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CHUGAI PHARMACEUTICAL CO., LTD.

A member of the Roche group

CONSOLIDATED FINANCIAL STATEMENTS (IFRS) (Non-Audited) (for the fiscal year 2018)

Name of Company: Chugai Pharmaceutical Co., Ltd. January 31, 2019
 Stock Listing: Tokyo Stock Exchange
 Security Code No.: 4519 (URL <https://www.chugai-pharm.co.jp/english>)
 Representative: Tatsuro Kosaka, President & CEO
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 Phone: +81-(0)3-3273-0881
 Date of Annual General Meeting of Shareholders: March 28, 2019
 Date of Submission of Marketable Securities Filings: March 28, 2019
 Date on which Dividend Payments to Commence: March 29, 2019
 Supplementary Materials Prepared for the Financial Statements: Yes
 Presentation Held to Explain the Financial Statements: Yes (for institutional investors, securities analysts and the media)

(Note: Amounts of less than one million yen are rounded.)

1. Consolidated results for FY 2018 (January 1, 2018–December 31, 2018)

(1) Consolidated operating results

	Revenues	% change	Operating profit	% change	Net income	% change
FY ended Dec. 2018	¥579,787 million	8.5	¥124,323 million	25.7	¥93,079 million	26.6
FY ended Dec. 2017	¥534,199 million	8.6	¥98,934 million	28.7	¥73,541 million	35.3

	Net income attributable to Chugai shareholders	% change	Total comprehensive income	% change
FY ended Dec. 2018	¥92,488 million	27.2	¥87,587 million	15.1
FY ended Dec. 2017	¥72,713 million	35.7	¥76,081 million	49.0

	Earnings per share (Basic)	Earnings per share (Diluted)
FY ended Dec. 2018	¥169.08	¥168.80
FY ended Dec. 2017	¥133.04	¥132.83

	Ratio of net income to equity attributable to Chugai shareholders	Ratio of operating profit to revenues
FY ended Dec. 2018	12.8%	21.4%
FY ended Dec. 2017	10.9%	18.5%

Note: Percentages represent changes compared with the same period of the previous fiscal year.

(2) Consolidated results (balance sheet)

	Total assets	Total equity	Equity attributable to Chugai shareholders	Ratio of equity attributable to Chugai shareholders	Equity per share attributable to Chugai shareholders
As of Dec. 31, 2018	¥919,548 million	¥756,529 million	¥755,864 million	82.2%	¥1,381.26
As of Dec. 31, 2017	¥852,473 million	¥692,897 million	¥691,924 million	81.2%	¥1,265.46

(3) Consolidated results (cash flow)

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Balance of cash and cash equivalents
FY ended Dec. 31, 2018	¥119,074 million	¥(74,060) million	¥(35,014) million	¥146,860 million
FY ended Dec. 31, 2017	¥107,623 million	¥(36,718) million	¥(29,563) million	¥139,074 million

2. Dividends

	Annual dividends per share				
	End of first quarter	End of second quarter	End of third quarter	End of fiscal year	Total
FY ended Dec. 2017	—	¥29.00	—	¥33.00	¥62.00
FY ended Dec. 2018	—	¥31.00	—	¥55.00	¥86.00
FY ending Dec. 2019 (Forecast)	—	¥48.00	—	¥48.00	¥96.00

	Total dividends (annual)	Dividend payout ratio (consolidated)	Ratio of dividends to equity attributable to Chugai shareholders (consolidated)
FY ended Dec. 2017	¥33,895 million	46.6%	5.1%
FY ended Dec. 2018	¥47,057 million	50.9%	6.5%
FY ending Dec. 2019 (Forecast)		—%	

3. Consolidated forecasts for FY 2019 (January 1, 2019–December 31, 2019)

	Revenues	% change	Core operating profit	% change	Core earnings per share		Core dividend payout ratio %
FY ending Dec. 2019 (Forecast)	¥592,500 million	+2.2	¥143,000 million	+9.7	¥198.00	+12.2	48.5
FY ended Dec. 2018 (Results)	¥579,787 million	+8.5	¥130,336 million	+26.3	¥176.42	+27.2	48.7

Notes: 1. Percentages shown for revenues, Core operating profit and Core EPS represent changes from the same period of the previous fiscal year.

2. The figures for the consolidated forecasts and actuals are calculated based on Core basis indicators established by Chugai Pharmaceutical Co., Ltd. ("Chugai") and used on a consistent basis. Core EPS is diluted earnings per share attributable to Chugai shareholders on a Core basis.

4. Others

(1) Changes in the state of material subsidiaries during the period (Changes in the state of specific subsidiaries with change in scope of consolidation): None

(2) Changes in accounting policies and changes in accounting estimates

(a) Changes in accounting policies required by IFRS: Yes

(b) Changes in accounting policies other than those in (a) above: None

(c) Changes in accounting estimates: None

(3) Number of shares issued (common stock):

(a) Number of shares issued at the end of the period (including treasury stock)

As of Dec. 31, 2018	559,685,889	As of Dec. 31, 2017	559,685,889
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(b) Number of treasury stock at the end of the period

As of Dec. 31, 2018	12,459,413	As of Dec. 31, 2017	12,909,947
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(c) Average number of shares issued during the period

FY ended Dec. 31, 2018	547,023,692	FY ended Dec. 31, 2017	546,538,483
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Note: For an explanation of the number of shares used for computing earnings per share (consolidated), please refer to "Earnings per share" on page 25 of the attached document.

Notes:

The consolidated financial statements are not subject to audits.

Explanation of the appropriate use of performance forecasts and other related items

(1) Portions of this report that refer to performance forecasts or any other future events are believed to be reasonable under information available at the time of the forecasts. Actual results may differ from these forecasts due to potential risks and uncertainties.

(2) The forecast which is published for shareholders and investors is based on the internal management indicator Core basis under International Financial Reporting Standards (“IFRS”). The difference between IFRS results and Core results will be explained at each event and presentation for the period.

(3) For the specifics of the forecasts, please refer to “Future outlook” on page 10, “Basic profit distribution principles and dividends for the fiscal year under review and the following fiscal year” on page 11, and “Management Principles and Goals” on pages 12-15 of the attached document.

(4) Chugai is scheduled to hold a presentation of the financial statements as noted below. The materials, video, Q&A, and other related documents for the presentation for institutional investors and securities analysts will be posted on the Chugai’s website following the conclusion of the presentation.

Presentation for the media (Japanese only): January 31, 2019, Thursday (Japan time).

Presentation for institutional investors and securities analysts (Japanese only): February 1, 2019, Friday (Japan time).

The English translation of the presentation materials will be posted on the website on the next business day.

Index of the Attachment

1. Overview of Operating Results, etc.	2
(1) Overview of operating results for the fiscal year under review	2
(2) Overview of financial position for the fiscal year under review	7
(3) Overview of cash flows for the fiscal year under review	8
(4) Future outlook	10
(5) Basic profit distribution principles and dividends for the fiscal year under review and the following fiscal year	11
2. Management Principles and Goals	12
(1) Basic management principles	12
(2) Target management indicators	12
(3) Management environment and issues to be addressed	12
(4) Medium-term business plan “IBI 21”	13
3. Basic Approach to the Selection of Accounting Standards	15
4. Consolidated Financial Statements and Major Notes	16
(1) Consolidated income statement and consolidated statement of comprehensive income	16
(2) Consolidated balance sheet	18
(3) Consolidated statement of cash flows	19
(4) Consolidated statement of changes in equity	20
(5) Notes regarding the going concern assumption	21
(6) Notes regarding the consolidated financial statements	21

1. Overview of Operating Results, etc.

(1) Overview of operating results for the fiscal year under review in billions of yen

	Year ended December 31		% change
	2018	2017	
Core results			
Revenues	579.8	534.2	+8.5
Sales (excluding Tamiflu)	517.2	482.4	+7.2
Tamiflu sales	10.7	16.9	(36.7)
Royalties and other operating income	51.9	34.9	+48.7
Cost of sales	(261.9)	(252.9)	+3.6
Gross profit	317.9	281.3	+13.0
Marketing and distribution	(73.7)	(72.8)	+1.2
Research and development	(94.2)	(88.9)	+6.0
General and administration	(19.7)	(16.3)	+20.9
Operating profit	130.3	103.2	+26.3
Net income	97.3	76.7	+26.9
IFRS results			
Revenues	579.8	534.2	+8.5
Operating profit	124.3	98.9	+25.7
Net income	93.1	73.5	+26.7

Consolidated financial highlights (IFRS results)

Revenues for the fiscal year under review were ¥579.8 billion (an increase of 8.5% year on year), operating profit for the fiscal year under review was ¥124.3 billion (an increase of 25.7% year on year), and net income for the fiscal year under review was ¥93.1 billion (an increase of 26.7% year on year). These results include non-Core items, such as amortization of intangible assets of ¥1.2 billion and impairment loss of intangible assets of ¥4.8 billion, which are excluded from the Core results that Chugai adopts to manage recurring business activities.

