

# **Accelerating Growth as a Global Healthcare Company**

**Acquisition of Calliditas Therapeutics AB** 

May 28, 2024 Asahi Kasei Corporation



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## i. Introduction

- ii. Growth Strategy for Healthcare
- iii. Growth Strategy for Global Specialty Pharma
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## Regarding this acquisition

- 1. Today, we announced our determination to acquire Calliditas Therapeutics AB ("Calliditas").
- 2. Calliditas has a strong presence in the U.S. pharmaceuticals market for renal diseases, with high growth prospects for the future.
- 3. The acquisition price is approximately ¥173.9 billion. The tender offer will begin in July 2024, with the aim of closing by the end of September.
- 4. Operating income after PPA amortization from this acquisition is expected to be positive in FY2025. Product on the market is expected to generate peak sales of more than 500M USD after FY2030.



# The vision we aim to achieve with this acquisition

Expand our US pharmaceuticals business from renal transplantation to the renal disease area and increase our presence

Contribute to the fulfilment of unmet medical needs by leveraging synergies with our products and pipeline

As a global specialty pharma, drive growth in the Healthcare sector along with the medical devices business

Contribute to the sustainable increase of Asahi Kasei's corporate value by achieving growth in the Healthcare sector to make it the third major pillar



## **Progress on GG10**

Health Care and Homes are expected to achieve profit growth in line with targets, and plan to invest in expansion as assumed; Environmental Solutions is increasing investments based on clearer growth opportunities from a medium-term perspective in Hipore

#### FY22-24 investment amount **Businesses to drive future growth** FY21 ⇒ FY24 and major projects to date 10 Growth Gears (GG10) profit increase<sup>1</sup> (¥ billion, decision-adopted basis) **First** Acquisition of Critical Care Bionova Scientific, **Priority** a U.S. biologics ≤200 + ≈15 billion Global Specialty Pharma **Health Care** CDMO, and Gaining income from expansion of Bioprocess past investments business base Continued aggressive Increased capacity investment, including Material for Pimel inorganic growth ≤100 $\pm 0$ billion **Digital Solutions** semiconductor buffer coat/interlaver dielectric Growth **Potential** Expansion of Energy Storage (separator) Growth drivers of future Material automotive LIB - **≈20** billion ≤300 Hydrogen-related separators business (Integrated plant in NA and Promoting alliance addition of coating facilities in NA. CO2 Chemistry Japan, and South Korea) strategies from a competitive perspective Acquisition of Focus North American & Australian Homes Companies in the ≤100 + ≈10 billion **Earnings Base** Homes U.S. **Environmental Homes** Acquisition of Arden and Construction Materials **Expansion** Homes in Australia Finding opportunities to expand scale while Material maintaining stable earnings U.S. automotive ≤50 + ≈10 billion Car Interior Material (focus on projects with high interior materials probability of success)

# GG10 financial targets

FY22–24 cumulative investment (decision-adopted basis)

## ¥700 billion

(total amount including maintenance investments, etc.)

Increase due to Hipore investment in North America etc.

#### FY24 operating income

**GG10** total

¥110 billion

>50% of all business income<sup>2</sup>

Below initial target of ¥150 billion due to downturn in separator

<sup>&</sup>lt;sup>1</sup> Operating income + amortization from PPA

<sup>&</sup>lt;sup>2</sup> Proportion of business income, excluding corporate expenses



## **GG10 Growth Strategies: Global Specialty Pharma**

Transformation into Global Specialty Pharma focused on immunology/transplantation and adjacent disease areas

#### Niche therapeutic areas

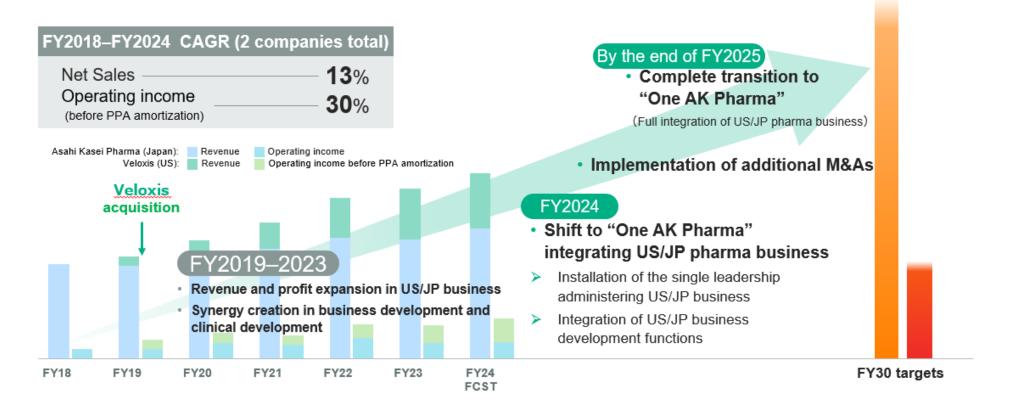
Focus on specialty areas such as immunology/transplant, renal diseases, and severe infection in immuno-compromised population

