

Financial Results FY2020

(January to December 2020)

Carna Biosciences, Inc.



Stock Code: 4572

Strategic Objectives

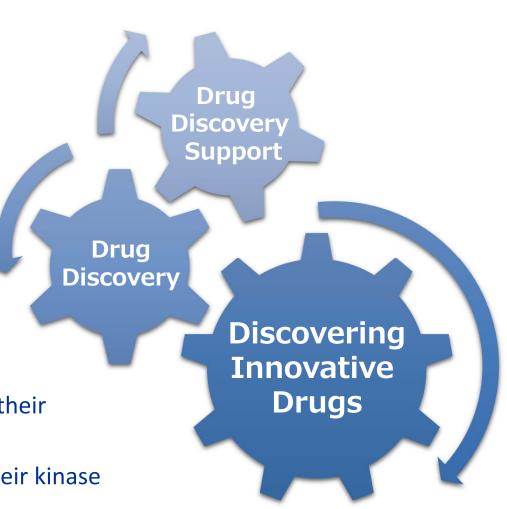


<Drug Discovery>

- Small but powerful team with talented professionals
- Focus on oncology and autoimmune diseases
- Well-balanced pipeline consists of first-in-class and best-in-class programs
- Comprehensive development strategy to maximize the therapeutic and commercial value of our pipeline

<Drug Discovery Support Business>

- Support pharmaceutical companies to accelerate their kinase inhibitor drug discovery
- Provide researchers with the new tools to drive their kinase research
- Secure funds to invest in our drug discovery programs



FY2020 Executive Summary



- Initiated our first FIH (First-in-Human) study of AS-0871 in August.
- Completed preclinical studies of AS-1763.
- Out-licensed AS-1763 to BioNova Pharmaceuticals for the Greater China territory.
- Reacquired worldwide rights to develop and commercialize CDC7 inhibitor AS-0141.
- Achieved record sales at Drug Discovery Support business.
- ☐ Measures at Carna in response to the COIVD-19 pandemic
- ✓ During the State of Emergency in Q1, employees were encouraged to work from home as much as possible to reduce interpersonal contacts. Drug discovery support team continued providing products and services as usual while taking measures such as shift work.
- ✓ Currently, most desk workers are working from home while drug discovery support team is providing products and services as usual and researchers are working at the lab, taking various measures to prevent infection.

Key Milestones in 2020



<Drug Discovery>

- AS-0871: Initiated Phase I healthy volunteer studies in August
- AS-1763: Completed preclinical studies
- AS-1763: Submitted a CTA in early January 2021

<Drug Discovery Support>

- Achieved record-breaking performance with sales of JPY1,080 million
- Launched 19 new protein kinase products, 5 new targets for assay kits, and 3 new targets for profiling service
- Strong sales growth of NanoBRETTM cell-based assay in North America and Japan



Drug Discovery and Development

Drug Discovery FY2020 Key Highlights



- Entered into a license agreement with BioNova Pharmaceuticals Limited, a Chinabased biopharmaceutical company, to develop and commercialize AS-1763, a novel next-generation BTK inhibitor, for the Greater China territory (1Q).
- Reacquired worldwide rights to develop and commercialize AS-0141 (2Q).
- United States Patent and Trademark Office granted a patent for BTK inhibitor (2Q).
- Initiated AS-0871 Phase I healthy volunteer studies (3Q).

Robust Pipeline



<Oncology>

Compound	Target	Indication	Discovery/ Preclinical	Clinical	Partner
AS-0141	CDC7/ASK	Cancer			
Small Molecule	Kinase	Immuno-Oncology			GILEAD
AS-1763	ВТК	Blood Cancer Immuno-Oncology			Bioflova * Pharmaceuticals
Small Molecule	ALK5	Blood Cancer Immuno-Oncology			
Small Molecule	CDK1	Cancer			

<Other Therapeutic Areas>

*Greater China only

Compound	Target	Indication	Discovery/ Preclinical	Clinical	Partner
Small Molecule	Kinase	Psychiatry & neurology			Sumitomo Dainippon Pharma
AS-0871	ВТК	Immune-inflammatory diseases			
Small Molecule	N/A	Malaria			
Small Molecule	STING	Immune-inflammatory diseases			

> We are actively pursuing early discovery programs to create next wave of pipeline.

