

Business Report

(From January 1, 2016 to December 31, 2016)

1. Nobelpharma

1.1. Progress and Results of Operations

The Company's mission is to "Contribute to society by providing necessary but neglected pharmaceuticals and medical devices."

Sales and profits are important management indicators that should be pursued; however, we regard these to be the result of carrying out the mission, as well as a means to accomplish the mission. The management policy and action criteria are as cited below:

Policy

1. General

- 1) Share Mission, Policy and Action Criteria among all stakeholders (employees, shareholders, officers)

*Unable to share without routine review

- 2) Pursue evolution, yet upsizing is not our goal
- 3) Comply with regulations and ethical codes
- 4) Ensure transparency and disclosure
- 5) Launch out overseas

2. Personnel

- 1) Value employees and families, respecting self-development
- 2) Value "Selected Few" and create an environment for the "Selected Few" to enjoy working
*"Selected 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 in products and data
- 2) Ensure post-marketing safety
- 3) Search for seeds externally

4. Capital

- 1) Profits as a result/means of achieving the Mission
- 2) Focus on higher return on sales/profits per employee
- 3) Investment decision by observing damage of failure, not unreliable counts of success
- 4) Profits distribution to shareholders (dividends)/employees/internal reserve
*Dividends: 1/3 of profits after tax
*Employees: Up to dividends
- 5) Asset management only with principal guarantee

Action Criteria

1. Principle: Give priority to patient benefits if inconclusive:

2. Challenge:

- 1) YMWS: "Yatte Minakucha Wakaranai, shikashi Songiri wo tamerauna"= You never know unless you try, but do not hesitate to cut losses

- 2) ZY: "Zenrei ga nainara Yattemiru"= If no precedence, try first
3. Speed:
- 1) Never forget patients are waiting
 - 2) Never fear to buy time with money
 - 3) Set a deadline first (specific date) regardless of possible delay
*Off Limits = "about - , " "early/late - , " etc.
 - 4) Start from whatever is feasible
 - 5) If there is a failure/trouble, prevent expansion first, then recurrence
*Pursuit of responsibilities is unnecessary
 - 6) Fast decisions for < X mil yen by the person responsible
*X = 3 for Div Mngr; 1 for Dept Mngr/Branch Mngr/PM/PL
4. Cost/Efficiency:
- 1) Never carry/purchase deadwood, never take/cause wasteful actions
 - 2) No overtime work considered good
 - 3) Consider patient needs, scientific rationality and nature of laws/regulations when pursuing higher quality in products/data
 - 4) Pursue cost reduction with the principle of multiple sourcing, while regarding providers as partners
5. Communication/Relationship:
- 1) Never prioritize loyalty to company over morals
 - 2) Superiors to confidingly entrust tasks to subordinates, but to never leave them unmanaged
 - 3) Hear anyone out and never interrupt them
 - 4) Start with a conclusion when explaining/responding
 - 5) Mere greetings are significant

As of March 2017, the Company is marketing the 13 new ethical drugs listed below. As the agreement with Clinigen expired at the end of 2016, Foscavir[®] was transferred to the licensor, Clinigen, and the Company discontinued marketing of the product. On March 2, 2017, the First Committee on Drugs deliberated and agreed on a new indication of Nobelzin[®] (hypozyincemia), which is expected to be approved in March. The drug has been registered in the NHI price list and will be available for this indication on the same day of approval. As Nobelzin[®] tablets were launched in February 2015, Nobelzin[®] capsules will be deleted from the NHI price at the end of March 2017, accordingly we will make a cancellation for its approval later.

	Brand Name	Launch	Indication	Route of Administration	Licensor	2016 Sales (NHI price basis) Yen in millions	Sales Channel	Remarks
1	Nobelzin [®] capsules Nobelzin [®] tablets	Apr 2008 Feb 2015	Wilson's disease Hypozyincemia (Scheduled to be approved in March 2017)	Oral Administration	Teva (Wilson's disease only)	230	Direct	
2	Lunabell [®] LD Lunabell [®] ULD	Jul 2008 Sep 2013	Dysmenorrhea	Oral Administration	Janssen	10,122	Nippon Shinyaku Fuji Pharma	Both products distributed by two companies
3	Nobelbar [®]	Dec 2008	Neonatal seizures, status epilepticus	Intravenous injection	In-house	124	Direct	
4	Fostoin [®]	Jan 2012	Status epilepticus, prevention of postoperative seizures, etc.	Intravenous injection	Pfizer	1,390	Eisai	Co-promotion
5	Gliadel [®]	Jan 2013	malignant glioma	Interstitial chemotherapy	Eisai	1,077	Marketing Approval (MA) transferred to Eisai	Co-promotion (Contracted product)
6	Alabel [®]	Sep 2013	diagnosis of malignant glioma	Oral Administration	SBI Pharmaceuticals (medac)	287	Direct	
7	Foscavir [®]	Feb 2012	cytomegalovirus retinitis, viremia and infection	Intravenous injection	Clinigen	421	Direct	MA transferred from MSD
8	Indacin [®]	Jan 2013	patent ductus arteriosus of prematurity	Intravenous injection	Lundbeck	75	Direct	MA transferred from MSD
9	Cosmegen [®]	Jan 2013	Wilms' tumor, choriocarcinoma, pediatric solid malignant tumor, etc.	Intravenous injection	Lundbeck	18	Direct	MA transferred from MSD
10	Unitalc [®]	Dec 2013	prevention of recurrent malignant pleural effusion	Intrapleural	Novatech	67	Direct	
11	Respia [®]	Dec 2014	apnea of prematurity	Intravenous injection/oral liquid	Nippon Boehringer	193	Direct	
12	Rapalimus [®]	Dec 2014	lymphangioleiomyomatosis	Oral Administration	Pfizer	182	Direct	
13	Zanosar [®]	Feb 2015	gastroenteropancreatic neuroendocrine tumor	Intravenous injection	Keocyt	276	Direct	
	Total					14,463		

