# Financial and Non-Financial Highlights

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries/Years ended December 31

## Financial Indicators (Core Basis)

#### Results

- Ratio of cost of sales to sales (%) - Ratio of operating expenses to revenues (%)



#### Chugai product

### Revenues/

Royalties and Other Operating Income (Billions of yen)



Revenues continue to expand, led by increases in exports of Chugai products and in royalties and other operating income (ROOI). ROOI is composed of recurring income, which has been increasing in conjunction with overseas sales of Actemra, and non-recurring income, which changes from year to year and is the principal factor in the fluctuations in ROOI.

#### Operating Profit/ Ratio of Operating Profit to Revenues

(Billions of yen/%)



Chugai's ratio of operating profit to revenues is consistently high due to the low ratio of operating expenses to revenues. In 2017, the increase in ROOI and the higher percentage of Chugai products in the sales mix resulted in a lower ratio of cost of sales to sales, which contributed to the increase in the ratio of operating profit to revenues. In 2018, we expect record profit for a second consecutive year due to growth of mainstay products and ROOI.

#### Net Income/Core EPS

(Billions of yen/Yen)



In mid-term business plan IBI 18, we set a Core EPS compound annual growth rate (CAGR) of less than 4 percent as the quantitative outlook, with 2015 as the baseline, and are using it as a key performance indicator shared both internally and externally. In the forecast for 2018, we project that this indicator will be 9.5 percent,<sup>1</sup> significantly higher than our original plan.

1. Based on average exchange rates for 2015



Chugai has substantially improved its cost structure in view of the rising cost of sales to sales ratio resulting from the increase in products in-licensed from Roche under the strategic alliance between the two companies. We have now secured high profitability by continuously achieving a ratio of operating expenses to revenues at a level that compares favorably with the world's leading pharmaceutical companies.

Sales have grown steadily in the area of oncology based on products in-licensed from Roche as well as Alecensa, a product from Chugai's research. Sales also continue to grow in the area of bone and joint diseases, driven by Chugai products Edirol and Actemra, the first therapeutic antibody created in Japan.

 Sales of the transplant, immunology and infectious diseases area, which were disclosed separately up until 2016, were included and disclosed in sales of the Others area from 2017.

 Actemra (subcutaneous injection, E.U.)
 Alecensa (U.S.) Hemlibra (U.S., E.U.)
Alecensa (E.U.)





Chugai product Actemra has grown into a mainstay product of the Roche Group, with global sales (including Japan) surpassing 1.9 billion Swiss francs in 2017. Alecensa, another product from Chugai research, received approval in Europe and the United States for the additional indication of first-line treatment at the end of 2017, and is expected to drive overseas sales.





Regarding shareholder returns, we target stable dividends with a Core EPS payout ratio of 50 percent on average, based on an approach of dividing core net income equally between the Company and our shareholders. This policy will continue unchanged under IBI 18, our current mid-term business plan.

### About Core Basis Results

Chugai reports its results on a Core basis from 2013 in conjunction with its decision to adopt IFRS. Core basis results are the IFRS basis results adjusted by excluding non-Core items, and are consistent with the concept of Core basis results disclosed by Roche. Core basis results are used by Chugai as internal performance indicators for representing recurring profit trends both internally and externally, and as indices for establishing profit distributions such as returns to shareholders. No items have been excluded from the IFRS balance sheet and cash flows, as the Core basis results concept only applies to the income statement.

### Research, Clinical Development and Production



#### R&D Expenditures/R&D Expenditures to Revenues/Pipeline Projects

As revenues grow, Chugai increases investment in research and development. In addition to the steady creation of innovative drugs, this leads to research findings that may contribute to the advancement of healthcare and the pharmaceutical industry worldwide. Our policy is to proactively conduct speedy research and development in light of the competitive environment, as well as upfront investment to acquire and enhance future competitiveness, while keeping growth in overall operating expenses within the rate of revenue growth as a general principle. Under our strategic alliance with Roche, we have been promoting new drug development with higher success rates and greater efficiency by collaborating with Roche in ways such as examining and deciding on which Roche products to in-license based on the results of early-stage clinical trials. In recent years, we have maintained a robust pipeline, with numerous products from Chugai research having moved into the clinical phase, including in-house products from Chugai Pharmabody Research (CPR),<sup>1</sup> which has expanded its operations to accelerate the creation of innovative therapeutic antibodies.

