

Financial Results FY2018 (January to December 2018)

Carna Biosciences, Inc.

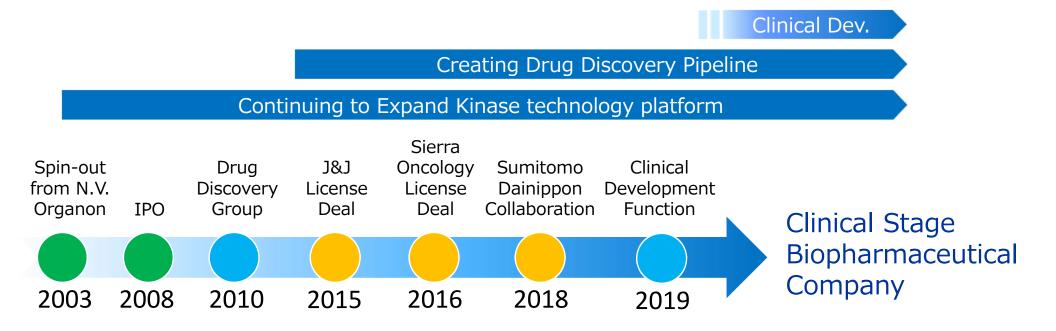


Stock Code : 4572

Building a Sustainable Company



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



Continuing to Expand Preclinical/Clinical Pipeline

 Established global clinical development capabilities to initiate clinical studies of two BTK inhibitor programs

Strategic Objectives



<Drug Discovery>

- Establish elite team with talented professionals
- Focus on oncology and autoimmune diseases
- Well-balanced pipeline consists of first-in-class and best-in-class programs
- Building clinical development capabilities to demonstrate clinical activity of our innovative therapy

<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



Drug

Discovery

Drug

Drugs

FY2018 Executive Summary



- \$100M Early stage deal focused on kinase inhibitors with Sumitomo Dainippon Pharm
- Advanced preclinical development of two potential blockbusters, reversible BTK inhibitors.
 - ✓ AS-0871 (Autoimmune diseases)
 - ✓ AS-1763 (Cancer)
- Sierra Oncology successfully completed the Investigational New Drug (IND) application filing process with FDA.
- Drug Discovery Supporting business achieved record high sales in overseas.

Progress and Milestones in 2018



<Drug Discovery>

- SRA141: Milestone payment upon initiation of Phase I study (\$4.0M)
 Expected to receive in 2019
- AS-0871: Initiate GLP toxicity studies

➡ Initiated GLP toxicity studies and GMP bulk material production

- AS-1763: Formulation, establish manufacturing process, and kg-scale production
 - Established manufacturing process and completed non-GMP batch production

<Drug Discovery Support>

- Achieve sales target of 750M yen Achieved 704M yen
- Add further revenue to the earnings plan by strategic focus on expanding DGK and other lipid kinases Marketing effort ongoing
- Boost sales in North America
 Increased 20% yoy in dollars



Drug Discovery and Development

Drug Discovery FY2018 Key Highlights

- Sumitomo Dainippon Pharma and Carna signed an agreement on joint research, development, and commercialization for psychiatric and neurological disorders. Carna will receive up to approximately \$100M milestone payments in total and sales royalties. (1Q)
- National Cancer Center and Carna entered into a new research collaboration agreement for a novel drug target (2Q)
- Established the clinical development team to initiate clinical trials of Carna's drug candidates (3Q)
- Sierra Oncology successfully completed the investigational New Drug Application (IND) filing process with FDA (3Q)
- Protecting intellectual properties globally
- \checkmark CDC7 inhibitor: Patent registration in Japan, EU, and the U.S.
- ✓ BTK inhibitor: Patent registration in EU, Canada, and Singapore
- \checkmark Wnt signal inhibitor: Patent registration in EU