Sales decreased more than anticipated due to generic competition for Lunabell[®] LD and the launch of a competitive drug for Fostoin[®]. Our sales forecast for Zanosar[®] was excessive and we could not achieve it, and sales of Gliadel[®] were sluggish. In terms of profit, net income before tax was close to the forecast without reducing R&D as we posted gains on sales of stocks, received public subsidies for R&D, and reduced expenses. As shown in the above table, the total sales from the 13 products in 2016 were 14,463 million yen on a wholesale price (NHI price) basis and 6,004 million yen on the Company price basis. Sales of the Company from the Lunabell[®] family were 3,889 million yen, accounting for 64.8% of total sales. Adding royalty revenue of 787 million yen, total sales in 2016 were 6,791 million yen, down 8.7% year-on-year.

The cost of goods sold was 1,617 million yen, down 5.4% year-on-year, and accounting for 23.8% of

total sales (23.0% in 2015). Sales, general and administrative expenses totaled 5,407 million yen, a decline of 12.8% year-on-year, and accounting for 79.6% (83.4% in 2015), mainly including personnel expenses of 1,917 million yen, down 8.1% year-on-year, and 28.2% (28.1% in 2015), R&D expenses of 1,603 million yen, down 1.9% year-on-year, and 23.6% (22.0% in 2015), outsourcing expenses of 714 million yen and royalty expenses of 701 million yen. The outsourcing expenses mainly included 126 million yen for safety database construction and operation by CMIC, 70 million yen for PMS-related services by CMIC PMS, 42 million yen for call center operation by EP-PharmaLine, 41 million yen for outsourcing expense of drug use investigation by A2 Healthcare Corp., 37 million yen for business management service by Hisanaga & Company, and 29 million yen and 21 million yen respectively for system development by Application Software Development Co., Ltd. and Perspective Co., Ltd. Royalty expenses were running royalties of 564 million yen and 130 million yen, respectively, to Jansen Pharma and Pfizer.

The resulting operating loss was 233 million yen (476 million yen in 2015), accounting for 3.4% of total sales (6.4% in 2015).

Ordinary loss was 56 million yen (270 million yen in 2015) accounting for 0.8% (3.6% in 2015) of total sales, after recording non-operating income of 242 million yen including subsidy revenue of 230 million yen partly offset by non-operating expenses of 65 million yen including interest expenses of 39 million yen and bond interest expenses of 22 million yen.

Gains on sale of stocks of 243 million were recorded as extraordinary income.

Extraordinary loss included lump-sum write-off of impairment for license fee of Ocnobel[®] of 49 million yen.

With the income taxes of 38 million yen and income taxes-deferred of 5 million yen, the net income was 93 million yen, down 40.3% year-on-year, and accounting for 1.4% of total sales (2015: 2.1%), and net income per employee was 399,000 yen (2015: 649,000 yen).

Retained earnings brought forward as of December 31, 2016 were 679 million yen, with the beginning balance of retained earnings brought forward of 637 million yen and a dividend payment of 52 million yen.

Item	mil yen		Year-on-year	% to total sales	
	2015	2016		2015	2016
Sales	7,435	6,791	91.3%	100.0%	100.0%
Product sales	6,854	6,004	87.6%	92.2%	88.4%
Other	580	787	135.6%	7.8%	11.6%
Cost of goods sold	1,709	1,617	94.6%	23.0%	23.8%
Gross profit	5,725	5,174	90.4%	77.0%	76.2%
SG&A expense	6,201	5,407	87.2%	83.4%	79.6%
* Personnel cost	2,085	1,917	91.9%	28.1%	28.2%
* R&D expenses	1,635	1,603	98.1%	22.0%	23.6%
* Commission fee	794	714	89.9%	10.7%	10.5%
* Loyalty expenses	923	701	75.9%	12.4%	10.3%
Operating income	△476	△233	48.9%	△6.4%	△3.4%
Non-operating income	282	242	85.8%	3.8%	3.6%
Non-operating expenses	76	65	85.7%	1.0%	1.0%
Ordinary income	△270	△56	20.8%	△3.6%	△0.8%
Extraordinary income	448	243	54.3%	6.0%	3.6%
Extraordinary loss	22	49	219.6%	0.3%	0.7%
Net income before tax	155	137	88.5%	2.1%	2.0%
Income taxes	△1	43	-	△0.0%	0.6%
Net income	157	93	59.7%	2.1%	1.4%
Ordinary income per employee ('000 yen)	△1,116	△239	21.4%	-	-
Net income per employee ('000 yen)	649	399	61.5%	-	-
Retained earnings brought forward					
Beginning balance	665	637	-	-	-
Prior period adjustment	△17	-	-	-	-
Retirement of treasury stock	△90	-	-	-	-
Dividend	76	52	-	-	-
Net income	157	93	-	-	-
Ending balance	637	679	-	-	-