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BTK Inhibitor Program

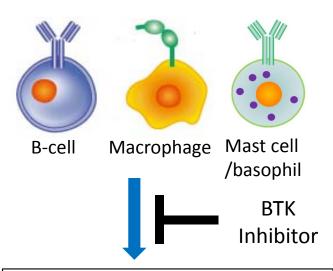


Bruton's Tyrosine Kinase (BTK)

- ✓ BTK is one of the crucial kinases for the B-cell maturation and macrophage activation
- ✓ BTK has been recognized as a validated therapeutic target since the success of Ibrutinib, the first FDA approved BTK inhibitor
- ✓ The expected peak sales of Ibrutinib is > \$10 billion*

◆ Sales of BTK inhibitors in market

Launch	Product	Company	Target	2019	2026 Est.
2013	Ibrutinib	AbbVie/J&J	Blood cancer	\$5.6B	\$10.7B*1
2017	Acalabrutinib	Astra Zeneca	Blood cancer	\$164M*2	



Blood Cancer
e.g. B-cell malignancies
Autoimmune diseases
e.g. Rheumatoid arthritis, chronic
- 0
spontaneous urticaria, systemic lupus

- In January 2019, Loxo Oncology, developing kinase inhibitors including non-covalent BTK inhibitor LOXO-305, was acquired by Eli Lilly for \$8.0 billion.
- In December 2019, ArQule, developing non-covalent BTK inhibitor ARQ 531, was acquired by Merck for \$2.7 billion.



High potential of non-covalent BTK inhibitors for sizable license deals

Source: 1. Evaluate Pharma

2. AstraZeneca Presentation

Non-covalent BTK Inhibitors Under Clinical Development by Competitors



◆ Under development targeting autoimmune diseases

Compound	Company	Development Phase
Fenebrutinib (GDC-0853)	Roche / Genentech	Р3

◆ Under development targeting cancer

Compound	Company	Development Phase
vecabrutinib (SNS-062)	Sunesis	P1b
ARQ531	Merck (ArQule)	P2
LOXO-305	Loxo / Lilly	P1/2



AS-0871: Development for <u>Autoimmune Diseases</u>

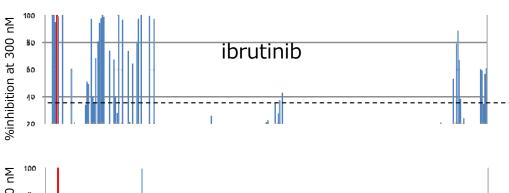
- Small molecule BTK inhibitor
- Non-covalent/reversible
- High kinase selectivity
- Orally available

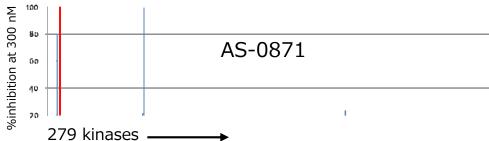
- Demonstrated significant efficacies in arthritis models
- Showed efficacy in systemic lupus erythematosus model
- Initiated P1 study in August 2020 and completed dosing in SAD studies
- ✓ Phase 1 Single Ascending Dose (SAD) study in healthy volunteers was initiated on August 25 in the Netherlands, after the delay due to the COVID-19 pandemic in Europe.
- ✓ The study was carefully conducted at the clinical site taking various measures against the spread of COVID-19.
- ✓ The dosing in the SAD was completed and first data from the SAD study are expected in Q1 2021.
- ✓ Multiple Ascending Dose (MAD) study using new drug formulation is planned in H2. The MAD study is expected to end in H1 2022.