#### **Global business expansion**

Implementation of additional M&A to strengthen business platform and pipeline

#### Global management style

Transition to "One AK (<u>A</u>sahi <u>K</u>asei) Pharma"



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## **Policies for Healthcare**

Healthcare to become the third major pillar and growth driver of Asahi Kasei

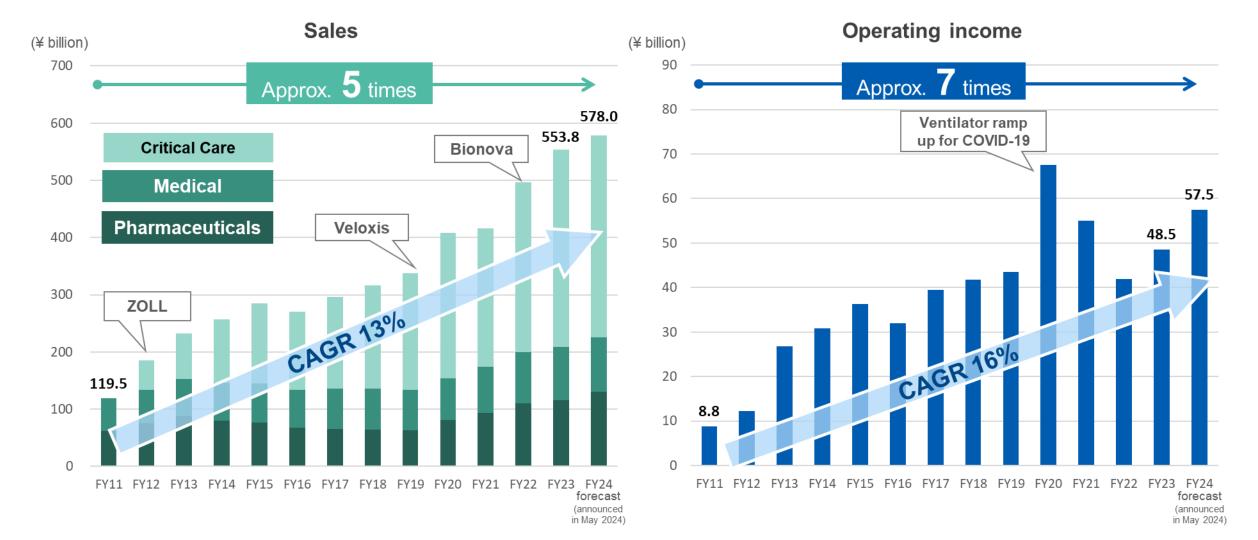
Operate both pharmaceuticals business and medical devices business

Target sales of ¥1,000 billion and operating income of ¥200 billion in FY2030

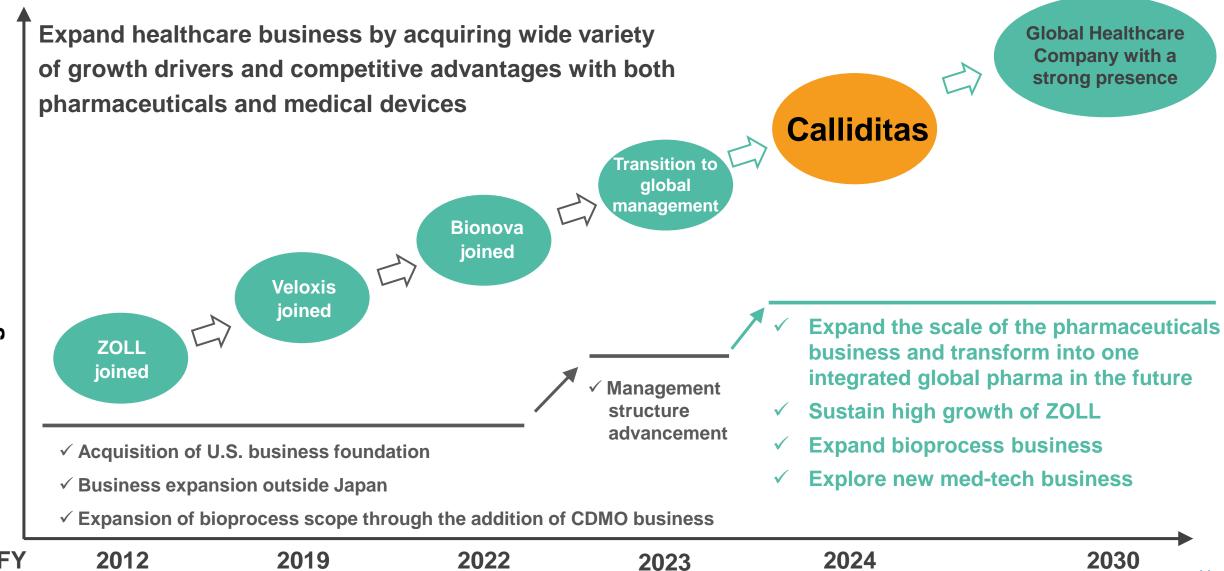


## **Financial History of Healthcare**

High growth in Critical Care and accelerating growth in Pharmaceuticals and Medical, with both sales and operating income growing at over 10% CAGR