* Major items included in SG&A expenses

1.2. Sales

Sales of the 13 products on market as of December 2016 are summarized as follows:

Brand Name	Wholesale sales (NHI price basis, mil yen)		Year-on-year ([2]/[1])
	2015 [1]	2016 [2]	
Nobelzin [®]	207	230	111%
Lunabell [®] (LD), ULD	13,149	10,122	77%
Nobelbar [®]	133	124	93%
Fostoin [®]	1,617	1,390	86%
Foscavir [®]	449	421	94%
Gliadel [®]	1,179	1,077	91%
Alabel [®]	243	287	118%
Indacin [®]	78	75	96%
Cosmegen [®]	17	18	106%
Unitalc [®]	63	67	106%
Respia [®]	124	193	156%
Rapalimus [®]	138	182	132%
Zanosar [®]	165	276	167%
Total	17,563	14,463	82%

To accomplish the Sales & Marketing mission to “Deliver the Company’s products to patients as soon as possible,” and its corresponding motto of “Change activities” to achieve the mission, in 2016, Sales & Marketing aimed at achieving a sales target of 17 billion yen (11.9 billion for Lunabell[®] and 5.1 billion yen for direct sales and co-promotion products) on the NHI price (wholesale price) basis. Actual sales in 2016 were 14.5 billion (10.1 billion for Lunabell[®] and 4.4 billion yen for direct sales and co-promotion products), showing very poor results.

Lunabell[®], our core product, is marketed on complete consignment basis by Nippon Shinyaku and Fuji Pharma. As a generic competitor of Lunabell[®] LD was launched in December 2015, sales of the total Lunabell[®] family fell short of the forecast by 1.8 billion yen (down 15% compared with the budget and a fall of 23% year-on-year). Although we had focused on transferring to Lunabell[®] ULD from LD, certain patients preferred to use LD, which was significantly affected by the generic. Sales of another core product of Fostoin[®] fell short of the forecast by 400 million yen (down 22% compared with the budget and a fall of 14% year-on-year) due to the launch of a competitive product. Sales of Gliadel[®] fell short of the forecast by 140 million yen (down 11% compared with the budget and a decline of 9% year-on-year) as a clinical test of a competitive drug limited its indication cases. For Zanosar[®], a new product launched in February 2015 and our most prioritized product in 2016, as we used a wrong and excessive sales forecast that was created before its launch, actual sales fell short of the forecast by 260 million yen (down 48% compared with the budget and up 67% year-on-year). We postponed procedures for registering Ocnobel[®] approved in July 2016 in the NHI price list due to various reasons.

As of March 1, 2017, 74 MRs cover the entire country, of which 29 MRs are sent by the Medipal Holdings Group. For one of our issues of “Change activities” for MRs, considering the characteristics of our products, we have worked on making appointments and interviewing healthcare professionals preferentially. As a result, in the second half of 2016, the number of interviews per MR per month was 14 on average (8 times per month in the first half).

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

1.3. Manufacturing and Capital Expenditure

The Company has no manufacturing facilities of its own, and outsources manufacturing of both APIs and products to domestic and overseas manufacturers, so the stabilization of the drug supply has been a big challenge. We are working on building a stable supply system for product outsourcing to overseas manufacturers, and to add domestic manufacturers to ensure multiple suppliers.

We applied for additional domestic API and product manufacturers for Fostoin[®], a product imported from overseas and which had manufacturing problems in the past, and that was approved in February 2017. However, Rapalimus[®], which is primarily packaged overseas, is facing some concerns over defects including spots on tablets caused by packaging, for which a fundamental solution has yet to be found. Thus, we are working on outsourcing its primary packaging to domestic manufacturers from March 2017. For other products, we are trying to add outsourcees for manufacturing products.

In view of the expansion of demand for Nobelzin[®] arising from a new indication scheduled in 2017, we are significantly increasing our supply of Nobelzin[®] tablets. We have developed a production plan for outsourcees for increasing production volume of both API and products in 2017 and 2018, and inventories to meet demand in 2017 have been produced.

For this period, there is no material capital investment.

1.4. Research and Development

In the past the Company mainly developed drugs that had already been approved in Europe and US but were not approved in Japan (“unapproved drugs”), and smoothly obtained approvals. Recently, the long-lasting social issue of unapproved drugs has been largely solved and the Company is shifting its target seeds to more difficult drugs that originated in Japan.