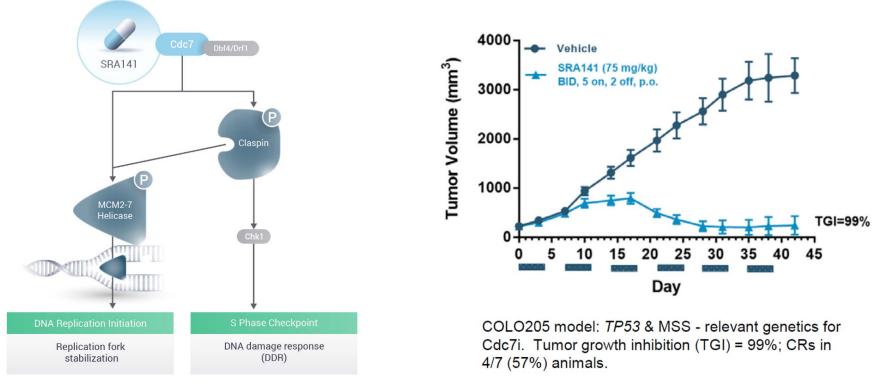
Robust Preclinical Pipeline



	÷ .		Development Phase				
Compound	Target	Indication	Discovery	Discovery Preclinical Clinical		Partner/ Collaboration partner	
SRA141 (AS-141)	CDC7/ASK	Cancer		IND completed		SIERRA ONCOLOGY	
AS-0871	ВТК	Autoimmune Diseases					
AS-1763	ВТК	Blood Cancer Immuno-Oncology					
Small Molecule	Wnt-signal	Cancer Immuno-Oncology				🥙 National Cancer Center Japan	
Small Molecule	Kinase	Psychiatry & neurology				Sumitomo Dainippon Pharma	
Small Molecule	TGFβ signaling	Blood Cancer Immuno-Oncology				HIROSHIMA UNIVERSITY	
Small Molecule	Kinase	Autoimmune Diseases					
Small Molecule	N/A	Malaria				KITASATO UNIVERSITY	
Small Molecule	DGK	Immuno-Oncology					
Small Molecule	Undisclosed	Cancer				🧐 National Cancer Center Japan	

SRA141 : CDC7 Inhibitor Targeting Cancer (Out-licensed to Sierra Oncology)

- ✓ Sierra has successfully completed the IND filing process with FDA, and plans to conduct a Phase 1/2 study in patients with colorectal cancer. Carna will receive the first milestone payment (\$4.0M) upon initiation of Phase 1 study.
- ✓ Sierra reported in its poster presentation at EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics that SRA141 potently and selectively inhibits CDC7 in vitro biochemical assays.



Source: Sierra Oncology

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Source: Sierra Oncology

AS-0871 : Non-covalent BTK Inhibitor targeting autoimmune diseases

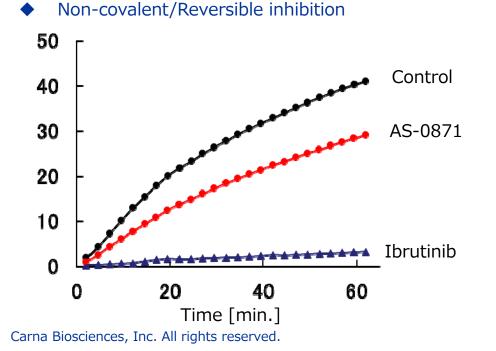


- ✓ Non-GMP bulk production for GLP tox studies has been completed.
- ✓ GMP bulk material production for Phase I clinical study is ongoing.
- ✓ No serious toxicity has been observed in single oral dose range-finding toxicity study in rodent even at the highest dose.

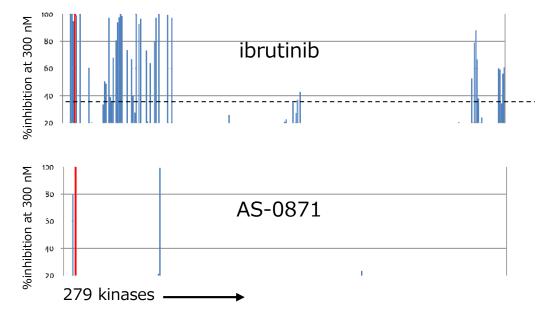
AS-0871 : Development undergoing targeting <u>autoimmune diseases</u>

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

- Demonstrated significant efficacies in arthritis models
- Showed efficacy in systemic lupus erythematosus model
- Preclinical development undergoing with CTA submission targeted in 2019



