Strategic Plan 2015-2017

Building Resilience for Sustainable Growth

May 27, 2015

Astellas Pharma Inc.

President and CEO
Yoshihiko Hatanaka

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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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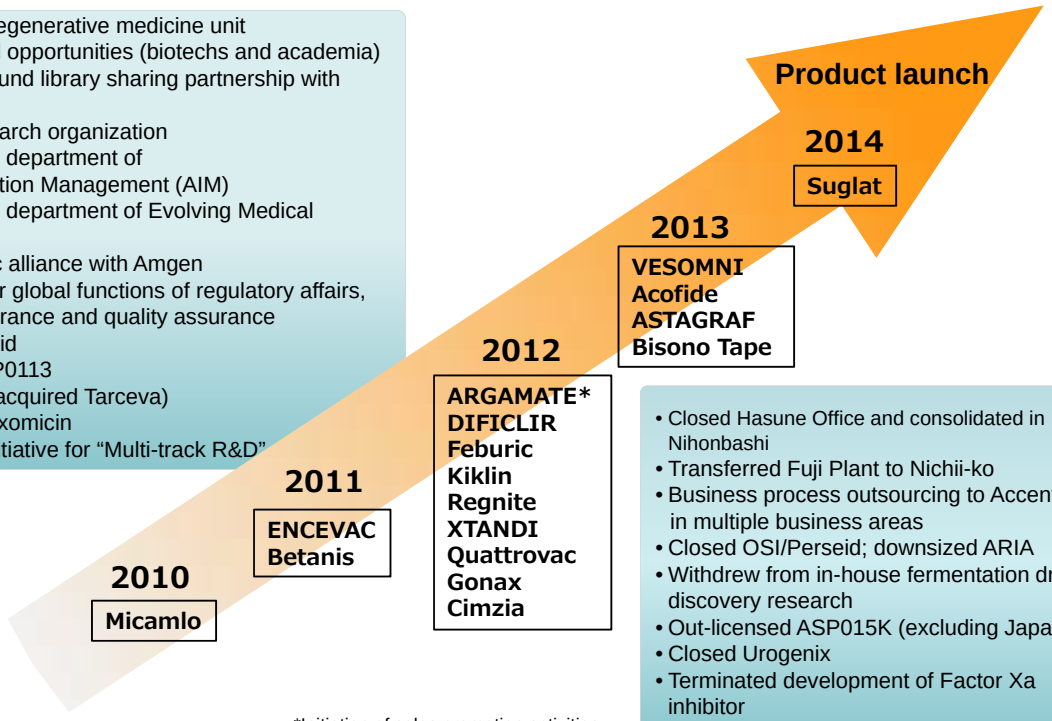
Review of FY2014 Mid-term Management Plan

Consistent implementation of Growth & Efficiency strategies; Growth trend re-established through continuous launch of new products

- Established a regenerative medicine unit
- Seized external opportunities (biotechs and academia)
- Formed compound library sharing partnership with Daiichi Sankyo
- Reshaped research organization
- Established the department of Astellas Innovation Management (AIM)
- Established the department of Evolving Medical Solutions
- Began strategic alliance with Amgen
- Enhance further global functions of regulatory affairs, regulatory assurance and quality assurance
- Acquired Perseid
- In-licensed ASP0113
- Acquired OSI (acquired Tarceva)
- In-licensed fidaxomicin
- Initiated new initiative for "Multi-track R&D"



- Closed Hasune Office and consolidated in Nihonbashi
- Transferred Fuji Plant to Nichii-ko
- Business process outsourcing to Accenture in multiple business areas
- Closed OSI/Perseid; downsized ARIA
- Withdrew from in-house fermentation drug discovery research
- Out-licensed ASP015K (excluding Japan)
- Closed Urogenix
- Terminated development of Factor Xa inhibitor

*Initiation of sales promotion activities

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1. VISION
2. **Strategic Plan 2015-2017**
   - I. Strategy
     - ➢ Maximizing the Product Value
     - ➢ Creating Innovation
       - Enhancing Capabilities to Deliver Innovative Medicines
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     - ➢ Pursuing Operational Excellence
   - II. Financial Guidance and Profit Distribution Policy
   - III. Creating Social Value and Corporate Governance
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Changes Impacting New Drug Businesses

DRIVERS

- Scientific progress
- Existing high UMNs*
- Emergence of new modalities and drug-discovery technologies
- Emergence of diverse medical solutions
- Accelerated approval processes
- Continued market growth

CHALLENGES

- Healthcare cost containment
- Increased influence of payers
- Increased requirement for approvals
- Finite product life cycle

* UMNs: unmet medical needs

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Opportunities to pursue

OPPORTUNITIES

- Innovative drug discovery in TAs* with high UMNs
- New modalities such as cell therapies, gene therapies, etc.
- Increasing number of technologies with applicability in various fields

