

Financial Results

FY2020 Q2

(January to June 2020)

Carna Biosciences, Inc.



Stock Code : 4572

- **Reacquired worldwide rights to develop and commercialize AS-0141(June).**
- United States Patent and Trademark Office granted a patent for BTK inhibitor (June).
- **Started subject screening for Phase I clinical trials of BTK inhibitor AS-0871 (June).**

- **Measures at Carna in response to the COVID-19 pandemic**
 - ✓ During the State of Emergency, employees were encourage 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.
 - ✓ We are currently operating as usual while taking various measures to prevent infection.

Drug Discovery and Development

Robust Preclinical Pipeline



Compound	Target	Indication	Discovery	Preclinical	Clinical	Partner
AS-0141	CDC7/ASK	Cancer			IND Completed	
Small Molecule	Kinase	Immuno-Oncology				GILEAD
Small Molecule	Kinase	Psychiatry & neurology				Sumitomo Dainippon Pharma
AS-0871	BTK	Immune-inflammatory diseases			CTA Completed	
AS-1763	BTK	Blood Cancer Immuno-Oncology				BioNova Pharmaceuticals *Greater China only
Small Molecule	Wnt-signal	Immuno-Oncology				
Small Molecule	TGFβ signaling	Blood Cancer Immuno-Oncology				
Small Molecule	Kinase	Autoimmune diseases				
Small Molecule	N/A	Malaria				
Small Molecule	CDK1	Cancer				
Small Molecule	STING	Immune-inflammatory diseases				



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. Sierra completed the IND filing process of AS-0141 in Q3 2018.

AS-0141 : Development for Cancer

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| <ul style="list-style-type: none">● Small molecule CDC7 inhibitor● High kinase selectivity● Potential First-in-class drug | <ul style="list-style-type: none">● 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. |
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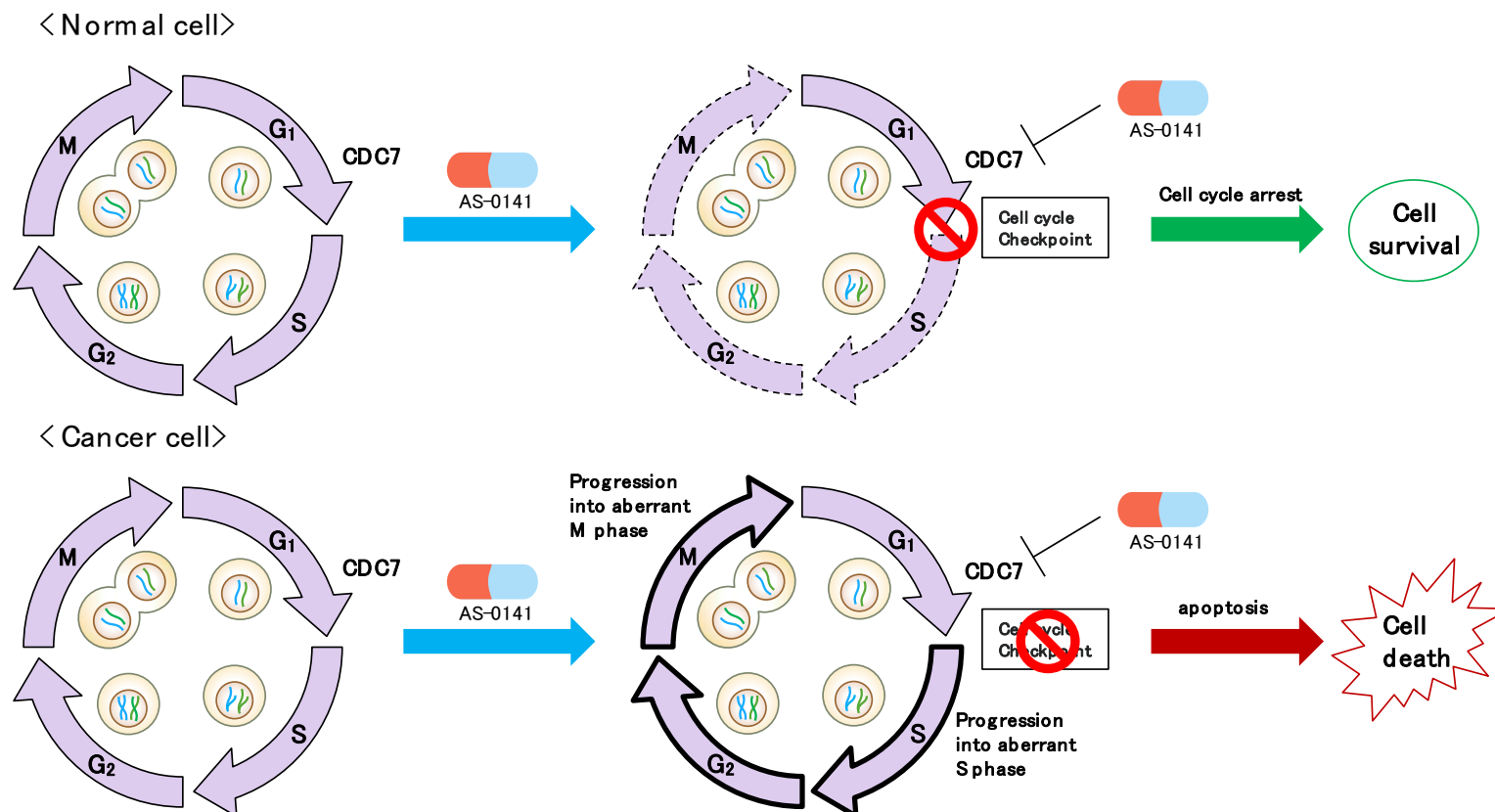
- ✓ IND package including all preclinical data and the API produced by Sierra are in the process of transfer.
- ✓ Carna is planning a new clinical development strategy to increase the probability of success.
- ✓ Phase 1 clinical trial is expected in 2021.