The table below summarizes the development stage, expected NDA and market size classification in three categories of New Drugs and Medical Devices, Life Cycle Management (LCM) and Overseas Development as of March 1, 2017. Many are drugs based on new concepts that originated in Japan. Of these products, those under development with our own funds without any public subsidies are NPC-16, NPC-15 and NPC-04 under New Drugs, and NPC-02 (hypo-zincemia) under LCM. In 2016, NPC-04 (Ocnobel[®]) was approved and NPC-02, a treatment for hypo-zincemia, on which we are now focusing, is expected to be approved in March 2017. Following these products, we are preparing for filing NDA for four items (NPC-12G, NPC-16, NPC-17 and NPC-18) in 2017.

As for the financing method for development funds including Overseas Development, we are considering obtaining public funds in addition to operating income and intend to introduce risk money according to the degree of risk of the theme.

Development items are classified into the following six classifications:

- I: Potential primary sources of revenue following Lunabell[®] (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 theme 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.
- V: LCM of the existing commercialized products. Lower development cost and increased marginal profit expected.
- VI: Theme under research (No applicable item in the table below)

(New Drugs and Medical Devices)

	Compound	Indication	Licensor	Development stage	Estimated approval	Classification
1	NPC-17 Titanium bridge	Adductor spasmodic dysphonia	Foundation of Biomedical Research and Innovation (Kobe) Wakayoshi Seisakusho	Clinical trial in preparation	Dec 2017	III
2	NPC-18 S-bFGF, etc.	Myringa regeneration	Foundation of Biomedical Research and Innovation (Kobe) Kaken Pharmaceutical	Clinical trial in preparation	Jun 2018	III
3	NPC-16 LEP combination drug	Gynecological diseases	In-house	PIII	Jun 2018	I
4	NPC-09 N-acetylneuraminic acid	Distal myopathy	In-house	PIII	Dec 2018	III
5	NPC-15 Melatonin	Sleep disorders in children with neurodevelopmental disabilities	In-house	PIII	Jun 2019	I
6	GM-CSF Molgramostim	Pulmonary proteinosis	Savara Inc.	PIII (Global clinical trial)	Dec 2019	II
7	NPC-14 Arbekacin	Duchenne muscular dystrophy	Undisclosed	PII	TBD	IV
8	NPC-x3 Pyruvic acid	Mitochondrial disorders	Kurume University	PII	TBD	IV
9	NPC-04 Oxcarbazepine	Partial epilepsy	Novartis	Approved	Jul 2016	II
10	NPC-x5 Skopolamin	Salivation	Kitasato University	Non-clinical	TBD	IV
11	NPC-x4 P092	Prion disease	Gifu University	Non-clinical	TBD	IV

(LCM)

	Compound	Indication	Development stage	Estimated approval	Classification
1	NPC-02 Nobelzin®	Hypo zincemia (new indication)	Under review	Mar 2017	I
2	NPC-12G Sirolimus® external preparation	External preparation (new drug form), angiofibroma (new indication)	PIII	Mar 2018	III
3	NPC-02 Nobelzin®	Child's preparation (new drug form)	PIII	TBD	III
4	NPC-05 Unitalc®	Refractory pneumothorax (new indication)	PII	TBD	III
5	NPC-07 Alabel®	Diagnosis of bladder cancer (new indication)	PIII(Addition)	TBD	V
6	NPC-12 Rapalimus®	Refractory blood/lymph vessel disease (new indication)	PIII in preparation	TBD	III
7	NPC-12 Rapalimus®	Fibrodysplasia ossificans progressiva (new indication)	PII in preparation	TBD	III
8	NPC-12 Rapalimus®	Prevention of GVHD after hematopoietic stem cell transplantation (new indication)	PII in preparation	TBD	IV
9	NPC-12G Sirolimus® external preparation	Severe hyperhidrosis, neurofibromatosis type 1 (new indication)	PI/II	TBD	III

(Overseas Development)

	Compound	Indication	Licensor	Development stage	Estimated approval	Classification
1	BK-SE36 Malaria vaccine	Prevention of falciparum malaria	Osaka University	PIb	TBD	I
2	NPC-18 S-bFGF, etc.	Myringa regeneration	Foundation of Biomedical Research and Innovation (Kobe) Kaken Pharmaceutical	PII	TBD	III
3	NPC-17 Titanium bridge	Adductor spasmodic dysphonia	Foundation of Biomedical Research and Innovation (Kobe) Wakayoshi Seisakusho	Clinical trial in preparation	TBD	III
4	NPC-12G Sirolimus [®] external preparation	Hemangiobroma	Osaka University	Clinical trial in preparation	TBD	III

NPC-12G (Hemangiobroma) and NPC-17 (Adductor spasmodic dysphonia) deserve special mention, as they are orphan drugs that were designated under the “Sakigake” fast-track review system and demonstrated positive outcomes in their clinical tests. Comprehensive evaluation under the Sakigake system is progressing as planned, with the aim of submitting the NDA in 2017.

1.5. Business Development & Strategy

Business Development & Strategy is responsible for core roles for the Company’s open innovation and contacts for business negotiations, specifically (1) Planning and research for new themes, (2) In/out-licensing negotiations with a potential business partner for a new development theme, (3) Follow-up negotiations with the existing business partners, (4) Preparation for overseas expansion, (5) Intellectual property management such as patents and technology-related contracts, and (6) procurement negotiations.