Consolidated financial highlights (Core results)

Revenues for the fiscal year under review were ¥579.8 billion (an increase of 8.5% year on year), due to increases both in sales and royalties and other operating income.

Of revenues, sales excluding Tamiflu were ¥517.2 billion (an increase of 7.2% year on year), mainly due to increases in exports of Actemra and Alecensa to Roche, along with the steady sales growth of domestic sales of new products as well as mainstay products in the Oncology area and mainstay products in the bone and joint diseases area. Royalties and other operating income amounted to ¥51.9 billion (an increase of 48.7% year on year), due to one-time income and others, primarily from the transfer of long-term listed products to Taiyo Pharma Co., Ltd. reported in the first quarter results and out-licensing of developed products to Eli Lilly and Company.

Cost to sales ratio was 49.6%, a 1.1 percentage point improvement year on year, due to a change in the product mix, etc. As a result, gross profit amounted to ¥317.9 billion (an increase of 13.0% year on year).

Operating expenses were ¥187.6 billion (an increase of 5.3% year on year). Marketing and distribution expenses were ¥73.7 billion (an increase of 1.2% year on year) due primarily to the increase in sales promotion activities for new products, etc. Research and development expenses amounted to ¥94.2 billion (an increase of 6.0% year on year) due primarily to the progress of projects. General and administration expenses amounted to ¥19.7 billion (an increase of 20.9% year on year) due to an increase in various expenses including legal expenses and the enterprise tax. As a result, Core operating profit was ¥130.3 billion (an increase of 26.3% year on year), Core net income was ¥97.3 billion (an increase of 26.9% year on year) and Core EPS was ¥176.42 (an increase of 27.2% year on year).

Meanwhile, compared to the full-year forecast announced on February 1, 2018, revenues increased by 7.1% to ¥579.8 billion. Results exceeded the initial forecast mainly due to increases in domestic sales and exports to Roche, as well as one-time income and others primarily from out-licensing of developed products to Eli Lilly and Company. In addition, while the cost to sales ratio was 49.6%, a 1.0 percentage point improvement compared to the full-year forecast, due to a change in the product mix, etc., operating expenses increased by 3.4% compared to the full-year forecast to ¥187.6 billion, owing to an increase in legal expenses and an increase in expenses related to further market penetration of new products and mainstay products. As a result, Core operating profit increased by 20.6% compared to the full-year forecast to ¥130.3 billion.

Note: Core results

Chugai discloses its results on a Core basis from 2013 in conjunction with its transition to IFRS. Core results are the results after adjusting non-recurring items recognized by Chugai to IFRS results, and are consistent with the Core concept disclosed by Roche. Core results are used by Chugai as an internal performance indicator, for explaining the status of recurring profits both internally and externally, and as the basis for payment-by-results.

Note: Core EPS

Core EPS is diluted earnings per share attributable to shareholders of Chugai, after subtraction of non-recurring profit and loss items determined by Chugai.

For further details regarding the adjustment to IFRS results, please refer to the Supplementary Materials on page 1, entitled “Reconciliation of IFRS results to Core results.”

Sales breakdown in billions of yen

	Year ended December 31		% change
	2018	2017	
Sales	527.8	499.3	+5.7
Domestic sales (excluding Tamiflu)	389.2	388.4	+0.2
Oncology	225.7	225.9	(0.1)
Bone and joint diseases	100.5	93.3	+7.7
Renal diseases	36.3	39.3	(7.6)
Others	26.8	29.9	(10.4)
Tamiflu sales	10.7	16.9	(36.7)
Ordinary use	10.1	11.9	(15.1)
Government stockpiles, etc.	0.5	5.0	(90.0)
Overseas sales	127.9	94.0	+36.1

Domestic sales (excluding Tamiflu)

Domestic sales excluding Tamiflu were ¥389.2 billion (an increase of 0.2% year on year) due to the steady growth of new products as well as mainstay products in the Oncology area and mainstay products in the bone and joint diseases area, despite a decrease in sales of certain anti-cancer agents as a result of the NHI drug price revisions in April 2018.

Oncology products sales were ¥225.7 billion (a decrease of 0.1% year on year). This decrease was due to a decrease in sales of Herceptin (an anti-HER2 humanized monoclonal antibody, anti-cancer agent) and Rituxan (an anti-CD20 monoclonal antibody, anti-cancer agent) mainly as a result of the NHI drug price revisions in April 2018, despite sales of ¥9.1 billion for Tecentriq (an anti PD-L1 humanized monoclonal antibody, anti-cancer agent), which was launched in April 2018, in addition to favorable performance of the mainstay product, Alecensa (an ALK inhibitor, anti-cancer agent).

Bone and joint diseases products sales were ¥100.5 billion (an increase of 7.7% year on year). This was due to the robust sales of mainstay products such as Actemra (a humanized anti-human IL-6 receptor monoclonal antibody) and Edirof (an oral therapeutic agent for osteoporosis).

Renal diseases products sales amounted to ¥36.3 billion (a decrease of 7.6% year on year) due to a decline mainly in sales of Oxarol (an agent for secondary hyperparathyroidism) and Mircera (a long-acting erythropoiesis-stimulating agent), primarily as a result of the NHI drug price revisions in April 2018.

Other products sales were ¥26.8 billion (a decrease of 10.4% year on year) due primarily to long-term listed products transferred to Taiyo Pharma Co., Ltd., despite sales of ¥3.0 billion for Hemlibra (coagulation factor VIII substitute) launched in May 2018, due to favorable market penetration.

Meanwhile, compared to the full-year forecast announced on February 1, 2018, domestic sales excluding Tamiflu increased by 3.8% to ¥389.2 billion, as a result of all areas exceeding the full-year forecast, including new products such as Tecentriq and Hemlibra, which progressed beyond expectations.

Tamiflu sales

Sales of Tamiflu (an anti-influenza agent) for ordinary use were ¥10.1 billion (a decrease of 15.1% year on year), while sales to government stockpiles, etc. were ¥0.5 billion (a decrease of 90.0% year on year).

Overseas sales

Overseas sales amounted to ¥127.9 billion (an increase of 36.1% year on year) due to increases in exports of Actemra and Alecensa to Roche.

Meanwhile, compared to the full-year forecast announced on February 1, 2018, overseas sales increased by 8.3% to ¥127.9 billion as exports of Actemra and Alecensa to Roche exceeded expectations.

R&D activities

In Japan and overseas, the Chugai Group (“the Group”) is actively engaged in prescription pharmaceutical R&D activities and is working to develop innovative products with global application. In Japan, the Group has established research bases in Fuji Gotemba and Kamakura, which are collaborating to develop new pharmaceuticals, and its research facilities in Ukima are conducting industrialization research. Overseas, Chugai Pharma USA, Inc. (United States); Chugai Pharma Europe Ltd. (United Kingdom); Chugai Pharma Science (Beijing) Co., Ltd. (China); and Chugai Pharma Taiwan Ltd. (Taiwan) are engaged in clinical development and submission of applications in their respective countries. Chugai Pharmabody Research Pte. Ltd. (Singapore) and jointly controlled businesses C&C Research Laboratories (South Korea) are engaged in pharmaceutical research and development.

In the fiscal year under review, R&D expenses on a Core basis totaled ¥94.2 billion.

Progress made in R&D activities during the period from January 1, 2018 to December 31, 2018 was as follows.

Oncology

- We obtained approval for the indication of CD20-positive follicular lymphoma for glycoengineered type II anti-CD20 monoclonal antibody RG7159 (Product name: Gazyva) in July 2018, and launched in August 2018.
- We obtained approval for the indication of neoadjuvant and adjuvant therapy for HER2-positive early breast cancer for HER2 dimerization inhibitory humanized monoclonal antibody RG1273 (Product name: Perjeta) in October 2018.
- We obtained approval for the indication of unresectable advanced or recurrent non-small cell lung cancer (NSCLC), for the engineered anti-PDL1 monoclonal antibody RG7446 (Product name: Tecentriq) in January, 2018 and launched in April. We filed an application in March and obtained approval in December 2018 for the additional dosing for the treatment of previously untreated unresectable advanced or recurrent non-squamous NSCLC. We filed applications for the expected indications for small cell lung cancer and breast cancer in December 2018. We started Phase III multinational study for the expected indications of hepatocellular carcinoma in April 2018, head and neck carcinoma (adjuvant) in June 2018, and early breast cancer in August 2018.
- We started Phase III multinational study for the anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody RG435 (Product name: Avastin) for the expected indication of hepatocellular carcinoma in April, 2018.
- We started Phase III multinational study for the AKT inhibitor RG7440 for the expected indication of breast cancer in January, 2018.
- We started Phase III multinational study for RG6264, fixed-dose combination of anti-HER2 humanized monoclonal antibody and HER2 dimerization inhibitory humanized monoclonal antibody (subcutaneous injection) for the expected indication of breast cancer in July, 2018.
- We started Phase III multinational study for ALK inhibitor AF802/RG7853 (Product name: Alecensa) for the expected indication of NSCLC (adjuvant) in August, 2018.
- We in-licensed ROS1/TRK inhibitor RG6268, and started domestic development for the expected indications of NSCLC and solid tumors (*NTRK* fusion-positive). We filed an application for the expected indication of solid tumors (*NTRK* fusion-positive) in December 2018.