AS-0871: Highly Selective, Potent BTK inhibitor



◆ High kinase selectivity





◆ AS-0871 inhibits an allergic reaction

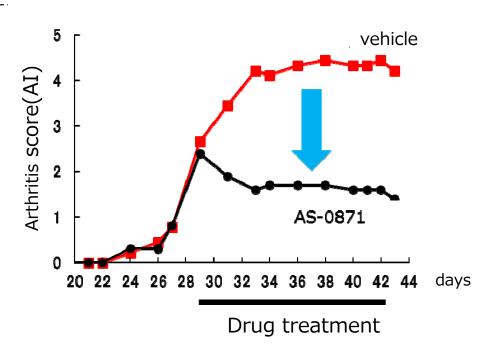




Vehicle

AS-0871

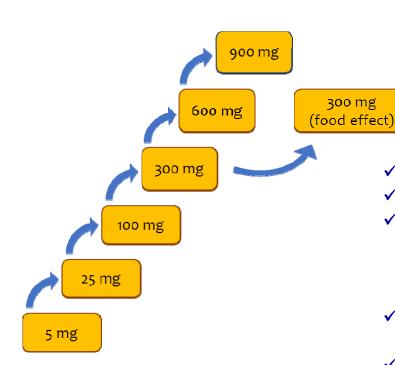
Therapeutic efficacy in Collageninduced arthritis (CIA) mice



AS-0871:FIH study



Step 1 Single Ascending Dose Study (SAD)	Step 2	
 Plan to perform 7 dose levels (8 subjects/cohort) Placebo controlled (6 active / 2 placebo) Safety and tolerability Pharmacokinetics and pharmacodynamics 	Food effect	Multiple Ascending Dose Study (MAD)



- ✓ AS-0871 is well-tolerated without any safety concerns.
- ✓ Favorable pharmacokinetic profile.
- ✓ Blood samples to assess PD effects were analyzed for evaluation of the B-cell and basophil responses. Administration of AS-0871 at 100mg or above resulted in strong inhibition of B-cell and basophil activation.
- ✓ Dose selection for the MAD study will be based on the results obtained from the completed SAD study
- ✓ Switching to the new formulation in the MAD study.

AS-1763: Next Generation BTK Inhibitor Targeting Blood Cancer



AS-1763: Development for <u>Blood Cancer</u>

- Small molecule BTK inhibitor
- Non-covalent/reversible
- High kinase selectivity
- Inhibits both BTK wild type and ibrutinib resistant BTK C481S mutants
- Orally available

- Displayed strong anti-tumor effects in lymphoma model with both wild type and C481S mutant BTK.
- Displayed efficacy in immuno-oncology model
- Potential applications for autoimmune diseases
- CTA submitted in January 2021
- Plan to accelerate the clinical studies utilizing the clinical data of BioNova, the licensee in Greater China.
- ✓ GLP toxicology studies required to initiate clinical study have been completed.
- ✓ Submitted a CTA (Clinical Trial Application) in the Netherlands in January 2021.
- ✓ Plan to initiate Phase 1 study in healthy volunteers in H1 2021.

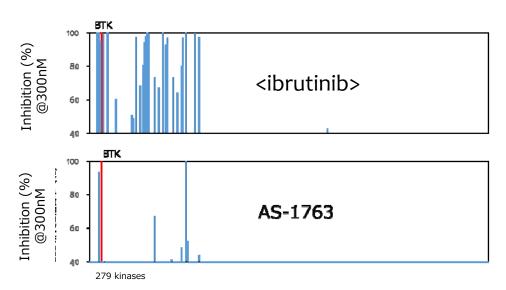
CTA: Clinical Trial Application in Europe

GLP: Good Laboratory Practice

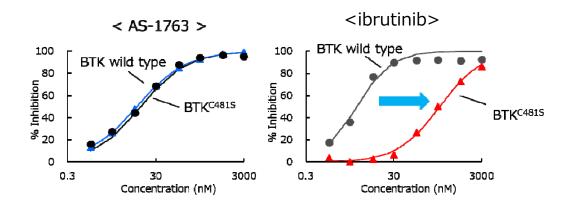
AS-1763: Strong Efficacy against C481S BTK mutant



