrate its 18th anniversary in June 2021. With the full-scale overseas expansion, the number of employees has increased to nearly 370 including foreign nationals, while those who were present at the time of Company foundation have decreased. It is necessary to rigorously adhere to the corporate mission, management policy and the “Request to line managers” as attached at the end of the Business Report in order for us to evolve the company and bring it to the next level of excellence.

While the Company set working from home as a usual style of working in March 2020, employees have cared about communication with each other and been conducting operations without hindrance.

1.2. Progress and Results of Operations

	mil yen		Year-on-year	% to total sales	
	2019	2020		2019	2020
Sales	13,403	16,929	126.3	100.0	100.0
Cost of goods sold	1,466	1,676	114.3	10.9	9.9
Gross profit	11,937	15,253	127.8	89.1	90.1
SG&A expense	8,921	11,705	131.2	66.6	69.1
* Personnel expenses	2,401	2,715	113.1	17.9	16.0
* R&D expenses	2,311	3,374	146.0	17.2	19.9
Operating income	3,015	3,547	117.6	22.5	21.0
Non-operating income/expenses	Δ64	Δ80	-	-	-
Ordinary income	2,951	3,466	117.5	22.0	20.5
Extraordinary income/loss	93	-	-	0.7	-
Net income before tax	3,045	3,466	113.9	22.7	20.5
Income taxes	674	955	141.6	5.0	5.6
Net income	2,370	2,511	105.9	17.7	14.8
Net income per employee ('000 yen)	7,476	7,195			
Retained earnings brought forward					
Beginning balance	2,093	4,104			
Dividend	359	789			
Net income	2,370	2,511			
Ending balance	4,104	5,825			

* Personnel expenses and R&D expenses are major items included in SG&A expenses.

* Personnel expenses did not include those of R&D, and R&D expenses included personnel expenses of R&D.

Total sales in 2020 were 16,929 million yen, up 26.3% year-on-year. NOBELZIN® and dysmenorrhea (LEP) family (LUNABELL® LD, LUNABELL® ULD, JEMINA® and Frewell®) posted sales of 10,172 million yen and 4,190 million yen, respectively, accounting for 61.7% and 25.4%, respectively, of total products sales. Melatobel® was launched as a new drug as scheduled in 2020, following RETYMPA® in 2019.

The cost of goods sold was 1,676 million yen, up 14.3% year-on-year, accounting for 9.9% of total sales (2019: 10.9%). Selling, general and administrative expenses totaled 11,705 million yen, an increase of 31.2% year-on-year, accounting for 69.1% (2019: 66.6%), mainly including personnel expenses of 2,715 million yen, up 13.1% year-on-year, and 16.0% (2019: 17.9%) of total sales, R&D expenses of 3,374 million yen, up 46.0% year-on-year, and 19.9% (2019: 17.2%) of total sales, sales promotion expenses of 2,836 million yen and outsourcing expenses of 1,045 million yen. Sales promotion expenses mainly included 2,301 million yen of sales commission on NOBELZIN®, JEMINA® and Melatobel® to MEDICEO CORPORATION, ASKA Pharmaceutical Co., Ltd. and SHIKOKU YAKUGYO Co., LTD. Outsourcing expenses mainly included 139 million yen for safety information processing support operation by CMIC, 75 million yen for royalties on Medichat by Medipal Holdings Corporation, 59 million yen for call center operation by EP-PharmaLine, and 52 million yen for business management service by Hisanaga Co., Ltd.

As a result, operating income was 3,547 million yen, up 17.6% year-on-year, and it accounted for 21.0% (2019: 22.5%) of total sales.

Ordinary income was 3,466 million yen, up 17.5% year-on-year, accounting for 20.5% (2019: 22.0%) of total sales, after recording non-operating income of 13 million yen including compensation received of

8 million yen, more than offset by non-operating expenses of 94 million yen including interest expenses of 32 million yen and bond interest expenses of 11 million yen.

With income taxes of 955 million yen, net income was 2,511 million yen, up 5.9% year-on-year, accounting for 14.8% (2019: 17.7%) of total sales, and net income per employee was 7 million yen (2019: 7 million yen).

Retained earnings brought forward as of December 31, 2020 were 5,825 million yen, with the beginning balance of retained earnings brought forward of 4,104 million yen and a dividend payment of 789 million yen.

To sum up our activities in 2020, we marked a steady progress in business operations through: (1) Steady sales growth despite the spread of the novel coronavirus infection (COVID-19); (2) robust R&D investment demonstrated by favorable increase in R&D expenses of approximately 45% year-on-year; (3) steady overseas expansion with expected marketing approvals in the United States and China in 2021; (4) business operations not affected by our policy of working from home; and (5) Gone half a step ahead in the industry by utilizing online system for sales activities.

The details are explained below.

1.3. Domestic sales

The table below shows sales by product in 2020 on a wholesale price (NHI price) basis.

Brand Name	Launch	Indication	Sales (on a wholesale price (NHI price) basis) (Yen in millions)		Year-on-year ([2]/[1])
			2019 [1]	2020 [2]	
NOBELZIN®	Apr 2008 Mar 2017	Wilson's disease, hypozincemia	9,123	11,895	130.4
LUNABELL® LD LUNABELL® ULD	Jul 2008 Sep 2013	Dysmenorrhea	4,375	3,104	70.9
NOBELBAR®	Dec 2008	Neonatal seizures, status epilepticus	115	107	93.7
Fostoin®	Jan 2012	Status epilepticus, prevention of postoperative seizures, etc.	1,036	945	91.2
GLIADEL®	Jan 2013	Malignant glioma	890	849	95.4
Alabel®	Sep 2013	Diagnosis of malignant glioma	284	297	104.8
INDACIN®	Jan 2013	Patent ductus arteriosus of prematurity	50	49	98.2
COSMEGEN®	Jan 2013	Wilms' tumor, choriocarcinoma, pediatric solid malignant tumor, etc.	22	24	111.4
Unitalc®	Dec 2013	Prevention of recurrent malignant pleural effusion	69	71	102.0
Respia®	Dec 2014	Apnea of prematurity	231	224	96.8
RAPALIMUS®	Dec 2014	Lymphangioleiomyomatosis	276	314	113.8
ZANOSAR®	Feb 2015	Gastroenteropancreatic neuroendocrine tumor	416	356	85.6
RAPALIMUS® Gel	Jun 2018	Skin lesions associated with tuberous sclerosis	385	376	97.6
TITANBRIDGE®	Jul 2018	Adductor spasmodic dysphonia	46	38	82.3
JEMINA®	Oct 2018	Dysmenorrhea	994	2,326	234.1
RETYMPA®	Dec 2019	Tympanic perforation	1	63	630.0
Melatobel®	Jun 2020	Sleep-onset difficulty associated with neurodevelopmental disorder in children	-	224	-
Total			18,312	21,262	116.1

In 2020, the Company promoted activities to expand the use of Melatobel® launched in June as the most focused product in addition to NOBELZIN® and JEMINA®. In this year, we have shifted to on-line MR activities from real face-to-face activities due to the COVID-19 pandemic. For the year ended December 2020, due to the COVID-19 pandemic, sales resulted in 21.3 billion yen, up 16.1% year-on-year, compared with the sales target of 24 billion yen (on a wholesale price (NHI price) basis).

While the method of sales has shifted from real face-to-face activities to online meetings, online lecture meetings and expert videos, we believe that our sales activities have successfully put us half a step ahead of other companies in the industry leading to some reduction of the gap in sales capabilities from major pharmaceutical companies. In addition, in order to further develop collaboration with the Medipal Holdings Group, which was already firmly established, we created the Sales & Wholesaler Management Department in January 2021. We are also developing a concrete plan to strengthen sales in areas where the Medipal Holdings Group is relatively weak.

In particular, the Company has collaborated with the Medipal Holdings Group to increase awareness of the product value of Melatobel®, which was newly launched in June 2020, for all pediatric doctors all over the country mainly through nationwide online lectures and area online lectures.