- We started Phase I study for the anti-CEA/CD3 bispecific antibody RG7802 for the expected indication of solid tumors in January, 2018.
- We started Phase I study for the anti-CD20/CD3 bispecific antibody RG7828 for the expected indication of hematologic tumors in March, 2018.
- We decided to discontinue the development of PI3K inhibitor RG7604 for solid tumors, considering the results of global studies conducted by Roche, an originator of the drug.

Bone and Joint Diseases

- We filed an application for activated vitamin D₃ agent ED-71 (Product name: Ediol) for the expected indication of osteoporosis in China in February, 2018.

Neurology

- We started Phase I study for the anti- α -synuclein monoclonal antibody RG7935 for the expected indication of Parkinson's disease in February, 2018.
- We started Phase I study for GYM329/RG6237 for the expected indication of neuromuscular disease in October, 2018.

Others

- We obtained approval for once-weekly subcutaneous injection of ACE910/RG6013 (Product name: Hemlibra) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A with factor VIII inhibitors in Europe and Japan in February and March, 2018, respectively. Then we launched the drug in Japan in May, 2018. In addition, we filed applications for routine prophylactic treatment for people with hemophilia A without inhibitors to factor VIII, administered once weekly, every two weeks, or every four weeks, as well as for additional dosing options of every two weeks or every four weeks in people with hemophilia A with factor VIII inhibitors in Japan, US and Europe in April 2018, and obtained approval in US and Japan in October and December 2018, respectively.
- We started Phase III multinational study for the anti-VEFG/Ang2 bispecific antibody RG7716 for the expected indication of diabetic macular edema in September, 2018.
- We started Phase I study for AMY109 for the expected indication of endometriosis in February, 2018.
- We decided to discontinue the development of the anti-IL-13 humanized monoclonal antibody RG3637 for Idiopathic pulmonary fibrosis considering the results of Phase II multinational study (RIFF study).
- We decided to discontinue the development of URAT1 inhibitor URC102 for gout, due to consideration of priorities in our R&D portfolio.

Results of the medium-term business plan "IBI 18"

The Group formulated its medium-term business plan "IBI 18," which covered the period from fiscal year 2016 through fiscal year 2018, and has been engaged in priority tasks in each of the areas below in an effort to transform into a company that continues making progress globally through demonstration of its competitive strengths by leveraging its strategic alliance with Roche.

1) Drug discovery

The Group accelerated the generation of innovative R&D projects by making priority investment in drug discovery technologies including the world's leading-edge antibody engineering technologies. During the period of "IBI 18," eight new projects were added to its portfolio, and we started clinical trials for four in-house developed products, namely ERY974, SKY59, AMY109 and GYM329. In addition, a technological platform was established for middle molecules as the next-generation core technology following small molecule and antibodies and preparations are well underway for the early generation of development projects. Furthermore, the Group has strengthened its framework for the generation of new projects through cooperation with academic institutions such as the comprehensive collaboration agreement with the Osaka University Immunology Frontier Research Center (IFReC), and several promising projects have been generated.

2) Development

By making concentrated investment of its resources into products that are expected to drive dramatic growth in the future, the Group was able to obtain accelerated global approval for Hemlibra, an in-house developed product, far earlier than initially planned. As for products in-licensed from Roche, Tecentriq obtained approval for the first-line and second-line treatments of non-small cell lung cancer, and development is currently continuing for an additional 19 indications. Furthermore, progress is being steadily made in development toward acquiring an approval for SA237 (satralizumab), an in-house growth driver candidate following Hemlibra, which received Breakthrough Therapy designation by the United States Food and Drug Administration (FDA) for neuromyelitis optica and neuromyelitis optica spectrum disorders.

3) Pharmaceutical technology

The Group made efforts to strengthen its pharmaceutical functions toward global simultaneous development of multiple products, accelerated market launches and cost reduction. To this end, the Group managed to shorten the development period of the antibody project and reduce the costs of Alecensa, as well as made progress in preparing for GMP manufacturing at “UK3,” the production plant of antibody API for initial commercial products. Furthermore, the Group made significant advances in establishing a structure to receive FDA inspection through the filing of applications for Hemlibra, and the development of the manufacturing and formulation technologies of middle molecule APIs.

4) Sales, medical affairs and safety

To meet the sophisticated and diversified needs of patients, medical care professionals, and other stakeholders, the Group has further strengthened the division of its specialized functions and cross-functional collaboration centered on sales, medical affairs and safety, and promoted provision of high-quality solutions. As a result, we were able to maintain the sustainable growth of our existing focus products such as Avastin, Actemra and Edoxol, while realizing the early market penetration of new products Hemlibra and Tecentriq, thereby achieving sales that substantially exceeded plans.

5) Global foundation

In dealing with the challenges mentioned above, the Group focused particularly on the strengthening of human resources. Initiatives included selecting focus positions under the policy of the right position filled by the right person; obtaining, nurturing and assigning global top-level talent who will bring strategies into action; and promoting diversity and inclusion. Furthermore, the Group executed various measures to concentrate its limited resources on innovation, such as the business transfer of 13 long-term listed products.

Through these initiatives, the Group amply achieved the initial qualitative target and quantitative plan, and its financial results reached a record high for two consecutive years.

During the period from 2015 through 2018, the final year of the medium-term business plan, the Group achieved an average annual growth in its Core EPS (assuming a constant exchange rate) of 17.1%, which far exceeded the initially-forecasted low single-digit rate (up to 3% range) and demonstrated strong results.

Note: In (1), amounts less than ¥0.1 billion have been rounded to the nearest ¥0.1 billion. Figures for changes in amounts and percentages have been calculated using data denominated in ¥0.1 billion units.

(2) Overview of financial position for the fiscal year under review in billions of yen

	December 31, 2018	December 31, 2017	% change
Net operating assets (NOA) and Net assets			
Net working capital	235.1	250.7	(6.2)
Long-term net operating assets	270.1	189.5	+42.5
Net operating assets (NOA)	505.3	440.2	+14.8
Net cash	249.2	242.8	+2.6
Other non-operating assets – net	2.1	9.9	(78.8)
Total net assets	756.5	692.9	+9.2
Consolidated balance sheet (IFRS basis)			
Total assets	919.5	852.5	+7.9
Total liabilities	(163.0)	(159.6)	+2.1
Total net assets	756.5	692.9	+9.2

Net operating assets (NOA) at December 31, 2018 were ¥505.3 billion, an increase of ¥65.1 billion since the end of the previous fiscal year. Of NOA, net working capital was ¥235.1 billion (a decrease of ¥15.6 billion since the end of the previous fiscal year), due mainly to a decrease in inventories, while long-term net operating assets increased by ¥80.6 billion since the end of the previous fiscal year to ¥270.1 billion, due mainly to an increase in property, plant and equipment. The increase in property, plant and equipment is as shown in “(3) Overview of cash flows for the fiscal year under review” on the next page.

Similarly, as indicated in “(3) Overview of cash flows for the fiscal year under review” on the next page, net cash, including marketable securities and interest-bearing debt, increased by ¥6.4 billion since the end of the previous fiscal year to ¥249.2 billion. Other non-operating assets – net decreased by ¥7.8 billion since the end of the previous fiscal year to ¥2.1 billion, due mainly to an increase in defined benefit plan liabilities.

With the application of IFRS 15 ‘Revenue from Contracts with Customers,’ deferred income of ¥10.6 billion after tax effect, which was included in net working capital and long-term net operating assets at the beginning of the year, has been presented as retained earnings.

As a consequence, total net assets were ¥756.5 billion (an increase of ¥63.6 billion since the end of the previous fiscal year).

Note: Net operating assets (NOA) and Net assets

The consolidated balance sheet has been prepared in accordance with International Accounting Standards (IAS) No. 1, “Presentation of Financial Statements.” On the other hand, Net operating assets (NOA) and Net assets are a reconfiguration of the consolidated balance sheet as internal indicators and are identical to the indicators disclosed by Roche. Furthermore, no items from Net operating assets (NOA) and Net assets have been excluded, as the Core results concept only applies to the income statement.

