

# Financial Results FY12/16

**Chiome Bioscience Inc.**

**February 14, 2017**



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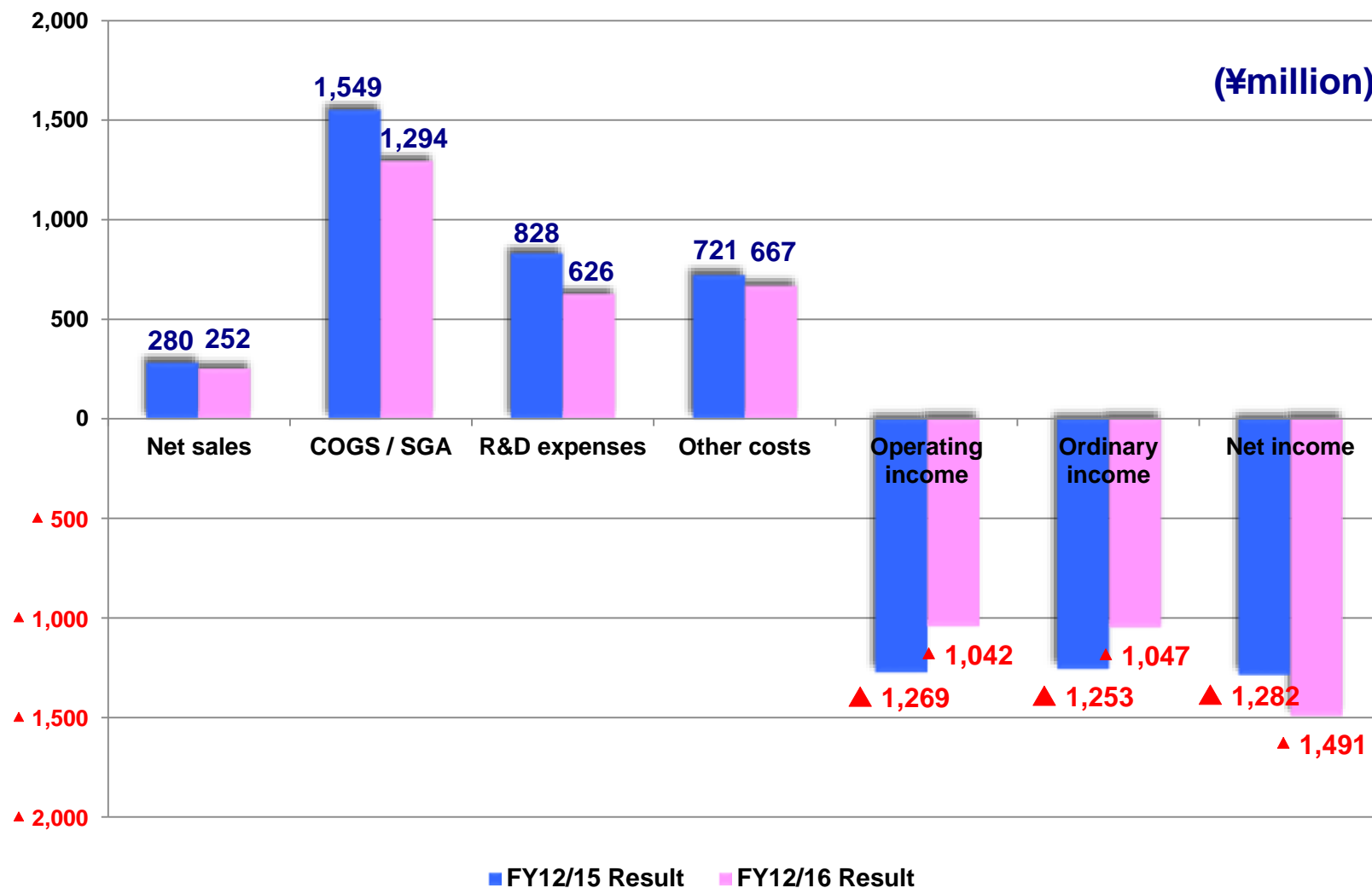
**Securities code : 4583**



- ◆ Overview of FY12/16 “Financial results”
- ◆ Overview of FY12/16 “Operation highlights”



# Financial results: Profit and Loss



# Financial results: Balance Sheet

(¥million)

As of December 31, 2015

As of December 31, 2016



# Agenda

◆ Overview of FY12/16 “Financial results”

◆ Overview of FY12/16 “Operation highlights”



## Drug discovery and development

- Anti-DLK-1 antibody (LIV-1205) was put onto the pediatric preclinical testing program (PPTP) funded by the National Cancer Institute (NCI) in the US, and is under evaluation in pediatric cancer models.



