

# ***Our Challenge for Innovative Drug***

**December 10<sup>th</sup>, 2014  
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President and CEO  
Astellas Pharma Inc.**

## Cautionary Statement Regarding Forward-Looking Information

This presentation material is an English translation of a Japanese presentation material delivered on December 10th, 2014. If there is a discrepancy between any English translation of the presentation materials and original (Japanese) presentation material, the original (Japanese) presentation material shall prevail.

This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties.

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# Agenda

- **External Environment and Astellas Business**
- **Initiatives to Build Resilience for Sustainable Growth**
- **Topics**
- **New Challenge**

# Trend of Pharma Industry

No changes in the trend, although accelerated

## Cost containment measures

- Promoting generic use
- Mandatory price cutting
- Increased social security costs

## Challenges in development and commercialization

- Stricter safety review and PMS
- Necessity of differentiation from existing treatments
- Improved satisfaction level in treatment of chronic disease

## Secure Transparency and Trust

*JP "Transparency Guideline" (published from 2013)*

*US "Sunshine Act" (published from 2014)*

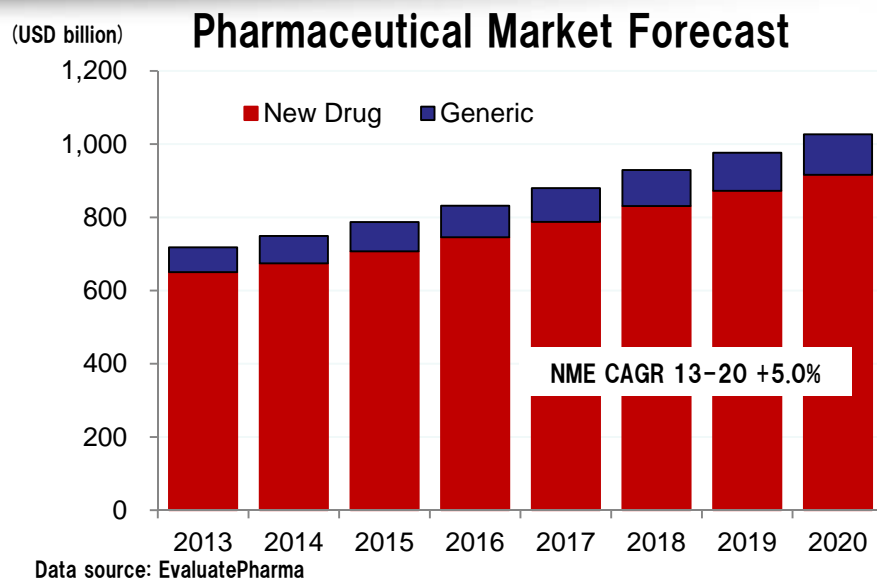
*EFPIA "Disclosure Codes" (expected in 2016)*

*EMA "Policy on Publication of Clinical Data" (published from 2014)*

*ID Medical Products (EU)*

*Drug Supply Chain Security Act (US)*

# Environment of NME Market



## Regulatory Moves for Innovation

### Examples



- ✓ Breakthrough Therapy Designation
- ✓ Qualified Infectious Disease Product (QIDP) Designation under GAIN Act



- ✓ NICE
- ✓ Early Access to Medicines Scheme (EAMS)
- ✓ Promising Innovative Medicine (PIM) Designation



- ✓ GBA (AMNOG)



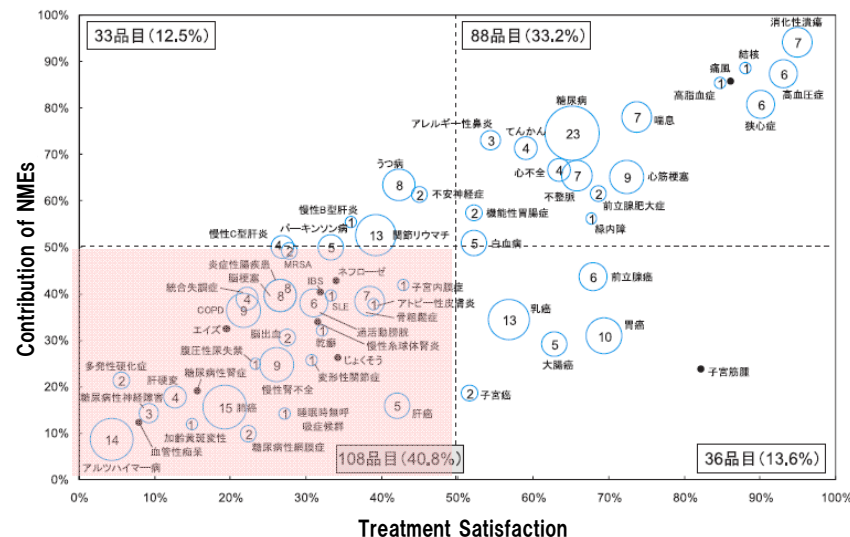
- ✓ Additional pricing for leading registration
- ✓ Leading examination system