For the logistics of the direct-sales products, the Medipal Holdings Group has exclusively taken over the distribution.

1.4. Overseas sales

Regarding the business development in the US, Europe and China, since the establishment of Overseas Business Development on April 1, 2019, we have integrated and executed the overseas business development. RAPALIMUS® Gel (NPC-12G) and TITANBRIDGE® (NPC-17) were granted approvals under the "Sakigake" fast-track review system in Japan. We aim at obtaining approvals and selling three products (these two products and RETYMPA® (NPC-18)) in the US, Europe and China. In 2020, while the pandemic of the new coronavirus infection spread from China to the US and Europe, which constrained our overseas business development, we have proceeded with our activities as much as possible.

In the US, we established Nobelpharma America, LLC (head office: Bethesda, Maryland; President & CEO: Yoshiki Kida), a wholly owned subsidiary of Nobelpharma Co., Ltd., in June 2019. It is preparing for sales in anticipation of the approval of RAPALIMUS® Gel in 2021.

In Europe, we established Plusultra pharma GmbH (head office: Dusseldorf, President & CEO: Takahiro Yamasaki), a wholly owned subsidiary of Nobelpharma Co., Ltd., in May 2020, and Plusultra pharma GmbH established Plusultra pharma UK Ltd., its wholly owned subsidiary, in October 2020. We are preparing for business development for RAPALIMUS® Gel and TITANBRIDGE® in Europe based on these two sites.

In China, Nobelpharma Financials Co., Ltd. (Head Office: Chuo-ku, Tokyo; Representative Director: Arata Tabata), a wholly owned subsidiary of Nobelpharma Co., Ltd., established Jiangsu Nobelpharma Co., Ltd. (Head Office: Taizhou, Jiangsu, General Manager: Weidong Chen), its wholly owned subsidiary, in December 2020. Jiangsu Nobelpharma plans to establish its sites in Shanghai and Beijing in addition to its headquarters in Taizhou, and it is preparing for sales of RAPALIMUS® Gel in anticipation of the approval in 2021.

1.5. Research and Development (Japan and overseas)

In the domestic development, Melatobel® (melatonin, sleep-onset difficulty associated with neurodevelopmental disorder in children) filed in April 2019 was granted an approval in March 2020. NOBELZIN® granule formulation (Wilson's disease and hypozincemia), which was developed in collaboration with National Center for Child Health and Development and filed in January 2020, was approved in January 2021. This medicine can be taken from infants to adults widely without crushing tablets. Cytomegalovirus (CMV) antibody (NPC-21), the Company's first antibody drug, has started the Japan-US international joint clinical trials in January 2020. Due to the coronavirus pandemic, however, case registration was delayed, and we took measures to add institutions, but the situation has not improved. As a novel coronavirus related project, a novel coronavirus infection vaccine (NPC-27) using vaccinia virus vector, on which we are working with the Tokyo Metropolitan Institute of Medical Science, was adopted by AMED, and we are advancing investigational product production and nonclinical studies for the early start of clinical studies. Sargramostim (GM-CSF, NPC-26: Final stage of development on autoimmune pulmonary alveolar proteinosis), a therapeutic drug candidate that was also selected by AMED, has commenced a clinical trial in September 2020.

We have started a full-scale examination on overseas development in 2017 under the policy of obtaining approvals of three products of RAPALIMUS® Gel, TITANBRIDGE® and RETYMPA® in three regions of the US, China and Europe. RAPALIMUS® Gel that the FDA designated as an orphan drug in 2017 filed an NDA to the FDA in February 2020. We also filed an application for the product in China in September 2019. These two filings are under review by authorities. In Europe, we are preparing for an NDA in 2021. We also hold Q-sub meeting with the FDA and continue activities for the EU CE marking certification for TITANBRIDGE®. In addition, the third study of malaria vaccine (NPC-19, prevention of falciparum malaria) in Africa, which was started in 2018 with the support of GHIT, was completed, and we are preparing for the next phase study.

The table below summarizes the development stage, expected NDA and market size classification in three categories of A. New Drugs and Medical Devices, B. Life Cycle Management (LCM) and C. Overseas Development as of March 1, 2021. Many are drugs based on new concepts that originated in Japan. Market size classification is as follows:

I: Potential primary sources of revenue (sales of over 3 billion yen)

II: Short term approval and marginal profit are expected; however, they are not likely to be a primary source of revenue.
III: Short term approval expected with a project from academia such as a university. Lower development cost with promising public subsidies. Difficult to estimate sales due to innovative concepts.
IV: Similar to III but relatively long time required for approval.

A.New Drugs and Medical Devices

	Compound	Indication	Licensor	Development stage	Estimated approval	Classification
1	NPC-26 Sargramostim	Autoimmune pulmonary alveolar proteinosis	Partner Therapeutics Inc.	Preparation for filing	Mar 2022	II
2	NPC-26 Sargramostim	Novel coronavirus infection	Partner Therapeutics Inc.	PIII	Mar 2023	II
3	NPC-09 Aceneuramic acid	Progressive muscle weakness in GNE myopathy	In-house	PIII	Jun 2023	II
4	NPC-21 CMV antibody	CMV infection	Evec Inc.	PII	TBD	I
5	NPC-22 Scopolamin	Hypersalivation	Kitasato University	PI	TBD	IV
6	NPC-27 Vaccinia virus vaccine	Coronavirus disease 2019 (COVID-19)	Tokyo Metropolitan Institute of Medical Science	Non-clinical	TBD	III
7	NPC-28	Jawbone regeneration	Niigata University Kohjin Bio Co., Ltd.	Non-clinical	TBD	III
8	NPC-x4 (P092)	Prion disease	Gifu University	Non-clinical	TBD	IV
9	NPC-x6	TBD	Hiroshima University Repertoire Genesis Inc.	Non-clinical	TBD	III

B. Life Cycle Management (LCM)

	Compound	Indication	Licensor	Development stage	Estimated approval	Classification
1	NPC-12 RAPALIMUS®	Intractable vascular tumor/vascular malformation (new indication)	Gifu University	Filed/PIII	Sep 2021 Sep 2023	II
2	NPC-05 Unitalc®	Intractable pneumothorax (new indication)	National Hospital Organization Nagoya Medical Center	PII	Mar 2022	III
3	NPC-12G RAPALIMUS® Gel	Neurofibromatosis type I (new indication)	Osaka University	PII/III	Sep 2022	II
4	NPC-06 Fostoin®	Neural field (new indication)	Pfizer Inc.	PII	discontinued	I
5	NPC-12 RAPALIMUS®	Fibrodysplasia ossificans progressiva (new indication)	Kyoto University	PII/III	TBD	III
6	NPC-12 RAPALIMUS®	Pendred syndrome (new indication)	Keio University	PI/IIa	TBD	III
7	NPC-12 RAPALIMUS®	Epilepsy with focal cortical dysplasia type II (new indication)	Showa University	PII	TBD	IV
8	NPC-12 RAPALIMUS®	Idiopathic multicentric Castleman's disease (new indication)	Nagasaki University	PII	TBD	IV
9	NPC-12 RAPALIMUS®	Primary immunodeficiency syndrome (new indication)	Tokyo Medical and Dental University	PII	TBD	IV

10	NPC-26 Sargramostim	Pulmonary non-tuberculous mycobacteriosis (new indication)	Niigata University	POC in preparation	TBD	I

C. Overseas Development

	Compound	Indication	Licensor	Development stage	Estimated approval	Classification
1	NPC-12G (RAPALIMUS® Gel)	Angiofibroma	-	USA: Filed	Jul 2021	I
				China: Filed	May 2021	
				Europe: Preparation for filing	Apr 2023	
2	NPC-17 Thyroid cartilage fixation device (TITANBRIDGE®)	Adductor spasmodic dysphonia	-	US: Clinical trial in preparation	TBD	III
				Europe: CE marking in process	Oct 2021	
3	NPC-18 (RETYMPA®)	Tympanic perforation	MEEI/ Harvard/ NY University	PII	TBD	III
4	NPC-19 (NPC-SE36) Malaria vaccine	Prevention of falciparum malaria	Osaka University GHIT	PIb	TBD	I

As a matter requiring special attention, NPC-21 was selected by Cyclic Innovation for Clinical Empowerment (CiCLE), a program launched by Japan Agency for Medical Research and Development (AMED), and NPC-26 and NPC-27 were selected by the "Research Project to Promote the Development of Innovative Drugs, etc. for Emerging and Re-emerging Infectious Diseases" of AMED. In addition, NPC-09 (progressive muscle weakness in GNE myopathy), NPC-12 (intractable vascular tumor/vascular malformation), and NPC-26 (autoimmune pulmonary alveolar proteinosis) have been designated as orphan drugs.