Opportunities to create innovative value for patients still exist

* TAs: Therapeutic Areas

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VISION

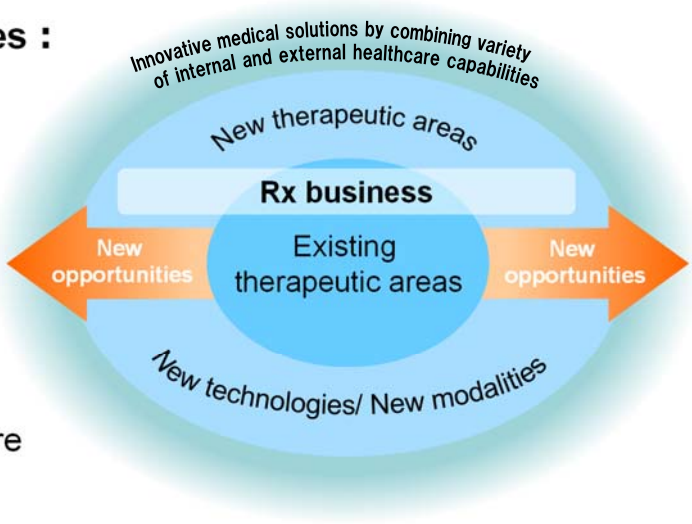
Turn innovative science into value for patients on the forefront of healthcare change

Turn changes into opportunities :

Create innovative new drugs and medical solutions by leveraging our core capabilities

Go beyond GCL* :

Identify business opportunities continuously by embracing healthcare changes with multiple perspectives



*GCL: Global Category Leader

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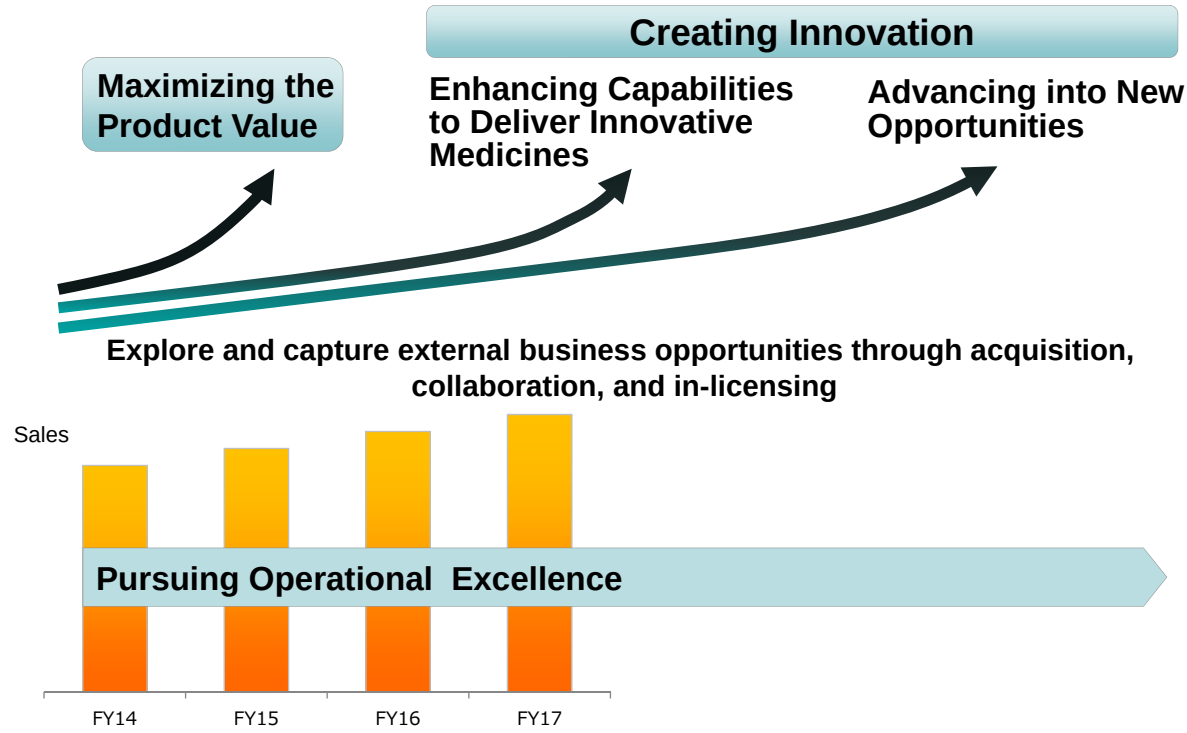
Achieving Sustainable Growth

**New products will drive mid-term growth;
Sustainable growth will be reinforced by continuous selective investment in innovation and strengthening of the business foundation**



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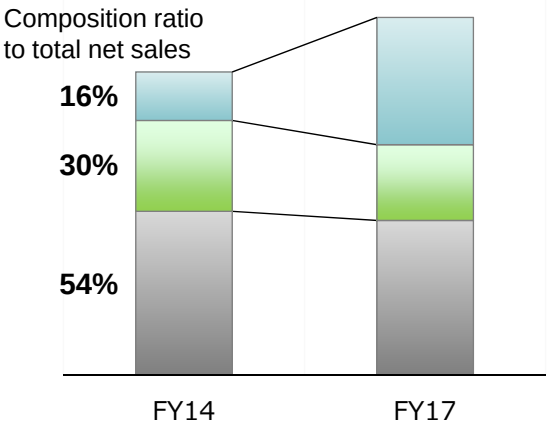
Maximizing the Product Value