**A key step toward clinical development of LIV-1205**

## Drug discovery support

- Concluded a three-year contract research agreement with Mitsubishi Tanabe Pharm Corporation (Osaka, Japan) and Tanabe Research Laboratories U.S.A. Inc. for the discovery of novel antibodies using the ADLib<sup>®</sup> system.
- Continued collaborative and contract R&D activities with Chugai Pharmaceutical Group. Extended the contract research agreement with Chugai Pharmabody Research Pte. Ltd. (until Dec. 2021).



**Secure stable income**

### **Report an extraordinary loss (impairment loss)**

**Based on the “Accounting Standard for Impairment of Fixed Assets”, Chiome recorded an extraordinary loss of impairment (¥321 million) by reducing the book value of fixed assets to recoverable value after assessment of possibility of future recovery since a signal of impairment of loss of fixed assets was seen due to continuous operation loss.**

# Operation highlights(1)

## ➤ **【Business development activities】**

- ✓ **Concluded an exclusive Option Agreement with ADC Therapeutics SA (ADCT) for the development and commercialization of LIV-1205 and LIV-2008b (humanized anti-TROP-2 antibody) as antibody-drug conjugates (ADCs\*) for cancer therapy**

\* ADCs are monoclonal antibodies attached to biologically active drugs with chemical linkers. By combining the unique target specific antibody with cytotoxic compound, ADCs are delivered specifically to disease area .

## ➤ **【R&D progresses】**

- ✓ **Continued research on refining the ADLib<sup>®</sup> system and run antibody selection projects using the fully human ADLib<sup>®</sup> system.**



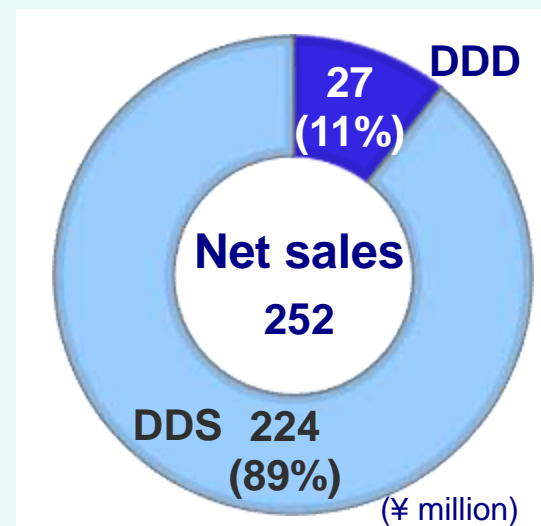
## Operation highlights (2)

### ➤ **【Net sales of Drug Discovery and Development (DDD)】**

- ✓ Option agreements of LIV-1205 and LIV-2008b by ADCT

### ➤ **【Net sales of Drug Discovery Support (DDS)】**

- ✓ Extended collaborative and contract research agreement with Chugai Pharmaceutical Group
- ✓ Concluded a contract research agreement with Mitsubishi Tanabe Pharm Corporation group for the discovery of novel antibodies
- ✓ Launched new antibody generating projects with other pharmaceutical companies



# Operation highlights (3)

## ➤ **【Others】**

- ✓ **Financing through third-party allotment by Merrill Lynch Japan Securities Co., Ltd.**

**Total amount of funds (Sep. 16, 2016~Dec. 31, 2016): 120 million JPY**

**Focus on investment that boosts the corporate value**

Use of funds	Cost (million JPY)	Scheduled period of spending
Pre-IND submission and early-phase clinical development	1,300	Jan. 2017~Dec. 2019
Expansion and licensing-in of new pipelines	300	Dec. 2016~Dec. 2018
Investment in/ M&A for companies with advanced technologies for synergism	1,294	Oct. 2016~Dec. 2018