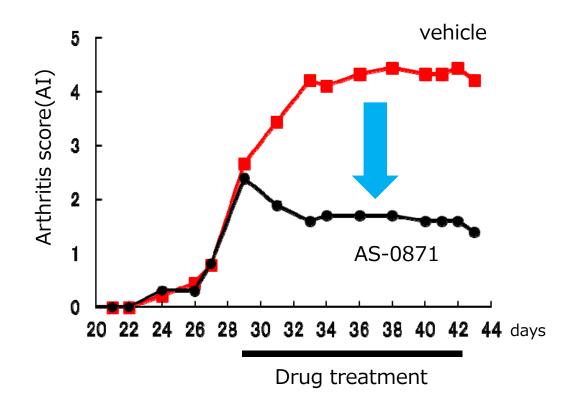
High kinase selectivity



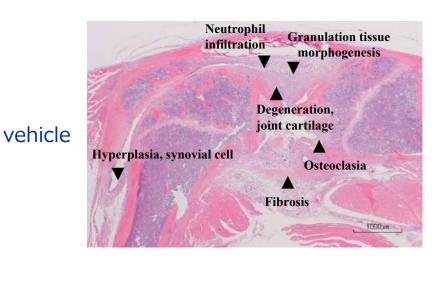
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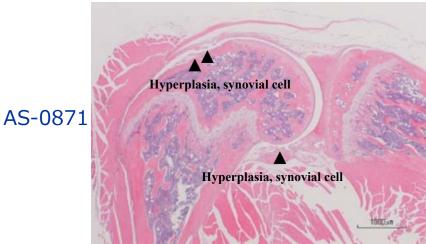


Therapeutic efficacy in Collagen-induced arthritis (CIA) mice



Histopathology of knee joints



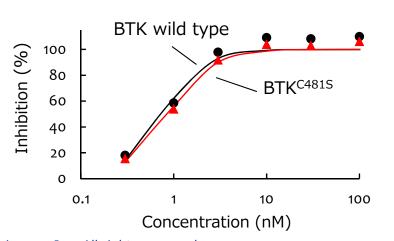


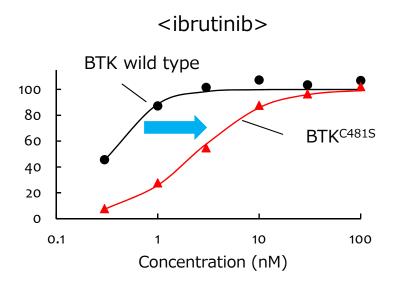
AS-1763:Next Generation BTK Inhibitor Targeting Blood Cancer

- ✓ We are accelerating the preclinical development of AS-1763 by leveraging Evotec AG's INDiGO platform.
- ✓ API process development was completed.
- ✓ The compound name "CB-1763" has been changed into the official clinical development code "AS-1763" as the IND-enabling studies have been progressed

AS-1763 : Development undergoing targeting <u>blood cancer</u>

- Non-covalent/reversible
 High kinase selectivity
 Inhibits both BTK wild type and ibrutinib resistant BTK C481S mutants
 Displayed strong anti-tumor effects in lymphoma model
 Preclinical development undergoing with IND submission targeted in 2019
 Potential applications for autoimmune diseases
 - AS-1763 inhibits both WT and C481S mutant BTK enzymes





< AS-1763 >

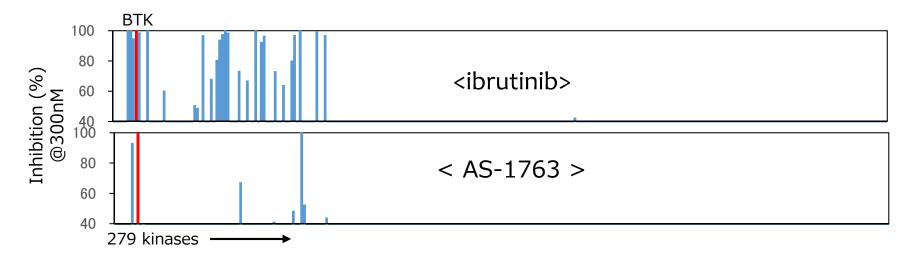
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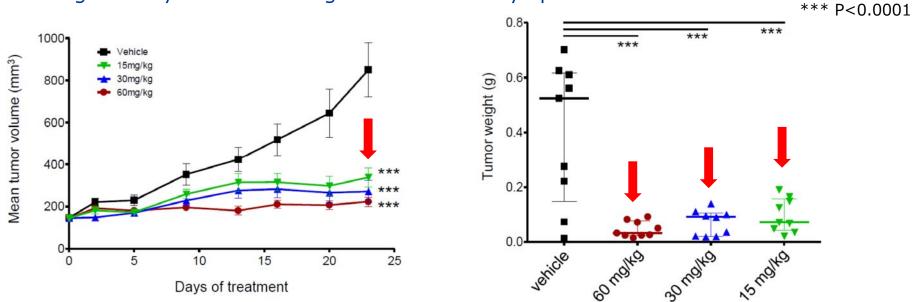
AS-1763:Next Generation BTK Inhibitor Targeting Blood Cancer