Other Countries

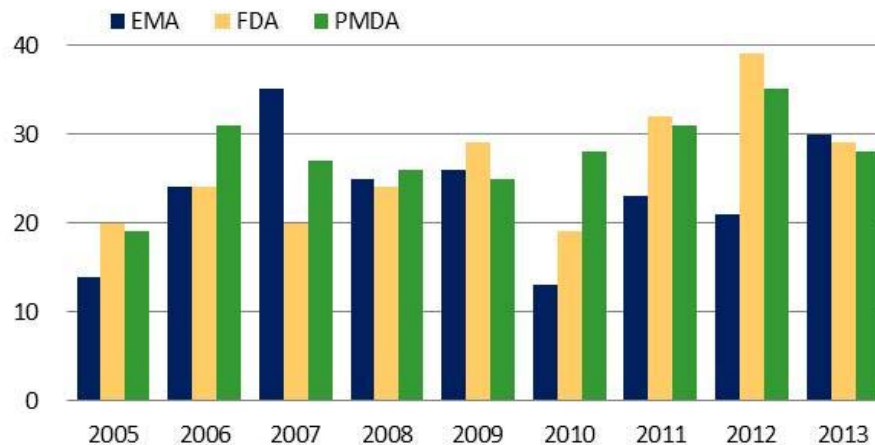
- ✓ Orphan drug designation



## NME Development and Treatment Satisfaction (Jun, 2010)



## Number of Approved NMEs



Based on the data from: Centre for Innovation in Regulatory Science Ltd

Industry

Lilly

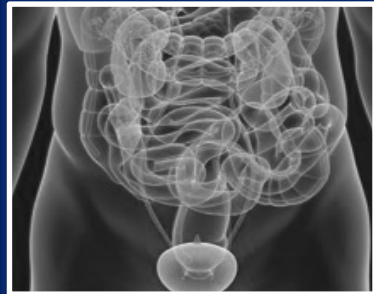
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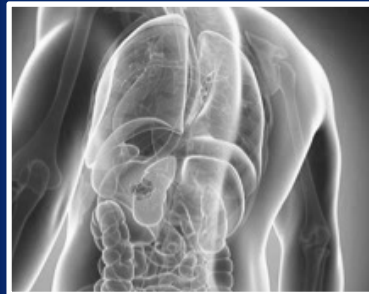
# Focus Therapeutic Area in Research and GCL Model

Concentrate Management Resources on  
Innovative Drug Business

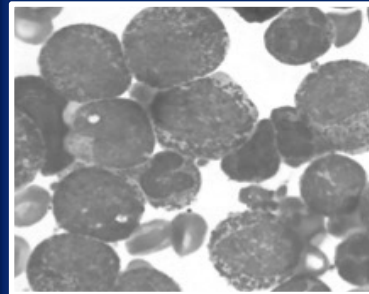
## Focus Therapeutic Area in Research



**Urology**



**Transplantation**



**Oncology**

**Immunology &  
Infectious Diseases**

**Neuroscience**

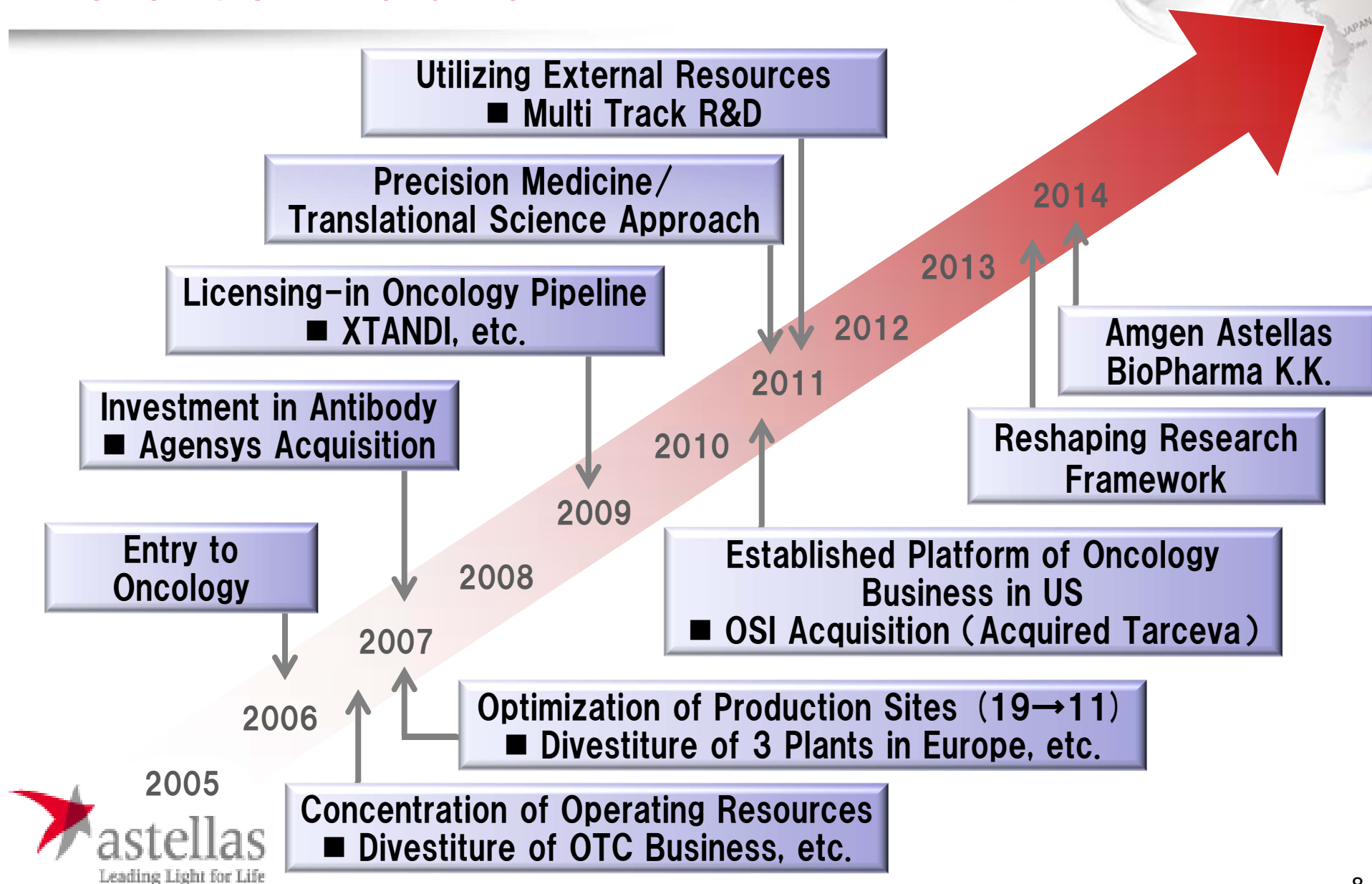
**DM Complications  
& Kidney Diseases**