1. Established in Singapore in 2012

#### Publications in Academic Papers and Presentations at Scientific Conferences regarding Chugai Research Findings<sup>2</sup>



Chugai develops innovative medicines that allow it to differentiate itself from competitors by continuously establishing proprietary drug discovery technologies and applying them to development candidates while promoting research on commercialization for high quality and high added value. We will continue to generate research findings that may contribute to the overall advancement of healthcare, presenting those findings at scientific conferences and publishing them in academic papers.

2. Total of drug discovery and pharmaceutical technology

#### New Products Launched and New Indications/Percentage of Product Sales Qualifying for Premium Pricing (Number/%)



New products launched and new indications
 Percentage of product sales qualifying for premium pricing

Products that qualify for premium pricing account for a consistently high proportion of Chugai's sales. With our stable revenue base from the efficient in-licensing of Roche products for the Japanese market, we will continue to concentrate on the creation of innovative medicines to provide new value to patients.

Note: Products subject to special market-expansion repricing (2013: Actemra, Avastin; 2016, 2017: Avastin) are counted as products qualifying for premium pricing because they were assumed to meet the conditions for such pricing in the relevant fiscal years.

#### Energy Consumption/ Energy Consumption per Employee

(Thousands of GJ/GJ per employee)



As it expands its production system for new drugs by introducing facilities, Chugai is also working to reduce energy consumption as one of its tasks based on its core value, "We care about the global environment." (See "Environmental, Health and Safety Data" on pages 76-77 for details.)

3. Benchmark year for mid-term environmental goals

### Human Resource Management

#### **Employees/Percentage of Female Employees**



Chugai is working to enhance its management of human resources based on the belief that its people are the source of its contribution to patients in terms of providing greater value. We have implemented a talent management system to develop and retain leaders and core personnel, and also promote diversity and inclusion and work-life synergy so our diverse human resources can generate new value. The percentage of female employees is rising, and women have been steadily making inroads not only in our personnel systems but also in our organizational culture.



 Number of male employees taking childcare leave as a percentage of all male employees with newborn children 5. Percentage of eligible employees