For further details, please refer to the Supplementary Materials on page 10, entitled “Financial position.”

Note: Net operating assets (NOA)

Net operating assets allow for an assessment of the Group’s operating performance of the business independently from financing and tax activities. Net operating assets are calculated as net working capital, long-term net operating assets that includes property, plant and equipment, intangible assets etc. minus provisions.

Note: In (2), amounts less than ¥0.1 billion have been rounded to the nearest ¥0.1 billion. Figures for changes in amounts and percentages have been calculated using data denominated in ¥0.1 billion units.

(3) Overview of cash flows for the fiscal year under review in billions of yen

	Year ended December 31		% change
	2018	2017	
Free cash flows			
Operating profit - IFRS basis	124.3	98.9	+25.7
Operating profit, net of operating cash adjustments	147.4	121.0	+21.8
Operating free cash flows	74.3	91.0	(18.4)
Free cash flows	43.7	64.7	(32.5)
Net change in net cash	6.4	37.9	(83.1)
Consolidated statement of cash flows (IFRS basis)			
Cash flows from operating activities	119.1	107.6	+10.7
Cash flows from investing activities	(74.1)	(36.7)	+101.9
Cash flows from financing activities	(35.0)	(29.6)	+18.2
Net change in cash and cash equivalents	7.8	43.7	(82.2)
Cash and cash equivalents at December 31	146.9	139.1	+5.6

Operating free cash flows for the fiscal year under review amounted to a net inflow of ¥74.3 billion (a decrease of 18.4% year on year). This was mainly due to expenditures of ¥71.8 billion for the purchase of property, plant and equipment, despite operating profit, net of operating cash adjustments of ¥147.4 billion (an increase of 21.8% year on year), which was calculated by adjusting for depreciation and other items that are included in operating profit but are not accompanied by cash inflows or outflows and all inflows and outflows related to NOA that are not accompanied by profit and loss. Purchases of property, plant and equipment were mainly for expenditures for the purchase of a business site in Totsuka Ward, Yokohama City for the construction of a new laboratory and investments into the production equipment for the high-mix low-volume production of antibody API for initial commercial products.

Free cash flows were a net cash inflow of ¥43.7 billion (a decrease of 32.5% year on year) due mainly to income taxes paid of ¥31.6 billion and settlement for transfer pricing taxation of ¥3.2 billion paid from operating free cash flows.

The net change in net cash calculated by subtracting dividends paid of ¥35.8 billion and foreign currency translation adjustments from free cash flows was an increase of ¥6.4 billion.

The net change in cash and cash equivalents, excluding changes in marketable securities and interest-bearing debt, was a net cash inflow of ¥7.8 billion. The cash and cash equivalents balance at the end of this period amounted to ¥146.9 billion.

Note: Free cash flows (FCF)

The consolidated statement of cash flows has been prepared in accordance with International Accounting Standard (IAS) No. 7, "Statement of Cash Flows." FCF is a reconfiguration of the consolidated statement of cash flows as internal indicators and is identical to the indicators disclosed by Roche. Furthermore, no items from FCF have been excluded, as the Core results concept only applies to the income statement.

For further details, please refer to the Supplementary Materials on page 11, entitled "Cash flows."

Cash flow related indicators

	Year ended December 31			
	2018	2017	2016	2015
Ratio of equity attributable to Chugai shareholders (%)	82.2	81.2	80.1	79.5
Ratio of equity attributable to Chugai shareholders on a market basis (%)	379.7	370.1	227.3	294.0
Interest-bearing debt to cash flows ratio (%)	0.2	0.3	1.7	1.2
Interest-coverage ratio (times)	26,274.1	19,772.7	4,708.4	8,582.4

Ratio of equity attributable to Chugai shareholders: $\text{Equity attributable to Chugai shareholders} / \text{Total assets}$
Ratio of equity attributable to Chugai shareholders on a market basis: $\text{Total market capitalization} / \text{Total assets}$
Interest-bearing debt to cash flows ratio: $\text{Interest-bearing debt} / \text{Cash flows}$
Interest-coverage ratio: $\text{Cash flows} / \text{Interest payments}$

Notes:

1. All of the figures in the aforementioned indicators were calculated on a consolidated basis.
2. Total market capitalization was calculated by multiplying the closing stock price at the end of the period by the total number of outstanding shares at the end of the period (excluding treasury stock).
3. Cash flows from operating activities in the consolidated statement of cash flows were used as cash flows in the calculations above.
4. Interest-bearing debt refers to all debt posted in the consolidated balance sheet upon which interest is paid.
5. Interest paid in the consolidated statement of cash flows was used as interest payment in the calculations above.

Note: In (3), amounts less than ¥0.1 billion have been rounded to the nearest ¥0.1 billion. Figures for changes in amounts and percentages have been calculated using data denominated in ¥0.1 billion units.

(4) Future outlook**Forecast assumptions**

In preparing Chugai performance outlook, Chugai has assumed exchange rates of ¥114/CHF, ¥128/EUR, ¥111/USD, and ¥82/SGD.

Outlook for the fiscal year**Revenues**

The negative impact from competition with generic drugs, etc. and NHI drug price revisions will exceed the sales growth in new products such as Hemlibra or Tecentriq, etc., which will result in ¥389.1 billion (a decrease by 2.7% year on year) of Domestic sales.

Reflecting the steady growth in Alecensa export to Roche and the continued growth in sales quantity of Actemra, sales in overseas are expected to increase to the amount of ¥138.9 billion (an increase by 8.6% year on year).

Royalties and other operating income are expected to reach ¥64.5 billion (an increase by 24.3% year on year).

Royalty and profit-sharing income are forecasted to rise to ¥53.5 billion (an increase by 122.0% year on year) because of increases in royalties from Roche mainly for Hemlibra.

Other operating income are expected to decrease to ¥11.0 billion (a decrease of 60.6% year on year) from the decrease of one-time income of the previous year from the transfer of long-listed products on HIP list, etc.

Core Operating Profit / Core EPS

Gross profit is expected to rise to ¥340.0 billion (an increase by 7.0% year on year) mainly due to the increase in these revenues. On the other hand, total expenses are expected to be the amount of ¥197.0 billion (a ¥9.4 billion increase compared to the previous year). Particularly, expenses for research and development are expected to increase to ¥102.0 billion (an increase by ¥7.8 billion year on year) mainly due to the increase of research and development activities such as progress in development themes etc.

Core operating profit is expected to be ¥143.0 billion (an increase by 9.7% year on year). Core EPS will be forecasted to be ¥198.00 (an increase of 12.2% year on year).

(Billions of yen)

	Outlook for FY 2019	% change
Revenues	592.5	+2.2
Sales	528.0	+0.0
Core operating profit	143.0	+9.7

Note: In (4), amounts less than ¥0.1 billion have been rounded to the nearest ¥0.1 billion. Figures for changes in amounts and percentages have been calculated using data denominated in ¥0.1 billion units.

(5) Basic profit distribution principles and dividends for the fiscal year under review and the following fiscal year

Regarding income distribution, taking into account the strategic funding needs and earnings prospects, Chugai aims for a consolidated dividend payout ratio of 50% on average in comparison with Core EPS to provide a stable allocation of profit to all shareholders. In addition, internal reserves will be used to increase corporate value through investments to attain further growth in existing strategic domains and to identify future business opportunities.

In the fiscal year ended December 31, 2018, which is the final year of the medium-term business plan “IBI 18,” Chugai achieved the highest results in the past, which resulted in Core EPS increasing by 27.2% year-on-year and exceeding the officially announced forecast by 20.0%. At the same time, in comparison to the quantitative guidance of “IBI 18” — “achieving average annual growth in Core EPS (at the average constant exchange rate) at a low single digit (below 3% level),” Chugai achieved a result of 17.1% far above the goal. As it turned out, the group realized our goal of “becoming a “top pharmaceutical company”.”

Reflecting the favorable results and based on our principles of “aiming a consolidated dividend payout ratio of 50% on average in comparison with Core EPS to provide a stable allocation of profit,” year-end dividends for the fiscal year ended December 31, 2018 are planned to be ¥55 per share, which is higher by ¥10 as increased regular dividend and ¥14 as special dividends than the forecast at the beginning of the fiscal year. As a result, total dividends for the fiscal year under review will be ¥86 per share, and the Core dividend payout ratio is 48.7% (an average of 48.6% for the past five years).

For the following fiscal year, ending December 31, 2019, Chugai expects total estimated dividends of ¥96 per share including interim dividends payment of ¥48 per share. Accordingly, the forecast for the Core dividend payout ratio is 48.5% (an average of 48.4% for the past five years) in 2019.