1.6. Finding of New Projects

Project Planning & Development is responsible for core roles for the Company's open innovation. Specifically, its role is classified into (1) Finding and research for new projects (drugs, medical devices and others) that become future pillars of the business, (2) In/out-licensing of a new development project, (3) Support for commercialization and collaborative research of academia seeds that are considered promising, (4) Financing and support of development expenses including acquisition of public subsidy. It proceeds with its task in strong collaboration with other divisions including Research & Development and Business Development & IP Management.

The following showed major achievements in 2020.

- Promotion of in-licensing/practical application of COVID-19 therapeutic drugs/vaccines
- Promotion of a joint program and commencement of new businesses with academia for the purpose of finding seeds
- Promotion of evaluation and joint projects of new modalities including tissue-engineered medical products
- Conclusion of collaborative research agreement and promotion of joint research with academia for multiple seeds
- Search, research and in-licensing negotiation for seeds of many overseas companies and VCs

Upon promoting in-licensing and collaborative research, we place the primary focus on whether these seeds met our mission, and conducted evaluations and made judgments for in-licensing large number and wide variety of medical drugs (low molecular, peptide, antibody and oligonucleotide therapeutics), medical devices and tissue-engineered medical products (regenerative medicine/cellular therapeutics and gene therapy). In view of the urgency, we also promoted the practical application of COVID-19 therapeutic drugs and vaccines. In addition, with a view to finding and obtaining information on better seeds as well as realizing early commercialization, we have launched a new joint business with academia to find seeds in 2020.

1.7. Business Development & IP Management

Business Development & IP Management is a keystone of our business, which is responsible for business development, intellectual property rights and agreements in the Company. Specifically, its role is classified into (1) Planning and research for new projects (drugs and medical devices), (2) In/out-licensing negotiations with a new development project, (3) Alliance management, (4) Investigation of licensing-in products and planning and management of preventive measures for intellectual property, (5) Handling technical agreements in the company, and (6) Procurement negotiations.

The following showed major achievements in 2020. The name was changed to Business Development in February 2021 as the operations related to intellectual property were spun off as Intellectual Property Department under Administrative Affairs & Corporate Planning.

[Business development]

- Negotiation and conclusion of new in-licensing agreements/memorandum and joint business contracts
- Planning, research and support for new projects through a tie-up with Project Planning & Development (including participation in the overseas business development web conference)

[Alliance]

- Various arrangements and negotiations with partner companies (including payments of contract consideration)
- Conclusion of various agreements such as memoranda for amendment, for expansion of territories, and related to manufacturing
- Negotiation of contract termination and conclusion of relevant confirmation document

[Contract review]

- Accumulation of precedents, preparation and maintenance of templates, and maintenance of contract database by grasping all of the technical agreements
- Streamlining of contract-related operations (share of operations to each division and speeding up of operations)
- Introduction of contract review tools using AI technology and liaison with lawyers

[Intellectual property]

- Strengthening of the portfolio including applications for patents, designs, etc. related to new in-licensing projects
- Strengthening of the portfolio through LCM-related patent applications for products
- Maintenance of trademark registration of company name, product name, etc. in association with overseas expansion
- Enhancement of third party rights investigation including FTO investigation

[Procurement]

- Engaged in more than 90 purchase negotiations and contributed to achievement of reasonable costs.

1.8. Regulatory Affairs and Negotiations

Regulatory Affairs is responsible for administrative procedures related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (PMD Act), actions as a division to supervise sales information provision activities, application filing and negotiations for NHI/material price, calculation of estimated NHI/material price and feasibility study for in-licensing/development candidates, and provide advise relating to NHI price system reform, working to apply for marketing approval of new drugs and new medical devices, to prevent deviation from medical related laws and regulations, and to improve the business environment. It is also responsible for patient group relations.

In terms of regulatory affairs, the Division further added two staff members, following an increase of the regulatory strategy personnel last year, for the purpose of improving change control operations to prevent "variance with certificates" as well as overseas expansion, and strengthened the system for change control operations that was a key for stable supply and preparation for global regulatory affairs. The withdrawal of approval for Ocnobel tablets 150 mg and 300 mg, and 6% oral suspension, which had been approved but had not been marketed for various reasons, was filed and accepted.

In addition, the Sales Promotion & Information Activities Superintendence Department, which was

established last year in accordance with the guidelines on providing sales information of ethical drugs released by the Japanese Ministry of Health, Labour and Welfare ("MHLW"), conducted reviews for 663 sales materials (2019: 408) that were increasing in number rapidly.

For NHI/material price related work by External Relations, Melatobel® granules for children 0.2% has been listed on the NHI price list. In addition, the estimation of NHI/material price and feasibility study for in-licensing and development candidates were conducted for more than 10 projects. External Relations added a staff member to provide evaluation with higher accuracy promptly responding to circumstances includingincreasing academia projects and changing NHI pricing system.

As for activities in the industry, the contributions were made to coordinate the “Request for early development of products on COVID-19 developed by member companies” by Samurai Biotech Association for which the Company works as a board member and coordinator office.

In terms of patient group relations, communications were promoted with 26 patient groups, two of which were new, and maintained a good relationship with them by renting its meeting rooms four times a year and actively participating as volunteers in five events while patient group activities were generally restrained due to COVID-19. Further, we held two in-house seminars inviting leading members of patient groups as the lecturers to promote better understanding of employees about intractable diseases.

1.9. Manufacturing and Capital Expenditure

Most of our products are medicines that are no substitute. The Company has no manufacturing facilities of its own, and outsources manufacturing of both APIs and products to domestic and overseas manufacturers. Under such circumstances, we believe that the stabilization of the drug supply becomes strong by (1) having many inventories of not only products but also important materials, and (2) by ensuring multiple OEM suppliers. In 2020, we continued to work on increasing inventories of products and materials. Fortunately, there have been no delays in supply due to the novel coronavirus crisis.

As for NOBELZIN® tablet, our core product, we developed a production plan for both Choseido Pharmaceutical Co., Ltd., the first contract manufacturer, and CMIC CMO Co., Ltd., the second contract manufacturer, to maintain the total production capacity of 50 to 70 million tablets per year. As the manufacturing and marketing approval of NOBELZIN® granule, a pediatric formulation of NOBELZIN®, was obtained in January 2021, we have arranged our supply system for the launch in the middle of this year. The Company selected CMIC CMO as a new contract manufacturer for INDACIN®, and started to manufacture commercial lots. Also, we selected Tomita Pharmaceutical Co., Ltd. as a new contract manufacturer for API of INDACIN®, with preparation for NDA filing. For Melatobel® granules released in June 2020, we developed a detailed production plan with Choseido Pharmaceutical, a contract manufacturer, and started to supply products steadily. The accumulation of stocks of ZANOSAR® was a major issue, but the production at the contract manufacturer in France has been progressing smoothly, and the stock level has been maintained for about eight months at all times.

The manufacturing system of RAPALIMUS® Gel for the US and China as the first overseas shipment product is being developed, and the product specifications at Toyo Pharmaceutical Co., Ltd., a contract manufacturer, and the overseas SCM system have been established.