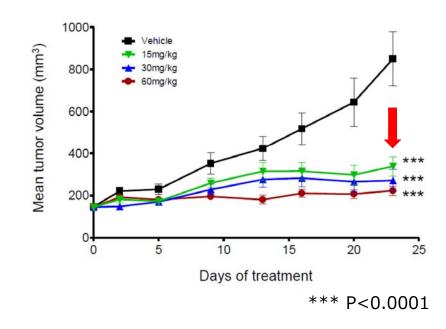
High kinase selectivity



◆ AS-1763 inhibits both WT and C481S mutant BTK enzymes



◆ AS-1763 significantly inhibits tumor growth in a B-cell lymphoma mouse model





AS-0141: Development for Cancer

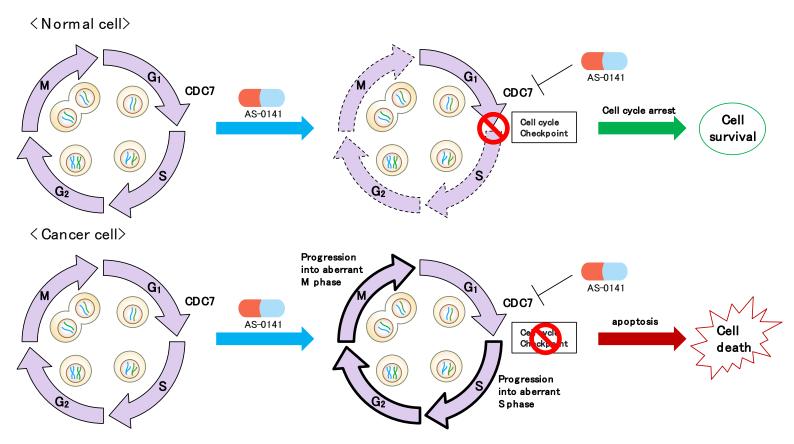
- Small molecule CDC7 inhibitor
- High kinase selectivity
- Potential First-in-class drug
- Potent anti-proliferative activity against various cancer cell lines
- Demonstrated strong anti-tumor activity in several human tumor xenograft models
- IND completed in the U.S.
- Planning a clinical study in Japan (1H 2021)
- ✓ Carna reacquired worldwide rights to AS-0141, licensed to Sierra Oncology in 2016, following Sierra's corporate prioritization of its portfolio to focus resource on the advancement of Phase 3 trials of momelotinib.
- ✓ IND package including all preclinical data and the API produced by Sierra have been transferred to Carna.
- ✓ Preparing for a clinical study in Japan, considering the risk of COVID-19 spreading in the U.S.
- ✓ Carna is planning a new clinical development strategy based on the scientific evidence to increase the probability of success, carefully analyzing the clinical data for the competitors' CDC7 inhibitors. Preparation undergoing to initiate a clinical study in Japan in H1 2021.

AS-0141: Highly Selective CDC7 Inhibitor



CDC7 kinase inhibitor

CDC7 (cell division cycle 7) is a serine-threonine kinase that plays a critical role in DNA synthesis and is required for the activation of DNA replication origins throughout the S phase of the cell cycle. Inhibition of CDC7 in cancer cells causes lethal S phase or M phase progression, whereas normal cells survive, most likely through induction of cell cycle arrest at the DNA replication checkpoint. It has been reported in the literature that CDC7 is overexpressed in many cancers. Therefore, CDC7 is an attractive target for cancer drug development.





Drug Discovery Support

Drug Discovery Support FY2020 Key Highlights



- Drug Discovery Support business achieved sales of JPY1,080 million, the record high sales.
 - ✓ Japan: +7.2% yoy
 - ✓ North America: +3.8% yoy
- New assay service was expanded.
 - ✓ Sales of cell-based assay service using NanoBRETTM technology developed by Promega were 46 million yen, 2.3x of the last year's sales.
- Expanded lineup of kinase proteins and profiling service
 - ✓ Our unique biotinylated kinase products; 14 products were newly added.
 - ✓ High-demand mutant kinase products; 5 products were newly added.
 - ✓ Assay kits; 5 products were added.
 - ✓ Profiling panel; 3 kinase targets were newly added.



