MediBic
株式会社 メディビックグループ


# Investor Presentation

April 2011

# Agenda

- Company Overview
- Mission
- Stock Information
- Consolidated Financial Data
- Financing
- “Going Concern” Note Removed
- Business Update
    1. Personalized Drug Development
    2. Personalized Healthcare Management Support
    3. Drug Development – Cancer Drug “Glufosfamide”
    4. Investment
- Progress Summary

# Company Overview

| | | |
|---|---|---|
| Founded | Feb 2000 | |
| IPO | Sep 2003<br>Tokyo Stock Exchange – Mothers Code 2369 | |
| Headquarters | Tokyo, JAPAN | |
| Representative | Yasuhiro Hashimoto, M.D. President & CEO | |
| Group Companies | MediBIC Pharma, Co., Ltd. | Drug Development |
| | MediBIC Co., Ltd. | Healthcare Management Support |
| | Site Quality Co., Ltd. | Clinical Trial Support |
| | Asia Private Equity Capital, Co., Ltd. | Investment |
| Customers | 20+ major pharmaceutical companies, research institutes and universities | |
| Mission | Realizing Personalized Medicine | |

# Mission

MediBic
株式会社メディビックグループ

## *Realizing Personalized Medicine*

**Personalized Drug Development:**

To develop a new drug designed for each individual

**Personalized Healthcare Management:**

To provide medical treatment and health management

# Stock Information

| | |
|---|---|
| Market | Tokyo Stock Exchange – Mothers Code 2369 |
| Capitalization | 2,166 million yen* |
| Market Cap | 1,678 million yen* |
| Issued Shares | 201,042 shares* |
| Stock Price | 8,350 yen* |
| Accounting Period | December |