**Current GCL**

**Third GCL**

**Global Category Leader (GCL)**

# Astellas Evolution



# Agenda

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- Topics
- New Challenge

# Recent Initiatives to Strategic Priority

Resiliently Respond to Changing Environments and Aim for Sustainable Growth

Growth Strategy

Maximize Value of New Products

## Extension of Growth Drivers

- Maximize OAB franchise (Vesicare and Mirabegron)
- Enhance oncology franchise (XTANDI sales growth, additional indication)

Enhance Innovation

## R&D Reshaping

- Develop new therapeutic areas and novel technology platform
- Designated 2<sup>nd</sup> FAST TRACK

Efficiency Strategy

Pursue Operational Excellence

## Optimize Resource Allocation and Utilize External Resources

- Business process outsourcing to Accenture (operations transferred by September)
- Medical Information moved directly under the CEO to enhance the cooperation with internal medical-related functions and increase transparency
- Reorganized sales offices

# Extension of Growth Drivers

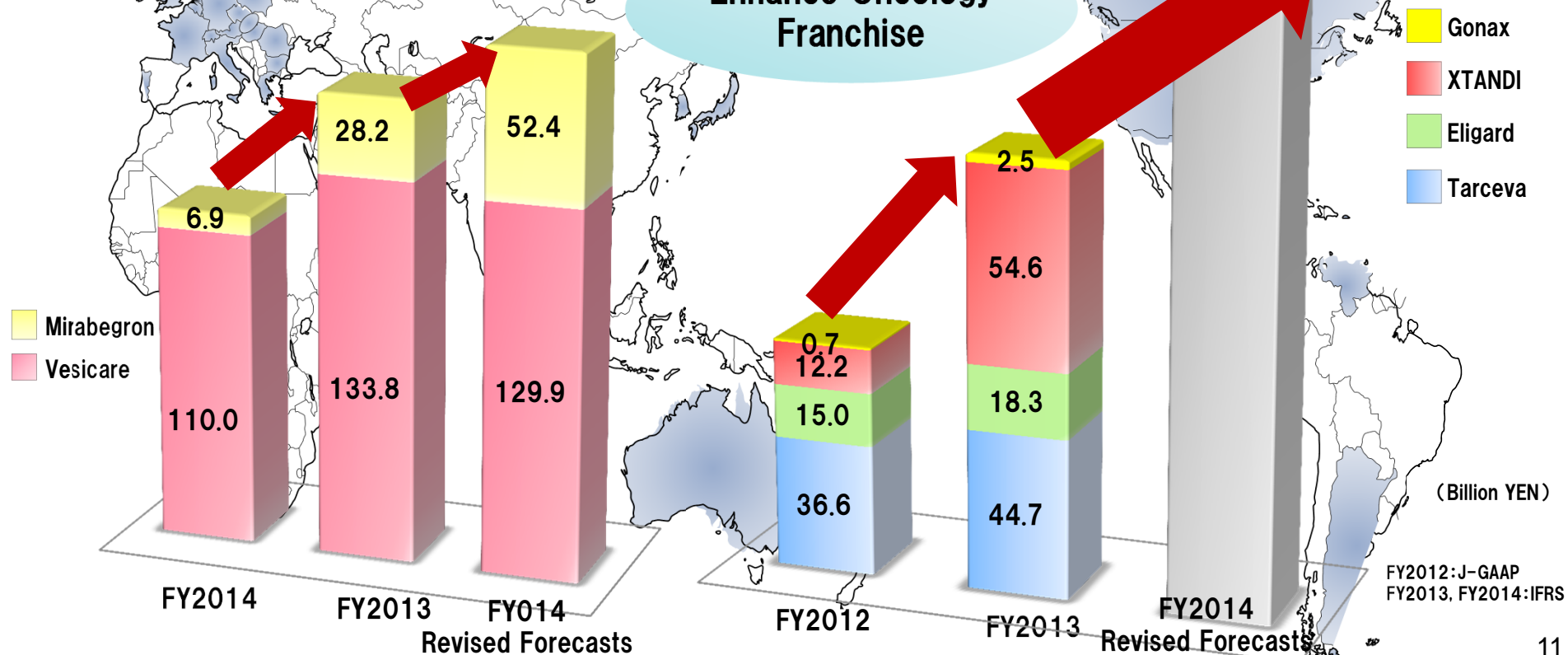
Maximize Value of  
New Products

Launched Countries Mirabegron: 27 XTANDI: 26

As of end of October, 2014

Maximize OAB Franchise

Enhance Oncology Franchise



# Leverage External Innovation

Enhance Innovation

**Best Science**

Seek world class cutting-edge innovation

**Best Talent**

Bring together leading talent from Astellas, biotech and academia, etc. around the world

**Best Place**

Use the most suitable Astellas research facility or a third party regardless of location

Target      Candidate      FIM      POC      Pivotal      NDA      Launch →

Innovation outside Astellas | Biotech, VC, Academia, CRO, KOL, etc

Search, Evaluate, Negotiate

Innovation Management

Business Development



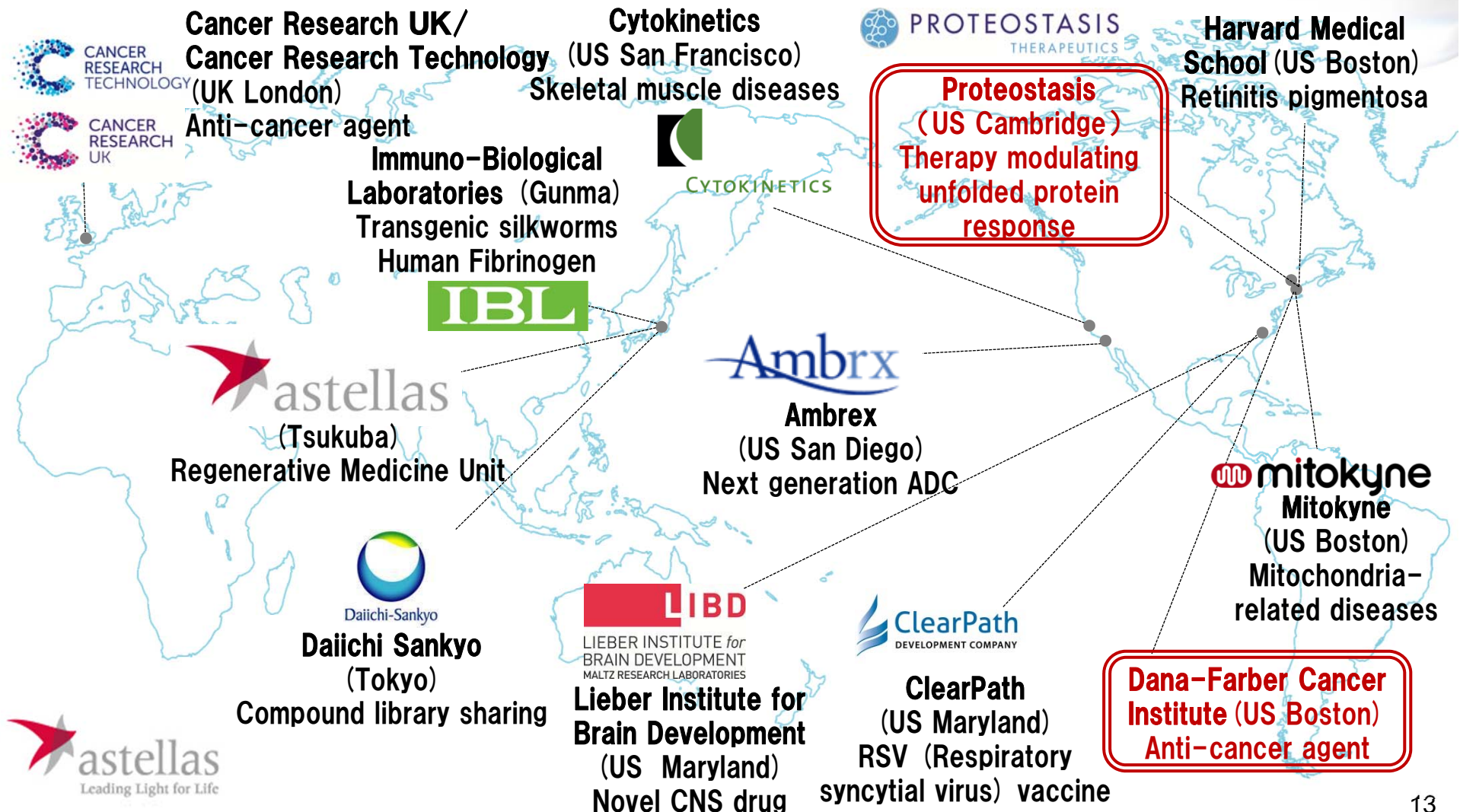
FIM: First in man  
POC: Proof of concept  
NDA: New drug application