In 2020, capital investment related to production is as follows (all acquisition values are excluding tax):

- Heating blender used for manufacturing NOBELZIN® granules (31.9 million yen, lent to Choseido Pharmaceutical)
- Ultrasonic crusher used for manufacturing study of NPC-19 (malaria vaccine) (1.87 million yen, lent to KM Biologics, Co., Ltd.)

1.10. Pharmacovigilance & Quality Assurance

PMS Regulatory Compliance & Assurance works on business improvement in a cost-conscious way in compliance with related laws and regulations, by posting its mission as the three pillars of passing re-examinations, causing no drug-induced diseases and quality assurance and stable supply of products. Also, in 2020, with the aim of further strengthening the basic education (Mission & Code of Conduct), we provided five workshops from June to November.

In terms of re-examination, NOBELBAR® (Neonatal seizures) and NOBELZIN® (Wilson's disease) obtained approval of category 1 on June 10, 2020 and December 9, 2020, respectively. In addition, PMDA

conducted the compliance inspection of Fostoin® on February 26 and 27, 2020, and the approval of Category 1 was obtained on September 9 of the same year.

In terms of safety-related matters, we have completed post-marketing surveillance of RETYMPA® and Melatobel®. In 2020, the number of domestic and overseas adverse event reports was 4,074 and 3,700, respectively, showing a decreasing trend in Japan compared to 5,057 and 3,650, respectively, in 2019. In the domestic adverse events, there were 1,128 cases of NOBELZIN® (hypozincemia), 506 cases of JEMINA® and 462 cases of LUNABELL® ULD. In the overseas adverse events, there were 1,352 cases of RAPALIMUS® (tablets, gels) and 1,276 cases of Ocnobel®.

In terms of post-marketing surveillance-related matters, general drug use surveillance of RETYMPA® was started in June 2020 in collaboration/cooperation with the Medipal Holdings Group, and we are preparing for general drug use surveillance of Melatobel® to begin in April 2021.

For revisions of package inserts and precautions, revisions were made for 12 products including five products in new forms, and provided information to medical institutions (four products in 2019).

In terms of quality-related matters, we checked 17 approved products and 18 drug manufacturers for shipping control, management/supervision of manufacturers (including operations related to manufacturing (testing, etc.)), handling of information on quality, etc. and quality defects, etc. and other operations necessary for quality control of products. A total of 184 lots were supplied with stability through proper manufacturing and release processes. In addition, there was no recall or return of the drugs shipped.

2020 was the year of renewal of the first-class marketing license for pharmaceuticals. The Tokyo Metropolitan Government conducted the on-site inspection for renewal of the license on July 28 and 29, and the Company received the license (validity period: October 11, 2020 to October 10, 2025) on August 25.

1.11. Funding and Major Lenders

In 2020, the Company borrowed 1,768 million yen, and repaid and redeemed 889 million yen to financial institutions.

As a result, as of the end of December 2020, the balance of loans payable and bonds was 6,082 million yen, and the balance of cash and deposits was 6,809 million yen.

As of December 31, 2020, the status of borrowing is as follows:

Loans payable

Mizuho Bank, Ltd.	1,400 million yen
Sumitomo Mitsui Banking Corporation	400 million yen
MUFG Bank, Ltd.	890 million yen
The Shoko Chukin Bank, Ltd.	356 million yen
The Tokyo Shinkin Bank	200 million yen
Japan Finance Corporation	35 million yen
Total	3,281 million yen

Japan Agency for Medical Research and Development 551 million yen

Corporate bond

2nd straight bond	Osaka Soda Co., Ltd.	500 million yen (Maturity: Dec 2024)
4th straight bond	Mizuho Bank, Ltd.	500 million yen (Maturity: Dec 2021)
6th straight bond	Resona Bank, Ltd.	300 million yen (Maturity: Mar 2022)
7th straight bond	Resona Bank, Ltd.	300 million yen (Maturity: May 2026)
8th straight bond	Resona Bank, Ltd.	150 million yen (Maturity: Mar 2027)
9th straight bond	Sumitomo Mitsui Banking Corporation	500 million yen (Maturity: Mar 2027)
Total		2,250 million yen

1.12. Financial Results, Assets and 2021 Forecast

The Company's financial results, assets and next year forecasts are as follows:

In the next year, the Company expects an increase in sales but a decrease in profits as R&D and overseas investment will grow significantly, though profits are supposed to grow as sales will increase.

* Mil yen except for *	2017 (Actual results) 15th year	2018 (Actual results) 16th year	2019 (Actual results) 17th year	2020 (Actual results) 18th year	2021 (Forecasts) 19th year
Sales	7,236	10,568	13,403	16,929	21,210
Ordinary income	161	1,960	2,951	3,466	3,847
Net income	53	1,437	2,370	2,511	2,516
* Net income per share	4,000 yen	111,000 yen	175,000 yen	185,000 yen	186,000 yen
Total assets	8,975	12,204	14,138	18,574	21,544
Net assets	685	3,319	5,330	7,052	8,594
* Equity ratio	7.6%	27.2%	37.7%	38.0%	39.9%
* Net assets per share	58,000 yen	245,000 yen	394,000 yen	521,000 yen	635,000 yen

1.13. Employees

As of March 1, 2021, the number of employees is 349 (including a total of 108 including 38 seconded employees, 16 temp staff members, 53 contract employees and one counsellor but excluding directors and employees seconded to external organizations) with an average age of 52.2. The number of employees increased by 32 compared with 317 as of March 1, 2020. The average number of years of continuous services (seconded employees and temp staff members are not included in the counting) is 4.5 years. The number of employees who work at overseas subsidiaries is 18 (including three employees dispatched from the Company), of which, 13 are in the US, four in Europe, and one in China.

Total personnel expenses of the overall company in 2020, including expenses for seconded employees and temp staff members, were 3,427 million yen, an increase in 13.7% compared with 3,015 million yen in 2019. This was mainly due to an increase in the number of employees to strengthen domestic sales of new three key products such as NOBELZIN®, JEMINA® and Melatobel®, and for full-scale overseas business.

Talent hiring is limited to employees with career experiences who can immediately work, and no new graduates are hired. However, we recruit postdoctorals regularly, and recruited one person each in 2019 and 2020.

In response to the COVID-19 pandemic, the Company shifted to working from home for a full scale since March 1, 2020, and decided to make working from home as a usual style of working (continuing working from home regardless of the end of the pandemic) on June 1. In association with this, we have established measures and rules according to various situations, such as provision of a telework allowance to cover utilities and other expenses at home, assistance in purchasing equipment necessary for telework, suspension of payment of commuter pass, office system where employees are free to change desk and reduction of head office space (halved after the end of the regular lease period by the end of 2021), use of a membership-based shared office, and resolution of unaccompanied assignment of employees working at the head office. In addition, as a result of promoting electronic approval in terms of business operations, we were able to smoothly shift without any marked trouble. This will cut the cost by about 80 million yen per year (excluding the layout change construction cost, etc.).

As the additional personnel hiring was not enough to keep up with the expansion of the Company, we could not rotate employees because we did not have enough employees to do so. As many companies have reduced their employees in the pharmaceutical industry, we successfully recruited approximately 20 employees from major pharmaceutical companies. This will enable personnel rotation and increase the diversity of human resources.

The monthly average overtime hours for all employees were 2.5 hours, which substantially decreased from 9.2 hours in the previous year, falling below ten hours for five consecutive years. It was mainly due to the reduction of the burden on commuting by the normalization of working from home and the review and improvement of the efficiency of work processes.