# Subsequent events

## ➤ **【Others】**

### ✓ **Investment in Trans Chromosomics, Inc. (TC)**

**Aiming for upgrading the level of science and technology  
in antibody development**

# Contract research agreement with Mitsubishi Tanabe Pharm Corporation



## For the discovery of novel antibodies using ADLib® system

### Mitsubishi Tanabe Pharm Corporation (MTPC)

- ◆ Manufacture and sale of pharmaceuticals, centered on ethical drugs

### Tanabe Research Laboratories U.S.A., Inc. (TRL)

- ◆ An independent subsidiary of MTPC whose role is to discover and develop biological drug candidates for targeting tumors and other diseases with high unmet needs



- ✓ Blanket agreement on antibody generation
- ✓ For antibodies entering into development stage for therapeutics or diagnostics, business agreement will be settled separately

# Option agreement for LIV-1205 and LIV-2008b

**ADC of LIV-1205 and LIV-2008b are in evaluation by ADCT**

## ADC Therapeutics SA

- ◆ A Switzerland-based company specialized in the development of ADCs in oncology field with clinical development projects
- ◆ Chiome has granted ADCT a worldwide exclusive option to develop and market such therapeutic antibody as an ADC



- ✓ Upfront payment on execution of this Option Agreement
- ✓ License fee on execution of the License Agreement based on evaluation results
- ✓ Milestone payments
- ✓ Sales tied Royalties

# Investment in Trans Chromosomics, Inc. (TC)



**Aiming at refining Chiome's technology for antibody discovery**

## Trans Chromosomics, Inc. (TC)





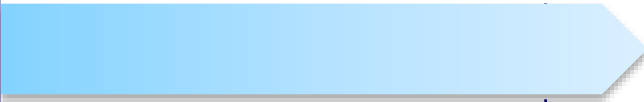

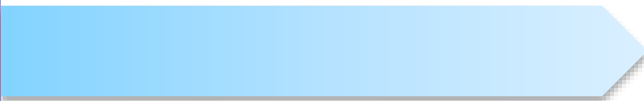
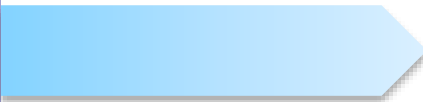
- ◆ R&D and the consignment study for the medical supplies utilizing chromosome engineering technology
  - Development of animals producing a fully human antibodies
  - Development of animal models of rare genetic diseases
  - Development of animal models of human immune system



✓ **Underwriting new shares from TC's third party allotment**

**Number of Required shares: 750**  
**(Acquisition amount 150 million JPY, acquisition rate 6.3%)**

# Pipeline - therapeutic antibody -

Project	Target	Therapeutic Area	Basic Research, Drug Discovery			Pre-clinical Studies	Clinical trials	Partner
			Target validation	Lead Selection	Lead Optimization			
LIV-1205	DLK-1	Oncology /Naked						Looking for partners
		Oncology /ADC						 ADCT
LIV-2008	TROP-2	Oncology/ Naked						Looking for partners
LIV-2008b	TROP-2	Oncology /ADC						 ADCT
BMAA	SEMA3A	Undisclosed						Looking for partners
New PJ	Undisclosed							