AS-0141: Highly Selective CDC7 Inhibitor



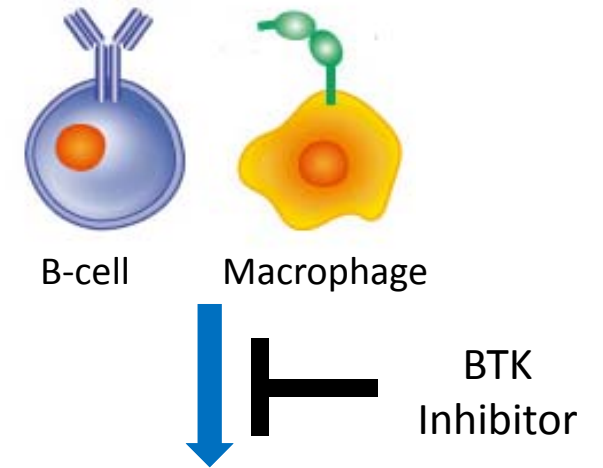
■ CDC7 kinase inhibitor

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.



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

Year	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, asthma, systemic lupus erythematosus

- 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	P2

◆ Under development targeting cancer

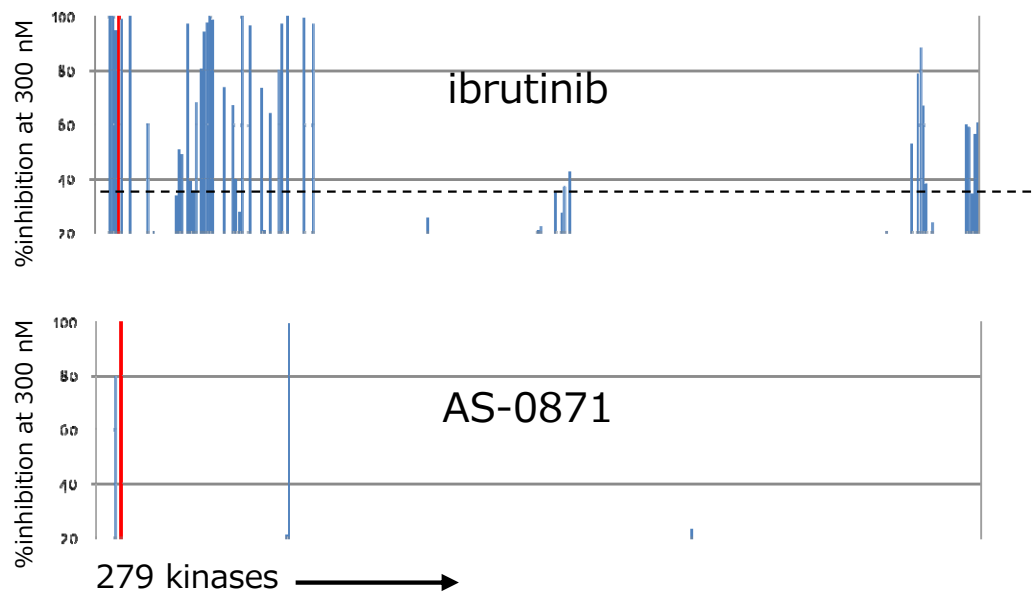
Compound	Company	Development Phase
vecabrutinib (SNS-062)	Sunesis	P1b/2
ARQ531	Merck(ArQule)	P2
LOXO-305	Loxo / Lilly	P1/2

AS-0871 : Development for Autoimmune Diseases

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|--|---|
| <ul style="list-style-type: none">● Small molecule BTK inhibitor● Non-covalent/reversible● High kinase selectivity | <ul style="list-style-type: none">● Demonstrated significant efficacies in arthritis models● Showed efficacy in systemic lupus erythematosus model● CTA approved in February 2020 |
|--|---|

- ✓ Clinical Trial Application (CTA) in Netherlands was approved by the Ethics Committee in February 2020.
- ✓ First-in-human (FIH) study of AS-0871 was planned in Q1 but has been postponed due to the COVID-19 pandemic in Europe.
- ✓ Initiation of dosing in the FIH study is currently planned in August.