1.14. Issues

Issues that each division should address are as follows:

(1) To accelerate digitalization such as online interviews, and to establish appropriate personnel and sales system accordingly. (Sales & Marketing)

(2) To make a profit from overseas business in the year 2023 in the US and Europe and in 2024 in China, as planned. To obtain manufacturing and marketing approval by ourselves and to sell products by ourselves. Overseas Sales should withdraw from an area where it cannot expect to make a profit in a single year as of November 2022. (Overseas Business Development)

(3) To commercialize development products as scheduled, and to actively introduce new development projects from academia and business companies. By doing so, to fill in the anticipated cliff in and after 2024 (a decrease in sales due to generics). (Research & Development, Project Planning & Development and Business Development)

(4) To change the system to global base so that each division can respond to requests from overseas subsidiaries in association with the development of overseas business. (Overseas Business Development, Research & Development, PMS Regulatory Compliance & Assurance, Regulatory Affairs, Supply Chain & Manufacturing, and Administrative Affairs & Corporate Planning)

(5) To implement personnel rotation across departments to diversify personnel. At the same time, to reinforce education for managers and non-management employees, and to provide education on the Company's mission, management policy and action criteria thoroughly. (Administrative Affairs & Corporate Planning)

As an issue of domestic sales, we anticipate that MR activities will change more drastically in 2021 due to the COVID-19 pandemic. This is because the online interview will become the norm. To this end, we have to (1) provide development and training for MRs (to respond digitalization), (2) establish an efficient (by digital utilization) and flexible sales organization system, and (3) promote DX (provision of valuable information) in line with the age of online. In order to proceed with these initiatives, we need a change in thinking. In January 2021, we established the Sales Strategy Department and selected appropriate people from MRs nationwide so that the sales front line enables smoothly realizing the measures of the head office as well as strengthening digital actions. In addition, AMs (Area Managers) assigned to each branch plays a central role in developing information activities that are evaluated in their areas, with the aim of becoming a "trusted company."

For NOBELZIN®, the mission is whether it can expand the scope of activities in other areas in addition to areas of liver, kidney and IBD that have been focused on so far. We will further increase awareness of the usefulness of continuous administration for JEMINA® through activities based on the revised guidelines. The mission is to accelerate close cooperation with co-promotion partners of ASKA Pharmaceutical and the Medipal Holdings Group at the major market for LEP (GP). Finally, prescription restriction of Melatobel® will be lifted in June 2021. The mission is to get recognition of sleep problems in children from specialists who have experience in prescribing Melatobel® to general pediatricians, and to have them understand the usefulness of Melatobel®.

The mission of overseas sales is to realize the expectation of making a profit in a single year in 2023 in the US and Europe, and in 2024 in China. Basically, overseas bases strive to obtain manufacturing and marketing approval by themselves and to sell the products through their own distribution channel.

As NDA filing for RAPALIMUS® Gel in the US was conducted by the Japan headquarters, a local subsidiary will act as a sales company. As GMP inspection by FDA is delayed due to the COVID-19 pandemic, it is difficult to expect when an approval is obtained. We are recruiting the minimum necessary number of local employees, and we will complete the preparation for the launch of RAPALIMUS® Gel around the autumn of 2021 so that we can launch the product as soon as GMP inspection by FDA is completed and we can see when an approval is obtained. In addition, we are examining the moving up of the timing of NDA filing for TITANBRIDGE® and RETYMPA®.

As the application for the approval of RAPALIMUS® Gel in Europe will be filed by a local subsidiary, we will prepare for basic functions as a pharmaceutical company, including quality assurance, safety control and medical affairs, to be completed within the local subsidiary under the support of the Japan

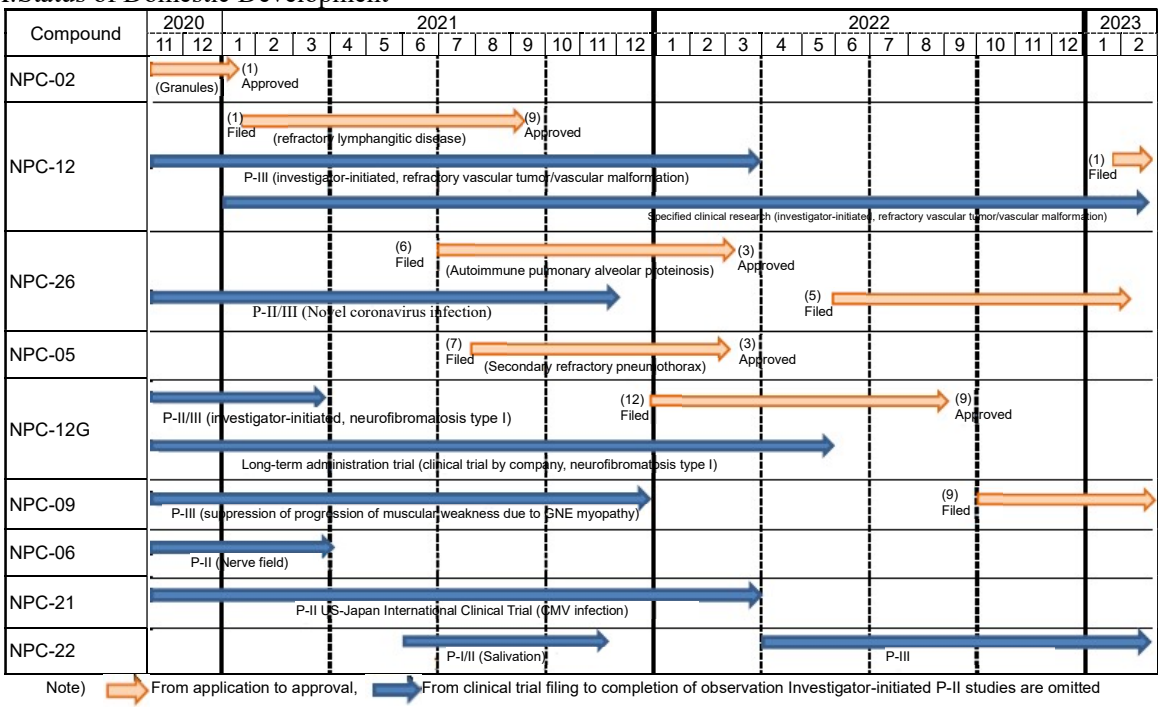
headquarters. We are also preparing for the EU CE marking certification for TITANBRIDGE® as an approach to the EU. The application for the approval of RETYMPA® is examined to be moved up.

In China, the application for RAPALIMUS® Gel was filed by the head office in Japan. In the future, a local subsidiary in China will establish its base and promote the recruitment of local employees, and prepare for the launch of RAPALIMUS® Gel. In China, we are also considering whether it is possible to obtain approval for other products currently marketed in Japan, such as Melatobel®, in addition to overseas products including TITANBRIDGE® and RETYMPA®.

Research & Development will push ahead of the development schedule. The development schedule is set out below. We will also promote the early launch of LCM such as Melatobel®.

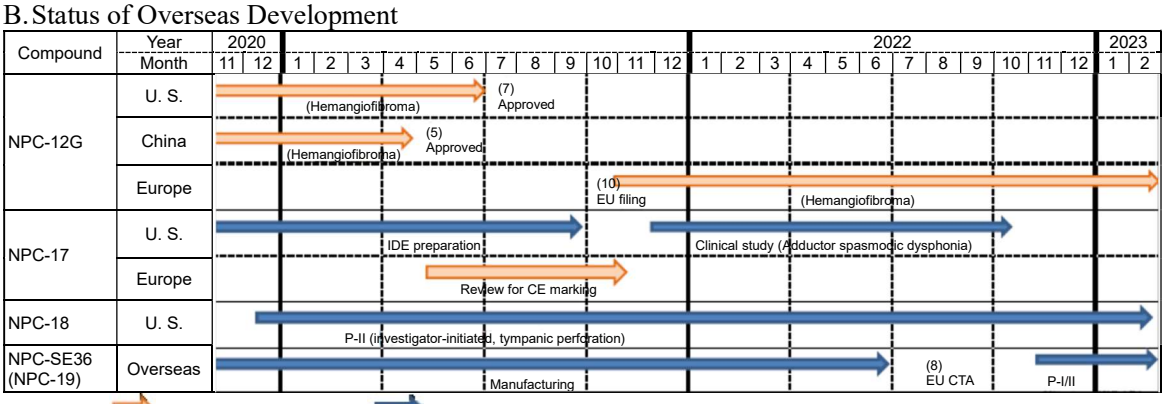
In view of overseas expansion, based on the aforementioned big strategy of launching three products of RAPALIMUS® Gel, TITANBRIDGE® and RETYMPA® in three regions of the US, Europe and China, the Company will continue responses to inquiries/ Q-sub meetings/ IND application with the US FDA, meetings with China's CFDA/CDE and Scientific Advice meeting with the EU EMA. We will also push ahead the establishment of a production system for NPC-SE36 (NPC-19, malaria vaccine) associated with a change in a manufacturing site.