Regarding (1), the Company is cultivating new seeds including some projects from domestic universities and public research institutions, actively researching and evaluating them, and considering suitability with the Company’s mission and for potential commercialization. As a part of such activities, we entered into an umbrella agreement with Foundation for Biomedical Research and Innovations in March 2016, under which we have access to seeds of national academia managed by the Foundation. Accordingly, the Company entered into a joint research agreement with a university in March 2017, and we also entered into a partnership agreement with a public research institute in January 2017. We will be able to disclose more detailed information at a later date.

For (2), the Company signed a license agreement on commercialization of Molgradex, a treatment for pulmonary proteinosis, in Japan with Danish Serendex Pharmaceuticals (currently, Savara in the U.S.) in May 2016. In November 2016, the Company entered a comprehensive business tie-up with ASKA Pharmaceutical Co., Ltd. with the aim of co-promotion in the field of obstetrics and gynecology, including NPC-16, a treatment for dysmenorrhea.

For (3), the Company transferred (returned) marketing authorization for Foscavir[®], cytomegalovirus retinopathy agent, to Clinigen KK in November 2016.

For (4), the Company had investigated to develop and sell NPC-17 and other products in East Asia, North America and Europe, and in March 2017, it established the Global Business department, independent from Business Development & Strategy.

For (5), in line with an increase in employee invention, the Company established “Regulations on Handling of Inventions” in August 2016. The Company took patent-related procedures to the Japanese

Patent Agency and submitted international applications by itself, which we had previously requested of a patent office, and reduced related costs by approximately 2 million yen, even though applications increased from 2015, with three new registrations of trademark and registration of company names in Europe, U.S. and China while the number of basic patent applications remained unchanged from 2015.

For (6), the Company engaged in more than 30 purchase negotiations to reduce costs by approximately 18 million yen annually.

1.6. Pharmacovigilance & Quality Assurance

Pharmacovigilance & Quality Assurance is largely responsible for three areas: (1) quality assurance for manufacturing, (2) safety control for the vigilance of side effects and adverse events and (3) Post-marketing Surveillance (PMS) for pharmacovigilance. The objectives of (2) and (3) are to avoid causing drug-induced diseases and to pass re-examinations, and it is important to achieve these objectives efficiently within pertinent laws and regulations.

We completed re-examination of Lunabell[®] LD in September 2016. For Nobelbar[®], a treatment for status epilepticus, the Company worked on responding to inquiries from the compliance inspection and completed that inspection process in February 2017. Currently, the authorities are reviewing its re-examination application documents.

In terms of quality related matters, in January 2016 the Japanese Ministry of Health, Labour and Welfare (MHLW) requested all pharmaceutical companies in Japan to inspect any difference between certificates of approval for manufacture and sale and the actual status of manufacturing simultaneously. The Company confirmed any differences between them for our 16 products. In March 2016, the Company reported to the MHLW that of 16 products, there is no difference only for Respia[®] and we found differences for the other 15 items. We completed revision of details of certificates of approval for all differences found by the end of May and cooperated with outsourcees to build regular check systems as recurrence preventive measures.

In 2016, the number of domestic adverse event reports was 5,100, up 25% from 4,055 in 2015, and overseas reports were 1,865, up 117% from 859 in 2015.

The table below shows the comparison of personnel cost and general and administrative expenses in Pharmacovigilance & Quality Assurance in 2015 and 2016.

	2015 ('000 yen)	2016 ('000 yen)
Personnel cost	351,210	314,981
General and administrative expenses	562,579 (including IT system introduction expenses)	449,336
Total	913,789	764,317

In 2016, personnel costs were reduced approximately 10% year-on-year due to the introduction of an IT system related to the above (2) and (3), which resulted in the enhancement of data quality and improvement of resources and operation processes, while we handled re-examination of two products, and MHLW's request for checking certificates of approval for our 16 products, as well as increasing domestic and overseas adverse event reports.

1.7. Regulatory Affairs

Regulatory Affairs is responsible for administrative procedures related to the PMD Act and for NHI price negotiations.

Special mentions related to regulatory affairs in the year included (1) NPC-12G and NPC-17 were designated under the Sakigake fast-track review system, which was recently started as a breakthrough

system. The Company has consulted and received guidance from Pharmaceutical and Medical Devices Agency (PMDA) regularly about these two items and expects to follow an application schedule as initially planned, and to obtain approvals in a short time. (2) The Company newly obtained a license for Marketing Class 1 Medical Devices with the aim of obtaining marketing authorization of NPC-17.

The Company increased staff and activated negotiations to reinforce negotiation ability regarding drug prices.

1.8. Funding and Major Lenders

In 2016, the Company didn't borrow new funds and repaid 1,165 million yen to financial institutions.

The resulting balance of loans payable and bonds as of December 31, 2016 was 4,519 million yen. As the Company has cash and deposits of 3,658 million yen, the actual amount of borrowing is 861 million yen (2015: 578 million yen).