• AS-1763 is a highly selective inhibitor



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





Drug Discovery Support



- Carna absorbed ProbeX, a former consolidated subsidiary, to streamline its operations in 2Q.
- Launched a new cell-based assay service using NanoBRET technology developed by Promega in 4Q.



- ✓ Overseas sales reached record high of 416M yen thanks to the robust sales in North America, Europe, and China.
- In Japan, in order to make up for decreasing sales from Ono Pharmaceutical, we aim to increase sales from other customers, making efforts to identify customer needs.
- ✓ In North America, in additions to the continuous orders from big pharmas, sales from new biotech companies are expanding. Carna will continue seeking new customers, aiming to expand market share further.
- ✓ Carna expects to expand sales in China where drug discovery research is rapidly expanding.



FY2018 Results



(JPY mn)	FY2017 Actual	FY2018 Actual	YoY Change	FY2018 Revised plan	Vs. Revised Plan	
Sales	657	754	+97 +14.8%	753	100.2%	 Sales were robust in the U.S., Europe, and China. Received an upfront payment for a new joint research agreement.
Operating Loss	(699)	(1,144)	-445	(1,136)		Investment in R&D.
Ordinary Loss	(711)	(1,159)	-447	(1,152)		
Net Loss	(737)	(1,210)	-473	(1,204)		
R&D Expense	670	1,140	+469 +70.1%	1,136	100.4%	The increase was primarily attributable to the costs for the IND enabling activities for AS-0871 and AS-1763, our BTK inhibitors. R&D expense also increased as a result of ongoing research efforts.

Note 1: Rounded down to the nearest million yen.

Note 2: YoY change % and comparison to FY2018 plan for Operating Loss, Ordinary Loss, and Net Loss are not presented since losses were recorded. Note 3: Revised FY2018 plan was disclosed on December 20, 2018.



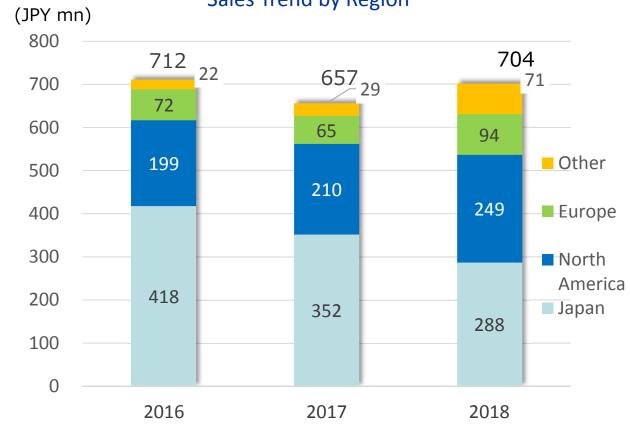
(JPY mn)	FY2017 Actual	FY2018 Actual	YoY Change	FY2018 Revised Plan	Vs. Revised Plan	
Total Sales	657	754	+97 +14.8%	753	100.2%	
Drug Discovery Support	657	704	+47 +7.2%	703	100.2%	Sales were robust in the U.S., Europe, and China. Kinase proteins and cell-based assay services were especially strong.
Drug Discovery & Development		50	+50	50	100.0%	Received an upfront payment for a new joint research agreement.
Total Operating Loss	(699)	(1,144)	-445	(1,136)		
Drug Discovery Support	142	117	-25 -17.7%	119	98.4%	R&D cost increased to develop new products and services.
Drug Discovery & Development	(841)	(1,261)	-420	(1,256)		Investment in preclinical studies.