FY2020 Results

Consolidated Financial Results



(JPY million)	FY2019 Actual	FY2020 Actual	YoY Change	FY2020 Plan as of Feb. 7, 2020	FY2020 Plan as of Dec. 8, 2020	
Sales	3,207	1,133	-2,074 -64.7%	1,036	1,103	 Support business achieved record sales Received an upfront payment from BioNova Received an upfront payment of JPY2,128M from Gilead in 2019
Operating Profit/Loss	977	(1,057)	-2,034	(1,779)	(1,190)	- Investment in R&D - Smaller upfront payment compared to FY2019
Ordinary Profit/Loss	957	(1,077)	-2,034	(1,794)	(1,202)	
Net Profit/Loss	828	(1,111)	-1,939	(1,822)	(1,229)	
R&D Cost	1,281	1,474	+ 192 + 15.0%	2,040	1,572	Investment in preclinical/clinical studies

Note 1: Rounded down to the nearest million yen.

Note 2: YoY change % for Operating Profit, Ordinary Profit, and Net Profit are not presented since losses were recorded in FY2020.

Results by Business Segment



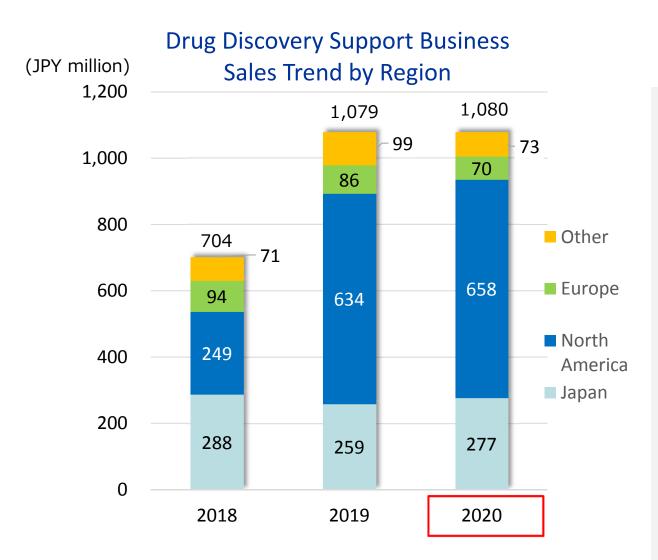
(JPY million)	FY2019 Actual	FY2020 Actual	YoY Change	FY2020 Plan as of Feb. 7, 2020	FY2020 Plan as of Dec. 8, 2020	
Total Sales	3,207	1,133	-2,074 -64.7%	1,036	1,103	
Drug Discovery Support	1,079	1,080	+0.8 +0.1%	1,036	1,050	Sales in the U.S. and Japan were solid
Drug Discovery & Development	2,128	53	-2,074 -97.5%		53	Received an upfront payment of JPY53 mn, compared to an upfront payment of JPY2.1b received in 2019
Total Operating Profit/Loss	977	(1,057)	-2,034	(1,779)	(1,190)	
Drug Discovery Support	400	458	+58 +14.5%	375	416	Profitability improved thanks to upbeat sales of internally developed products/services
Drug Discovery & Development	577	(1,515)	-2,093	(2,155)	(1,607)	Investment in preclinical/clinical studies

Note 1: Rounded down to the nearest million yen.

Note 2: YoY change % for Operating Profit is not presented since loss was recorded in FY2020.