As of December 31, 2016, the status of borrowing is as follows:

Short-term loans payable	
Current portion of long-term loans payable	607 million yen
Long-term loans payable	
The Bank of Tokyo-Mitsubishi UFJ, Ltd., Odenmachi Branch	297 million yen
Mizuho Bank, Ltd., Yokoyamachi Branch	80 million yen
Sumitomo Mitsui Banking Corporation, Kandaekimae Branch	590 million yen
Japan Finance Corporation	121 million yen
The Shoko Chukin Bank, Ltd., Kanda Branch	92 million yen
Resona Bank, Akihabara Branch	60 million yen
The Tokyo Shinkin Bank, Nihonbashi Branch	72 million yen
Total	1,312 million yen
Balance of bonds	
Straight bond	
2nd straight bond -> Osaka Soda Co., Ltd.	500 million yen
3rd straight bond -> Medipal Holdings Corporation	* 1,500 million yen
4th straight bond -> Mizuho Bank, Ltd.	500 million yen
5th straight bond -> The Shoko Chukin Bank, Ltd.	100 million yen
Total	2,600 million yen

* 300 million yen was redeemed before maturity on January 31, 2017, and the remaining balance was 1,200 million yen.

1.9. Financial Results, Assets and 2016 Forecast

The Company's financial results, assets and 2016 forecasts are as follows:

mil yen except for *	2013	2014	2015	2016	2016	2017
	11th year	12th year	13th year	(Forecasts) 14th year	(Actual results) 14th year	(Forecasts) 15th year
Sales	6,542	6,628	7,435	7,456	6,791	7,514
Ordinary income	462	577	Δ270	160	Δ56	233
Net income	338	240	157	103	93	113
* Net income per share	257,000 yen	182,000 yen	54,000 yen	89,000 yen	80,000 yen	97,000 yen
Total assets	6,098	9,291	9,671	7,830	7,671	7,260
Net assets	728	1,238	984	993	691	832
* Equity ratio	11.9%	13.2%	10.2%	12.7%	9.0%	11.5%
* Net asset per share	553,000 yen	941,000 yen	844,000 yen	852,000 yen	593,000 yen	714,000 yen

1.10. Employees

As of March 1, 2017, the number of employees is 235 (including a total of 85 including 33 seconded employees, 6 temp staff, and 46 contract employees but excluding directors) with an average age of 53.0. The number of employees decreased by 7 compared with 242 (including seconded employees) as of March 1, 2016.

Total personnel costs including expenses for seconded employees and temp staff in 2016 and 2015 were 1,954 million yen, down 7.7% year-on-year, and 2,116 million yen, up 9.9% year-on-year, respectively. Total personnel cost in 2016 included 37 million yen for temp staff expenses. Of which, personnel cost of employees consisting of full-time and contract employees in 2016 decreased by 3.5% year-on-year, compared with an increase of 5.7% year-on-year in 2015. Expenses for seconded employees in 2016 decreased by 20.6% year-on-year, compared with an increase of 29.7% year-on-year in 2015, due to timing of their replacement. Expenses for temp staff surged by 76.8% year-on-year in 2015. However, due to the completion of large-scale operations related to post-marketing surveillance, expenses for temp staff in 2016 dropped significantly by 56.3% year-on-year.

In the most recent five years, the Company has recruited six postdoctorals and those with equivalent status, who have become key driving forces in their departments, and additionally two will join us this April. The Company has been actively promoting excellent temp staff and contracted employees to full-time positions.

In 2015, monthly average overtime hours per employee exceeded 20 hours. However, after making related operations such as post-marketing surveillance more efficient and improving working conditions, monthly average overtime hours in 2016 were significantly reduced to approximately 9 hours.

As a part of transformation of working style, the Company has launched various systems focusing on work-life balance including encouraging taking paid leave all together, teleworking and consecutive leave system. As a result, the rate of annual paid leave taken by employees in 2016 was nearly 80% on average.

The Company has adopted personnel exchanges between and within departments.

1.11. Issues

In 2017, company-wide issues are five as follows:

- ① Strengthening sales of Nobelzin[®] and securing profit
- ② Application and approval of development items as planned and obtaining profitable drug prices
- ③ Full-scale development for overseas marketing authorization and preparation of overseas sales
- ④ Active access to seeds from academia
- ⑤ Optimize cost of related operations such as post-marketing surveillance

The Sales & Marketing mission is to ensure achievement of this year's sales target of 15.1 billion yen (9 billion with Lunabell[®], 2.4 billion yen with Nobelzin[®] and 3.7 billion yen with other direct sales and co-promotion products) on a NHI price (wholesale price) basis. The most important mission is to achieve sales of Nobelzin[®] that meet or exceed its sales target of 2.4 billion yen. As sales promotion measures, the Company reorganized its branch network to eight from 11 to ensure closer cooperation between the head office and branches in January 2017. The Nobelzin[®] Mobilization Project Division is established in the head office to ensure that all employees work together to promote sale of Nobelzin[®]. Regarding the practitioner market to which the Company does not have access, we entered into a co-promotion agreement with Medipal Holdings Corporation to outsource full operations from promotion to PMS to its group companies. The Company also entered into a co-promotion agreement with ASKA Pharmaceutical Co., Ltd. for outsourcing similar business for certain facilities of obstetrics and gynecology. Sales & Marketing will invest 70% of its operating resources (manpower, goods and

capital) in “hypozyncemia” of Nobelzin[®].