A. Status of Domestic Development



Note) From application to approval, From clinical trial filing to completion of observation Investigator-initiated P-II studies are omitted

B. Status of Overseas Development



Note) From application to approval From IND to completion of observation, etc.

The task to find seeds for new research is to strengthen and accelerate the preparation for a new development project continuously. Upon finding seeds, we will focus on the point that these seeds meet the Company's mission (Contribute to Society by Providing Critical but Neglected Pharmaceuticals and Medical Devices) and actively introduce and commercialize them from academia and bio ventures from scientific and objective viewpoints. We will further promote support for commercialization of academia seeds to ensure a smooth shift to a development phase from a basic study through our involvement with the initial stage.

We continue to make an effort to acquire public subsidy and financing of development expenses for commercialization.

As the mission of Business Development, (1) it will proceed with business development operations by actively promoting license activities for introducing new projects that can be commercialized from 2024 to 2025 through a tie-up with Project Planning & Development. In addition, it plans to develop a system to reflect the negotiation result of an agreement in the proposed agreement promptly so as to enter into the agreement in the short term. It also continues to consider medical device projects through a business feasibility study. (2) For alliance activities, it is important to grasp the overall progress of the project from the business aspect and prevent problems in advance. (3) We will also consider the possibility of use of funds in cooperation with Administrative Affairs & Corporate Planning. (4) In purchase negotiations, we strive to realize ongoing cost reduction by paying due attention even to details.

As tasks of regulatory affairs and negotiations, Regulatory Affairs actively supports operations of both Research & Development and PMS Regulatory Compliance & Assurance, continues to help efficient and speedy responses to the authority, and focuses on development affair operations continuously with the aim of promoting a more strategic response of regulatory affairs.

External Relations utilized the know-how for negotiations of NHI/material price to be involved in a development strategy and support active responses to the authority from the development phase, and it aims to obtain adequate prices for new drugs and medical devices in the future. In addition, in order to contribute to the selection of appropriate candidates for in-licensing/development, we will also aim to improve the accuracy of the estimated NHI/material price calculation and feasibility study. It also follows the NHI price reform and health insurance reform to feed back to in-house strategies from a technical perspective. In addition, through activities of Samurai Biotech Association, for which the Company acts as a board member and coordinator office, lobbying and advising the authorities will be continued.

Tasks of the Sales Promotion & Information Activities Superintendence Department are to increase efficiency of materials review, which has been increasing sharply, and to take monitoring measures for the sites when providing information. We plan to provide information to improve the applicant's preliminary check for the former, and for the latter, a questionnaire survey to understand the actual situation at the sites of medical care is planned.

The PMD Act revised and promulgated in December 2019 requires entities to establish a system for compliance with laws and regulations in August 2021. Regulatory Affairs will take the initiative in taking necessary and sufficient actions.

As for the global deployment of Regulatory Affairs, we are working to establish a system as much as possible to become a hub for global regulatory affairs. While the pharmaceutical regulations in each country are different, we will evaluate and organize information provided by Research & Development, PMS Regulatory Compliance & Assurance and Supply Chain & Manufacturing, and summarize their opinions in order to realize adequate responses without omission. We are preparing a system to provide information on this to a person in charge of local regulatory affairs and, if necessary, to instruct how to respond to local authorities.

As for production, Supply Chain & Manufacturing continues to work on a stable supply of the existing products. The important points are to maintain the production capacity of NOBELZIN®, our core product, at the level of 50 to 70 million tablets annually, to establish the production system of NOBELZIN® granule, a new product, and to maintain the product inventory of ZANOSAR® for about 8 months at all times. A generic drug manufacturer violated the Pharmaceutical Affairs Act related to manufacturing. We immediately investigated whether there was any similar case in the Company and confirmed that there was no violation, but we recognized that there is a potential problem, and we intend to work on

improvement in cooperation with our contract manufacturers.

In addition, we will prepare to launch a new formulation of NOBELZIN® tablet to the market with the aim of further increasing and maintaining the sales volume. Specifically, we are considering syrup, OD tablet and amino acid zinc preparations. It is also an urgent need to establish a production system for biological products which we have developed as new drugs. NPC-19, 21, 26, and 27 are products in this field, and we will proceed with earnest consideration for these products as supply of these products presents a high hurdle.

With the launch of RAPALIMUS® Gel in the US and China in mind, we will continue to improve our sales supply system.

The mission of PMS Regulatory Compliance & Assurance is to establish a system as Global Head and a system as the host department of Global QMS to ensure that we meet overseas regulatory requirements in line with the development of overseas business.

We have already established systems and mechanisms for the Global Pharmacovigilance Quality Management System (PV-QMS), including SOPs. With regard to the Quality Management System, we will proceed with the establishment of Corporate-QMS which is ranked ahead of PV-QMS. For this reason, we will reorganize PMS Regulatory Compliance & Assurance, maximize and optimize resources, and secure human resources for handling overseas business.

While we keep the business style centered on working from home, we will promote further effective use of the Gyomu Designer (approval and management system for documents and projects) that has already been introduced in order to facilitate smooth communication and streamline operations.

Regarding the basic education (Mission & Action Criteria), we will continue to follow up to achieve the goals created individually based on the slogan of the headquarters, "Autonomy and Independence."

The tasks of corporate planning and accounting are to completely shift reimbursement and invoice processing to electronic approval to improve convenience in line with the shift to working from home, and to examine effective methods for further paperless and IT promotion.

We will make efforts for highly transparent management of local subsidiaries in accounting, tax, funds, personnel affairs and management by making full use of accounting and tax outsourcing and cloud systems. We will also enhance a budget control system that was introduced to ensure quick and accurate understanding of business figures in line with business expansion and overseas development.

Cash management is planned mainly in cash flows arising from operating activities. However, we will borrow long-term funds from financial institutions to maintain sufficient cash in hand to ensure a flexible response to unscheduled fund needs since we are repaying borrowings steadily and financing conditions are currently positive.

In response to the request from Hisanaga & Co., Ltd., our parent company, the administrative division will be transferred to Hisanaga to promote efficient operation.

As for issues of human resources and general affairs, we will continue to promote organic development through securing of human resources to promote development in the US, China and Europe, and implementation of job rotation and in-house business schools based on human resources hired to strengthen domestic sales capabilities. In addition, we will make the personnel system transparent and promote understanding within the Company (especially, line managers).

With regard to work style reform, we will examine the environment and rules of telework, which was promoted in full scale due to the COVID-19 pandemic, and try to respond to situations from time to time. In addition, as an actual example, we will continue to hire experienced and skilled personnel regardless of their location of residence. On the other hand, in order to prevent poor communication, we will ensure that superiors continue to hold one-on-one meetings, and also set up a section for self-introduction of all employees on the in-house portal site, with particular attention to the acclimatization of mid-career employees to the organization. Meanwhile, the ratio of taking paid leave was 57.8%, down significantly from 75.3% in the previous year. It may be due to voluntary restraint on leisure, travel, etc. for the prevention of COVID-19. However, we will strive to improve the ratio of taking paid leave by setting long-term leave as an essential internal rule thoroughly.

Regarding recruitment, we will consider fundamental measures in order to recruit a few postdoctorals annually.

With regard to employee education, we will conduct the follow up of company-wide training on harassment conducted last year and disseminate the Company's philosophy and president's message ("Request to Line Managers"). We also use E-learning that provides useful knowledge and skills for all employees, such as basics of intellectual property patents and tips for web conferences.