New products will drive both mid-term growth and growth longer term after patent expiry of Vesicare and Tarceva

- Expand the ratio of sales coming from new products during this strategic plan period
- Reduce reliance on products with patents expiring by 2020



*For illustrative purposes only

*Betanis/ Myrbetriq/ BETMIGA, XTANDI, Cimzia, Suglat, CRESEMBA

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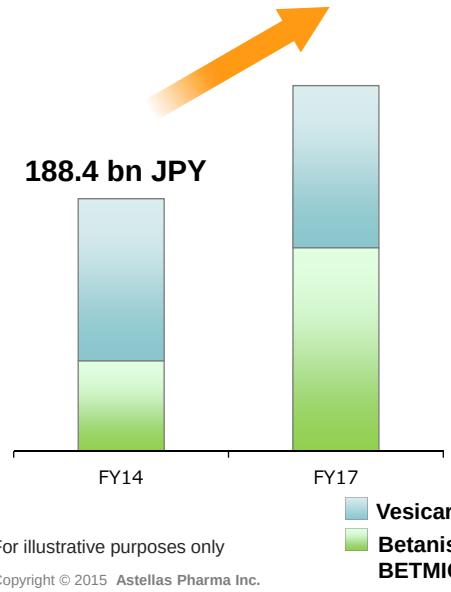
Maximizing the Product Value : Urology/ OAB Franchise

Drive rapid market penetration of Betanis/ Myrbetriq/ BETMIGA and establish its position as a new therapeutic option for OAB* treatment

OAB Franchise Global sales CAGR (%): High single-digit



*For illustrative purposes only

Maximizing the OAB franchise value

- **Accelerate market penetration by Betanis/ Myrbetriq/ BETMIGA**
  - Launch in more than 70 countries by 2016
  - Differentiate by superior balance between efficacy and tolerability with unique mode-of-action to establish its position as a new therapeutic option for OAB treatment
  - Expand into combination treatment with Vesicare
  - Conduct post-marketing studies on adherence, in combination, and important sub-populations such as 'elderly'
- **Further reinforcement of Vesicare as the first choice of anti-muscarinic drug**
  - Continue to build on the trusted profile of Vesicare through the abundance of clinical data and experience

*OAB: Overactive bladder

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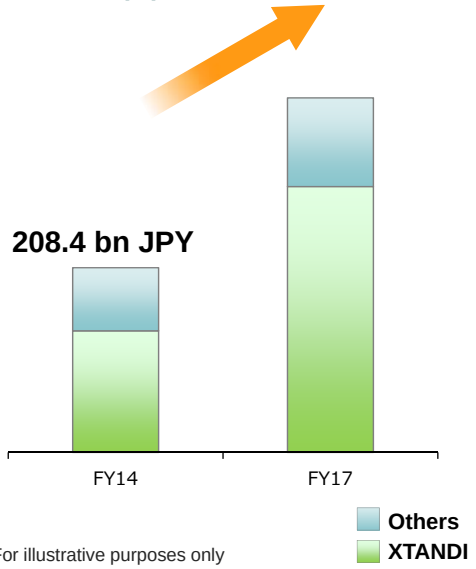
Maximizing the Product Value: Oncology Franchise

Maximize XTANDI rapidly in the chemo-naive indication, and pursue long-term growth by expanding indications

Oncology Franchise Global sales CAGR (%): mid twenties



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Maximizing the value of XTANDI

Expand sales geographies

- Post chemo indication: Expand geographies with a focus on emerging markets
- Chemo-naive indication: Ensure successful launch of PREVAIL and obtain reimbursement

Establish a market-leader position in chemo-naive indication

- Differentiate by superior product profile including administration conditions with fewer restrictions and good tolerability in addition to the efficacy for the overall survival as demonstrated by the PREVAIL trial
- Utilize our strong presence in the urology field

Expand indications

- Expand indications to earlier stage prostate cancer (M0 CRPC, M0 BCR)
- Pursue indications in other tumor types, such as breast cancer and hepatocellular carcinoma (HCC)

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Maximizing the Product Value: XTANDI Development Progress