## Review by Disease Area

	Opportunities and Risks	Review of 2017 Performance
Oncology Sales and Percentage of Total Sales 50.6% ¥252.4 billion (+6.7% YoY)	<ul> <li>Opportunities</li> <li>Cancer is the largest area of unmet medical need (the leading cause of death in Japan).</li> <li>Drugs are expected to have better efficacy and fewer side effects due to advances in personalized healthcare.</li> <li>Phase Three of the Basic Plan to Promote Cancer Control Programs is accelerating cancer genomic medicine.</li> <li>Risks</li> <li>Intensifying global competition for cancer immunotherapies including anti-PD-1/PD-L1 immune checkpoint inhibitors</li> <li>Return of premium for new drug creation for mainstay products</li> <li>Entry of large pharmaceutical companies into biosimilar markets</li> </ul>	In Japan, despite the slower growth of Avastin, sales increased 2.5 percent year on year to ¥225.9 billion, led by the strong performance of Alecensa, a product from Chugai research, and Perjeta. Overall sales, including overseas sales, increased 6.7 percent to ¥252.4 billion supported by a 275.7 percent increase to ¥13.9 billion in Alecensa exports to Roche.
Bone and Joint Diseases/ Autoimmune Diseases Sales and Percentage of Total Sales <sup>1</sup> ¥154.2 billion (+5.3% YoY) 30.9%	<ul> <li>Opportunities</li> <li>The emergence of biologics has dramatically improved the effectiveness of rheumatoid arthritis (RA) treatment, and the treatment goal is shifting to remission (a symptom-free state).</li> <li>The number of osteoporosis patients is increasing yearly as populations age.</li> <li>There are many potential osteoporosis patients because the treatment rate and adherence to treatment remain low.</li> <li>There are many autoimmune diseases with high unmet medical need (neuromyelitis optica, large-vessel vasculitis, systemic sclerosis, etc.).</li> <li>Pisks</li> <li>Intensifying global competition in the RA market</li> <li>Slower growth due to the maturing of Actemra in the medium to long term</li> <li>The emergence of biosimilars that compete with biologics</li> </ul>	In Japan, sales increased 8.4 percent year on year to ¥93.3 billion. The increase was driven by the solid performance of core products Actemra, a product from Chugai research for treatment of RA and other diseases; Edirol, another product from Chugai research and the top brand in oral osteoporosis drugs; and Bonviva, which treats osteoporosis by inhibiting bone resorption. Overall sales including overseas sales such as exports of Actemra, which is approved in more than 115 countries and is sold through Roche, increased 5.3 percent to ¥154.2 billion.
Renal Diseases Sales and Percentage of Total Sales 7.9% ¥39.4 billion (-4.4% YoY)	<ul> <li>Opportunities</li> <li>The Japanese government is taking focused measures to address chronic kidney disease (CKD). Early intervention in potential patients is also expected to improve the treatment rate of renal anemia.</li> <li>Renal anemia is divided into the dialysis stage and the pre-dialysis stage, and the number of patients treated in the pre-dialysis stage is trending upward every year.</li> <li>Risks</li> <li>Intensifying competition in the renal anemia market</li> </ul>	In Japan, sales decreased 4.4 percent year on year to ¥39.3 billion. Sales of Oxarol, an agent for secondary hyperparathyroidism, and Mircera, a long-acting erythropoiesis- stimulating agent, decreased in part because of the effect of competition, including from generics.
Others Sales and Percentage of Total Sales 10.7% ¥53.2 billion (+9.7% YoY)	<ul> <li>Opportunities</li> <li>Neurology is an area of very high unmet medical need, with many pathologies and syndromes.</li> <li>Influenza is an acute infectious disease that can confine over 10 percent of the population to bed with sudden high fever.</li> <li>For hemophilia patients, the burden of treatment and the occurrence of inhibitors are issues.</li> <li>In addition to skin deterioration, itching associated with atopic dermatitis reduces patients' quality of life by disrupting sleep.</li> <li>Risks</li> <li>Intensifying global competition due to the limited number of known molecular targets</li> <li>Possibility of few target patients despite high unmet medical need</li> </ul>	Sales of anti-influenza agent Tamiflu for ordinary use decreased 0.8 percent year on year to ¥11.9 billion, and sales for government stockpiles, etc. increased 233.3 percent to ¥5.0 billion. Overall sales in the other diseases category increased 9.7 percent year on year to ¥53.2 billion, as immunosuppressant CellCept showed solid growth.