As an issue of promotion of DX, we will support, from IT side, the business development that continues to expand, and promote business reform by applying digital technology. The development of overseas bases and the establishment of the collaboration system with Japan are also major tasks. In addition, with the growth of the presence of the Company, various risks such as cyberattacks are expected to increase, and we will make efforts to strengthen the security to prepare for them. This year, we plan to introduce multi-factor authentication and shift to zero trust network.

As a matter of intellectual property, it is desired to build a strategic portfolio to prevent serious problems in the future in line with an increase in the introduction of early cases in the drug discovery stage derived from academia in particular. But we have only just begun and hope to further enhance it. In addition, with the expansion of overseas development, the importance of ensuring an FTO survey and enhancing the patent clearance in each country has been increasing, and it is also important to improve the intellectual property portfolio of each product in each country. We will make efforts to complete the said inspection before the approval application for each product. There were two cases that we announced before the patent application and that could not be patented. In order to make use of these lessons learned, we enhanced intellectual property education and incorporated E-learning for the first time in this fiscal year. We strive to further foster an intellectual property mindset.

We set the targets for the mid-long term future vision of sales and profit as an immovable high goal named North Star. In 2019, the numerical targets in 2023 as North Star in the 2019-23 mid-term business plan were sales of 50 billion yen and ordinary income of 10 billion yen. In 2021 in the 2021-25 mid-term business plan, we believe that it is highly likely to achieve the 2023 North Star target though it differs from the accumulated figures.

North Star (2023)	Target
Sales	50 billion yen
Ordinary income	10 billion yen

1.15. Other Important Matters

1.15.1. Relocation of the headquarters

Nobelpharma Co., Ltd. relocated the headquarters to the following address effective April, 2019. Sales & Marketing and Tokyo Branch moved to the same address in February and November 2020, respectively.

New address: 1-17-24 Shinkawa, Chuo-ku, Tokyo 104-0033

New Tel: +81-3-6670-3800, Fax: +81-3-6670-3801

1.15.2. Establishment of overseas subsidiaries

In June 2019, Nobelpharma America, LLC, a wholly owned subsidiary of Nobelpharma Co., Ltd. and capital of 3 million dollar, was registered as a US sales company in Delaware, and opened an office at Bethesda, Maryland in October, as the first overseas base for the Company. In May 2020, we established Plusultra pharma GmbH, a wholly owned subsidiary of Nobelpharma Co., Ltd. and capital of 25,000 euro, in Dusseldorf, which established Plusultra pharma UK Ltd., as its subsidiary, in October in London so that we established a sales structure in Europe. In December 2020, we established Jiangsu Nobelpharma Co., Ltd. (a wholly owned subsidiary of Nobelpharma Financials Co., Ltd. that is a wholly-owned local subsidiary management company of Nobelpharma Co., Ltd., established in Japan in October, and registered capital of 5 million dollar) in the Taizhou Pharmaceutical High-Tech District in Jiangsu, China. Thus, we completed the establishment of overseas subsidiaries in the US, Europe and China as scheduled. In the future, we will consolidate these overseas subsidiaries under Nobel Pharma Financials for efficient management.

2. Current Status of the Company

2.1. Shares (as of December 31, 2020)

(1) Number of shares authorized		50,000 shares
(2) Number of shares issued	Ordinary share	13,525 shares
	Number of shareholders	3

(3) Status of Major Shareholders

Hisanaga & Co., Ltd. (ordinary share)	10,000 shares (73.9%)
Medipal Holdings Corporation (ordinary share)	2,705 shares (20.0%)
Inabata & Co., Ltd. (ordinary share)	820 shares (6.1%)

2.2. Share Warrant

2.2.1. Share warrant that is issued to and held by the Company's executive officers as consideration for execution of their duties

Not applicable

2.2.2. Share warrant that is issued to and held by the Company's employees as consideration for execution of their duties

Not applicable

2.2.3. Share warrant in issue

Not applicable

2.3. Corporate Executives

2.3.1. Management Reshuffle

(1) Directors and Company Auditors

As of March 30, 2021, the status of full-time and part-time directors is as follows:

Managing Director & CEO:	Jin Shiomura	
Director (part-time):	Isamu Sojyo	(former Executive Managing Director of Japan Intellectual Property Association)
Director (part-time):	Nobukuni Taneya	(Part-time company auditor of Arara Inc.)
Director (part-time):	Takahisa Iizuka	(Deputy General Manager, Business Development Division, Medipal Holdings Corporation)
Director (part-time):	Koichi Noda	(General Manager, Financial Management Office, Inabata & Co., Ltd.)
Director (part-time):	Toshio Miyata	(Director of Mih Clinic Yoyogi)
Audit & Supervisory Board Member (part-time):	Yoshitaka Kishi	(Former full-time company auditor, Dia Rix Co., Ltd.)
Audit & Supervisory Board Member (part-time):	Tomoyasu Toyoda	(Company auditor, Medipal Holdings Corporation)

(2) Executive Officers

As of March 30, 2021, the status of executive officers and directors is as follows:

Vice President & Chief Operating Officer	Shigeki Shimasaki	(Head of Research & Development / PMS Regulatory Compliance & Assurance)
Chief Operating Officer	Arata Tabata	(Head of Business Development)
Chief Operating Officer	Tetsuo Hayase	(Head of Supply Chain & Manufacturing)
Senior Executive Officer	Hitoshi Yokoyama	(Head of Sales & Marketing)
Executive Officer	Kenji Shimizu	(Deputy Head of Research and Development, General Manager of Clinical Research 2)
Executive Officer	Masato Iwamoto	(General Manager of Supply Chain Management, Supply Chain & Manufacturing)
Executive Officer	Yoshiki Yagi	(Head of Project Planning & Development)
Executive Officer	Toshiaki Okamura	(Head of Regulatory Affairs)
Executive Officer	Kozo Hayase	(Head of Administrative Affairs & Corporate Planning)
Executive Officer	Yoshihide Yamamoto	(Head of President Office and Overseas Business Development)
Executive Officer	Hitoshi Hasegawa	(Head of PMS Regulatory Compliance & Assurance / General Marketing Compliance Officer)
Executive Officer	Masanori Osakabe	(Deputy Head of Research & Development, General Manager of Overseas Development)

Executive Officer	Yoshiki Kida	(President & CEO, Nobelpharma America, LLC)
Executive Director	Atsunori Iwao	(General Manager of Quality Assurance, Quality Assurance Officer)
Executive Director	Takako Aburada	(General Manager of CMC Development, Supply Chain & Manufacturing)
Executive Director	Shigeru Doseki	(General Manager of Product Marketing Department 3, Sales Division)
Executive Director	Katsuhiro Kimura	(Region Manager of Saitama-Kanshinetsu Region)
Executive Director	Masahiko Tanaka	(Manager of Clinical Research 3, Research & Development, Deputy Head of Project Planning & Development)
Executive Director	Masatomi Nemoto	(General Manager of Pharmacovigilance / Safety Management Officer)
Executive Director	Yasuo Suga	(Deputy Head of Sales & Marketing)
Executive Director	Tsutomu Iwasa	(Region Manager of Kansai Region)
Executive Director	Makoto Matsuda	(Region Manager of Tokyo Region)
Executive Director	Yasuo Satake	(General Manager of HR & General Affairs)
Executive Director	Takahiro Yamasaki	(President & CEO, Plusultra pharma GmbH)
Executive Director	Weidong Chen	(General Manager, Jiangsu Nobelpharma Co., Ltd.)
Executive Director	Yumi Imai	(General Manager of PMS Regulatory Compliance)
Executive Director	Motomichi Kono	(General Manager of Intellectual Property, Administrative Affairs & Corporate Planning)
Executive Director	Nobuyuki Sato	(General Manager of Digital Transformation, Administrative Affairs & Corporate Planning)

2.3.2. Remuneration paid to directors and company auditors

Classification	Headcount	Amount paid
Directors	6	9,600,000 yen
Company auditor	2	4,800,000 yen
Total	8	14,400,000 yen

2.4. Matters related to accounting auditor

2.4.1 Name of accounting auditor

Deloitte Touche Tohmatsu LLC

2.4.2 Amount of remuneration, etc. for accounting auditor

Amount of remuneration, etc. for accounting auditor in the current business year: 14 million yen

(Note) This is remuneration, etc. for business stipulated by Article 2, Paragraph 1 of the Certified Public Accountants Act (Law No. 103 of 1948) and compensation to audit certification under the Companies Act.