# LIV-1205 under PPTP

## A key progress toward clinical development of LIV-1205

### Pediatric Preclinical Testing Program (PPTP)

<http://www.ncipptc.org/>



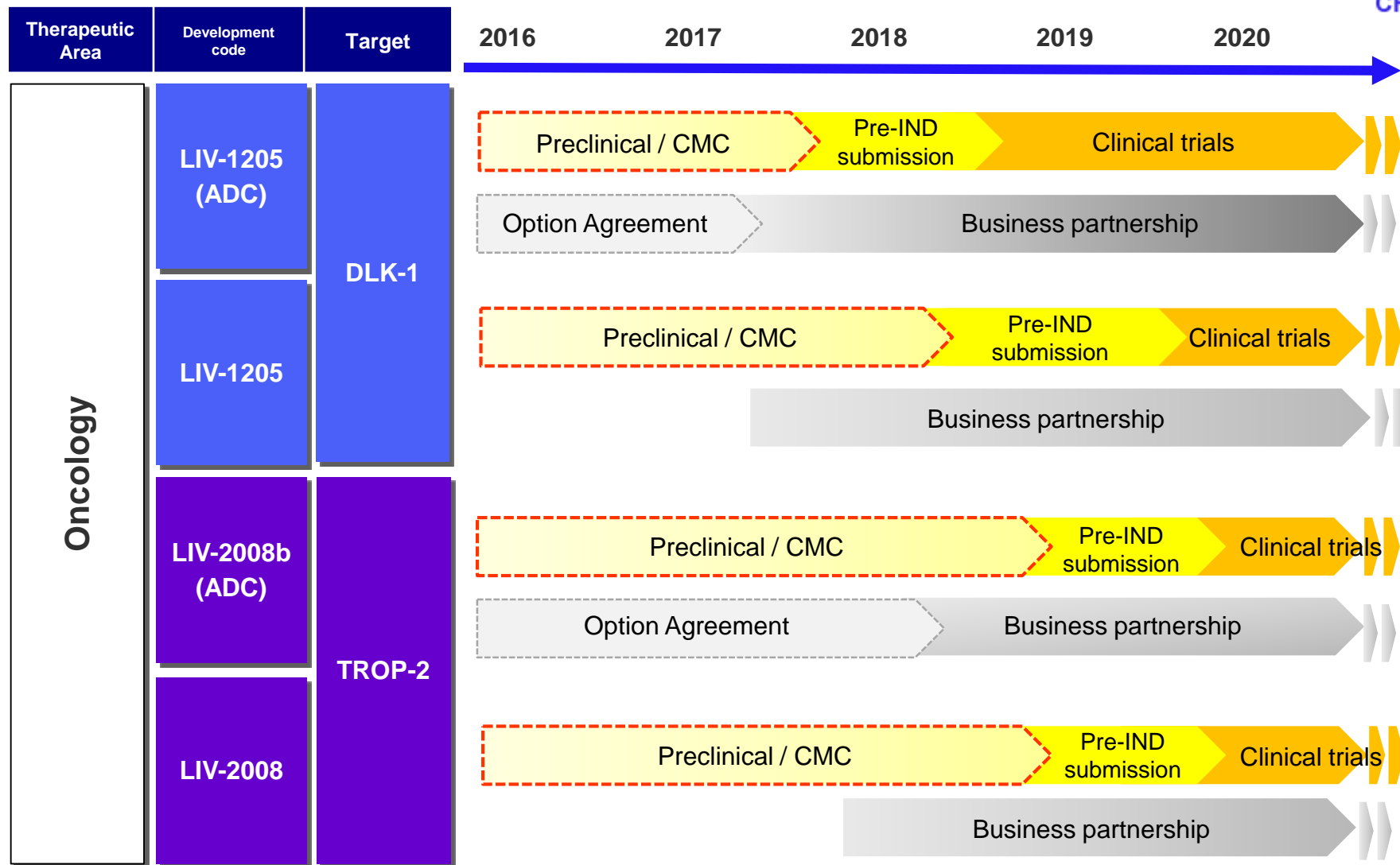
- Preclinical testing program for childhood cancers led by NCI
- Test new agents in pre-IND stage in adult
- Evaluate anticancer activity in child patient-derived xenograft model (PDX model). Potential candidates will be tested in clinical trials



- ✓ **Started in Oct. 2016**
- ✓ **Preclinical development of LIV-1205 for childhood cancer**



