

# **Supplement Documents for Financial Results Q2 FY12/19**

August 13, 2019



To accelerate drug discovery and development of mAb for therapeutics to overcome current medical unmet-needs

**Chiome Bioscience Inc.** 



- 1. Overview of Q2 FY12/19 "Financial results"
- 2. Overview of Q2 FY12/19 "Operation highlights"

Appendix.

**Corporate information Pipeline information** 

# Overview of Q2 FY12/19 "Financial results"

#### **Financial results: Profit and Loss**



(JPY mn)

	Q2 FY2018	Q2 FY2019	Increase (decrease)	
Net sales	92	140	48	
Drug Discovery & Development	0	1	1	<ul> <li>Option fee for BMAA corresponding to the period of second year.</li> </ul>
Drug Discovery Support	92	139	47	<ul> <li>Growth in business with Chugai Pharmaceutical Group and Ono Pharmaceutical.</li> </ul>
COS/SGA	699	890	190	
R&D Expense	435	636	200	<ul> <li>Costs of preclinical studies and manufacturing of drug substance of CBA-1205.</li> </ul>
Other costs	264	254	(10)	
Operating Loss	(607)	(749)	(142)	
Ordinary Loss	(603)	(758)	(155)	
Net Loss	(603)	(757)	(153)	

#### **Financial results: Balance Sheet**



(JPY mn)

	As of Dec. 31,2018	As of June 30, 2019
Current assets	2,609	3,205
(Cash on hand and in banks)	2,328	2,899
Non-current assets	221	217
Total assets	2,831	3,422
Current liabilities	113	206
Non-current liabilities	41	41
Total liabilities	154	247
Total net assets	2,676	3,174
Total liabilities and net assets	2,831	3,422

#### Financial results: Cash Flows



(JPY mn)

	Q2 FY2018	Q2 FY2019
Cash flows from operating activities	(690)	(677)
Cash flows from investing activities	_	_
Cash flows from financing activities	(4)	1,248
Net increase (decrease) in cash and cash equivalents	(694)	570
Cash and cash equivalents as of the beginning of the year	4,027	2,328
Cash and cash equivalents as of the end of the year	3,332	2,899

#### (Cash flows from operating activities)

• Expenses for CMC development to manufacture CBA-1205 for clinical development.

#### [Cash flows from financing activities]

• Proceeds from issuance of shares resulting from exercise of subscription rights to shares by Merrill Lynch Japan Securities Co., Ltd.

# Overview of Q2 FY12/19 "Operation highlights"



#### **Drug Discovery and Development Business**

To discover and develop novel antibody drugs in-house or in collaboration with a partner up to late pre-clinical stage which enables to prepare data package for IND or early clinical stage in therapeutic areas where high unmet medical needs exist. The drug candidates will be out-licensed to pharmaceutical company under appropriate financial conditions such like upfront, milestone, and royalty payments etc.

#### **Drug Discovery Support business**

To provide "fee-for-service" to pharmaceutical and diagnostics company, and academia to support their research works. Main line of this business is 1) to generate a monoclonal antibody for their targets by our proprietary platform, and 2) to express, culture, and purify proteins including antigen and antibody.

#### **Pipeline**



#### **Out-Licensed Product**

Code	Target	Therapeutic Area	Basic research, Drug Discovery	Preclinical Study	Clinical Trials	Partner
ADCT-701 (LIV-1205 ADC)	DLK-1	Oncology /ADC	Pla	an to submit IND	in late 2019	THERAPEUTICS

#### **Pipelines**

Project	Target	Therapeutic Area	Basic research, Drug Discovery	Preclinical Study	Clinical Trials	Status
CBA-1205 (ADCC enhanced)	DLK-1	Oncology				Developing in- house
CBA-1535 (Tribody)	5T4×CD3 ×5T4	Oncology				Developing in- house
LIV-2008 /2008b	TROP-2	Oncology				Licensing opportunity
ВМАА	SEMA3A	DME, Others				SemaThera (Exclusive option agreement)
Discovery PJ (5)	Undisclosed	Oncology infectious/ rare diseases				_

#### **CBA-1205**

Humanized afucosylated anti-DLK1 antibody

- ✓ Preparation for a clinical study is on track.
- CMC works are proceeding to meet the regulatory requirements before entering into a clinical study.
- ✓ Phase 1 study is scheduled to initiate in 2020 or afterwards.