2.4.3 Reasons that company auditor approves remuneration, etc. for the accounting auditor

The company auditor obtained necessary documents and received reports from the relevant department of the Company and the accounting auditor, and confirmed and verified the details of the accounting auditor's audit plan, the status of the execution of duties by the accounting auditor and calculation basis of estimated remuneration. As a result, the company auditor determined that the amount of remuneration, etc. for the accounting auditor was appropriate and approved it in accordance with Article 399, Paragraph 1 of the Companies Act.

2.4.4 Policy on decision to dismiss or not to reappoint accounting auditor

When the accounting auditor meets any of the items of Article 340, Paragraph 1 of the Companies Act, and when it is deemed to be difficult to carry out an adequate audit due to events that damage the accounting auditor's quality and independence, the company auditor may determine the details of a proposal on dismissal or refusal of reappointment of an accounting auditor to be submitted to a general meeting of shareholders.

2.5. Other matters

No matters requiring special attention

Attachment

September 1 Postscript (commentaries)
July 16, 2019
Managing Director and CEO

Request to Line Managers

Commentary We have many employees who have joined us mid-career and those with management experiences have been appointed as line managers; accordingly, manager education has not been adequately provided. In 2019, as the company is evolving into a new stage, I thought it would be a good idea to offer some kind of guidelines as to what line managers should be mindful of.

Just let me clarify these guidelines are not meant to make an alibi or an excuse after something wrong happens, as is often the case in organizations these days. In order for a company of a certain size to operate functionally, it is necessary to maintain good human relationships, and for this reason we have created this. In addition, it is also a commandment to myself. In any case, we are not necessarily saying that you have no qualification as line manager just because you cannot carry out on these guidelines. My intention is to encourage you to be conscious of and work towards these guidelines.

1. Review the Corporate Mission, Management Policies, and Code of Conduct periodically, to understand and take them deeply to heart.
Commentary The Corporate Mission is the meaning of our company to exist in society, or the life of the company, if you will. Talk about it from time to time with valued customers, contractors, business partners, personal friends, and your family.

2. Be aware that your behavior is always being observed. Any behaviors that look like mixing of work and private are the most unacceptable.
Commentary The point is “look-like” work and private mixing. Even if there is no intention to mix work and private, it is not acceptable so long as any member takes it as work-private mix. Keep in mind that even the littlest things tend to be taken as mixing.

3. It is when a job is tough (such as apologizing to a customer) that the manager should take the lead. Staff members respect courageous managers.
Commentary It is not just apologies to customers; making important decisions is also tough. Everyone has something they are not good at. It may be hard but showing your staff that you will not run away from any tough jobs is also an important duty of a line manager.

4. Do not create an impression of favoritism, such as having lunch/going out for drinks with a specific staff member (even a group of staff members).
Commentary The point is creating “wrong impression.” Even if there is no intention, some staff members may take it as an act of favoritism. This is not anything to restrict a lunch with staff members, which is ok as long as it does not give wrong impression of favoritism. On the other hand, let me point out to staff members that it is a common sense, in my opinion, to accept friendly gathering invitations from line managers “once in a while.”

5. Inviting a staff member of the opposite gender out for one-on-one lunch/drinks is not acceptable. Staff find it difficult to refuse, so it could be construed as harassment.
Commentary Such invitations are unacceptable. As staff are in the weaker position, they might be smiling outside and angry inside. “Don’t straighten your cap under a plum tree (Don’t do anything that could be misconstrued, because when you raise your hand it might look as if you are trying to steal the plums.).” Of course, as long as it is not one-on-one, such invitations should be fine every now and then.

6. Do not hesitate to make amends for your wrongs (Analects of Confucius).

Commentary What this means is that everyone makes mistakes and acknowledging one's own mistakes can be hard, yet, we should have the courage to do just that. Words of Confucius from more than 2,000 years ago are convincing. The Analects of Confucius contain universal wisdom.

7. Do not point out other's mistakes, nor boast of your own achievements (Nakane Tori).
Commentary Criticizing others and boasting about yourself can make you feel good. That is why we tend to do so without thinking. However, if we take these words to heart, it will curb such behavior. If you are not conscious of it, you will become mediocre person who has lost sight of the purpose of life. Staff will not respect someone like that.
Nakane Tori was a scholar from Japanese Edo Period who turned his back on fame and fortune to pursue a life of seclusion. If you are interested, visit the link below to find about Nakane Tori (Japanese only).
https://www.sanogaku.jp/course/012/

8. Managers should greet out loud when you come into or leave the office. Also, if the manager is quick with harmless jokes, the workplace becomes brighter. Puns are just fine.
Commentary Workplaces that have smile and laughter will raise efficiency and lower stress. I would ask line managers to take the lead in this regard. Greetings are something that shows "I have no hostility toward you." Conversely, without greetings, the other person may feel bitterness in you.

9. Have one-on-one communication with your staff regularly and repeatedly under no influence of alcohol. The purpose of such talks is to listen to what your staff want to say.
Commentary It may be difficult, but the "regularly and repeatedly" is the important point. Talks over drinks are not very effective. In these one-on-one communications, if your staff member does 60% of the talking, it is successful. Be careful not to make it your one-man show.

10. Do it in private when giving lectures or in public when giving compliments.
Commentary While this may sound familiar for everyone, we tend to find ourselves doing the opposite. Try to keep this in mind all the time.

11. There is nothing good to result by a heavy-handed order. The harsher the message, the more carefully you should express it.
Commentary In the pre-war Japanese army, high-handed orders and obedience through violence were commonplace. It is clear what the results have been.

12. Never reject a staff member's proposal on the spot. Listen first, then if necessary, leave a day or two before saying no.
Commentary It takes courage for staff to bring proposals to their managers. More often than not, they come forward with it after giving serious thoughts. Having more knowledge and experience than staff, line managers may think the proposals from staff are not so good. Even so, if you reject them on the spot, they will lose motivation. Conversely, if their proposals are given even a little praise, your staff will try even harder and come up with better proposals. It is also often the case that proposals that seem insignificant at first glance turn out to have some good points upon reflection.

13. There are times when you must give your staff instructions that are against their intent. At such times, strive to gain their understanding by carefully explaining the background and objective of your instructions. However, if they are still not convinced even after you have carefully explained three times, you may carry through with the instructions.
Commentary This relates to No. 11. People who understand and are convinced will show better performance. You may find it onerous, but if you make the effort to convince them, it will be more efficient in the end. If they still do not understand after explaining three times, you should direct them to do as you ask. That is not being high-handed.

14. If a staff member does not improve even after giving guidance five times, there is a strong chance that such member is not suited to that work. Making such staff understand this and recommending to transfer may be a thoughtful thing to do.
Commentary There is no guarantee that the current work is the best for the staff. Nor is there any guarantee that their current manager is the best for them. Even the company may not be the best fit for them. They might demonstrate their strengths better somewhere else. You should not give up easily, but if you have guide them carefully five times and they still have not improved, recommendation for a change will also be a kind consideration for them. However, the key point here is "having that staff understand," and you must not transfer them blindly.

15. Do not buy or sell the shares of related parties, either listed or unlisted.
Commentary This is an extra point. More than 3,600 companies in Japan have their shares listed on the stock exchange, so if you want to invest in shares, you should do so in companies that are not related to your work, either directly or indirectly. Even just being suspected of conducting insider trading can be troublesome. If you already own shares that are related to your work and want to sell them, it would be safer to consult with the Administration Division before you do so. Unlisted shares can be complicated, so it would be wiser not to deal with them in the first place. This is another of those "don't tie your shoelaces in a watermelon patch (lest you be thought of as a watermelon thief)" lessons.