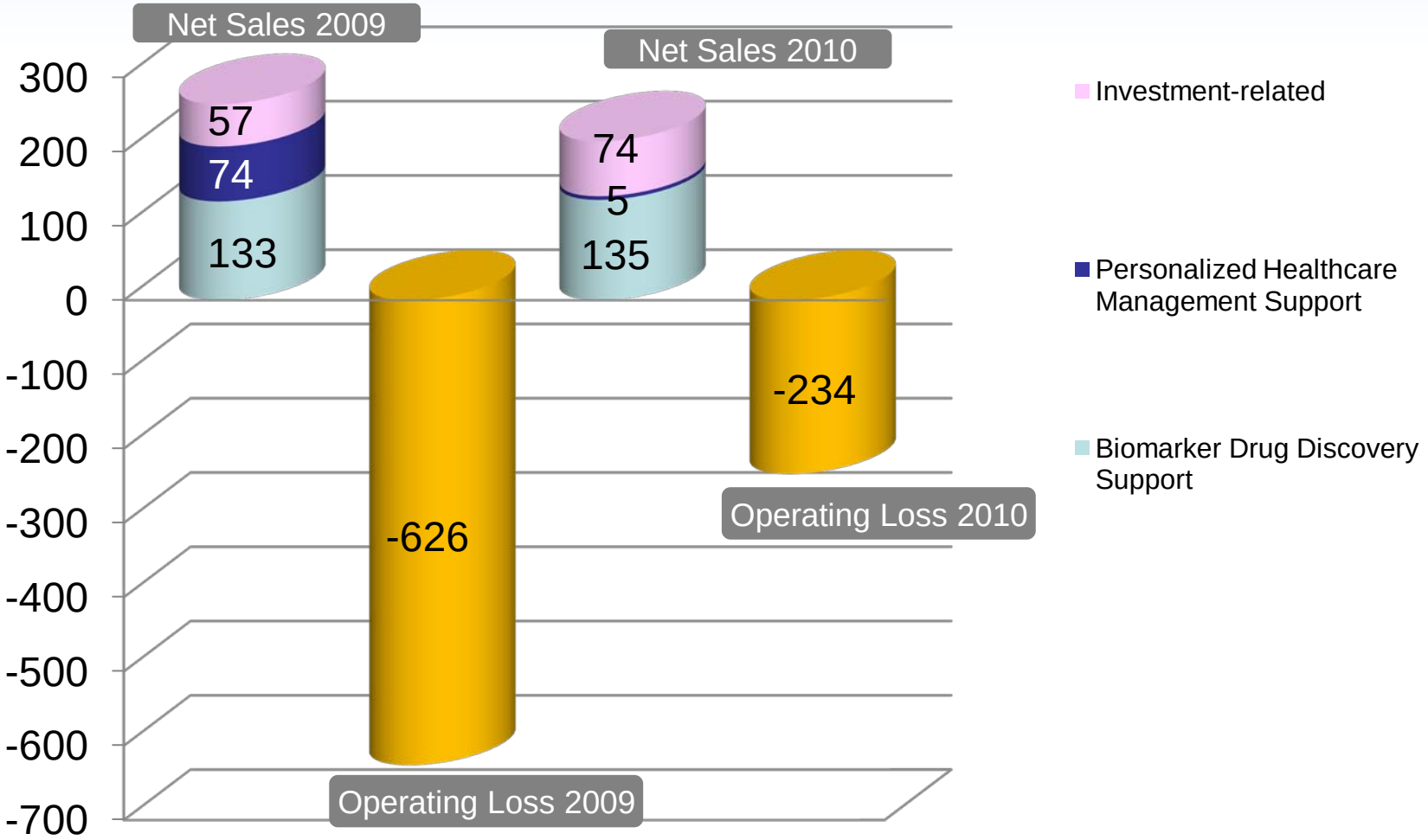
*as of Feb 28, 2011

# Consolidated Financial Data – Dec 2010

('000 yen)

| | Dec 2009 | Dec 2010 | Dec 2011 (Estimate) | 2010 vs 2009 |
|---|---|---|---|---|
| Net Sales | 266,239 | 214,758 | 200,000 | △51,481 |
| Ordinary Income | △609,533 | △257,300 | △192,000 | 352,233 |
| Net Income – 4th Quarter | △615,542 | △263,295 | △193,000 | 352,247 |
| Net Assets | 396,550 | 255,229 | – | △141,321 |
| Total Assets | 475,796 | 334,165 | – | △141,631 |
| Net Income per Share | △3,492.60 | △1,465. 68 | △1,012.90 | 2,026.92 |

# Consolidated Financial Data – 2010 vs 2009



# Consolidated Financial Data - 2010

- **Biomarker Drug Discovery Support Business**
  Secured operating profit due to the strong result in our Pharmacogenomics (PGx) test support services for new drug development.

- **Personalized Healthcare Management Support Business**
  The profit side was greatly improved through the cost reduction though the sales declined. “Genetic Testing for Drug Response”, a newly launched service, is expected to be the next profit-making source.

- **Investment Business**
  The sales grew by successful disposal of business investment securities. The profit side was much improved after recognizing impairment losses.

# FY2011 Estimates

## Sales

The same level as FY2010 results

- Our new service “Genetic Testing for Drug Response” is expected to contribute to the sales in the second half of FY2011.
- Sales from the Investment Business is estimated to decrease from FY2010.

## Profit

Will be improved from FY2010 results

- Decrease in sales from the Investment Business will reduce the deficit.
- Our continuous efforts for cost-cutting since mid last year will be further effective for reducing the deficit.

# Financing

| | |
|---|---|
| Method | Issuance of Share Purchase Warrants |
| Issue Date | November 1, 2010 |
| Numbers of Rights (Shares) Issued | 260 rights (for 26,000 shares) |
| Exercise Price | 8,325 yen |
| Exercise Period | November 1, 2010 – October 31, 2012 (two years) |
| Financing Target | 217 million yen |
| Amount Financed | 171 million yen (20,500 shares) |
| Changes in Numbers of Shares Issued | Nov 2010 end Feb 2011 At Completion<br>180,542 shares => 201,042 shares => 206,542 shares |

# “Going Concern” Note Removed

- FY 2010
  - 42 million yen financed by exercising the 3rd Share Purchase Warrants and Stock Options
  - 68 million yen capitalized by disposing business investment securities.
  - 83 million yen financed by exercising the 4th Share Purchase Warrants (Nov – Dec ‘10)

- Jan - Feb 2011
  - 87 million yen financed by exercising the 4th Share Purchase Warrants (Jan – Feb ‘11)
  - 80 million yen credit line provided by the Financing Support Agreement

# 1. Personalized Drug Development - Service Overview

Foundation for Biomedical Research and Innovation
財団法人先端医療振興財団

Partnership

MediBic

A central organization designed to work in cooperation with industry, government and academic institutions to carry out clinical research and technological development in the field of cutting-edge medical treatment with the overall aim of improving standards of medical services and helping to bring medical-related industries closer together.