#### CBA-1535

Humanized anti 5T4/WAIF1 antibody, multi-specific antibody

- ✓ CMO and CRO selection towards clinical development.
- ✓ We expect to submit an Investigational New Drug
  Application (IND) in the second half of 2021.

#### LIV-2008

Humanized anti-TROP2 antibody

✓ Under evaluation for in-licensing by several pharmaceutical companies.

#### **BMAA**

Humanized anti-Semphorin3A antibody ✓ Being evaluated by SemaThera Inc. under Collaborative Development License and Exclusive Option Agreement concluded in March 2018.

#### **Discovery PJ**

✓ Compiling Preclinical data package for licensing opportunity

## License agreement with Fujirebio in relation to its new diagnostic kit consists of antibody from ADLib® system

- ✓ A new licensing agreement with Fujirebio was concluded on June 18,2019.
- ✓ This Agreement allow them of using Chiome's intellectual property rights related to the second diagnostic kit consist of antibody produced by the ADLib® system. Chiome will receive future royalties on product sales by this agreement.
- ✓ Fujireio has successfully obtained an antibody which has been further developed to a new diagnostic kit. This is the second product that uses an antibody generated by ADLib® system. Fujirebio has already initiated sales of diagnostic kit containing an antibody for Vitamin D obtained by the ADLib® system in Europe in 2014 and Japan in 2017.

#### Fujirebio Inc.

Fujirebio inc. (Head office: Tokyo, Japan) is a international healthcare company founded in 1950, and has more than 50 years' accumulated experience in the discovery, development, manufacture and worldwide commercialization of robust in vitro diagnostics (IVD) products.

## **Execution of the Basic Entrusting Service Agreement** with Kyowa Kirin Co., Ltd.

- ✓ The Basic Entrusting Service Agreement with Kyowa Kirin Co., Ltd.. was concluded as of July 29, 2019.
- ✓ The services under the individual contracts which Chiome has been providing since 2018 have been positively evaluated. This master agreement was concluded for further steady and sustainable business.

#### **Services provided under the Agreement**

- ✓ Antibody generation, including works such as preparation of antigens and proteins required for antibody generation
- ✓ Generation of monoclonal antibodies by using Chiome's antibody platform technologies

#### **Kyowa Kirin Co., Ltd.**

Kyowa Kirin Co., Ltd. (Head Office: Tokyo, JAPAN) is an R&D-based life sciences company with special strengths in biotechnology. Kyowa Kirin is dedicated to human health and well-being worldwide through innovative drug discovery and global commercialization, driven by state-of-the-art antibody technologies, in the core therapeutic areas of oncology, nephrology, central nervous system and immunology.

#### **Drug Discovery Support**



#### Business with pharmaceutical companies, etc.

- ✓ Steady growth in Net Sales (an increase of 51% year on year)
  - ✓ Transactions with Chugai and Ono have steadily grown.
  - ✓ Provided services of antibody generation and protein related technical service to pharmaceutical companies, research institutions, and universities.
  - ✓ Continue to strive for expanding new accounts by offering high quality service, and for improving our technologies.



#### **Financing**

- > Series 14th Subscription Rights to Shares
  - ✓ Status of Exercise(as of end of July 2019)

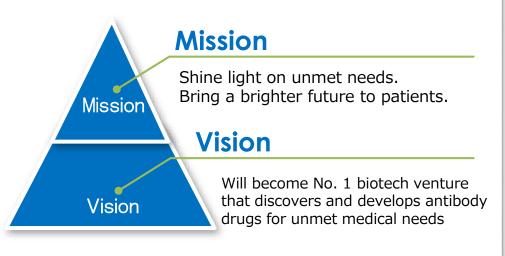
Total number of shares exercised	6,353,000 shares (98.83% of total rights)	
Total value exercised	1,323 million JPY	

✓ Use of funds

Use of funds	Cost(million JPY)	Scheduled period of spending
① Pre-IND submission and early-phase clinical trials for CBA-1535	1,200	Apr.2019~ Dec.2021
② Expansion and licensing-in of new pipelines	282	Jan.2019∼ Dec.2020

### **Appendix.** Corporate information

#### Biotech company dedicating to satisfy unmet medical needs



#### Management principle

- Place the highest priority on sound management and credibility and aim to become a corporation that grows with society.
- With creativity and science, develop therapeutic drugs for unmet medical needs, and contribute to the health of patients.
- Achieve successive product pipelines and improvement of corporate value through collaboration with external institutions.