# Development timeline



dotted frame : ongoing milestone

CMC: Chemistry, Manufacturing and Control  
IND: Investigational New Drug

# Profile : LIV-1205 • LIV-2008/2008b

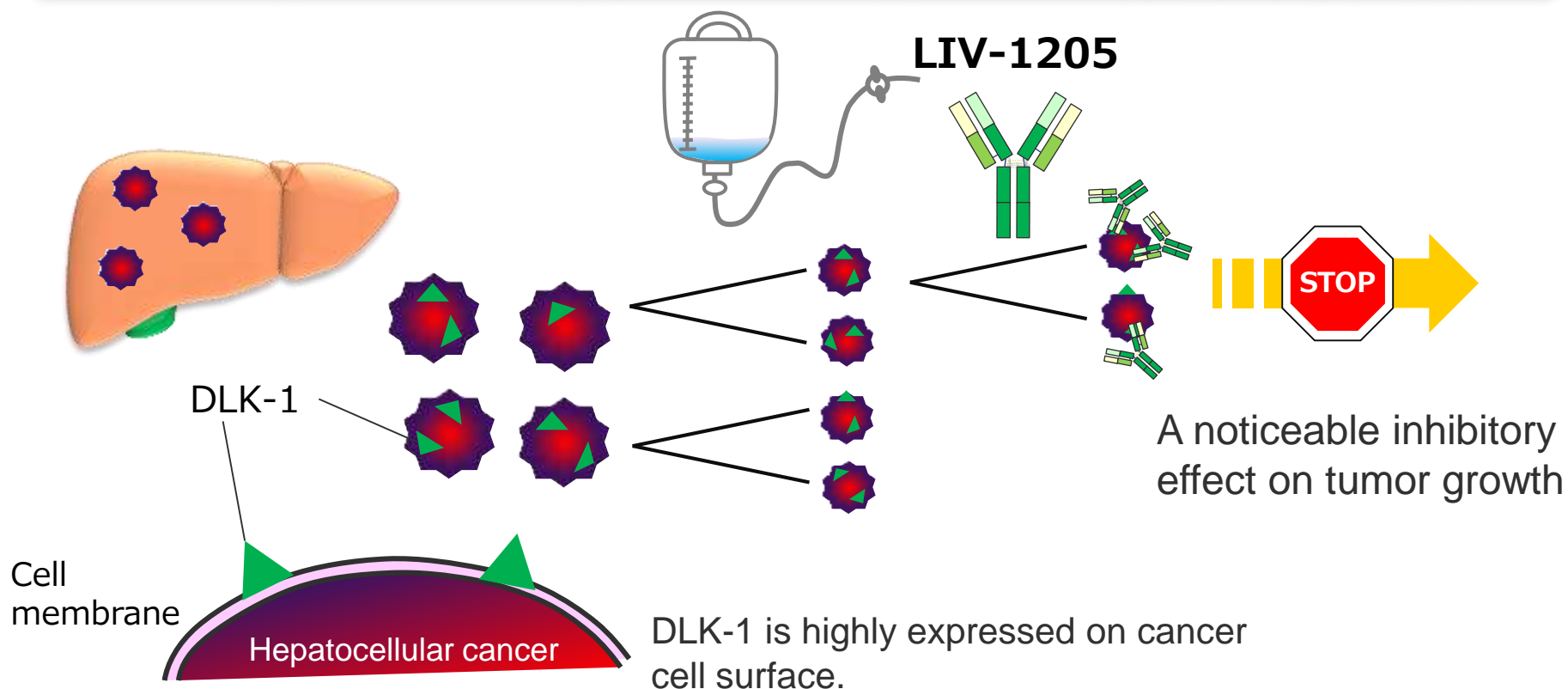


	<b>LIV-1205</b> (Humanized anti-DLK-1 antibody)	<b>LIV-2008/2008b</b> (Humanized anti-TROP-2 antibody)
Target	DLK-1	TROP-2
Therapeutic Area	Liver cancer, lung cancer, neuroblastoma etc.	Breast cancer (TNBC), lung cancer, colorectal cancer etc.
Characteristics	Potentially lower side effects compared to existing medication	TROP-2 is overexpressed in various types of cancer cells, suggesting its role as therapeutic target.
Expectation	First-in-class therapeutic antibody targeting intractable cancers	Best-in-class therapeutic antibody targeting breast cancer (TNBC), lung cancer etc.
Naked antibody	LIV-1205 exhibited a noticeable inhibitory effect on tumor growth using animal model with single-agent administration	Potent anti-tumor activity has been observed in various cancers with single-agent administration of naked antibody (LIV-2008) animal model.
Fitness for ADC	LIV-1205 has internalization activity	LIV-2008b has internalization activity