Note 1: Rounded down to the nearest million yen.

Note 2: YoY change % and comparison to FY2018 plan for Operating Loss, Ordinary Loss, and Net Loss are not presented since losses were recorded. Note 3: Revised FY2018 plan was disclosed on December 20, 2018.

FY2018 Sales Trend by Region Drug Discovery Support Business





Drug Discovery Support Business Sales Trend by Region

- Japan: Decreased 18.1% YoY
 Sales to Ono Pharmaceutical were weak.
- North America: Increased 18.5% YoY Profiling services were strong as well as cell-based assay services and kinase proteins sales.
- Europe: Increased 44.9% YoY
 <u>Sales of kinase proteins were strong.</u> Cellbased assay services were also robust.
- Other: Increased 146.5%YoY
 Sales of kinase proteins increased significantly in China.
 - (Note) Sales to Ono Pharmaceuticals FY2017 ··· 144M yen FY2018 ··· 90M yen

Consolidated Balance Sheet



(JPY mn)

	As of Dec. 31, 2017	As of Dec. 31, 2018	Change	Reason for changes
Current assets	2,134	1,671	-462	
Cash and deposits	1,856	1,355	-500	
Non-current Assets	56	98	+42	
Total assets	2,190	1,770	-420	
Current liabilities	341	400	+ 58	Current portion of long-term loans payable +50
Non-current liabilities	470	482	+11	Long term loans payable +39 Bonds payable -28
Total liabilities	812	882	+70	
Total net assets	1,377	887	-490	Capital stock and capital surplus +730, Retained earnings -1,210
Total liabilities and net assets	2,190	1,770	-420	

Shareholders' equity ratio	62.2%	49.7%
BPS	142.68 yen	86.8 yen
PBR	7.91x	10.37x
Share price of Carna Biosciences	1,128 yen	900 yen

Note: Share price of Carna Biosciences is based on the closing price of JASDAQ growth

Financing



Financing strategy to secure funds to invest in R&D

- ✓ Maximize the revenue from the drug discovery and drug discovery support business.
- ✓ Funds from Series 16th and 17th Subscription Rights to Shares.
- $\checkmark\,$ New fund raising.

Series 16th and 17th Subscription Rights to Shares

Series	Status of Exercise (as of end of January 2019)Total Number of shares exercised 804,000 shares (86.5% of total rights)Total value exercised975,528,000 yen		
Series 16th Subscription Rights to Shares			
Series 17th Subscription Rights to Shares	Not exercised		



Business Plan for FY2019

Enhancing Sales Capabilities

- ✓ North America: Sales and marketing organization has been reinforced with a new head of sales with a mission to expand supporting business further.
- \checkmark EU: Planning to expand sales network by adding agents.
- China: Strengthening partnership with the agent to expand our presence further.



Enhancing Clinical Development Capabilities

 \checkmark Opened a clinical development office in South San Francisco on February 1.

'ARNA BIOSCIE

 Carna will commence clinical studies of our drug candidates in the U.S. in cooperation with CarnaBio USA to accelerate the clinical development of new therapies worldwide.

> Clinical Development Department Clinical Vertication Clinical Development Division



<Drug Discovery>

- SRA141: Milestone payment upon initiation of Phase I study (US\$ 4.0M)
- AS-0871: Submit a Clinical Trial Application(CTA) and Initiate Phase I study
- AS-1763: Submit an Initial New Drug (IND) application

<Drug Discovery Support>

- Achieve sales target of 800M yen
- Boost sales in North America
- Establish new services including NanoBRET

FY2019 Financial Plan



(JPY mn)	FY2018 Actual	FY2019 Plan	YoY Change		
Total Sales	754	1,240	+485 +64.3%		
Drug Discovery Support	704	800	+95 +13.5%	Expand sales in the U.S.	
Drug Discovery & Development	50	440	+390 +780.0%	Milestone payment from Sierra upon initiation of Phase I clinical study	
Total Operating Loss	(1,144)	(1,658)	-513		
Drug Discovery Support	117	144	+26 +22.9%		
Drug Discovery & Development	(1,261)	(1,802)	-540	Milestone payment from Sierra Invest in R&D	
Ordinary Loss	(1,159)	(1,671)	-511		
Not Loss	(1,210)	(1,693)	-483	Impairment loss due to capex	
R&D Cost	1,140	2,011	+870 +76.3%	Investment in preclinical & clinical studies of AS-0871 and AS-1763	
Сарех	58	43	-15	Equipment for R&D	

Note 1: Rounded down to the nearest million yen.