Studies to build value of XTANDI progress steadily

	Study Phase/Region*	Target	Design	P1	P2	P3	Filed
Prostate Cancer	P3 EU/US/Asia [PROSPER study]	M0 CRPC Non-metastatic CRPC	Placebo-controlled, n=1,500	First Patient In: Nov. 2013			
	P3 EU/US/Asia [EMBARK study]	M0 BCR Non-metastatic prostate cancer, biochemical recurrence	To compare with ADT and combination, n=1,860	First Patient In: Jan. 2015			
	P2 EU/US [TERRAIN study]	Pre-chemo Metastatic CRPC	To compare with bicalutamide, n=375	Presented data at EAU			
	P2 US [STRIVE study]	Pre-chemo Metastatic or non-metastatic CRPC	To compare with bicalutamide, n=400	Presented data at AUA			
	P2 US	Neoadjuvant therapy Undergoing prostatectomy	Monotherapy or combo with leuprolide or dutasteride, n=50	Obtained data			
Breast Cancer	P2 US/EU	Triple-negative Advanced, androgen receptor-positive, triple-negative breast cancer	Open-label, n=118	Plan to present full data at ASCO			
	P2 US/EU	ER/PgR positive Advanced breast cancer that is ER positive or PgR positive and HER2 normal	Placebo-controlled, in combination with exemestane, n=240	Last Patient In: Mar. 2015			
	P2 US/EU	HER2 positive Advanced, androgen receptor-positive, HER2 positive/ER negative breast cancer	Open-label, n=80	First Patient In: Sep. 2014			
HCC	P2 US/EU	Hepatocellular carcinoma (HCC)	-	In preparation			

ADT: Androgen-deprivation therapy, ER: Estrogen receptor, PgR: Progesterone receptor, HER2: Human epidermal growth factor receptor 2
AUA: American Urological Association, EAU: European Association of Urology, ASCO: American Society of Clinical Oncology

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**The region where the study is performed

Maximizing the Product Value: Other Therapeutic Areas

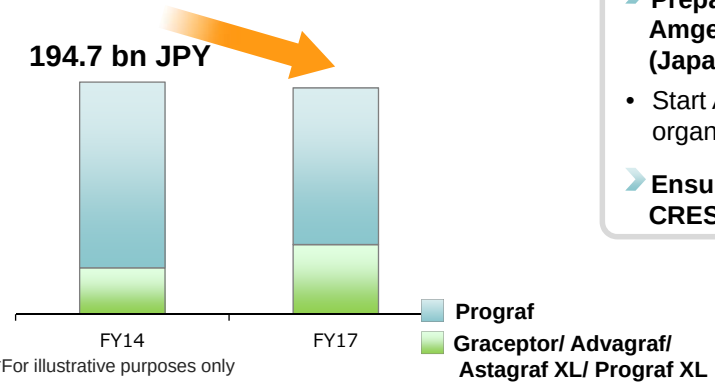
Maintain our leadership position in the transplant field; Pursue local value maximization of new products by driving sales through focused resource prioritization

Maintain the Tacrolimus franchise

- Pursue further growth of Graceptor/ Advagraf/ Astagraf XL/ Prograf XL
- Continuous growth by the expansion of market and indications in emerging markets mainly in Asia

Tacrolimus Global sales

CAGR (%): minus low single-digit



*For illustrative purposes only

Maximizing value in other fields

Ensure the uptake of Suglat (Japan)

- Continue to obtain No.1 market share in the SGLT2 market
- Execute a large-scale post-marketing survey (elderly and long-term tests)
- Develop combination product with DPP-4 inhibitor

Prepare launch for collaborative products with Amgen (evolocumab and romosozumab etc.) (Japan)

- Start Amgen Astellas BioPharma sales organization

Ensure steady market penetration of CRESEMBA (U.S.)

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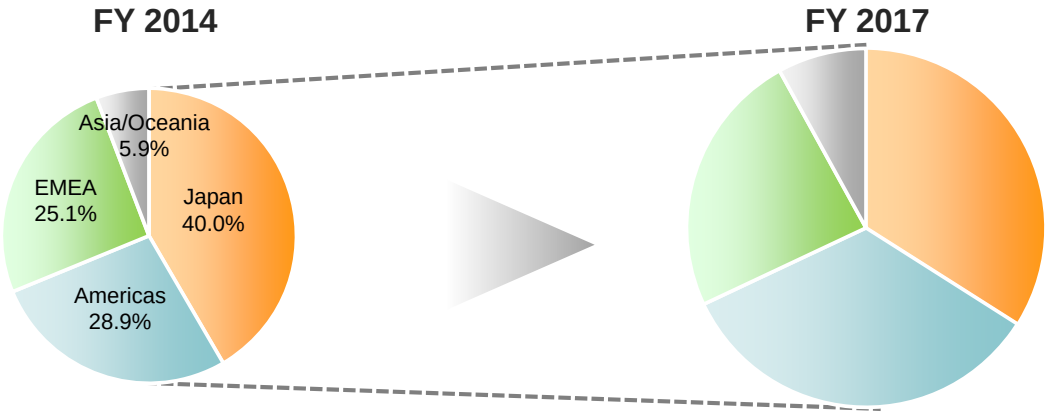
Sales by Region

Improving balance of sales across key regions with growth of US, EMEA and Asia/Oceania portions, and continuation of Japan sales growth



Fx Rate: $1=110 JPY, €1=139 JPY

Fx Rate (expected): $1=120 JPY, €1=125 JPY

Global and regional sales CAGR (%) *Regional sales: on local currency basis

Global Sales	Mid single-digit
Japan	Marginal increase
Americas	High single-digit
EMEA	High single-digit
Asia/Oceania	Mid teens