◆ High kinase selectivity



◆ AS-0871 inhibits an allergic reaction

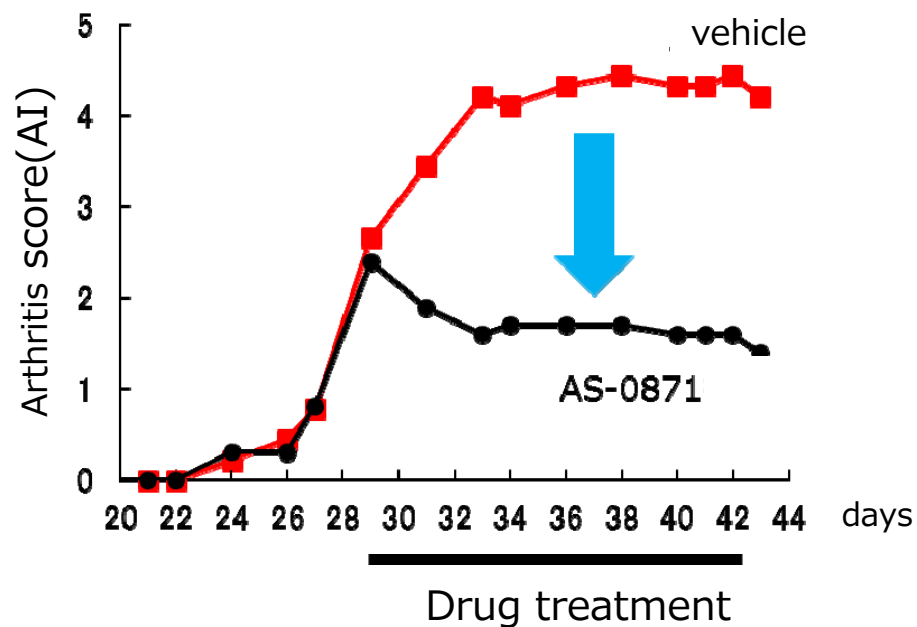


Vehicle



AS-0871

Therapeutic efficacy in Collagen-induced arthritis (CIA) mice



AS-1763 : Development for Blood Cancer

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| <ul style="list-style-type: none">● Non-covalent/reversible● High kinase selectivity● Inhibits both BTK wild type and ibrutinib resistant BTK C481S mutants | <ul style="list-style-type: none">● Displayed strong anti-tumor effects in lymphoma model● Preclinical development undergoing with CTA submission targeted in 