TNBC: Triple-negative breast cancer

Internalization: A phenomenon that antibodies being taken into cells after binding to the antigen

## LIV-1205 binds to DLK-1 expressed on cancer cell surface and inhibits its proliferation activity

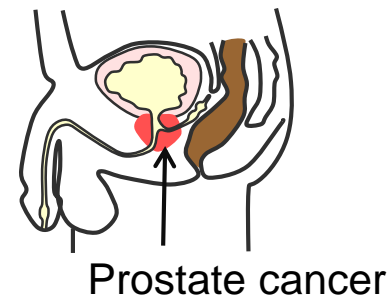
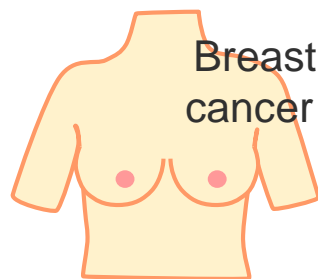
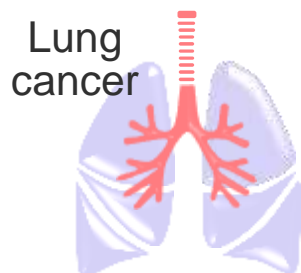
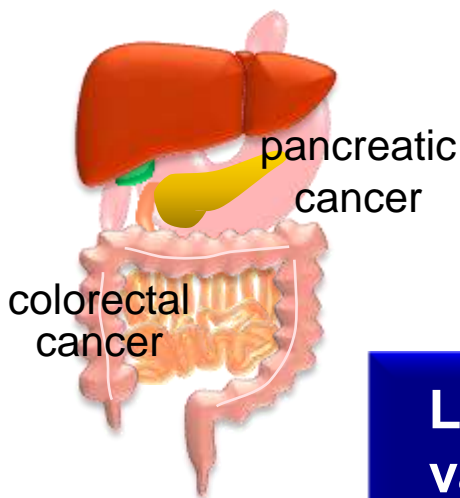


DLK-1 is a positive regulator of stem cell and precursor cell growth and differentiation