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Enhancing Capabilities to Deliver Innovative Medicines

Creating innovative drugs efficiently through optimal resource allocation and active acquisition of innovative science

Network Research System

Greater utilization of external R&D resources

Take on challenges in new therapeutic areas and drug discovery technologies

- **Best Science**
- **Best Talent**
- **Best Place**

F A S T E N (FAST-Ex-New-standard)

- **FAST TRACK** — Highest resource priority
- **NEW STANDARD TRACK** — Fastest POC
- **Ex. TRACK** — Utilize external resources

POC* → **Launch**

*POC: Proof of Concept

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Focused Disease Areas for Research

Prioritize disease areas for research focus by following aspects

- **Changes of unmet medical needs**
- **The latest feasibility for research and development**

Focused Disease Areas for Research

Existing TAs* : Urology | Oncology | Immunology | Nephrology | Neuroscience

New TAs : Muscle Diseases | Ophthalmology

*TA: Therapeutic Area

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Development Project and Research Approach by TA: Urology

Maintain and strengthen our leadership position for urology area

Post-POC Project

- **Maximize OAB franchise**
  - Pursue pediatric indication for Vesicare and Myrbetriq/Betmiga
  - Pursue development of EB178

Pre-POC Project & Research Approach

- **Build a next generation franchise by addressing new urology disorders with high unmet medical needs**
  - Nocturia with nocturnal polyuria (ASP7035*)
  - Stress urinary incontinence (ASP2205, ASP5633)
  - Underactive bladder (ASP6282)

*Development by Drais as a part of activities of “Multi-Track R&D”. MultiTrack: multi-tracking of the research and development process

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Development Project and Research Approach by TA: Oncology

Seek additional indications for XTANDI, advance development of ASP2215 and ASP8273; In the long–term, transform research approach to create a highly competitive pipeline

Post-POC Project

- **Advance the development of XTANDI for early stage prostate cancer**
  - Aim to expedite Phase 3 results
- **Advance the development of ASP2215**
  - Aim to accelerate launch of ASP2215 for AML as a FLT3/AXL inhibitor

Pre-POC Project & Research Approach

- **Obtain POC of XTANDI for breast cancer and hepatocellular carcinoma (HCC)**
- **Approach to intractable cancers with Precision Medicine**
  - Approach to target EGFR active mutation / resistant mutation for NSCLC (ASP8273)
  - Approach to target FGFR aberrant signal / genetic mutation for intractable cancer indications (hepatocellular cancer and bladder cancer, etc.) (ASP5878)
  - ADC projects that target specific antigen (AGS-16C3F and ASG-22ME, etc.)
- **Drug discovery research with novel approaches including cancer immunology and cancer metabolism to tackle cancer indications or patient populations which do not respond to existing therapies**
  - Creation of novel cancer immunology portfolio (collaboration with Potenza, etc.)
  - T cell receptor-like mAb (h8F4) targeting a conformational epitope of PR1/HLA-A2 (collaboration with MD Anderson)
  - Modulating energy generation through oxidative phosphorylation in mitochondria in cancer cell (ASP4132)
  - Modulating autophasy in cancer cell (collaboration with Cancer Research UK)
  - K-RAS inhibitor (collaboration with Dana-Farber Cancer Institute)

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AML: acute myeloblastic leukemia, ADC: antibody-drug conjugate

Development Project and Research Approach by TA: Immunology

Explore targets for new drug discoveries that involve several immune disorders and engage in drug creation with the aim of developing a causal treatment/ cure for immune disorders

Post-POC Project

- **Advance the development of ASP015K**
  - Aim to strengthen product portfolio in immunology with early launch for rheumatoid arthritis

Pre-POC Project & Research Approach

- **Create immune disorder drugs that achieve causal treatment/ cure, or significant improvement of symptoms**
  - Development of therapeutic vaccine for Japanese Red Cedar Pollinosis (ASP4070/ JRC2-LAMP-vax)
  - Develop rheumatoid arthritis drug targeting synovial cells (ASP5094)
- **Discover next generation innovative immuno-modulating drugs**
  - Aim to discover drugs addressing several immune-related disorders (AK projects)

(AK: Astellas Pharma and Kyoto University)

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Development Project and Research Approach by TA: Nephrology & Neuroscience

In nephrology, aim to launch roxadustat as first-in-class and prove the efficacy of development projects in early stage;
In neuroscience, aim to obtain POC for development projects in early stage

Post-POC Project

[Nephrology]

Advance the development of roxadustat

- Aim to launch as the first in class novel mechanism for oral treatment of anemia of CKD

Pre-POC Project & Research Approach

[Nephrology]

Seek to develop first-in-class drugs for kidney diseases with high unmet needs

- Aim for preventing albuminuria and proteinuria, slowing reduction of renal function and delaying time to dialysis in diabetic nephropathy by suppressing low grade inflammation and oxidant stress in kidney (ASP8232)
- Approach to prevent progression of chronic kidney disease by reducing glomerular load and suppressing accumulation of uremic toxins (ASP6858)