	Amount decided	Latest forecast for dividend (February 1, 2018)	Actual in the previous fiscal year (ended Dec. 31, 2017)
Record date	December 31, 2018	December 31, 2018	December 31, 2017
Dividends per share	¥55.00	¥31.00	¥33.00
Total dividends	¥30,097 million	—	¥18,044 million
Effective date	March 29, 2019	—	March 23, 2018
Dividend resource	Retained earnings	—	Retained earnings

2. Management Principles and Goals

(1) Basic management principles

In line with its strategic alliance with the world-leading pharmaceutical company Roche, the Group's basic management principles is to develop hand in hand with society under its mission of "dedicating itself to creating new values through the provision of innovative medical products and services for the benefit of the medical community and human health around the world" and its goal of "becoming a top innovator in the healthcare industry that realizes sophisticated and sustainable patient-centered medical care."

As the Group works to achieve these goals, it will carry out its business activities in line with its core values of "patient-centered," "frontier spirit" and "sincerity."

Under these basic management principles, and in line with the philosophy "Innovation all for the patients," the Group focuses on innovation based on innovative drug discovery, with the aim of resolving social issues and developing a sound society through the provision of optimal medical care for each and every patient, while also expanding corporate value in a sustainable manner.

Furthermore, the Group will proactively work on environmental, social, governance and other issues in order to ensure that its business activities influence society in the best way possible. The Group is convinced that these activities will contribute to enhancing the sustainability of society as a whole, while laying a foundation for the long-term development of the Group.

(2) Target management indicators

The Group places emphasis on increasing corporate value by generating innovation. When formulating medium-to-long-term plans, the Group drafts its growth strategy after clarifying the gap between targets and the existing situation, taking into account equity spread. Whenever making investment decisions such as development projects, the Group allocates resources and makes management decisions with emphasis on profitability and capital efficiency, including evaluations based on capital costs. Moreover, as an indicator that directly expresses sustainable increase in corporate value and that can be shared with shareholders and other stakeholders, under its medium-term business plan "IBI 21," which covers the period from the fiscal year 2019 through fiscal year 2021, the Group aims an average annual growth in its Core EPS (assuming a constant exchange rate) at a high single-digit rate for the three-year period.

(3) Management environment and issues to be addressed

Amid increasing expectations and needs for pharmaceuticals due to an increase in the world population and progressive demographic graying in each country, the realization of sustainable medical care with limited resources has become a common issue in the world. In addition, while the dramatic progress of life sciences and ICT has significantly changed the social structure and expanded opportunities to generate innovation for solving medical issues, competition among companies is speeding up beyond existing industries and intensifying more than ever.

As the interplay of these changes is expected to bring about exponential upheavals in society as a whole, the pharmaceutical industry is called on to undergo major transformation as well.

Pursuit of "innovation" is the most important challenge. There is a need for the development of new drugs that respond to unmet medical needs through the search for new therapy targets and further innovation in drug discovery technologies. Furthermore, in order to realize optimal medical care for each and every patient, the challenge is to acquire and enhance capabilities that break through conventional drug discovery capabilities, while flexibly incorporating new technologies that leverage advances in life sciences as well as the evolution of digital technologies such as big data and AI.

"Business structural reform" to realize these goals is also a pressing issue. Amid an increasingly severe business environment for pharmaceutical companies due to stronger financial pressure and measures to curb drug costs worldwide, there is even greater need of transformation to a structure that enables concentrated investment of limited resources on innovation. Particularly in Japan, in the wake of a series of stringent system reforms aimed at curbing drug costs, the market is expected to contract increasingly in the future. The challenge is to design a new business structure that fundamentally revises existing processes and cost structures and makes use of digital and other technologies.

In addition to these challenges in the pharmaceutical industry, society as a whole is facing growing threats to the sustainability of the social system, including recent changes in the global environment and socio-economic issues such as poverty caused by economic disparity. In order to sustainably develop business activities, companies must seriously face up to the underlying social issues, identify the issues related to their respective value chains, and make efforts to resolve them.

In these circumstances, the Group achieved top-class growth in Japan based on the development of innovative new drugs and its strategic alliance with Roche. While securing a stable revenue foundation through Roche's fully stocked pipeline of new drugs, the Group concentrates resources on in-house drug discovery and continually generates innovative R&D projects. As a result, the Group's drug discovery capabilities have been highly evaluated worldwide, with four drugs (Actemra, Alecensa, Hemlibra and SA237 (Satralizumab)) generated by Chugai being designated as Breakthrough Therapy by the U.S. FDA. In addition, the Group's late-stage development and sales activities leverage the Global Roche platform and achieve a high level of productivity.

Going forward, the Group will steadily maximize value for growth drivers such as Alecensa and Hemlibra in the global market and generate in-house the next growth drivers ahead of competitors through swift development in an aim for sustainable profit growth.

Meanwhile, as society faces major changes in a global scale, Chugai recognizes that its initiatives must further evolve together.

(4) Medium-term business plan "IBI 21"

The Group formulated its new medium-term business plan "IBI 21," which covers the period from fiscal year 2019 through fiscal year 2021. Based on the business foundation built under the previous medium-term business plan "IBI 18" and the strategic alliance with Roche, the Group has entered a new stage of transformation aiming to acquire further competitive advantage as well as achieve sustained profit growth and expanded corporate value.

The Group's goal with "IBI 21" is to accelerate the development of itself and society through the creation of innovative drugs and services. The Group has set out "five strategies" to achieve that goal, based on the priority agenda of "create global growth drivers and maximize value" and "strengthen human resources and infrastructure that support the business."

Under "IBI 21," Chugai aims for sustained corporate growth through innovation by further enhancing its basic approach to innovation which is expressed in "IBI," "INNOVATION BEYOND IMAGINATION."

1) Value Creation (Drug Discovery, Development, Pharmaceutical Technology)

The Group has been making priority investment in the world's leading-edge antibody engineering technologies to accelerate the creation of innovative R&D projects. In addition, the Group has selected middle molecules as its next-generation core drug discovery technologies along with small molecule and antibody technologies, and has been striving for the establishment of technologies through concentrated investment and early generation of R&D projects.

Under "IBI 21," the Group will tackle a new dimension of drug discovery to realize innovative drug discovery to cure and control diseases. The Group will incorporate biology (deeper understanding of pathology) into its proprietary drug discovery technologies cultivated thus far, in addition to their ongoing enhancement, to identify original drug discovery targets. Vigorous efforts will be made to achieve PoC and development in the shortest lead time and prove patient value. In-house, the Group will advance development with global top-class quality and speed under its promotion system for translational research centered on three regions, namely Japan, the United States and Europe, as well as cooperate with Roche to achieve continuous generation of innovative new drugs that will be next-generation growth drivers.

In order to achieve the earliest delivery of such innovative new drugs to patients, the Group will enhance its systems for accelerated development and product supply, especially the further evolution of manufacturing technologies for R&D projects with a high degree of difficulty in formulation such as middle molecule drugs. The Group will also continue striving to enhance quality control, quality assurance and regulatory functions to meet global standards.

2) Value Delivery (Marketing & Sales, Medical Affairs, Safety)

By launching numerous promising therapy products developed in-house or in-licensed from Roche, the Group has been building a solid presence in oncology, renal disease, bone and joint disease, rheumatic diseases as well as other fields.

Under “IBI 21,” the Group aims to accelerate its growth through furthering its activities to promote the appropriate use of pharmaceuticals, including provision of information and safety management in a patient-centered manner, and the generation of evidence to enhance the value of drugs from the patients’ viewpoint. At the same time, the Group will strengthen digital solutions incorporating evolutions in technology, and provide other solutions to meet the advanced and diversified needs of stakeholders, in order to contribute to “advanced and sustainable patient-centered healthcare.” The Group will also focus its activities on growth driver products in Japan and overseas.

3) Promote advances in personalized healthcare

Backed by the dramatic progress of genome medicine and data analysis technology, “Personalized Healthcare (PHC)” has advanced considerably in recent years. In addition, the evolution of digital devices and other developments have enabled a wide range of benefits for patients, including QOL, to be quantified, beyond the conventional qualities of “efficacy and safety.” As a result, it is increasingly vital to provide optimal solutions for patients and verify their value. In that context, as a member of the Roche Group, a world leader in PHC, the Group will work in close cooperation with the government and academic institutions, aiming for a new stage in PHC that provides optimal therapy for each individual. Furthermore, the Group will stay ahead of the competition in striving to strengthen its capabilities to provide and verify a wide range of value to patients and their families. Moreover, the Group will also proactively promote greater efficiency in the search for drug discovery targets and molecules, streamlining of clinical development using real-world data (RWD), and other innovations in the R&D process, through initiatives leveraging digital technologies and data.