1. Bone and joint diseases only



2. Copyright © 2018 IQVIA. Source: JPM 2017. Reprinted with permission. The scope of the market is defined by Chugai.

# Development Pipeline (As of February 1, 2018)

(*Additional Indication)	Indication	Status Phase I	Phase II	Phase 🏾	Filed	Approved	Approved/Filing Date [Planned Year of Filing]
Oncology							
AF802 (RG7853)	<ul> <li>Non-small cell lung cancer (NSCLC) [1st line]</li> </ul>						(U.S.) Nov. 2017
		1					(E.U.) Dec. 2017
RG7446	<ul> <li>NSCLC [2nd line]</li> </ul>					0	Jan. 2018
	<ul> <li>NSCLC [1st line]</li> </ul>			•	(Multinational	Study)	[2018]
	<ul> <li>NSCLC (adjuvant)</li> </ul>				(Multinational	Study)	[2020 or later]
	<ul> <li>Small cell lung cancer</li> </ul>				(Multinational	Study)	[2019]
	<ul> <li>Urothelial carcinoma</li> </ul>				(Multinational	Study)	[2020 or later]
	<ul> <li>Muscle invasive urothelial carcinoma (adjuvant)</li> </ul>				(Multinational	Study)	[2020 or later]
	<ul> <li>Renal cell carcinoma</li> </ul>				(Multinational	Study)	[2018]
	<ul> <li>Renal cell carcinoma (adjuvant)</li> </ul>				(Multinational	Study)	[2020 or later]
	<ul> <li>Breast cancer</li> </ul>				(Multinational	Study)	[2018]
	<ul> <li>Ovarian cancer</li> </ul>			•••••	(Multinational	Study)	[2020 or later]
	<ul> <li>Prostate cancer</li> </ul>				(Multinational	Study)	[2020 or later]
GA101 (RG7159)	Follicular lymphoma						Aug. 2017
RG1273*	<ul> <li>Breast cancer (adjuvant)</li> </ul>				0		Oct. 2017
RG435*	Renal cell carcinoma				(Multinational		[2018]
RG3502*	<ul> <li>Breast cancer (adjuvant)</li> </ul>			·	(Multinational	Study)	[2020 or later]
RG7440	<ul> <li>Prostate cancer</li> </ul>			•	(Multinational	Study)	[2020 or later]
	◆ Breast cancer			0	(Multinational	Study)	[2020 or later]
RG7596	Diffuse large B-cell lymphoma (DLBCL)			•	(Multinational	Study)	[2020 or later]
GC33 (RG7686)	<ul> <li>Hepatocellular carcinoma</li> </ul>		(Multinationa	l Study)*			
CKI27	<ul> <li>Solid tumors</li> </ul>						
		-	(Overseas)				
RG7604	<ul> <li>Solid tumors</li> </ul>						
ERY974	<ul> <li>Solid tumors</li> </ul>		(Overseas)				
RG7421	Solid tumors	<b>—</b>					
Dono and Joint Diagona							
Bone and Joint Diseases				1			
ED-71	Osteoporosis				(China)		[2018]
NRD101	Knee osteoarthritis/Shoulder periarthritis			•	(China)		[2019]
Renal Diseases							
EOS789	Hyperphosphatemia						
			(Overseas)				
D'				1	1	1	1
Autoimmune Diseases					1		
MRA* (RG1569)	Giant cell arteritis						(E.U.) Sep. 2017
	Takayasu arteritis/Giant cell arteritis					·····	Aug. 2017
	Systemic sclerosis				(Multinational	1.	[2018]
SA237 (RG6168)	Neuromyelitis optica (NMO)				(Multinational	Study)*	[2019]
RG7845	Rheumatoid arthritis						
Veurology							
RG1450	♦ Alzheimer's disease				(Multinational	Study)	[2020 or later]
RG7412	Alzheimer's disease				(Multinational		[2020 or later]
RG6206	Duchenne muscular dystrophy (DMD)				(II/II) (Multina		[2020 or later]
RG7916	Spinal muscular atrophy (SMA)			(Multinational		alonal otaay)	
				(artinational			
Others			1		1	-	
ACE910 (RG6013)	Hemophilia A (Inhibitor)					0	(U.S.) Nov. 2017
					0		(E.U.) Jun. 2017
					0		Jul. 2017
	Hemophilia A (Non-inhibitor)				(Multinational	Study)	[2018]
RG3637	<ul> <li>Idiopathic pulmonary fibrosis</li> </ul>			(Multinational	Study)		[2020 or later]
CIM331	Pruritus in dialysis patients						[2020 or later]
	Atopic dermatitis			0	(Multinational	Study)	
JRC102	Gout			(Overseas)			
SKY59 (RG6107)	Paroxysmal nocturnal hemoglobinuria (PNH)			(I/I) (Multina	tional Study)		
	Hypoparathyroidism		(Overseas)				
VCO371							
PCO371 RG7716	Wet age-related macular degeneration/						