Advance the drug discovery research focusing on damage for glomerular and renal tubular epithelial cells in kidney

[Neuroscience]

Explore psycho-neurologic diseases and pain with high unmet medical needs through drugs with new mechanism of action

- Neuropathic pain (ASP8477, ASP3662)
- Osteoarthritis pain, chronic low back pain (ASP7962)
- Cognitive impairment associated with schizophrenia (ASP4345)

Identify first-in-class drugs through collaboration with the Lieber Institute for Brain Development

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Main Development Projects in Existing TAs

Continue pursuit of multiple development projects to drive sustainable growth

	High potential Pre-POC Project		Main Post-POC Project	
Stage	**Phase 1**	**Phase 2**	**Phase 3**	**Filed**
Urology	ASP5633 (Stress urinary incontinence)	ASP7035 (Nocturia) *	EB178 (OAB)	
	ASP2205 (Stress urinary incontinence)			
	ASP6282 (Underactive bladder)			
Oncology	ASP5878 (Cancer)	ASP8273 (NSCLC)	enzalutamide (M0 CRPC)	
	ASP4132 (Cancer)	enzalutamide (Breast cancer)	enzalutamide (M0 BCR)	
		enzalutamide (HCC)	ASP2215 (AML)	
Others	ASP5094 (RA)	ASP8477 (Neuropathic pain)	ASP015K (RA)	ASP7374 (Seasonal influenza)
	ASP6858 (CKD)	ASP3662 (Painful diabetic peripheral neuropathy)	roxadustat (Anemia associated with CKD)	evolocumab (Hypercholesterolemia)
	ASP7962 (Osteoarthritis pain, Chronic low back pain)		isavuconazonium sulfate (Candidemia)	
	ASP4345 (Cognitive impairment associated with schizophrenia)	ASP8232 (Diabetic nephropathy)	romosozumab (Osteoprosis)	

※Approval may not be achieved and the approved indications may be different from this slide.

*Development by Drais as a part of activities of "Multi-Track R&D".

Expected total peak sales: around 300 billion yen

NSCLC: Non-small cell lung cancer, HCC: Hepatocellular carcinoma, M0 CRPC: Non-metastatic castration-resistant prostate cancer, M0 BCR: Non-metastatic biochemical recurrence, AML: Acute myeloid leukemia, CKD: Chronic kidney disease, RA: Rheumatoid arthritis,

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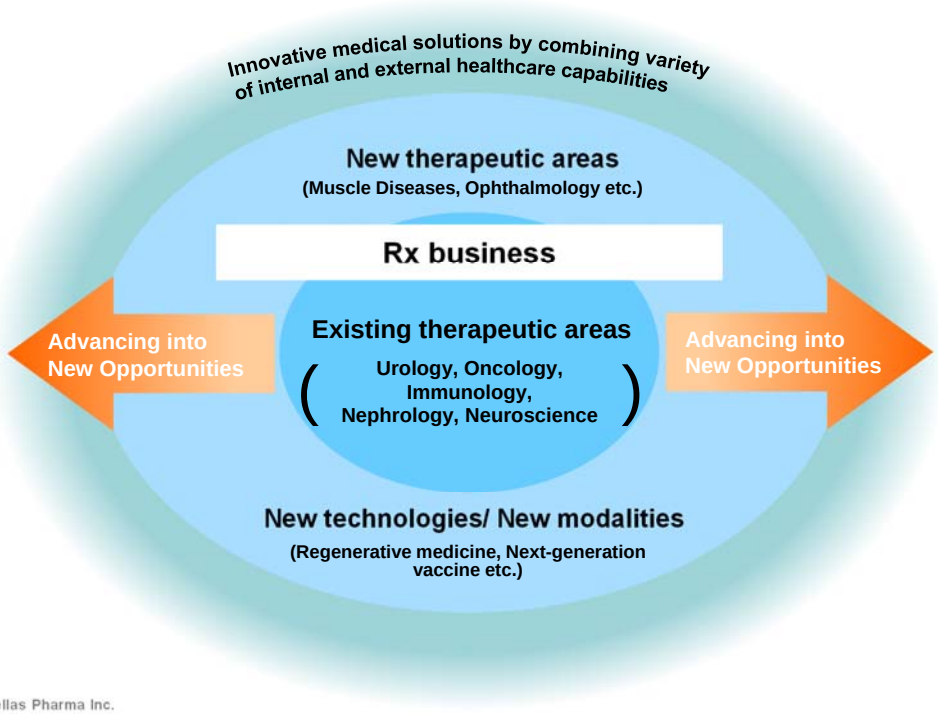
Advancing into New Opportunities

Explore new opportunities in research for developing new drugs in new therapeutic areas and new technologies/ new modalities



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Advancing into New Opportunities (Part 1)

Accelerate drug discovery research in new therapeutic areas as potential candidates for the next-focus;
Continue investment in innovation to achieve long-term growth by leveraging external partnerships