2020● Displayed efficacy in immuno-oncology model● Potential applications for autoimmune diseases |
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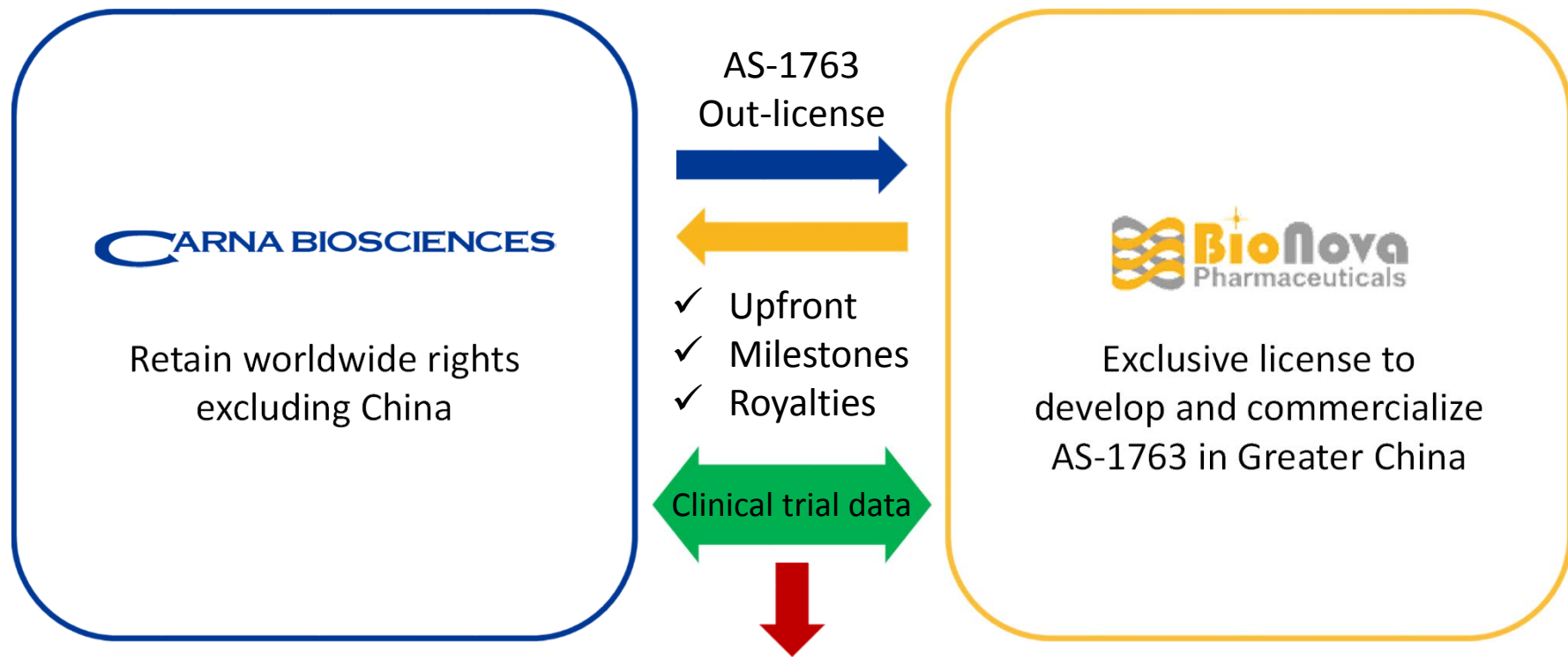
- ✓ Preclinical development undergoing with CTA submission targeted in 2020.
- ✓ Most preclinical studies have been completed.
- ✓ Currently manufacturing of the clinical trial drug product is undergoing.
- ✓ We granted BioNova Pharmaceuticals an exclusive license to develop and commercialize AS-1763 in Greater China to conduct the clinical studies of AS-1763 in China, facilitating enrollment of potential patients.