Pro-Cluster Kobe

Institute of Biomedical Research and Innovation Laboratory (IBRI)

Translational Research Informatics (TRI) Center

**Sample Storage & Management Business Started on 11/7/2005**

Facility
- •Ultralow temperature freezer
- •Liquid nitrogen freeze preservation container (liquid- and gas-phase)
- •Sample control system
- •Anonymization system

Samples

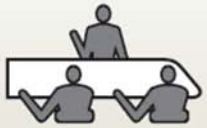
Blood samples (whole blood, serum etc), DNA samples, Urine samples, Spinal fluid samples (incl. PK samples)

Operated by

The Foundation for Biomedical Research and Innovation (FBRI)
MediBIC Co., Ltd.

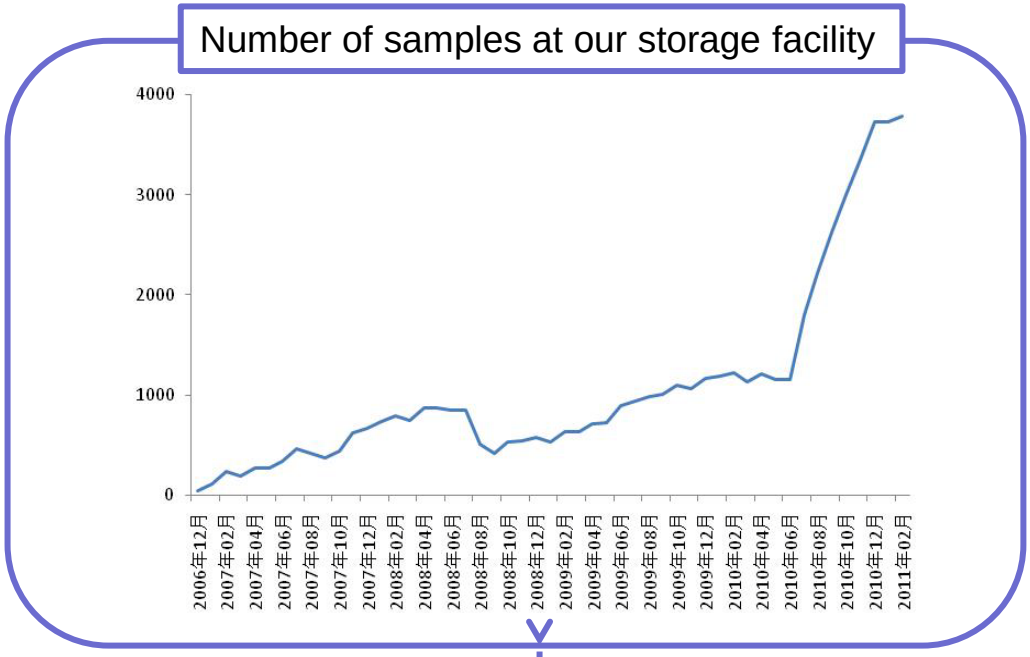
# 1. Personalized Drug Development - PGx Trials Total Support

■ MediBIC offers total consultation to support drug development, which is undergoing a change toward Tailor-made drug discovery. Our services include consultation on protocol planning for PGx trials, data analysis, support for new drug application.

| (1) Strategy Development | (2) Trials Planning & Preparation | (3) Trials Implementation & Management | (4) Data Analysis | (5) Commercialization |
|---|---|---|---|---|
|  |  |  |  |  |
| Strategy development & document preparation service | | | Contracted analysis | in vitro diagnostic (IVD) & Application support |
| | Anonymization service | | Anonymization system | |
| | Site management service | | Sample management system | |
| | Sample storage service | | | |

# 1. Personalized Drug Development - PGx Clinical Trials Support

- Number of samples in our storage facility , a major indicator of PGx business, has increased rapidly.
- In Feb 2011, the US FDA has issued a PGx draft guidance, which may further increase in the number of sample  storage  and stored samples.