FY2020 Sales Trend by Region Drug Discovery Support Business





- Japan: Increased 7.2% YoY Profiling and NanoBRET assay service were robust while sales of kinase proteins were weak as client's labs were partly closed.
- North America: Increased 3.8% YoY Sales increased yoy contributed by sales to Gilead and new biotech companies despite some negative impact from closure of client's labs.
- Europe: Decreased 18.5% YoY Although profiling service provided to a mega pharma contributed positively, overall sales declined due to weak kinase proteins sales.
- Other: Decreased 26.1%YoY Sales in China were weak due to the spread of COVID-19. Started to see a recovery since November.

Consolidated Balance Sheet



(JPY million)

			_	(JPY million)
	As of Dec. 31, 2019	As of Dec. 31, 2020	Change	Reason for changes
Current assets	5,274	4,708	-566	
Cash and deposits	4,915	4,299	-615	
Non-current Assets	101	127	+25	
Total assets	5,376	4,835	-541	
Current liabilities	1,055	727	-327	Current portion of long-term loans payable -109, Accounts payable +67, Unearned revenue -141, Income taxes payable -120
Non-current liabilities	467	284	-183	Long term loans payable -161 Bonds payable -28
Total liabilities	1,523	1,011	-511	
Total net assets	3,853	3,824	-29	Increase in share capital and capital surplus from exercise of share acquisition rights +1,034, Net loss -1,111
Total liabilities and net assets	5,376	4,835	-541	
Shareholders' equity ratio	71.5%	79.0%		

Shareholders' equity ratio	71.5%	79.0%
BPS	329.8 yen	308.0 yen
PBR	6.4 x	3.9 x
Share price of Carna	2,123 yen	1,212 yen

Note: Share price of Carna Biosciences is based on the closing price as of the end of 2020

Financing



Realize Drug Discovery Vision 2030 and become a Leading Drug Discovery company that continuously deliver innovative drugs

- Funds raised from warrants will be used to accelerate research and development.
 - ✓ Advance developments of two BTK inhibitors, AS-0871 and AS-1763.
 - --> Preclinical studies of AS-0871 and AS-1763 were completed and initiated clinical study of AS-0871.
 - ✓ Prime next wave of development programs.
 - ✓ Expand research pipeline.

Series 18th Subscription Rights to Shares

Series	Status of Exercise (as of the end of Jan.)
Series 18th Share Acquisition Rights	Total number of shares issued 1,195,000 shares (73.5% of total warrants issued) Funds raised JPY2,173 million



Business Plan for FY2021

Anticipated Progress and Milestones through 2021



<Drug Discovery>

- AS-0871: Initiate MAD part of Phase I study in H2.
- AS-1763: Initiate Phase I study in H1.
- AS-0141: Initiate Phase I study in H1.
- Bring one or more programs to preclinical stage.

<Drug Discovery Support>

- Achieve sales target of JPY923 million.
- Launch new products.
- Expand cell-based assay service using NanoBRETTM technology.
- Propose project-based service to collaborate with clients, leveraging Carna's drug discovery technology.

Drug Discovery: Vision 2030



Started drug discovery	Demonstrated strong capabilities in drug discovery	Maximize the value of pipelines	Continue delivering profits
2010~2015	2016~2020	2021~2025	2026~2030
 Established inhouse research capability Established pipeline 	 Out-licensed multiple programs Initiate clinical trials 	 POC in human Strengthen cash position by milestone revenue 	 Drive sustainable revenue growth by milestones and royalties from multiple products



Leading Drug Discovery company that continuously deliver innovative drugs

<2021 R&D Plan>

- > AS-0871
 - √ Ph1 MAD Part (2H 2021)
- > AS-1763
 - ✓ Ph1 (1H 2021)
- > AS-0141
 - ✓ Ph1 (1H 2021)