AS-1763 : License Agreement with BioNova in Greater China



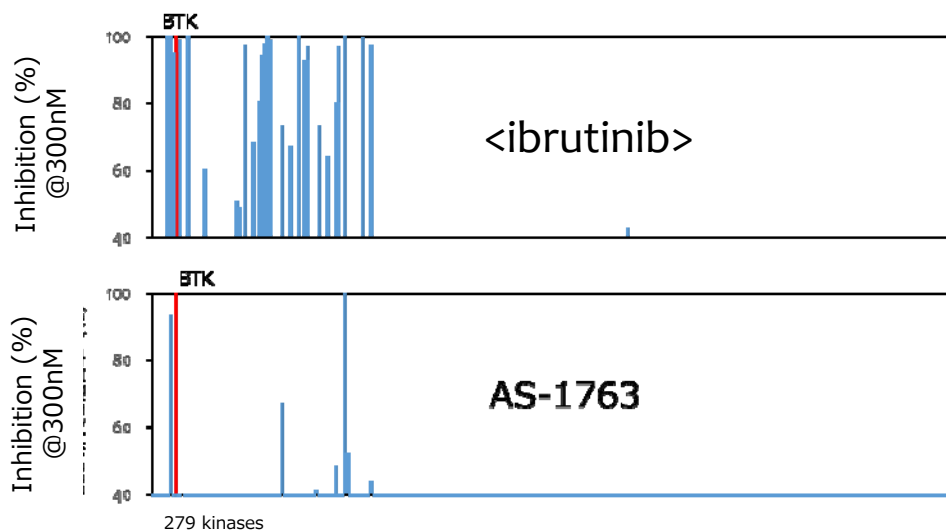
Carna granted BioNova Pharmaceuticals in China an exclusive license to develop and commercialize AS-1763 in Greater China.

- Deal Size An upfront payment and \$205 million in potential milestone payments upon achievement of certain development and commercial milestones
- Royalties Tiered royalties up to double digits on net sales in Greater China