VC: Venture capital  
CRO: Clinical research organization

# Develop New Therapeutic Areas and Novel Technology Platform

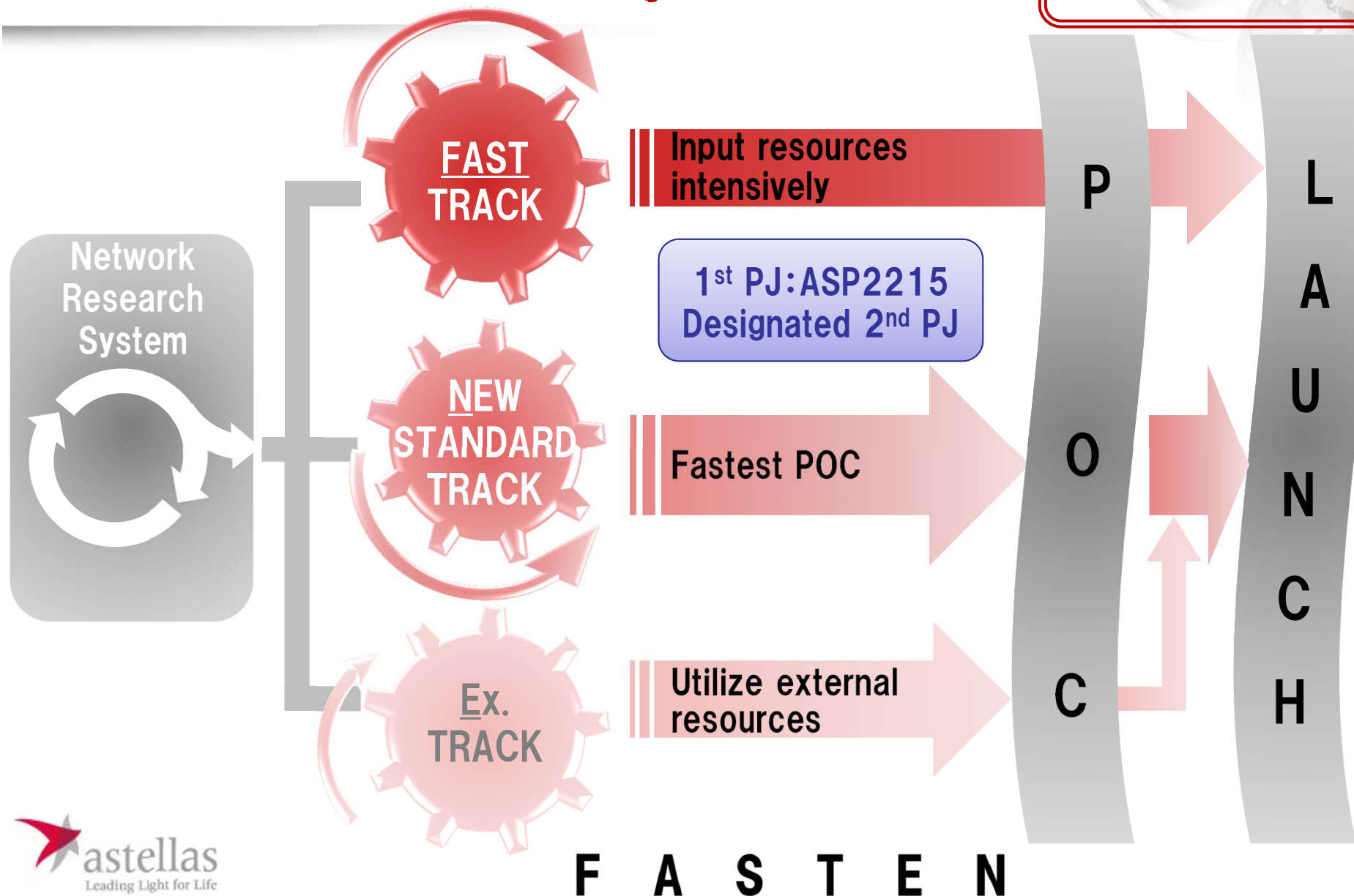
Enhance Innovation

Advance Best Science, Best Talent, Best Place  
with Network Research System



# Accelerate R&D Project

Enhance Innovation



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# Reorganization of Sales Offices