***PGx Total Solution Services***

Infrastructure development | Operation Support | **Sample Storage** | Wet Analysis Contract Research | Data Analysis

# 1. Personalized Drug Development - PGx System Support

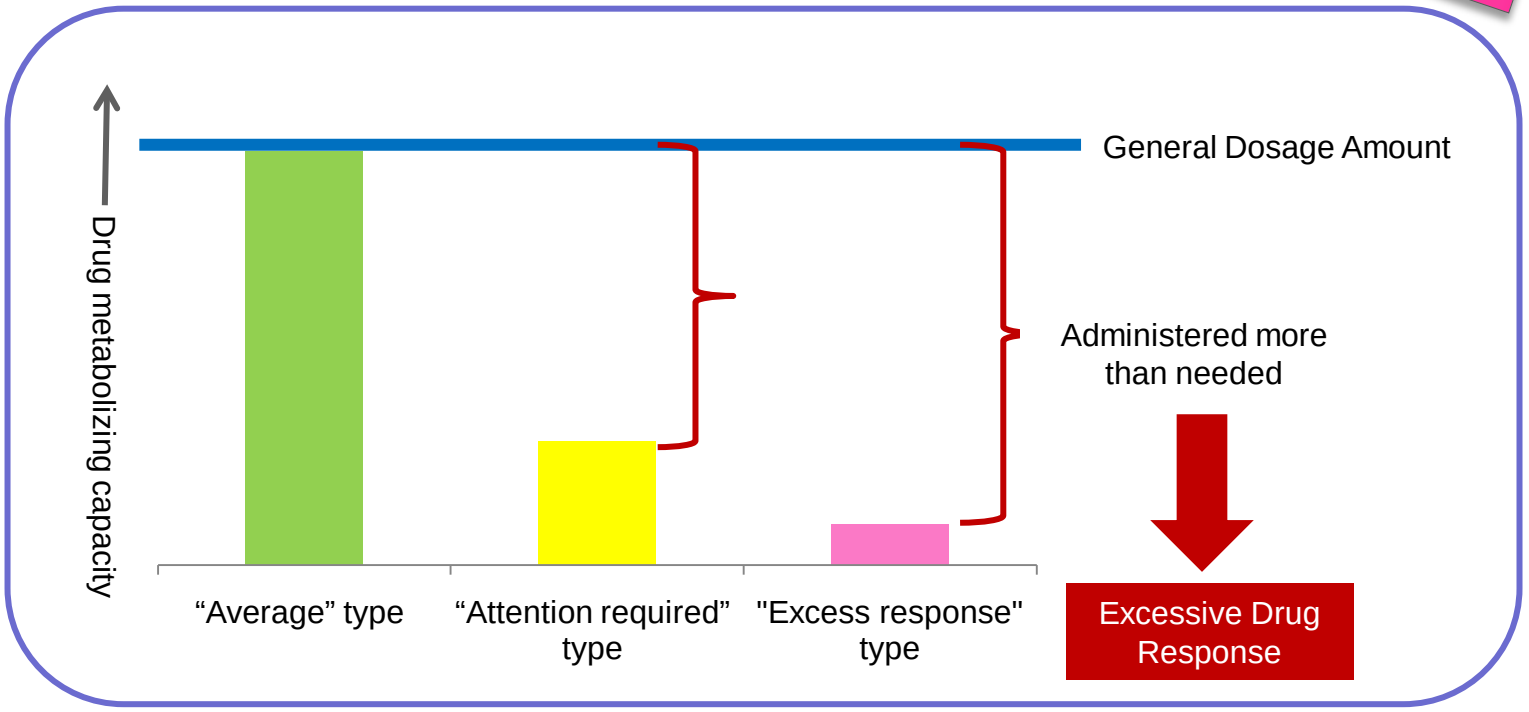
- Sample Tracking System
  - System essential to develop personalized medicine (PGx trial)
  - Manages sample information including storage condition and sample location
  - Can connect sample information to clinical data and test results
  - Anonymization in compliance with the Personal Information Guideline


✓Sole system for sample management used in Japan

✓Growing orders from pharmaceutical companies and national research institutions

# 2. Personalized Healthcare Management - “Genetic Testing for Drug Response” Service


- “Genetic Testing for Drug Response” is a DNA screening test designed for individuals to find out if his/her genetics will affect excessive response to some drugs.