**The expression of TROP-2 on various cancer cell surface is associated with tumor malignancy**

**A novel therapeutic target for cancer**

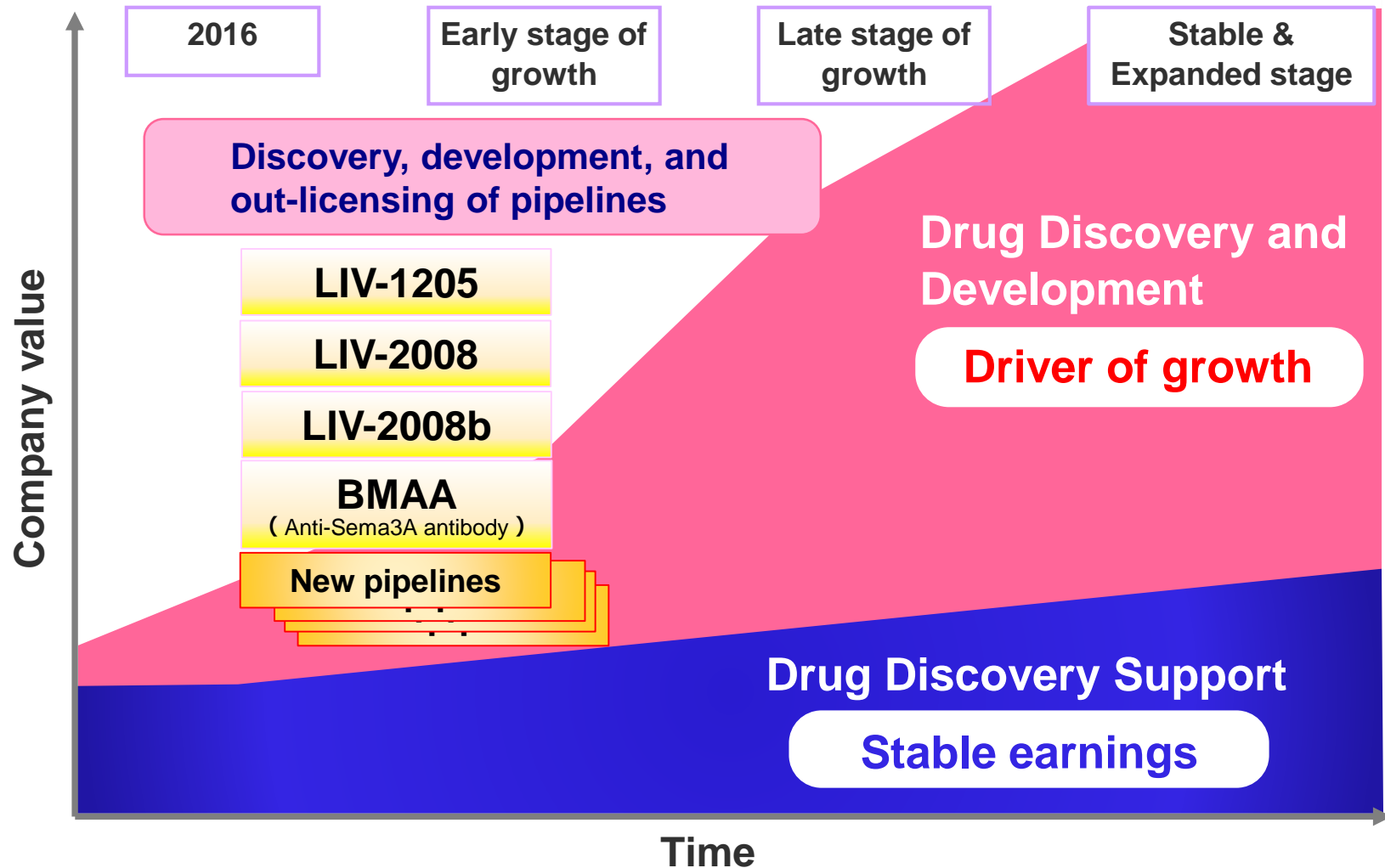
Elevated expression of TROP-2 compared to normal tissues has been observed in various type of cancer, including breast cancer (TNBC), colorectal cancer, pancreatic cancer, prostate cancer, lung cancer, etc.



**LIV-2008/LIV-2008b bind to TROP-2 that express on various intractable solid tumor cell surfaces and inhibit cancer proliferation activity**

# Long-term business strategy

**Focused investment on Drug Discovery and Development business for boosting corporate value**



## Maximize the value of Drug Discovery and Development segment



**Secure funds for operation and maximize efficiency of investment by reforming operational structure and focusing on selected business**

**Secure stable earnings by promoting Drug Discovery Support**

**Shape the organization to achieve higher efficiency that can afford early clinical development costs, boosting corporate value**

- **Concentrate on drug development programs targeting unmet medical needs and collect data required for out-licensing**
- **Expand pipelines by actively introducing novel targets and discovery technologies through collaboration or alliance.**

# Our mission

**For all people around the world who are waiting for new medication**

**1st  
Stage**

**We strive for creating novel technologies for drug discovery based on genetic diversity**

**2nd  
Stage**

**We deliver innovative medicines**

**3rd  
Stage**

**We bring revolutionary innovation into the medical care**

**We aim for “a conversion into business model that produces high-added value”**

# Contribute to human society

**We will be,  
“A healthcare innovator that pursues  
100% treatment efficacy”**

## Key milestones toward our vision

**2018 Countermeasures against pandemic  
infectious diseases**

**2023 Fulfill the ultimate personalized medicine**





**Ethics & Transparency**

**Evolution & Creation**

**Chiasma & Global Exchange**

*We strive to be a sound, well-respected company that values human life.*

*We strive to create the future through the development of each person and the company as a whole.*

*We are committed to the transcendence of national and international borders.*



# Disclaimer

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