New TAs

- **Designate Muscle Diseases and Ophthalmology to the focused disease areas for research**
  - Aim to explore new drugs with high UMN for preventing progress of diseases or achieving causal therapies in muscle diseases (Cytokinetics, Mitobridge)
  - Focus on posterior eye segment in ophthalmology (Retinitis pigmentosa: Constance L. Cepko, Ph. D., Harvard Medical School)
- **Further exploration of future research focus**

Next-Generation Vaccine

- **Develop a preventive vaccine against RSV (ClearPath)**
- **Develop a vaccine as a causal therapy for Japanese Red Cedar Pollinosis (Immunomic)**

Stage

Pre-POC Project / Post-POC Project

		Pre-clinical	Phase 1	Phase 2	Phase 3
New TAs	Muscle Diseases	Mitobridge Collaboration	CK-2127107 (Spinal muscular atrophy)		
	Ophthalmology	Harvard Medical School Collaboration (Retinitis pigmentosa)		ASP8232 (Diabetic macular edema)	
Next-generation vaccine	CMV prevention			ASP0113 (SOT)	ASP0113 (HCT)
	RSV prevention	ClearPath Collaboration			
	Japanese Red Cedar Pollinosis		ASP4070/ JRC2-LAMP-vax		

CMV: Cytomegalovirus, RSV: Respiratory syncytial virus, HCT: Hematopoietic cell transplant, SOT: Solid organ transplant

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Advancing into New Opportunities (Part 2)

Accelerate research of cell therapy as a new modality;
Develop new opportunities through leveraging internal strengths and external healthcare capabilities to create innovative medical solutions

Regenerative Medicine (Cell Therapy)

- Established Regenerative Medicine Labs. (April 2015)
  - Targeting areas with high unmet medical needs, such as cardiovascular disease and cancer
  - Stem cell formulation (Start the first clinical trial within a few years)
- Set joint research chair with Osaka Univ. for next-generation cell therapies (January 2015)
  - Development of technologies to make transfused/ transplanted cells highly functional and to enhance their therapeutic effects through optimization of the sources of transfused/ transplanted cells

Evolving Medical Solutions

- Identify multiple projects and start clinical trials of the first project during the period of this management plan. Anticipate contribution to profits roughly from around 2020.
  - Provide more accurate early diagnosis methods for localized primary tumor and micro-metastasis, etc. (make use of antibody technology)
  - Provide products that will contribute to reduction of surgery time and better outcome (hemostatic agent and pain management after surgery, etc.)

Drug repurposing

- Established a department of Drug Repurposing & Application Management aiming at the development for new indications by applying new scientific approach to terminated products and launched products (April 2015)
- Promote the research and development of 5 compounds in other indications by localized administration with new technologies

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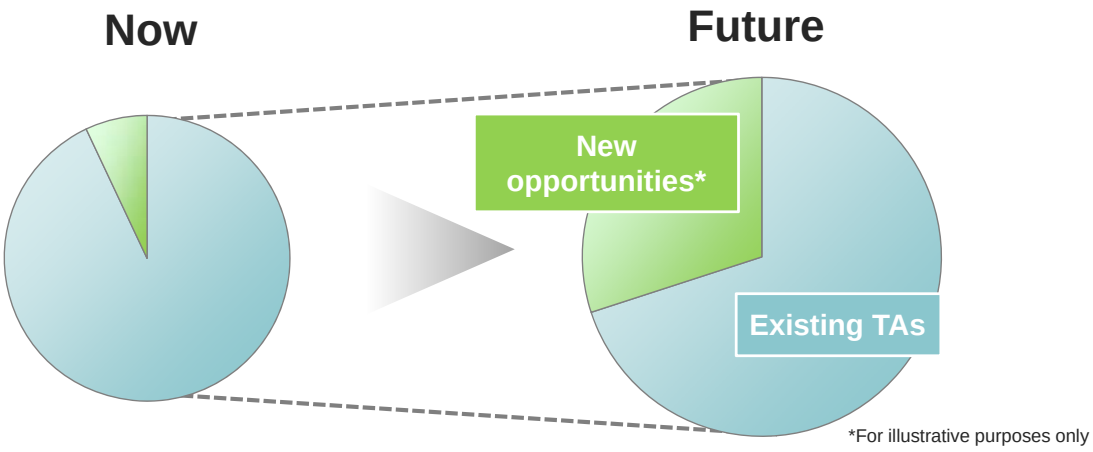
R&D Investment Allocation Philosophy

Maintain investment in existing TAs and ensure sufficient investment in new opportunities



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Investment scale: More than 17% of sales

New opportunities: new TAs (Muscle Diseases and Ophthalmology, etc.),
new technologies/ modalities (regenerative medicine and next-generation vaccines, etc.)
+ innovative medical solutions by combining variety of internal and external healthcare capabilities

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Pursuing Operational Excellence

Create organizations and systems that can flexibly respond to rapidly changing environments and work toward higher quality and efficiency of operations