○ ○ ○ ○ ○ O Designates change in status in 2017 and thereafter ◆PHC-based drug discovery →Development out-licensed to Galderma S.A. (Overseas)/Maruho Co., Ltd. (Japan) \* Multinational study managed by Chugai Pharmaceutical

Generic Name/Product Name	Origin (Collaborator)	Mode of Action
alectinib/Alecensa	In-house (Roche)	ALK inhibitor (Oral)
atezolizumab/Tecentriq	Roche	Engineered anti-PDL1 monoclonal antibody (Injection)
obinutuzumab/ Product name undetermined	Roche (Nippon Shinyaku)	Glycoengineered type II anti-CD20 monoclonal antibody (Injection)
(Overseas name: Gazyva/Gazyvaro (E.U.)) pertuzumab/Perjeta	Roche	HER2 dimerization inhibitory humanized monoclonal antibody (Injecti
	Roche	Anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody (injecti
bevacizumab/Avastin		
trastuzumab emtansine/Kadcyla	Roche	Anti-HER2 antibody-tubulin polymerization inhibitor conjugate (Inject
ipatasertib/Product name undetermined	Roche/Array BioPharma	AKT inhibitor (Oral)
polatuzumab vedotin/ Product name undetermined	d Roche	Anti-CD79b antibody-drug conjugate (Injection)
codrituzumab/Product name undetermined	In-house (Roche)	Anti-Glypican-3 humanized monoclonal antibody (Injection)
Generic and product names undetermined	In-house	Raf and MEK dual inhibitor (Oral)
taselisib/Product name undetermined	Roche	PI3K inhibitor (Oral)
Generic and product names undetermined	In-house	Anti-Glypican-3/CD3 bispecific antibody (Injection)
cobimetinib/Product name undetermined	Roche/Exelixis Cotellic	MEK inhibitor (Oral)
eldecalcitol/Edirol	In-house	Activated vitamin D₃ agent (Oral)
purified sodium hyaluronate/Suvenyl	In-house	Sodium hyaluronate (Injection)
Generic and product names undetermined	In-house	— (Oral)
tocilizumab/Actemra (Overseas name: Actemra/RoActemra (E.U.))	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
satralizumab/Product name undetermined	In-house (Roche)	Anti-IL-6 receptor recycling antibody (Injection)
Generic and product names undetermined	Roche	BTK inhibitor (Oral)
Generic and product names undetermined	noche	
gantenerumab/Product name undetermined	Roche/MorphoSys	Anti-amyloid-beta human monoclonal antibody (Injection)
crenezumab/Product name undetermined	Roche/AC Immune	Anti-amyloid-beta humanized monoclonal antibody (Injection)
Generic and product names undetermined	Roche/Bristol-Myers Squibb	Anti-myostatin adnectin (Injection)
Generic and product names undetermined	Roche/PTC Therapeutics	SMN2 splicing modifier (Oral)
emicizumab/Hemlibra	In-house (Roche)	Anti-factor IXa/X bispecific antibody (Injection)
lebrikizumab/Product name undetermined	Roche	Anti-IL-13 humanized monoclonal antibody (Injection)
nemolizumab/Product name undetermined	In-house	Anti-IL-31 receptor A humanized monoclonal antibody (Injection)
Generic and product names undetermined	In-house/JW Pharmaceutical(JW Pharmaceutical)	URAT1 inhibitor (Oral)
Generic and product names undetermined	In-house (Roche)	Anti-C5 recycling antibody (Injection)
Generic and product names undetermined	In-house	PTH1 receptor agonist (Oral)
denene and product names undetermined	in nouce	

Note: In principle, completion of first dose is regarded as the start of clinical studies in each phase.