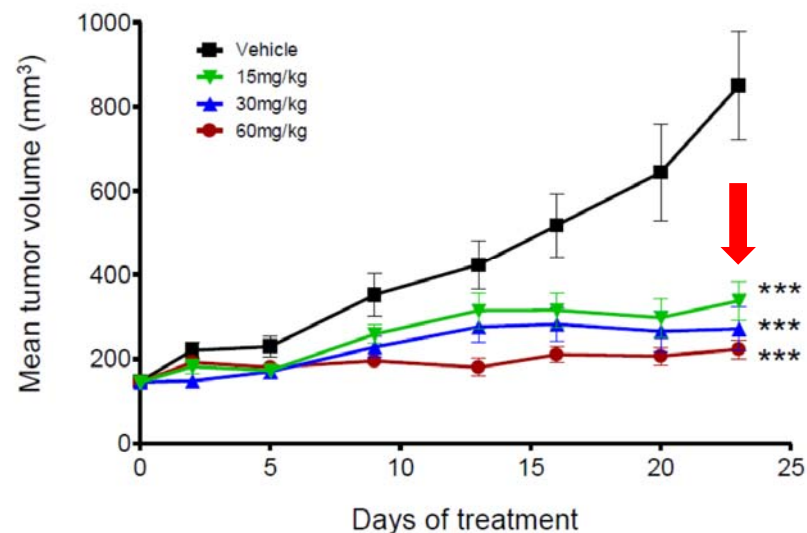


Accelerate the clinical development of AS-1763

◆ High kinase selectivity

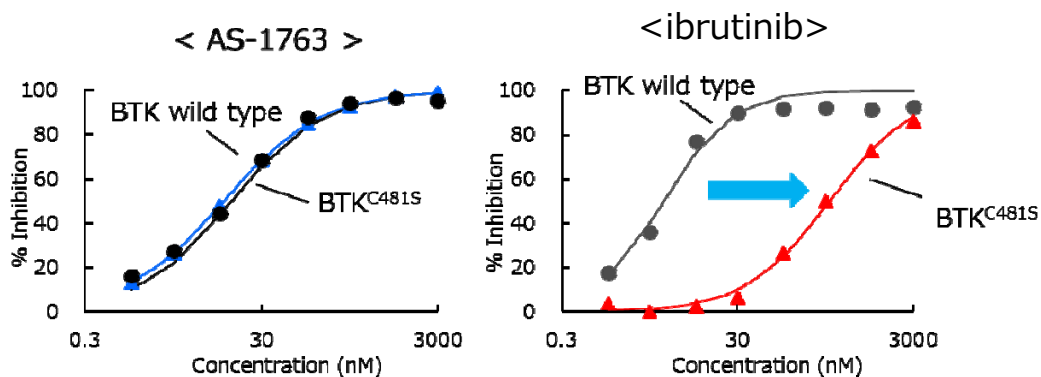


◆ AS-1763 significantly inhibits tumor growth in a B-cell lymphoma mouse model



*** P<0.0001

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



Drug Discovery Support

- Drug Discovery Support business achieved sales of JPY526 million, up 58.3% yoy.
 - ✓ North America: +130.6% yoy thanks to sales to Gilead and biotech startups. In Q2, sales from some customers, whose labs were closed due to the COVID-19 pandemic, weakened.
 - ✓ Japan: Profiling service and cell-based assay service using NanoBRET™ technology were robust. The impact of the COVID-19 pandemic on sales have been small.
 - ✓ Europe: Despite the impact of the pandemic, sales remained almost unchanged from the previous year thanks to a new order from a mega pharma.
 - ✓ Other regions: Sales in China recovered in March but weakened in Q2 again. Activities of CROs in China may have been slowed down due the pandemic in the U.S. and Europe.

- We aim to achieve full-year sales forecast in the difficult environment where the spread of COVID-19 continues, especially in the U.S.
- While sales promotion by customer visits are expected to be restricted, we will try to identify customer needs by frequent contacts using emails, phones, and web meetings, etc.
- We will continue developing new products such as biotinylated kinases, mutant kinases, or customized kinases to meet customer needs.
- Cell-based assay service using NanoBRET™ has been growing steadily and we will take various measures to expand sales further.

FY2020 Q2 Results

(JPY mn)	FY2019 Q2 Actual	FY2020 Q2 Actual	YoY Change	FY2020 Plan	
Sales	2,460	579	-1,881 -76.4%	1,036	-Support business was strong in the U.S. -Received an upfront payment in Q1 from licensing. -Received an upfront payment from Gilead in Q2 2019.
Operating Profit/Loss	1,451	(375)	-1,826	(1,779)	-Investment in R&D. -Upfront payment decreased from the previous year.
Ordinary Profit/Loss	1,446	(380)	-1,827	(1,794)	
Net Profit/Loss	1,195	(397)	-1,593	(1,822)	
R&D Cost	504	615	+111 +22.1%	2,040	-Investment in preclinical and clinical studies.

Note 1: Rounded down to the nearest million yen.

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

Note 3: FY2020 plan was disclosed on February 7, 2020.