Key initiatives during strategic plan period

- Proactive and high-quality actions for pharmacovigilance initiatives
- Strengthen corporate disclosure mechanism including further actions for transparency
- Continuous resource allocation for the functions driving our competitive advantage
- Review and optimize our business platform and cost structure continuously

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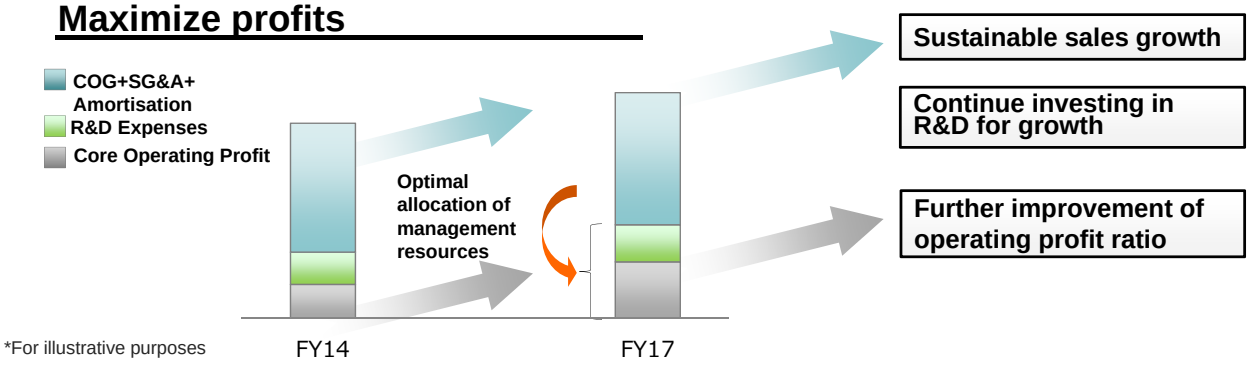
Financial Guidance

ROE*	**15% or more** **Maintain and improve this level after the strategic plan period**

Consolidated Sales	**CAGR（%): Mid single-digit**
Core Operating Profit	**CAGR that exceeds sales' CAGR**
R&D Expenses	**Higher than 17% against sales**

Core EPS	**CAGR that exceeds CAGR of core operating profit**
DOE	**6% or more**

Maximize profits



*For illustrative purposes

Generate cash to support growth and enhance capital efficiency

- Pursue balance sheet management (Maximize free cash flows)
- Continuous improvement of shareholder returns

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*Full basis

Profit Distribution Policy

1 **Top priority on investment for growth of Rx business**

2 **Dividends to be increased continuously based on mid- and long-term growth**

3 **Share buybacks to be implemented in a flexible manner**

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Creating Social Value

astellas
Leading Light for Life

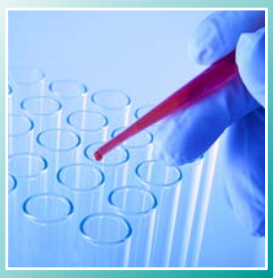
Solve problems related to Access to Health, harnessing our strengths and taking advantage of partnerships with other organizations

Resolve social issues and enhance our corporate reputation over the long-term

Joint drug-discovery research for NTDs



Core business activities



Development of Pediatric Formulation for Schistosomiasis



NTDs: Neglected Tropical Diseases

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Further Strengthen Corporate Governance

Based on expectation and request from all stakeholders, aim at further improvement of government function including transparency, objectivity and mobility

- Increase number of outside auditors* --- Board of Directors (4 of 7) and Audit & Supervisory Board (3 of 5) comprised of more than half independent external executives
- Reorganize the global management committees and Establish an Executive Committee (No. of members reduced from 11 to 5)
- Establish a Global Risk Management Office --- Ascertain global risks and promote optimal risk management measures
- Establish a Corporate Disclosure Committee --- Target all information disclosure items including non-financial information and meet diversified expectations

*To be discussed at general shareholders' meeting on June 17

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1. VISION
2. Strategic Plan 2015-2017
   I. Strategy
      - Maximizing the Product Value
      - Creating Innovation
        - Enhancing Capabilities to Deliver Innovative Medicines
        - Advancing into New Opportunities
      - Pursuing Operational Excellence
   II. Financial Guidance and Profit Distribution Policy
   III. Creating Social Value and Corporate Governance
   IV. Conclusion

Achieving sustainable growth

<Strategy>

1 Maximizing the Product Value

- Maximize the value of product driving mid-term growth, such as OAB franchise and XTANDI

2 Creating Innovation

- Prioritize investment in post-POC projects
- Proactively seek new opportunities and ensure sufficient investment allocated to them

3 Pursuing Operational Excellence

- Create organizations and systems that can flexibly respond to rapidly changing environments and work toward higher quality and efficiency of operations

Explore and grasp external business opportunities through acquisition, collaboration, and in-licensing

<Financial Guidance>

15% or more of ROE by maximization of profits and improvement of capital efficiency

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On the Forefront of Healthcare Change