The tasks of Business Development & Strategy to find new themes continue to include collaboration with the aim of active introduction and commercialization of academia seeds through open innovation. The Company will continue to work on obtaining public funds for development individually or in collaboration with academia, to promote development of seeds and maximize business value.

The Company has certain matters under negotiation with existing business partners and will advance negotiations by resolving the said matters to gain profit. The Company will pursue detailed and exhaustive cost-cutting negotiations pertaining to procurement, including raw material costs and drug processing expenses, and particularly for Nobelzin[®], whose production volume is expected to increase sharply.

Research & Development will push ahead the development schedule, with the aim of submitting the NDA for four items (NPC-12G, NPC-16, NPC-17 and NPC-18) in 2017, and obtaining an approval of NPC-17 in 2017, following NPC-02 (hypozyncemia) that is expected to be approved in March 2017.

In view of overseas expansion, the Company will submit the NDA for NPC-17 in Europe and the U.S. in 2017 and plans to apply for orphan drug designations for BK-SE36, NPC-12G, NPC-17 and NPC-18 in Europe and the U.S., and start to contact the U.S. FDA.

Concerning the safety assurance of pharmaceutical products, an IT system has been put into place in 2015. The Company endeavors to streamline organizations and systems within laws and regulations to reduce costs, while achieving the two objectives of causing no drug-induced diseases and passing re-examinations.

As for production, the most serious concern is to ensure stable supply of drug products from overseas manufacturers. As a fundamental resolution, the Company is promoting the shift of manufacturing of imported drug products to Japan. As a major urgent issue, the Company will carry out an increased production schedule that has already been started in view of the expansion of demand due to a new indication of Nobelzin[®] while reducing costs significantly. We plan to submit the NDA for four items in 2017 and are expected to launch new products from the end of 2017 to 2018. We are preparing to produce these products.

Regulatory Affairs is now required to actively support both Research & Development and Pharmacovigilance & Quality Assurance, and to help efficient and speedy response to the authority. It also utilizes the know-how for NHI price negotiations to involve 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 addition, it will scrutinize unprofitable items and request “recalculation for unprofitable items” for certain items that it deems necessary. Through the activities of Samurai Biotech Association of which the Company is a board member, lobbying and advising the authorities for NHI price system reform, which is expected to be drastically changed, will be continued.

Administrative Affairs & Corporate Planning (corporate planning and accounting) will primarily increase the accuracy in obtaining real-time budgetary variance analysis and the forecasts to achieve budgets. It will continue cost control that had considerable achievements in 2016, and build a flexible management system that enables taking additional measures prospectively if the forecast shows a downward trend. Secondly for financial affairs, the Company intends to raise around 2 billion yen for maintaining sufficient funds in hand as demand for working capital is increasing followed by sales

expansion of Nobelzin[®] due to the new indication. Considering risky development themes and full-scale overseas development, the Company will consider flexible financing and the introduction of risk money. Thirdly, the Company believes that it is important to adopt accounting standards equivalent to listed companies despite its policy to remain unlisted, and thus, the accounting audits by Deloitte Touche Tohmatsu LLC since 2011 were changed from quasi-Financial Instruments and Exchange Act audits to quasi-Companies Act audits in 2015, which the Company intends to continue using.

As for the issue of Administrative Affairs & Corporate Planning (HR & general affairs), the Company has been hiring experienced mid-career workers in principle but refreshing personnel is inevitable considering the currently aging workforce. For fostering successors of important positions, the Company continues to recruit young employees, including postdoctorals and professional mid-level and young employees. The Company established the Global Business Department with the aim of future overseas expansion and will seek personnel who can work globally. In these circumstances, the Company launched a new personnel system for arranging working conditions under which young employees and high performers can work with high motivation. The new system will reduce overtime work and encourage employees to take vacation as in the past, considering a work-life balance. Also, personnel exchanges between and within departments are promoted actively as in the past.

The Company implemented an internal audit system in November 2015, and regular audits have been conducted for all departments since January 2016. While the Company endeavors to delegate authority to each division, it will reinforce business audits. Accordingly, business audits are to be added to Company Auditor's responsibility in addition to the current accounting audits (Articles of Incorporation related to Company Auditor's responsibility will be revised in the annual meeting of shareholders to be held on March 28, 2017). For the accounting audits, the Company entrusts quasi-Companies Act audits to the accounting firm in cooperation with the Company Auditor. We will request the Company Auditor to focus on business audits.

Overall, in 2016, due to the impact of generics on Lunabell[®], the Company entered a phase of challenging financial results for the first time since its foundation. However, we believe that financial results may recover remarkably as sales are expected to increase due to the new indication of Nobelzin[®] (hypo-zincemia), which is expected to be approved in March 2017 and certain items in the final development stage will be approved after 2018. Nobelpharma is an evolving young company and with the motto of "YMWS" explained in the beginning of 1.11, we plan to invest profits arising from these new products into

- ③ Full-scale development for overseas marketing authorization and preparation of overseas sales, and
- ④ Actively accessing seeds from academia.

With regard to ③, the Company established Global Business Department in March 2017.