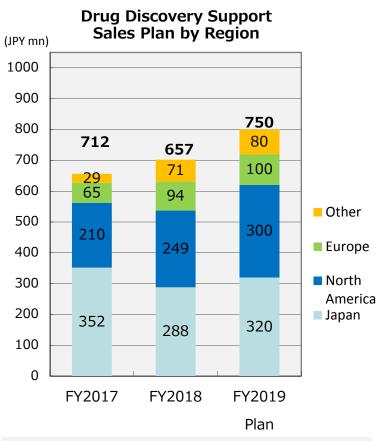
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ARNA BIOSCIENCES
Canada

(JPY mn)	FY2017 Actual	FY2018 Actual(a)	FY2019 Plan (b)	Change (b)-(a)
Drug Discovery Support	657	704	800	+95
Protein Kinases	241	314	351	+36
Assay Development	35	27	32	+5
Profiling & Screening	257	227	248	+21
Cell-based Assay	9	4	13	+8
Cell-based Assay (agent business)	90	109	136	+27
Others	23	21	18	-3

Exchange rate(US\$):	108.81 yen	110.45 yen	110 yen
% of Overseas sales:	46.4%	59.1%	60.0%

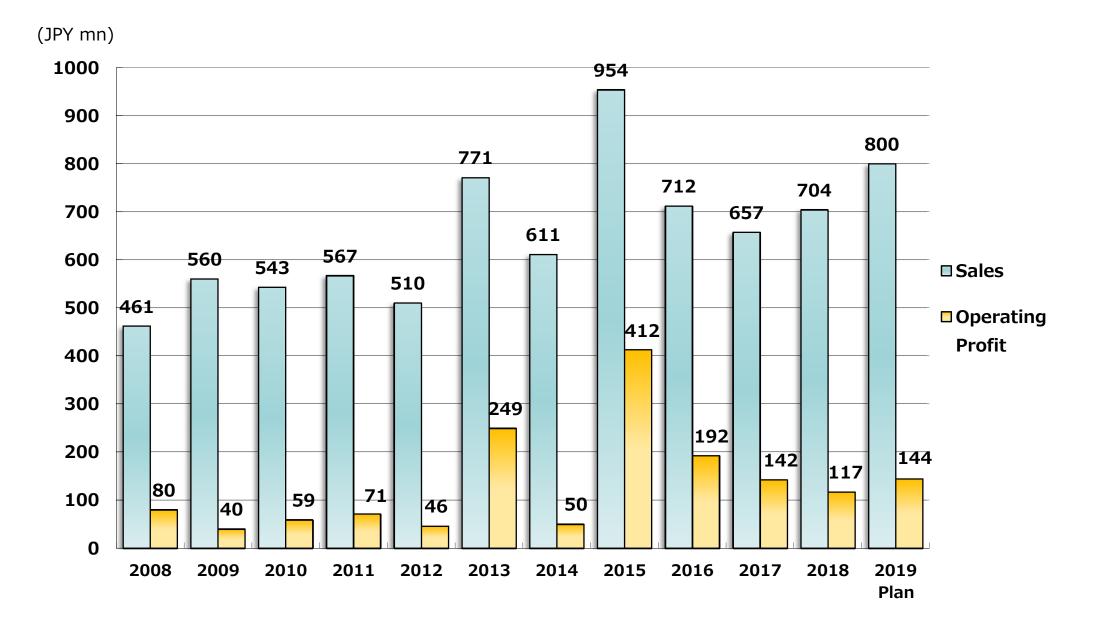
Note: Actual foreign exchange rate is average rate of the term



- ✓ Expand sales in North America by reinforcing sales organization and from continued orders for profiling service from the existing customers.
- ✓ Expand sales in Japan with new protein kinase products and services.

Drug Discovery Support: Sales and Operating Profit Plan









"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.

Carna Biosciences, Inc.

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