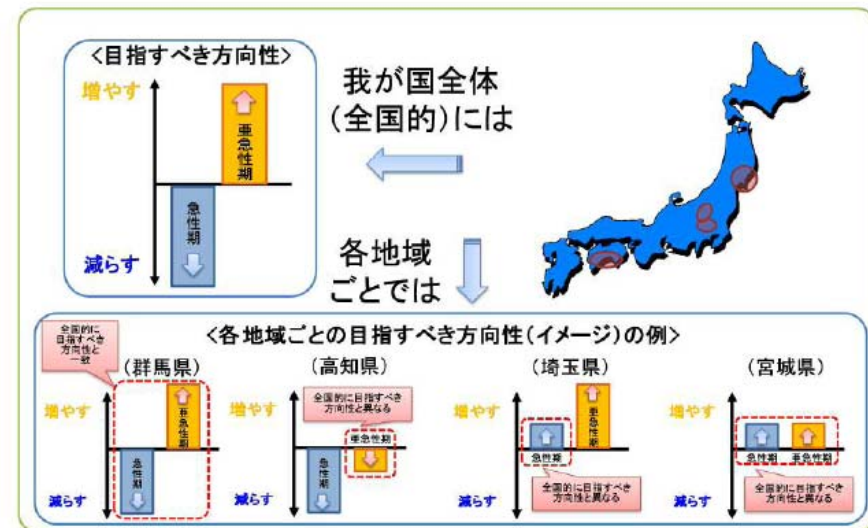
Pursue Operational Excellence

The Strategy in Japan we are implementing varies greatly from area to area because the circumstances of health provisions vary  
(6th Amendment to the Medical Care Act, Effective April 2014)

Increased importance of strategic solutions tailored to specific areas and facilities ↑

- Difference of generic erosion speed
- Market variation from changes in product structure
- Disparities in market share

etc.



Source:

"Vision of the Direction that Should be Taken in Japanese Health Service Reform"

Presentation by Professor Tai Takahashi for the Fiscal System Council  
October 16, 2013

## Reorganize Sales Office Structure to Optimize Planning and Execution of Area Strategy

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# Business Strategy in Growth Markets

EMEA HQ (London)



EMEA:  
Europe, Middle East and Africa

Astellas Singapore  
(2013)



Global HQ (Tokyo)

Americas HQ (Chicago)



Astellas MENA/SSA  
in Dubai (2014)

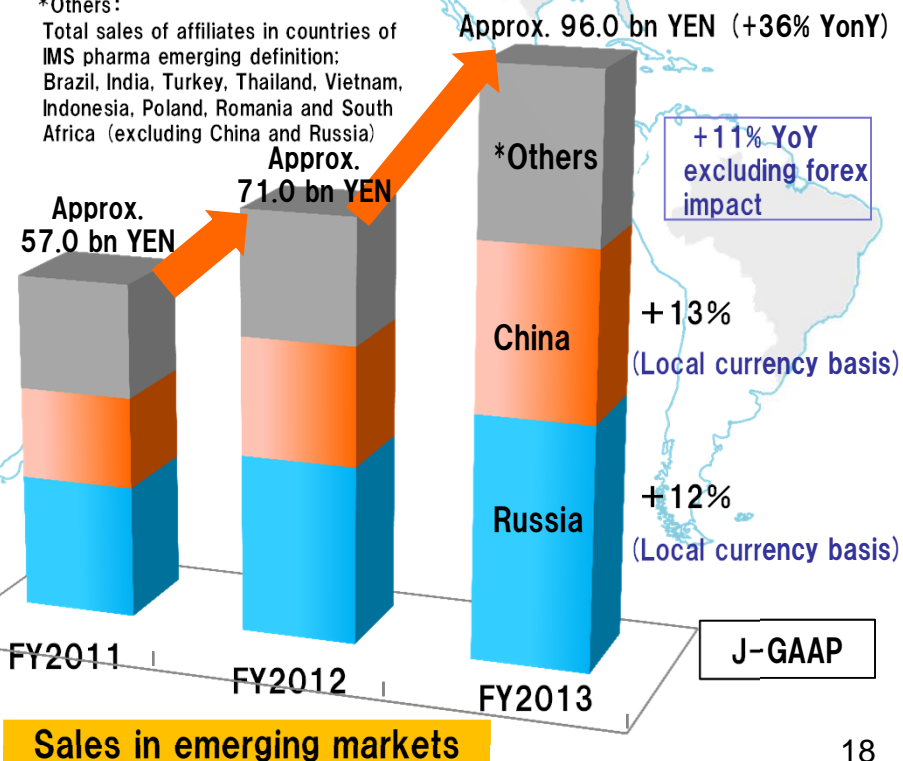


MENA/SSA:  
Middle-East, North Africa  
and Sub-Saharan Africa

Vietnam  
Rep Office  
(2014)

\*Others:

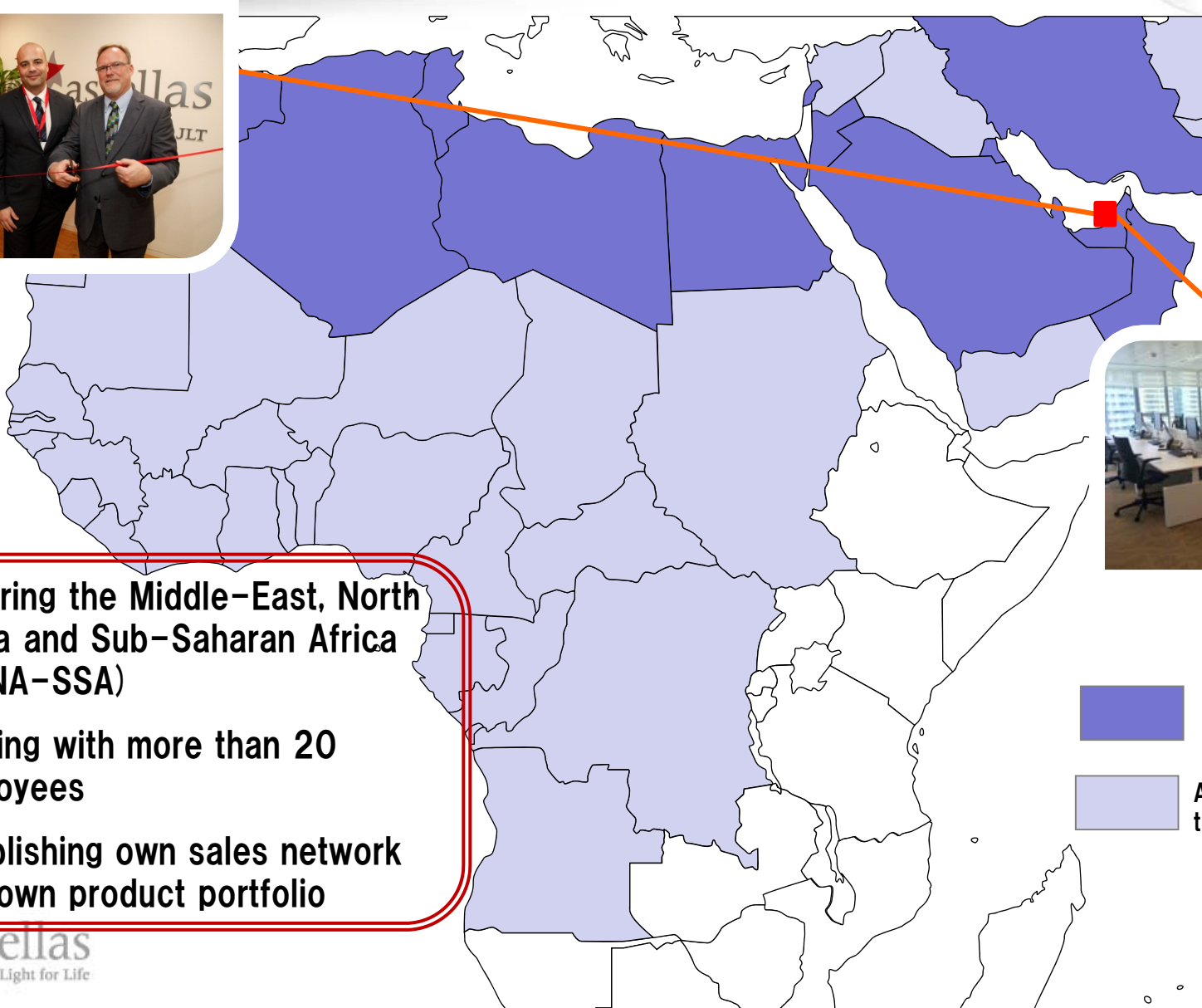
Total sales of affiliates in countries of  
IMS pharma emerging definition:  
Brazil, India, Turkey, Thailand, Vietnam,  
Indonesia, Poland, Romania and South  
Africa (excluding China and Russia)



- Enhancing sales platforms mainly in China and Russia
- Establishing sales network **with own product portfolio**
- Considering characteristics and environmental changes of the respective markets
- Building business that can deliver consistent profits

Sales in emerging markets

# Established Astellas MENA/SSA



- Covering the Middle-East, North Africa and Sub-Saharan Africa (MENA-SSA)
- Starting with more than 20 employees
- Establishing own sales network with own product portfolio