- Founded: February 2005
- Listed on the stock exchange:

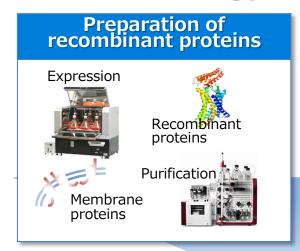
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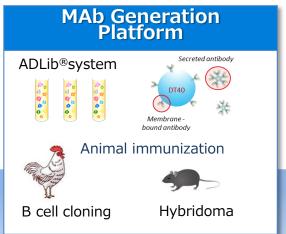
  (Tokyo Stock Exchange Mothers Section)
- President and Chief Executive Officer: Shigeru Kobayashi, M.E.
- Location:
- <Head Office and Research Laboratories> 3-12-1Honmachi, Shibuya-ku, Tokyo <Drug Discovery Laboratories> 907 Nogawa, Miyamae-ku, Kawasaki-city, Kanagawa
- Number of Employees: 53 (As of July 31,2019)
- Business: Chiome Bioscience (4583.T), is a public company leveraging a proprietary monoclonal antibody generating technology, for drug discovery and development, as well as providing drug discovery supports.

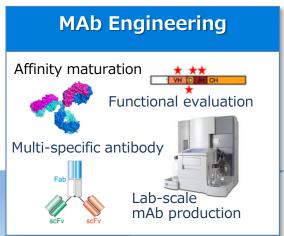
#### **Core competence for developing business**



#### Technology Platform (Chiome's mAb Discovery Engine)







Chiome possesses antibody platforms including its proprietary technology, and extensive know-hows and experiences in protein/antibody engineering to streamline the process of drug discovery.