In addition, as a leading company in oncology, Chugai believes that it has an important responsibility to contribute to the realization of cancer genome medicine and the development of its supply structure. “FoundationOne CDx Cancer Genomic Profile” was developed under this mission. It is a product that provides comprehensive genomic profiling (CGP) assays for cancer using next-generation sequencers, and contributes to the development and spread of PHC in cancer treatment. In 2018, Chugai established the “Foundation Medicine Unit” and vigorously promotes the business.

4) Strengthening human capital and conduct structural reform

In implementing the strategies mentioned so far, obtaining and nurturing diverse human resources that drive the creation of innovation while responding to a rapidly changing environment is important. Under “IBI 21,” the Group will further strengthen its efforts to obtain, nurture and assign sophisticated and diverse human resources with a view to the medium to long term. Specifically, the Group will strengthen its system to implement talent management/position management to assign the right leader to the right position; acquire specialized human resources who will play key roles in carrying out strategies; transform the personnel and compensation system so that it supports a corporate culture with a spirit for challenges; and further promote diversity and inclusion. Through these measures, the Group will strive to foster an organizational culture where innovation is created by the active participation of diverse human resources.

In addition, as financial pressure increasingly undermines the business environment for pharmaceutical companies, transforming cost structures is an important issue for companies to enable the concentration of resources on innovation. In order to concentrate limited resources on innovation, Chugai has taken measures such as carrying out the business transfer of 13 long-term listed products in 2018. Under “IBI 21,” the Group is resolved to fundamentally revise its business processes and cost structure in order to simultaneously achieve flexible investment in innovation and sustained profit growth.

5) Strengthening sustainable platforms

In order to achieve advanced and sustainable medical care and contribute to human health, the Group conducts its business in line with its core values. The Group strives to carry out its business activities with sincerity at all times with the highest ethical standards, compliance and quality management as befits a corporate group involved in the healthcare industry. The Group has addressed business activities considerate of the global environment as well as social contribution activities conducive to “medical care,” “welfare,” “education,” “local communities” and the “environment” as a good corporate citizen.

Under “IBI 21,” the Group will work on key issues (materiality) identified in light of its mission and the impact of its business on the economy, society and the environment. Particularly, the focus will be to maintain the high quality of its pharmaceutical products and services as well as to contribute Chugai’s technology and expertise to health care, improving people’s access to which will promote global health. The Group will aim to minimize its negative impact on natural capital by pursuing business activities that consider the global environment.

The Group will take up the key issues (materiality) above in its proactive disclosure and dialogue with stakeholders.

Under “IBI 21,” the Group will work for the development of society and itself through innovation, centered on these five strategies.

3. Basic Approach to the Selection of Accounting Standards

The Group engages actively in international business with the aim of providing a continuous flow of innovative medical products domestically and internationally. These activities include sales of pharmaceuticals and research and development overseas. In light of this, International Financial Reporting Standards (IFRS) has been adopted from the first quarter of the fiscal year ended December 31, 2013 to improve the international comparability of financial information for investors and other users of the financial statements.

4. Consolidated Financial Statements and Major Notes

(1) Consolidated income statement and consolidated statement of comprehensive income

1) Consolidated income statement in millions of yen

	Year ended December 31	
	2018	2017
Revenues	579,787	534,199
Sales	527,844	499,308
Royalties and other operating income	51,943	34,891
Cost of sales	(262,847)	(254,171)
Gross profit	316,940	280,028
Marketing and distribution	(73,706)	(72,800)
Research and development	(99,202)	(92,947)
General and administration	(19,710)	(15,347)
Operating profit	124,323	98,934
Financing costs	(111)	(110)
Other financial income (expense)	449	(87)
Other expense	(3,212)	(1,706)
Profit before taxes	121,449	97,031
Income taxes	(28,370)	(23,490)
Net income	93,079	73,541
Attributable to:		
Chugai shareholders	92,488	72,713
Non-controlling interests	591	827
Earnings per share		
Basic (yen)	169.08	133.04
Diluted (yen)	168.80	132.83

2) Consolidated statement of comprehensive income in millions of yen

	Year ended December 31	
	2018	2017
Net income recognized in income statement	93,079	73,541
Other comprehensive income		
Remeasurements of defined benefit plans	(2,472)	916
Fair value changes on equity investments at fair value through OCI	363	—
Items that will never be reclassified to the income statement	(2,109)	916
Available-for-sale investments	—	1,204
Fair value changes on debt investments at fair value through OCI	0	—
Cash flow hedges	(225)	(3,293)
Currency translation of foreign operations	(3,158)	3,713
Items that are or may be reclassified to the income statement	(3,383)	1,624
Other comprehensive income, net of tax	(5,492)	2,540
Total comprehensive income	87,587	76,081
Attributable to:		
Chugai shareholders	87,078	75,154
Non-controlling interests	509	927

(2) Consolidated balance sheet in millions of yen

	December 31, 2018	December 31, 2017
Assets		
Non-current assets:		
Property, plant and equipment	222,388	171,569
Intangible assets	22,699	21,078
Financial non-current assets	9,723	11,350
Deferred tax assets	35,568	34,501
Other non-current assets	29,077	14,836
Total non-current assets	319,455	253,333
Current assets:		
Inventories	159,360	169,056
Accounts receivable	179,556	174,284
Current income tax assets	3	717
Marketable securities	102,533	104,018
Cash and cash equivalents	146,860	139,074
Other current assets	11,781	11,990
Total current assets	600,093	599,141
Total assets	919,548	852,473
Liabilities		
Non-current liabilities:		
Long-term debt	(82)	(207)
Deferred tax liabilities	(9,031)	(9,211)
Defined benefit plan liabilities	(14,671)	(9,292)
Long-term provisions	(2,072)	(2,041)
Other non-current liabilities	(1,946)	(15,923)
Total non-current liabilities	(27,802)	(36,674)
Current liabilities:		
Short-term debt	(133)	(129)
Current income tax liabilities	(19,567)	(18,541)
Short-term provisions	(1)	(79)
Accounts payable	(71,706)	(63,518)
Other current liabilities	(43,810)	(40,635)
Total current liabilities	(135,218)	(122,902)
Total liabilities	(163,019)	(159,576)
Total net assets	756,529	692,897
Equity:		
Capital and reserves attributable to Chugai shareholders	755,864	691,924
Equity attributable to non-controlling interests	664	973
Total equity	756,529	692,897

(3) Consolidated statement of cash flows in millions of yen

	Year ended December 31	
	2018	2017
Cash flows from operating activities		
Cash generated from operations	151,857	124,776
(Increase) decrease in working capital	4,486	14,465
Payments made for defined benefit plans	(2,652)	(2,483)
Utilization of provisions	(29)	(34)
Other operating cash flows	(3,022)	(6,447)
Cash flows from operating activities, before income taxes paid	150,639	130,278
Income taxes paid	(31,565)	(22,655)
Total cash flows from operating activities	119,074	107,623
Cash flows from investing activities		
Purchase of property, plant and equipment	(71,785)	(32,881)
Purchase of intangible assets	(5,886)	(11,645)
Disposal of property, plant and equipment	49	64
Disposal of intangible assets	—	452
Interest and dividends received	200	271
Purchases of marketable securities	(263,503)	(208,480)
Sales of marketable securities	264,711	215,510
Purchases of investment securities	(709)	—
Sales of investment securities	2,863	—
Other investing cash flows	(0)	(8)
Total cash flows from investing activities	(74,060)	(36,718)
Cash flows from financing activities		
Interest paid	(5)	(5)
Dividends paid to Chugai shareholders	(35,010)	(30,054)
Dividends paid to non-controlling shareholders	(791)	(944)
Exercise of equity compensation plans	996	922
(Increase) decrease in own equity instruments	(19)	(20)
Other financing cash flows	(187)	538
Total cash flows from financing activities	(35,014)	(29,563)
Net effect of currency translation on cash and cash equivalents	(2,215)	2,363
Increase (decrease) in cash and cash equivalents	7,785	43,706
Cash and cash equivalents at January 1	139,074	95,368
Cash and cash equivalents at December 31	146,860	139,074