<Revenue>

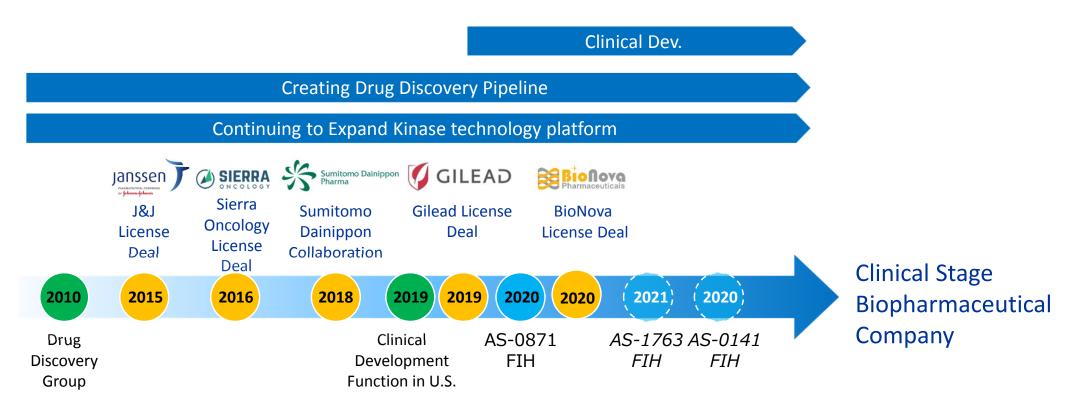
- Milestone payments and royalties from Sumitomo Dainippon Pharma, Gilead and Bio Nova Maximum potential income from milestone payments: JPY79 bn in total + Sales royalties
- Potential Revenue from new license deals

POC: Proof of Concept

Building a Sustainable Company



Continuously Discovering and Delivering Innovative Therapies for Patients by leveraging Carna's powerful kinase technology platform



- Conducting clinical studies of AS-0871, AS-1763, and AS-0141
- Strengthening global clinical development capabilities
- Advancing discovery-stage programs to expand clinical-stage pipeline

FY2021 Financial Plan



(JPY million)	FY2020 Actual	FY2021 Plan	YoY Change	
Total Sales	1,133	923	-210 -18.5%	
Drug Discovery Support	1,080	923	-157 -14.6%	Considering the potential impact of COVID- 19
Drug Discovery & Development	53	1	-53	Revenue from license deals is difficult to project
Total Operating Loss	(1,057)	(1,811)	-754	
Drug Discovery Support	458	207	-250 -54.7%	
Drug Discovery & Development	(1,515)	(2,019)	-503	Investment in R&D
Ordinary Loss	(1,077)	(1,816)	-739	
Net Loss	(1,111)	(1,825)	-714	
R&D Cost	1,474	1,981	+507 +34.4%	Investment in clinical studies
Capex	68	21	-47	Equipment for R&D and information system

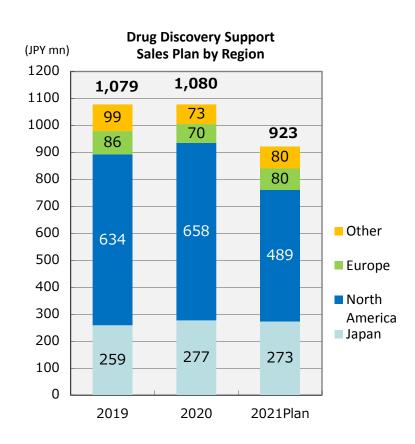
Note 1: Rounded down to the nearest million yen.

Drug Discovery Support: Sales Plan



(JPY mn)	FY2019 Actual	FY2020 Actual	FY2021 Plan
Drug Discovery Support	1,079	1,080	923
Kinase Proteins	385	276	291
Assay Development	310	433	183
Profiling & Screening	252	230	218
Cell-based Assay	19	46	136
Cell-based Assay (agent business)	78	67	73
Others	32	23	19

Exchange rate(US\$):	109.30	106.77	105
% of Overseas sales:	76.0%	74.3%	70.4%



Note: Actual foreign exchange rate is average rate of the term





"Carna" is a goddess of Roman mythology who takes care of human health, protecting the human heart and other organs as well as everyday life, and is said to be the root for the word "cardiac."

The word "biosciences" is derived from the words 'biology' and 'life sciences.'

Carna Biosciences has created contemporary Carna goddess with protein kinase.

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