# 2. Personalized Healthcare Management - “Genetic Testing for Drug Response” Service

- The 4 important variants of Cytochrome P450 (CYP) are tested, which cover metabolism of over 80% commercially available drugs.


CYP1A2

CYP2C9

CYP2C19

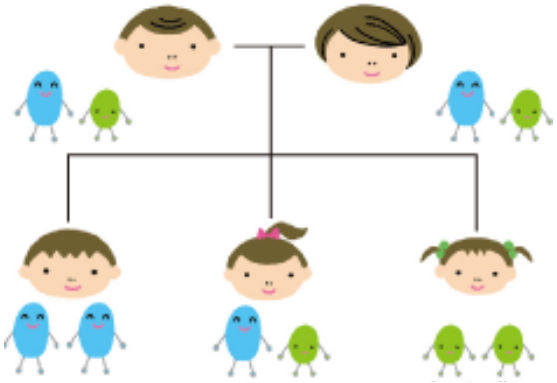
CYP2D6

# 2. Personalized Healthcare Management - Ethical Issues in Genetic Testing

- Genetic testing identifies genetic information owned by each individual innately.

**What makes genetic testing special?**

1. No change in the test result through lifetime
2. Family members share a part of genetic information
3. Genotype and phenotype of a family member can be predicted at a relatively high level of accuracy




**Ethical issues must be considered based on the characteristics of genetic information**

# 2. Personalized Healthcare Management - New Guidelines for PGx Genetic Testing

The results of genetic tests do not change through lifetime, and family members share a part of the genetic information. HOWEVER, phenotype is not always expressed, or is not predicted perfectly.

*Even if a gene is determined to cause a serious side effect of a certain medication, and his/her relatives share the same risk, the relatives still can avoid taking the specific medicine. There are few cases either where the medication is required in their lifetime. For the reasons above, it is thought that the level of the ethical issues on pharmacogenomics information is considerably lower than that on single-gene disease.*

**"Guideline for pharmacogenomics-applied clinical research and testing", The Japan Society of Human Genetics , Dec 16, 2010**

*The pharmacogenetics testsincluded in the pharmacogenomics testing can be treated as a regular clinical records at medical practice.*

**"Guideline for genetic testing and diagnostics" , The Japan Association of Medical Sciences, Feb, 2011**

**Our "Genetic Testing for Drug Response" is a genetic test categorized in PGx test, but can be treated as a clinical testing**

**The new guidelines bring a big opportunity to expand our business**

# 2. Personalized Healthcare Management - “Genetic Testing for Drug Response” Progress

| | |
|---|---|
| Sep 2010 | Started trial testing with volunteers<br>Announcement of “Guideline for pharmacogenomics-applied clinical research and testing” |
| Dec 2010 | Started pilot-sales at 4 partner clinics in Tokyo & Osaka areas<br>Exhibition & sale at the business presentation meeting |
| Feb 2011 | Announcement of “Guideline for genetic testing and diagnostics”<br>Presentation & sale to pharmacist groups |
| Mar 2011 | Started active discussion with major dispensing pharmacies on introducing the testing service<br>**Achieved 500+ orders of testing** |
| May 2011 | **Plan to launch a testing kit, a handy version of the original testing, aiming order increase** |
| Sep 2011 | **Plan to introduce a new swab specially designed for DNA collection. Patent application being prepared.** |

# 3. Drug Development
# - Cancer Drug “Glufosfamide”

- Glufosfamide, a novel small molecule with promising activity in several cancer types, was licensed from Baxter International Inc. to Threshold Pharmaceuticals, Inc. in 2003.

- In 2004, MediBIC entered into a Development Agreement with Threshold whereby MediBIC would conduct clinical development activities for Glufosfamide in certain Asian countries, including Japan, South Korea, India, China, Taiwan and Hong Kong.