(4) Consolidated statement of changes in equity in millions of yen

	Attributable to Chugai shareholders					Non-controlling interests	Total equity
	Share capital	Capital surplus	Retained earnings	Other reserves	Subtotal		
Year ended December 31, 2017							
At January 1, 2017	72,967	63,500	507,399	1,642	645,508	989	646,497
Net income	—	—	72,713	—	72,713	827	73,541
Available-for-sale investments	—	—	—	1,204	1,204	—	1,204
Cash flow hedges	—	—	—	(3,293)	(3,293)	—	(3,293)
Currency translation of foreign operations	—	—	—	3,613	3,613	100	3,713
Remeasurements of defined benefit plans	—	—	916	—	916	—	916
Total comprehensive income	—	—	73,630	1,524	75,154	927	76,081
Dividends	—	—	(30,055)	—	(30,055)	(944)	(30,998)
Equity compensation plans	3	102	—	—	105	—	105
Own equity instruments	—	1,213	—	—	1,213	—	1,213
At December 31, 2017	72,970	64,815	550,974	3,166	691,924	973	692,897
Year ended December 31, 2018							
At January 1, 2018	72,970	64,815	550,974	3,166	691,924	973	692,897
Impact of changes in accounting policies	—	—	10,606	—	10,606	—	10,606
At January 1, 2018 (revised)	72,970	64,815	561,580	3,166	702,530	973	703,503
Net income	—	—	92,488	—	92,488	591	93,079
Net change in fair value – financial assets at fair value through OCI	—	—	—	363	363	—	363
Cash flow hedges	—	—	—	(225)	(225)	—	(225)
Currency translation of foreign operations	—	—	—	(3,077)	(3,077)	(82)	(3,158)
Remeasurements of defined benefit plans	—	—	(2,472)	—	(2,472)	—	(2,472)
Total comprehensive income	—	—	90,016	(2,938)	87,078	509	87,587
Dividends	—	—	(35,003)	—	(35,003)	(817)	(35,820)
Equity compensation plans	31	(97)	—	—	(66)	—	(66)
Own equity instruments	—	1,325	—	—	1,325	—	1,325
Transfer from other reserves to retained earnings	—	—	1,498	(1,498)	—	—	—
At December 31, 2018	73,000	66,043	618,091	(1,270)	755,864	664	756,529

(5) Notes regarding the going concern assumption

None

(6) Notes regarding the consolidated financial statements**1) General accounting principles and significant accounting policies****a. Basis of preparation of the consolidated financial statements**

These financial statements are the annual consolidated financial statements (“Consolidated Financial Statements”) of Chugai, a company registered in Japan, and its subsidiaries (“the Group”). The common stock of Chugai is publicly traded and listed on the Tokyo Stock Exchange under the stock code “TSE: 4519.” The Consolidated Financial Statements were approved by the Board of Directors on January 31, 2019.

Roche Holding Ltd. is a public company registered in Switzerland and the parent company of the Roche Group, which discloses its results in accordance with International Financial Reporting Standards (“IFRS”). The shareholding percentage of Roche Holding Ltd. in Chugai is 59.89% (61.25% of the total number of shares issued excluding treasury stock). The Group became principal members of the Roche Group after entering into a strategic alliance in October 2002.

The Group meets all of the requirements for a “Specified Company under Designated International Financial Reporting Standards” as stipulated under Article 1-2 of the “Ordinance on Terminology, Forms, and Preparation Methods of Consolidated Financial Statements” (Ministry of Finance of Japan Ordinance No. 28, 1976, “the Ordinance”). Hence, in accordance with Article 93 of the Ordinance, the Consolidated Financial Statements have been prepared in accordance with IFRS.

The Consolidated Financial Statements are presented in Japanese yen, which is Chugai’s functional currency and amounts are rounded to the nearest ¥1 million. They have been prepared using the historical cost convention except for items that are required to be accounted for at fair value.

b. Significant accounting policies

The Group applies the same significant accounting policies that are used for the previous fiscal year to the Consolidated Financial Statements, except for those stated in c. Changes in accounting policies below.

c. Changes in accounting policies

In 2018 the Group implemented the following new standards, including any consequential amendments to other standards, with a date of initial application of January 1, 2018.

- IFRS 9 ‘Financial Instruments’
- IFRS 15 ‘Revenue from Contracts with Customers’

The nature and the effects of the changes most relevant to the Group’s Consolidated Financial Statements are given below.

IFRS 9 ‘Financial Instruments’

Effective January 1, 2018 the Group has implemented IFRS 9 ‘Financial Instruments.’ The new standard replaces IAS 39 ‘Financial Instruments: Recognition and Measurement.’ The standard deals with the classification, recognition and measurement (including impairment) of financial instruments and also introduces a new hedge accounting model.

There is no material impact on the Group’s performance or financial position from the application of this standard.

Classification and measurement of financial instruments.

In accordance with the transitional provisions of IFRS9, financial instruments are classified, on the basis of the facts and circumstances that exist at the date of initial application, as follows: Items such as equity securities and debt securities which were previously classified as available-for-sale under IAS 39, with the exception of time accounts over three months, are classified as financial assets at fair value through other comprehensive income (OCI), and time accounts over three months as amortized cost. Though the Group takes advantage of the exemption allowing it not to restate comparative information for prior periods with respect to classification and measurement changes, since there were no changes in the carrying amounts, no adjustments were made to retained earnings as of January 1, 2018.

Changes in the fair value of equity instruments designated as financial assets at fair value through other comprehensive income are recognized in other comprehensive income, and the cumulative amount of other comprehensive income is transferred to retained earnings when the instruments are derecognized.

Impairment of financial assets.

On January 1, 2018 the Group changed the methodology of assessing impairment of its financial assets from the incurred loss model (used in IAS 39) to the expected credit loss model (used in IFRS 9). The new impairment model is applied to financial assets measured at amortised cost and debt securities measured at fair value through OCI, but not equity securities. In accordance with the transitional provisions of IFRS 9, the Group has not restated prior periods but it has reassessed the impairment allowances under the new approach as of January 1, 2018.

Hedge accounting.

As the Group may continue to apply the hedge accounting requirements of IAS 39 instead of those in IFRS 9 at the initial application of IFRS 9, the Group has chosen to continue to apply the hedge accounting requirements of IAS 39.

IFRS 15 ‘Revenue from Contracts with Customers’

Effective January 1, 2018 the Group has implemented IFRS 15 ‘Revenue from contracts with customers.’ The new standard replaces IAS 18 ‘Revenue’ and IAS 11 ‘Construction Contracts.’ IFRS 15 establishes a comprehensive framework for determining whether, how much and when revenue is recognized, and also contains new requirements related to presentation. The core principle in that framework is that revenue should be recognized dependent on the transfer of promised goods or services to the customer for an amount that reflects the consideration which should be received in exchange for those goods or services. The objective of the standard is to provide a five-step approach to revenue recognition that includes identifying contracts with customers, identifying performance obligations, determining transaction prices, allocating transaction prices to performance obligations, and recognizing revenue when or as performance obligations are satisfied. Judgement will need to be applied, including making estimates and assumptions, for multiple-element contracts in identifying performance obligations, in constraining estimates of variable consideration and in allocating the transaction price to each performance obligation. The new standard results in an increased volume of disclosure information in the Annual Financial Statements.

Changes introduced by the standard relevant to the Group.

The new standard provides new requirements and additional guidance that are relevant to the Group, notably on the following areas:

- Revenues from licenses of intellectual property, including sales-based royalties, on constraining estimates of variable consideration such as e.g. development milestones that may be regarded as a separate performance obligation involving variable consideration. There is no material impact from these changes.
- The new standard also clarifies how to allocate sales, including the treatment of discounts, to each element in multiple-elements contracts and when to recognize sales for each of those elements. It requires the use of estimates and assumptions and some judgement to apply this guidance in practice. There is no material impact from this guidance.
- Out-licensing contracts may be entered into with no further obligation or may include commitments to research, late-stage development, regulatory approval, co-marketing or manufacturing. These may be settled by a combination of up-front payments, milestone payments, and reimbursements for services provided. Whether to consider these commitments as a single performance obligation or separate ones, or even being in scope of IFRS 15, is not straight-forward and requires some judgement. Depending on the conclusion, this may result in all revenue being calculated at inception and either being recognized at once or spread over the term of a longer performance obligation. With the application of this standard, upfront payment received, which was formerly recognized over time as deferred income, is recognized as one-time income on out-licensing.

Transition approach.

The Group recognizes the cumulative effect of applying the new standard at the date of initial application, with no restatement of the comparative periods presented. It records the cumulative effect, the amount of ¥10,606 million after tax effect, as an adjustment to the opening balance of retained earnings at the date of initial application. Except for this adjustment, there is no material impact on the Group’s performance or financial position from the application of this standard.

d. Future new and revised standards

Of the new and revised standards that have been issued by the International Accounting Standards Board (IASB) by the date of approval of the Consolidated Financial Statements, the Group will implement the following from 2019.

Although there were other new establishments, minor revisions, etc. to the standards, the Group believes there is no material impact on the Group's performance or financial position.

(a) Standards that will be effective from January 1, 2019**IFRS 16 Leases**

The main impact of the new standard will be to bring operating leases (lessee) on-balance sheet. In applying this standard, the Group will adopt a method that recognizes the cumulative effect at the date of initial application, which is permitted as a transitional measure.