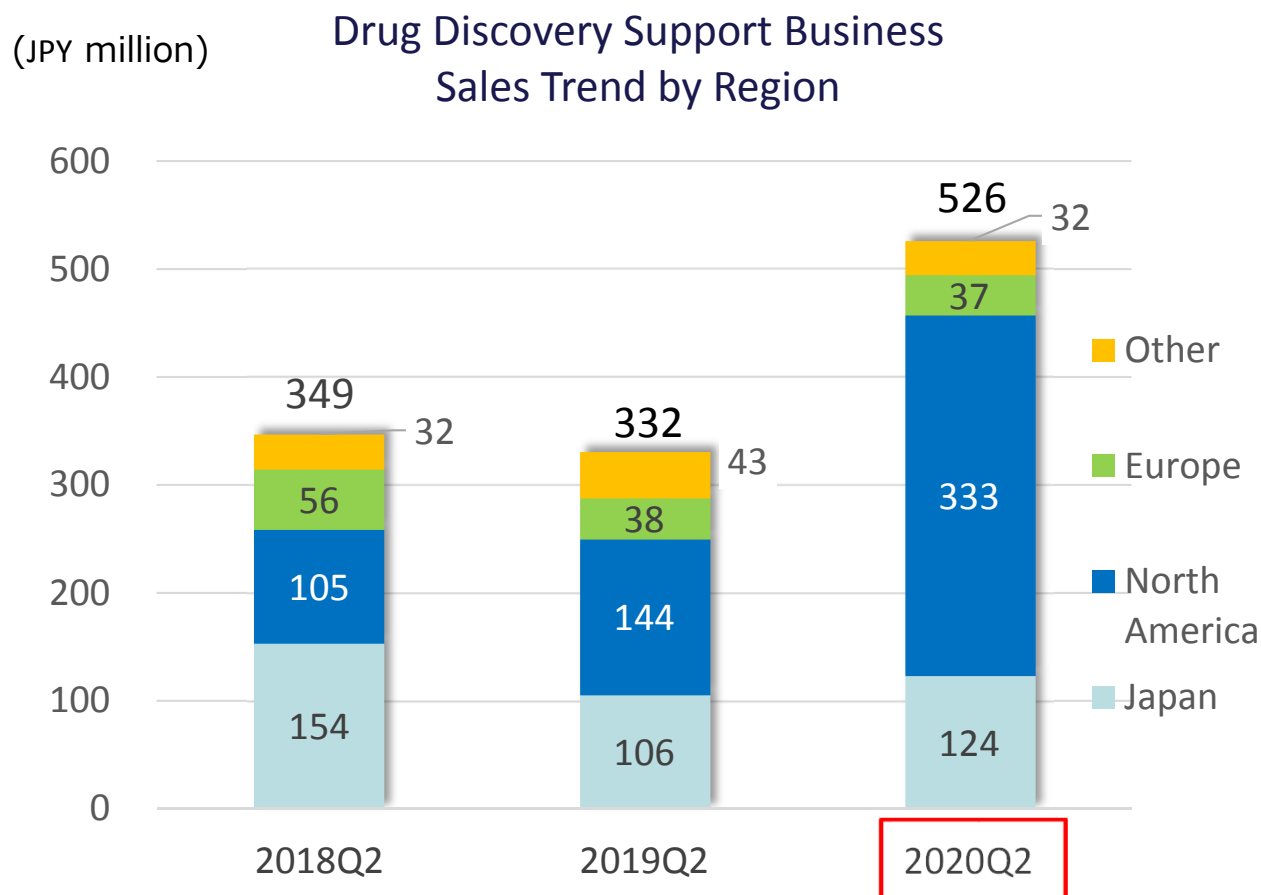
(JPY mn)	FY2019 Q2 Actual	FY2020 Q2 Actual	YoY Change	FY2020 Plan	vs. FY Plan	
Total Sales	2,460	579	-1,881 -76.4%	1,036	55.9%	
Drug Discovery Support	332	526	+193 +58.3%	1,036	50.8%	Sales in the U.S. were strong.
Drug Discovery & Development	2,128	53	-2,074 -97.5%	—	—	Received an upfront payment of JPY53 mn in Q1, compared to an upfront payment of JPY2.1b in Q2 2019.
Total Operating Loss	1,451	(375)	-1,826	(1,779)	—	
Drug Discovery Support	15	237	+222 1412.6%	375	63.3%	Gross profit increased thanks to upbeat sales of internally developed products/services.
Drug Discovery & Development	1,435	(613)	-2,048	(2,155)	—	Investment in preclinical and clinical studies.