This enables us to contribute in

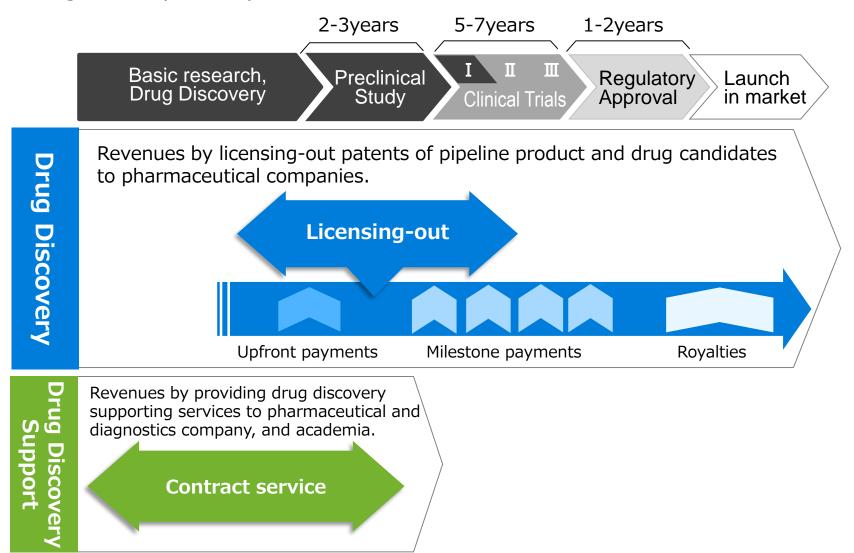
## Drug Discovery and Development

Development of therapeutic drug and diagnostic agent

#### **Drug Discovery Support**

Contract service for drug discovery

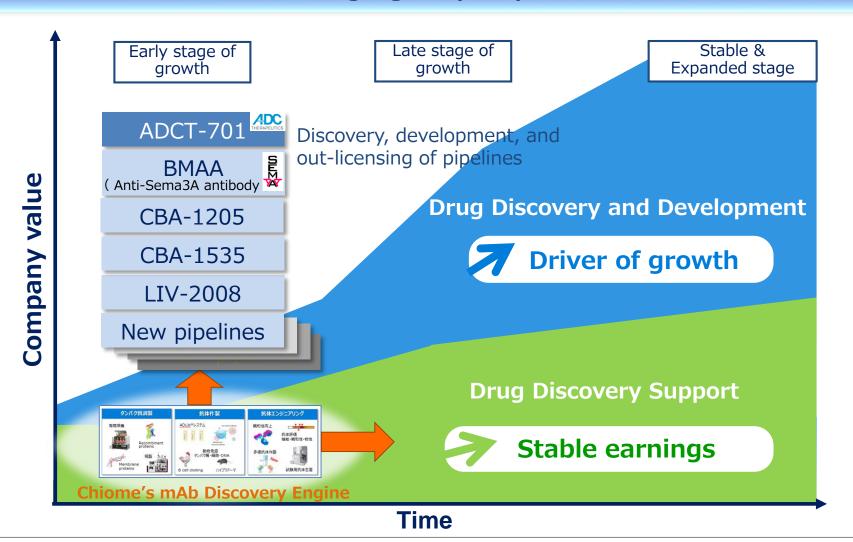
#### Drug development process and Chiome's revenue model



#### Our stability and growth potential



Core technology will sustain continuous development of therapeutic antibody while offering higher quality of service



### **Appendix. Pipeline information**

#### **Pipeline -Out-Licensed-**



#### **ADCT-701\*** (Humanized anti-DLK1 antibody ADC)

- ✓ An Antibody Drug Conjugate (ADC) form of LIV-1205 that was licensed out to Switzerland-based ADC Therapeutics SA in September 2017.
- ✓ Its development is on track where the final stage of pre-clinical study is about completing.
- ✓ An Investigational New Drug Application (IND) is expected to be submitted in late 2019.

\*Chiome granted ADCT a worldwide exclusive license with a right to sublicense, develop, manufacture, and commercialize an ADC format of LIV-1205, which is coded "ADCT-701".



#### Pipeline -In-house program-



#### CBA-1205 (Humanized afucosylated anti-DLK1 antibody)

First in class

- An ADCC enhanced antibody by applying glyco-engineering technology.
- GMP production of the drug substance for Phase 1 study has completed.
- Clinical Development Department was set up to carry out the clinical development. They select a CRO for Phase 1 and are working on the clinical development plan.
- Based on the preclinical data and timeline of GMP manufacturing, Phase 1 study is scheduled to initiate in 2020 or afterwards.

#### CBA-1535 (Humanized anti 5T4/WAIF1 antibody, multi-specific antibody)

First in class

CBA-1535

(Tribody)

- ✓ CBA-1535 is a T-cell engager, trispecific antibody, directed against the 5T4 tumor antigen, a protein found on various solid tumors and is thought to be involved in metastasis.
  - Cancer cell
- CMO&CRO selection is proceeding towards clinical development
- We expect to submit an Investigational New Drug Application (IND) in the second half of 2021.

#### Pipeline -In-house developed-



#### LIV-2008 (Humanized anti-TROP2 antibody)

- ✓ LIV-2008 is a humanized monoclonal antibody targeting cell surface antigen "TROP-2" which is overexpressed in breast cancer, colon cancer, lung cancer and several types of solid cancers and also expected to play a key role in the proliferation of cancer cells.
- ✓ The patent was granted in the US in October 2018. (Patents have become effective in a total of five countries and region, including Japan, EU, and China.)
- ✓ Licensing activities continue based on the pre-clinical testing data obtained thus far. A couple of pharma companies are evaluating this antibody.

#### **BMAA** (Humanized anti-Semphorin3A antibody)

First in class

- ✓ Being evaluated by SemaThera Inc. which will decide whether or not to exercise the option right by the end of the evaluation period specified in the Agreement.
- ✓ Following US, Patent has been issued in Japan (Jun., 2018) and in Europe (Oct., 2018).

\*Chiome has granted SemaThera Inc. an exclusive option right to obtain a worldwide exclusive license to develop the antibody as a therapeutic and/or diagnostic agent for diabetic macular edema and other diabetic complications including non-ophthalmic diseases.





- Materials and information provided during this presentation may contain so-called "forward-looking statements." These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements.
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