- Threshold granted the exclusive license for all indications to Eleison Pharmaceuticals, Inc. in 2009. Pursuant to these agreements, Baxter and MediBIC may be entitled to certain royalty and milestone payments, if Eleison's clinical development efforts are successful.

- Previous Threshold’s Phase 3 study showed 25% improvement in median survival, but did not achieve statistical significance.

- Eleison will commence a new Phase 3 international trial in mid 2011 under a Special Protocol Assessment (SPA) agreed with FDA. Planned to be completed in 2012.

# 3. Drug Development
# - Cancer Drug “Glufosfamide”

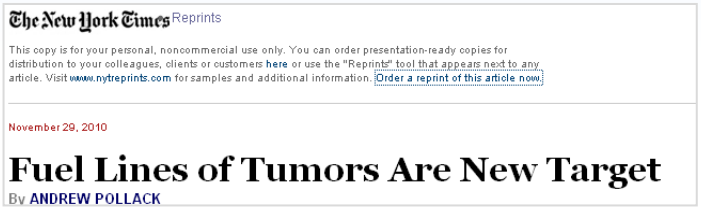
- Market Opportunity for Pancreatic Cancer Drug
  - Current market $1.1 billion worldwide
  - 40,000 new cases annually in US, 80,000 in Europe
  - Only two approved drugs for first-line (gemcitabine and erlotinib), none for second-line
  - Eventually, almost all patients will fail first-line therapy

- Indication for Glufosfamide approval study: second-line pancreatic cancer

- Off label market opportunities
  - First-line pancreatic
  - New and better alkylating agent: supplanting ifosfamide,cyclophosphamide

# 3. Drug Development
# - Cancer Drug “Glufosfamide”

- NY Times & China Daily introduced Glufosfamide as a promising cancer drug utilizing the principle of Positron Emission Tomopgraphy (PET) scan.
  - Refers possibility of the effectiveness based on data analysis of the previous trials considering patients’ blood sugar level.


The New York Times Reprints

This copy is for your personal, noncommercial use only. You can order presentation-ready copies for distribution to your colleagues, clients or customers here or use the "Reprints" tool that appears next to any article. Visit www.nytreprints.com for samples and additional information. Order a reprint of this article now.

November 29, 2010

**Fuel Lines of Tumors Are New Target**

By ANDREW POLLACK

- NIH awarded research grants in November 2010 in support of late stage drug development of Glufosfamide for pancreatic cancer.

- The European Medicines Agency (EMA) recommended the approval of Glufosfamide for Orphan Drug Designation in Europe.

- Negotiation has restarted for development and licensing in Japan and Asian countries.
  - Proposals to acquire the license from Chinese and Korean companies are being reviewed.
  - Time for approval is relatively short in both China and Korea if the same drug is approved by FDA.

# 4. Investment

■ Reviewed the holding securities individually in terms of market trend, disposal feasibility and profitability and selected stocks for disposition.

2010 Sales
- Number of stocks sold: 6 stocks
- Sales of stock disposition: 68 million yen

## FY 2011

Active discussion is underway
for disposing the holding shares
of a drug development start-up company

# Summary of Business Progress

- Financing
- “Going-concern” note removed
- Significant deficit reduction
- “Genetic Testing for Drug Response”: Big opportunity by the new guidelines
- Biomarker Drug Discovery Support Business: Operating profit secured

株式会社メディビックグループ

www.medibic.com

Contact:
Yasuhiro Hashimoto, M.D. President & CEO
MediBIC Group, Co., Ltd.
Dai2 Shiba Bldg. 3F, 27-2 Sakuragaoka-cho, Shibuya-ku, Tokyo 150-0031 JAPAN
Tel: +81-3-6415-4032
yashashimoto@medibic.com

This presentation contains forward-looking statements. Statements that are not historical facts, including statements about MediBIC Group's beliefs or expectations, are forward-looking statements. These statements are based on plans, estimates and projections at the time MediBIC Group made the original statement, and you should not place undue reliance on them. The continued inclusion of any such statements on this presentation is not a re-publication thereof. MediBIC Group does not undertake to update any of these statements in light of new information or future events.

Forward-looking statements involve inherent risks and uncertainties and MediBIC Group cautions you that a number of important factors could cause actual results to differ materially from those contained in any such forward-looking statement.