Note 1: Rounded down to the nearest million yen.

Note 2: YoY change % and comparison to FY2020 plan for Operating Loss are not presented since losses were recorded.

Note 3: FY2020 plan was disclosed on February 7, 2020.

FY2020 Q2 Sales Trend by Region Drug Discovery Support Business



- Japan: Increased 16.6% YoY Profiling service and NanoBRET assay service were robust.
- North America: Increased 130.6% YoY Sales to Gilead and new biotech companies contributed positively.
- Europe: Decreased 3.5% YoY Profiling service and cell-based assay service were weak.
- Other: Decreased 25.7% YoY Sales in China recovered in March but weakened again in Q2. Sales in Korea were also weak compared to strong performance in the previous year.

Consolidated Balance Sheet



(JPY mn)

	As of Dec. 31, 2019	As of Jun. 30, 2020	Change	Reason for changes
Current assets	5,274	5,222	-52	
Cash and deposits	4,915	4,920	+5	
Non-current Assets	101	126	+24	
Total assets	5,376	5,349	-27	
Current liabilities	1,055	439	-615	Income taxes payable -106, Accounts payable -187
Non-current liabilities	467	365	-102	Long term loans payable -88 Bonds payable -14
Total liabilities	1,523	805	-717	
Total net assets	3,853	4,543	+689	Increase in capital stock and capital surplus from exercise of subscription rights to shares + 1,097, Retained earnings -397
Total liabilities and net assets	5,376	5,349	-27	
Shareholders' equity ratio	71.5%	84.9%		
BPS	329.8 yen	366.1 yen		
PBR	6.4 x	4.2 x		
Share price of Carna	2,123 yen	1,540 yen		

Note: Share price is the closing price of the term end.

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

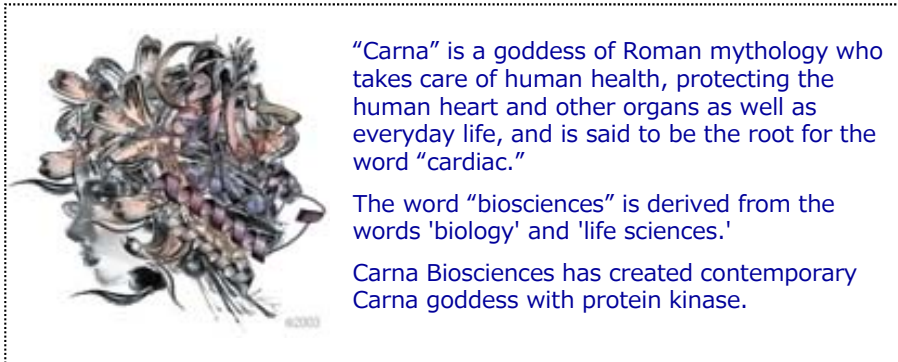
■ Funds raised from warrants will be used to accelerate research and development.

- ✓ Advance developments of two BTK inhibitors, AS-0871 and AS-1763.
- ✓ Prime next wave of development programs.
- ✓ Expand research pipeline.

■ Series 18th Share Acquisition Rights

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

- ✓ With JPY4,920 million in cash and cash equivalents, we have sufficient funds to advance our R&D as planned.



“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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