 Astellas Sales and Marketing Operations

 Astellas MENA/SSA territory

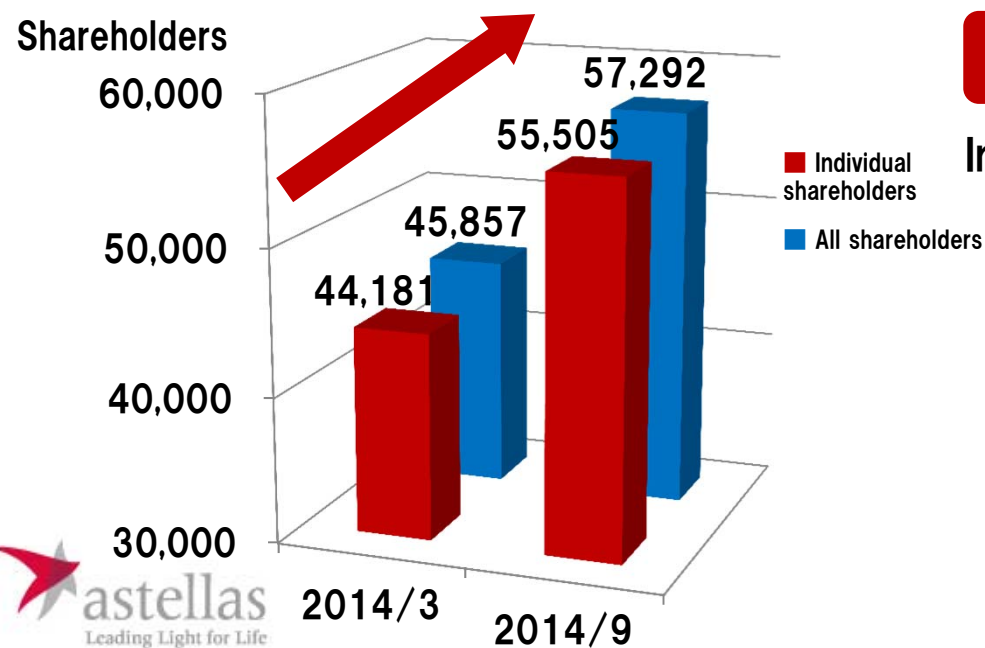
# Capital Strategy

## Profit Distribution Policy

- ✓ Top priority on investment for growth of Rx business
- ✓ Dividends to be increased continuously based on mid- and long-term growth
- ✓ Share buybacks to be implemented in a flexible manner

### April 2014: Stock Split

Each stock was split into five shares



### May/June 2014: Share Buybacks

Share buybacks worth approx. 30 billion YEN

### October 2014: Dividend Increase

Increase of 1YEN compared to the initial forecast

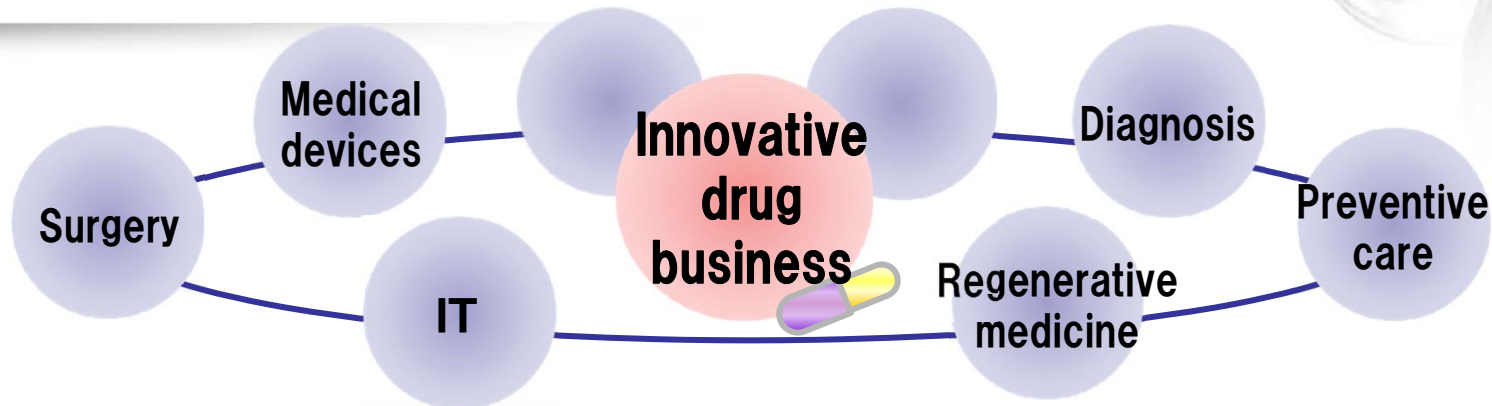
	Dividends per share (YEN)			
	FY2013	FY2014		
	Actual*	Initial forecast	Actual	Revised forecast
Interim	13	14	14	–
Year-end	14	15	–	16
Annual Total	27	29	–	30

\*Restated in consideration of 5-for-1 stock split on April 1, 2014 for convenience purpose

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# Provide New Value



## Establish Pharma Breakthrough in order to Create New Business

Products Combined with Medical Devices	<ul style="list-style-type: none"> <li>• Create new therapeutic fields through combination of drugs and medical devices</li> <li>• Provide new therapeutic methods in urology</li> </ul>
Expansion to diagnosis and preventive care	<ul style="list-style-type: none"> <li>• Provide more accurate early diagnosis methods for localized primary tumor and micro-metastasis (make use of antibody technology)</li> </ul>
Solutions to surgery needs	<ul style="list-style-type: none"> <li>• Provide products that will contribute to reduction of surgery time and better outcome</li> <li>• Perioperative period management</li> </ul>
Application of IT to drug discovery	<ul style="list-style-type: none"> <li>• Joint research of drug development regarding neglected tropical diseases (NTDs) by using supercomputers</li> </ul>

**Provide High Value-Added**

# Transform the Progress of Science into Value for Patients



Changing tomorrow