The following shows the numerical targets for the mid-long term future vision of sales and profit as an immovable high goal named North Star. We believe that these targets are not necessarily unattainable.

North Star	2020
Sales	20 billion yen
Ordinary income	5 billion yen
Net income	3 billion yen

1.12. Other Important Matters

No matters requiring special attention

2. Current Status of the Company

2.1. Shares

① Number of shares authorized	As of December 31, 2016		5,000 shares
② Number of shares issued	As of December 31, 2016	Ordinary share	1,165 shares
③ Number of shareholders	As of December 31, 2016		2
④ Status of Major Shareholders (as of December 31, 2016)			
	Hisanaga & Company (ordinary share)		1,000 shares (85.8%)
	Inabata & Co., Ltd. (ordinary share)		165 shares (14.2%)

On February 3, 2017, a portion of ordinary shares held by Inabata & Co., Ltd. was transferred to Medipal Holdings Corporation. As a result, the number of shareholders and status of major shareholders are changed as follows:

• Number of shareholders		3
• Status of Major Shareholders		
	Hisanaga & Company (ordinary share)	1,000 shares (85.8%)
	Medipal Holdings Corporation (ordinary share)	83 shares (7.1%)
	Inabata & Co., Ltd. (ordinary share)	82 shares (7.0%)

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

On August 24, 2016, a share warrant (334 shares) held by Inabata & Co., Ltd. was extinguished due to the expiration of the exercise period.

2.3. Corporate Executives

2.3.1. Management Reshuffle

(1) Scheduled directors (scheduled on March 28, 2017)

Nobukuni Taneya (Part-time company auditor, Arara Inc.)

Takahisa Iizuka (Deputy General Manager, Business Development Division, Medipal Holdings)

Corporation)

(2) Director to resign (scheduled on March 28, 2017)

Yasuyuki Fujimoto (General Manager, Life Industry Division, Inabata & Co., Ltd.)

(3) Scheduled company auditor (scheduled on March 28, 2017)

Yoshitaka Kishi (Former full-time company auditor, Dia Rix Co., Ltd.)

(4) Company auditor to resign (scheduled on March 28, 2017)

Takashi Akiyama (Section Head, Accounting Dept., Accounting, Financial Management Office, Inabata & Co., Ltd.)

(5) Directors and Company Auditors

As of March 28, 2017, the status of full-time and part-time directors is as follows:

CEO and President:	Jin Shiomura	
Directors (part-time):	Eiji Suzuki	(Corporate advisor)
Directors (part-time):	Isamu Sojyo	(former Executive Managing Director of Japan Intellectual Property Association, former General Manager of Intellectual Property Department at Mitsubishi Chemical Corporation)
Directors (part-time):	Nobukuni Taneya	(Part-time company auditor of Arara Inc.)
Directors (part-time):	Takahisa Iizuka	(Deputy General Manager, Business Development Division, Medipal Holdings Corporation)
Directors (part-time):	Nobukazu Kuboi	(General Manager, Financial Management Office and General Manager, Accounting Dept., Inabata & Co., Ltd.)
Company Auditor (part-time):	Yoshitaka Kishi	(Former full-time company auditor, Dia Rix Co., Ltd.)

(6) Executive Officers

As of March 28, 2017, the status of executive officers and directors is as follows:

Chief Operating Officer:	Shigeki Shimasaki	(Head of Research & Development)
Chief Operating Officer:	Tsutomu Sugaya	(Head of Administrative Affairs & Corporate Planning)
Senior Executive Officer:	Tetsuo Hayase	(Head of Supply Chain & Manufacturing)
Senior Executive Officer:	Soichi Ikegaya	(General Marketing Compliance Officer, Head of Pharmacovigilance & Quality Assurance)
Senior Executive Officer:	Arata Tabata	(Head of Business Development & Strategy)
Executive Officer:	Kenji Shimizu	(General Manager of R&D Department 2)
Executive Officer:	Akira Ikeda	(Deputy Head of Administrative Affairs & Corporate Planning)
Executive Officer:	Masato Iwamoto	(General Manager of Supply Chain Management, Supply Chain & Manufacturing)

Executive Officer:	Osamu Kato	(Head of Regulatory Affairs)
Executive Director:	Masanobu Murakami	(General Manager of R&D Department 1)
Executive Director:	Yoshinobu Takahashi	(Head of Marketing & Sales)
Executive Director:	Yoshihide Yamamoto	(Deputy Head of Marketing & Sales)
Executive Director:	Masanori Osakabe	(Deputy Head of Research & Development)
Executive Director:	Hitoshi Hasegawa	(Safety Management Supervisor, Deputy Head of Pharmacovigilance & Quality Assurance)
Executive Director:	Yoshiki Yagi	(Deputy Head of Business Development & Strategy)
Executive Director:	Akira Yumoto	(Deputy Head of Marketing & Sales)
Executive Director:	Mitsunobu Hara	(Deputy Head of Business Development & Strategy)

2.3.2. Remuneration paid to directors and company auditors

Classification	Head-count	Amount paid
Directors	5	8,880,000 yen
Company auditor	1	0 yen
Total	6	8,880,000 yen

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