The Group is assessing the potential impact, but currently anticipates that the new standard will result in the carrying value of leased assets being increased by approximately ¥15.0 billion, with lease liabilities increased by a similar amount at the date of implementation. The application of the new standard will result in part of what are currently reported as operating lease costs being recorded as interest expenses. Given the leases involved and the current low interest rate environment, the Group does not currently expect this effect to be material. The new standard will also result in an increased volume of disclosure information in the Annual Financial Statements.

(b) Standards that will be effective from January 1, 2020 and beyond

The Group is currently assessing the potential impacts of new standards and interpretations that will be effective from January 1, 2020 and beyond.

2) Operating segment information

The Group has a single business of pharmaceuticals and does not have multiple operating segments. The Group's pharmaceuticals business consists of research and development of new prescription medicines and subsequent manufacturing, marketing and distribution activities. These functional activities are integrated and managed effectively.

Information on revenues by geographical area in millions of yen

	2018		2017	
	Sales	Royalties and other operating income	Sales	Royalties and other operating income
Japan	399,906	21,569	405,280	5,635
Overseas	127,939	30,374	94,028	29,256
of which Switzerland	109,938	24,250	76,359	28,957
Total	527,844	51,943	499,308	34,891

Information by major customer in millions of yen

	2018	2017
F. Hoffmann-La Roche Ltd.	134,188	105,262
Alfresa Corporation	103,959	104,952
Mediceo Corporation	76,004	80,390
Suzuken Co., Ltd.	53,251	52,668

3) Other expense

Chugai had filed the Advance Pricing Arrangement covering the certain transactions with F. Hoffmann-La Roche Ltd., to Japanese and Swiss tax authorities. In the first quarter of FY 2017, Chugai received a notice of agreement from both tax authorities which includes the instruction that the taxable income of Chugai shall be decreased by a certain amount and that of Roche shall be increased by the same amount in each fiscal year from 2016 to 2020, and if necessary, additional adjustments to the accounts shall be made in 2021.

As a result of this agreement, Chugai will transfer a part of the deducted amount of corporate tax etc., to Roche as the estimated tax payable for Roche, in accordance with the license agreement between Chugai and Roche. In addition, it has posted ¥3,212 million of adjustment from transfer pricing taxation.

4) Earnings per share**Basic earnings per share**

	2018	2017
Net income attributable to Chugai shareholders (millions of yen)	92,488	72,713
Weighted average number of common stock	559,685,889	559,685,889
Weighted average number of treasury stock	(12,662,197)	(13,147,406)
Weighted average number of shares in issue	547,023,692	546,538,483
Basic earnings per share (yen)	169.08	133.04

Diluted earnings per share

	2018	2017
Net income attributable to Chugai shareholders (millions of yen)	92,488	72,713
Weighted average number of shares in issue	547,023,692	546,538,483
Adjustment for assumed exercise of equity compensation plans, where dilutive	892,227	886,414
Weighted average number of shares in issue used to calculate diluted earnings per share	547,915,919	547,424,897
Diluted earnings per share (yen)	168.80	132.83

There were no stock options that were eliminated from the weighted average number of shares in issue used to calculate diluted earnings per share since they do not have dilutive effects.

5) Statement of cash flows**Cash flows from operating activities**

Cash flows from operating activities arise from the Group's primary activities including research and development, manufacturing and sales in the Pharmaceuticals business. These are calculated by the indirect method by adjusting the Group's operating profit for any operating income and expenses that are not cash flows (for example depreciation, amortization and impairment) in order to derive the cash generated from operations. Operating cash flows also include income taxes paid on all activities.

Cash generated from operations in millions of yen

	2018	2017
Net income	93,079	73,541
Financing costs	111	110
Other financial income (expense)	(449)	87
Other expense	3,212	1,706
Income taxes	28,370	23,490
Operating profit	124,323	98,934
Depreciation of property, plant and equipment	14,590	14,549
Amortization of intangible assets	1,988	1,785
Impairment of property, plant and equipment	59	4
Impairment of intangible assets	4,844	4,035
Operating expense for defined benefit plans	4,427	4,231
Operating expense for equity-settled equity compensation plans	282	415
Net (income) expense for provisions	—	(11)
Inventory write-downs	1,051	630
Other adjustments	294	205
Cash generated from operations	151,857	124,776

Cash flows from investing activities

Cash flows from investing activities are principally those arising from the Group's investments in property, plant and equipment and intangible assets. Cash flows connected with the Group's portfolio of marketable securities and other investments are also included, as are any interest and dividend payments received in respect of these securities and investments.

Interest and dividends received in millions of yen

	2018	2017
Interest received	85	88
Dividends received	115	183
Total	200	271

Cash flows from financing activities

Cash flows from financing activities are primarily dividend payments to Chugai shareholders.

Significant non-cash transactions

There were no significant non-cash transactions (2017: none).

6) Related parties

a. Controlling shareholder

Effective from October 2002, Roche and Chugai concluded an alliance to create a leading research-driven Japanese pharmaceutical company, which was formed by the merger of Chugai and Roche's Japanese pharmaceuticals subsidiary, Nippon Roche. Through the merger, Chugai became a principal member of the Roche Group as the surviving company.

Chugai has entered into certain agreements with Roche, which are discussed below:

Basic Alliance Agreement: As part of the Basic Alliance Agreement signed in December 2001, Roche and Chugai entered into certain arrangements covering the future operation and governance of Chugai. Amongst other matters, these cover the following areas:

- The structuring of the alliance.
- Roche's rights as a shareholder.
- Roche's rights to nominate members of Chugai's Board of Directors.
- Certain limitations to Roche's ability to buy or sell Chugai's common stock.

Chugai may issue additional shares of common stock in connection with its convertible debt and equity compensation plans, and for other purposes, which affects Roche's percentage ownership interest. The Basic Alliance Agreement provides, amongst other matters, that Chugai will guarantee Roche's right to maintain its shareholding percentage in Chugai at not less than 50.1%.

Licensing Agreements: Under the Japan Umbrella Rights Agreement signed in December 2001, Chugai has exclusive rights to market Roche's pharmaceutical products in Japan. Chugai also has right of first refusal on the development and marketing in Japan of all development compounds held by Roche.

The Rest of the World Umbrella Rights Agreement (excluding Japan and South Korea) signed in May 2002 was revised and the Amended and Restated Rest of the World Umbrella Rights Agreement (excluding Japan, South Korea and Taiwan) was signed in August 2014. Under this Agreement, Roche has the right of first refusal on the development and marketing of Chugai's development compounds in markets outside Japan, excluding South Korea and Taiwan.

Further to these agreements, Roche and Chugai have signed a series of separate agreements for certain specific products. Depending on the specific circumstances and the terms of the agreement, this may result in payments on an arm's length basis between Roche and Chugai, for any or all of the following matters:

- Upfront payments, if a right of first refusal to license a product is exercised.
- Milestone payments, dependent upon the achievement of agreed performance targets.
- Royalties on future product sales.

These specific product agreements may also cover the manufacture, supply etc. of the respective products to meet the other party's clinical and/or commercial requirements on an arm's length basis.

Research Collaboration Agreements: Roche and Chugai have entered into research collaboration agreements in the areas of small-molecule synthetic drug research and biotechnology-based drug discovery.

Dividends: The dividends distributed to Roche by Chugai in respect to its holdings of Chugai shares totaled ¥21,454 million (2017: ¥18,437 million).

b. Material transactions and balances with related parties**Transactions with F. Hoffmann-La Roche** in millions of yen

	2018	2017
Sales	109,938	76,359
Purchases of inventory and other materials	125,657	124,792

Balances with F. Hoffmann-La Roche in millions of yen

	December 31, 2018	December 31, 2017
Trade accounts receivable	25,307	19,593
Trade accounts payable	(29,567)	(24,805)

c. Remuneration of key management personnel**Remuneration of members of the board and audit & supervisory board members** in millions of yen

	2018	2017
Board of directors		
— Regular remuneration	304	333
— Bonuses	120	234
— Tenure-based restricted stock compensation	57	92
— Performance-based restricted stock compensation	72	35
— Chugai common stock options	21	83
— Chugai stock options as stock-based compensation	—	34
Total	573	811
Audit & supervisory board members		
— Regular remuneration	87	85
Total	87	85

Starting from the fiscal year ended December 31, 2017, Chugai has introduced a restricted stock compensation for its Directors, as replacement for the current stock option compensation for the purpose of further promoting shared value with shareholders and providing an incentive for Directors to sustainably increase Chugai's corporate value by further strengthening the linkage between Directors' remuneration and medium-to-long-term business performance.

7) Subsequent events

There were no subsequent events in the fiscal year under review.