# Accelerate growth as a Global Healthcare Company



## **Leadership of Healthcare Sector**

From FY2023, transition to a global management system suited for incorporating innovation and accelerate our growth strategy



- Transitioned to a single leader structure
- Established a Healthcare HQ in the U.S.
- Strong mix of international executives

**ZOLL Medical** 



Jonathan Rennert

Asahi Kasei Pharma



Yoshikazu Aoki

Veloxis Pharmaceuticals



**Mark Hensley** 

From FY2024: Integration of Japanese and U.S. pharmaceuticals operation Transition to One AK Pharma Asahi Kasei Medical



Ken Shinomiya

Grow Calliditas under advanced global management structure



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# **Growth Strategy as a Global Specialty Pharma**

Business model focused on specialty therapeutic area with relatively low risk

Business model	<b>Business</b> area	<ul> <li>Less competitive</li> <li>Modest probability of success in development</li> <li>Smaller clinical trial size / lower R&amp;D expenditure</li> <li>Covered by fewer sales reps and marketing numbers</li> </ul>
	Profit Structure	<ul> <li>Low promotional costs, making it easier to maintain profitability while investing in clinical trials and business development</li> </ul>
	Business development	<ul> <li>Too small for big pharma but too big for small biotech</li> </ul>
Management structure		<ul> <li>Appointment of senior management with diverse backgrounds and nationalities</li> </ul>



# **Global Specialty Pharma Focus Areas**

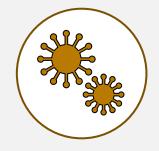
## Target large hospitals and focus on specialist/rare diseases

Focus Areas

**Products** 

R&D

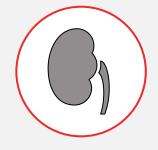
## **Immunology**



- Kevzara
- Plaquenil
- Bredinin

AK1910

#### Renal disease



- Bredinin
- 「Tarpeyo」

• AK196

#### Organ Transplantation area



Envarsus XR

# Severe infectious disease\*



- Cresemba
- Recomodulin

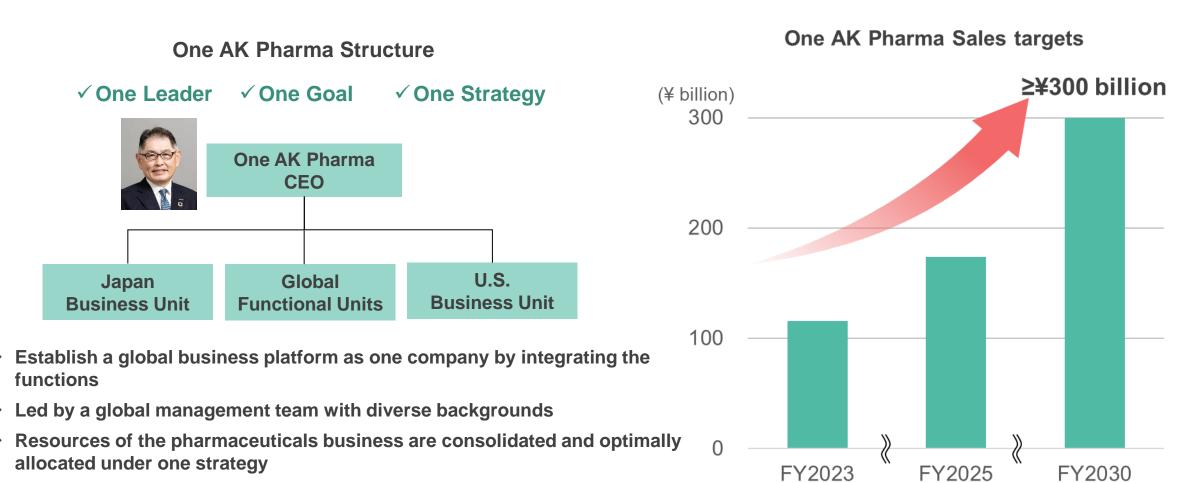
VEL-101

\*invasive/severe infection (e.g. deep mycosis)



## Transition to One AK Pharma capable of implementing growth strategy

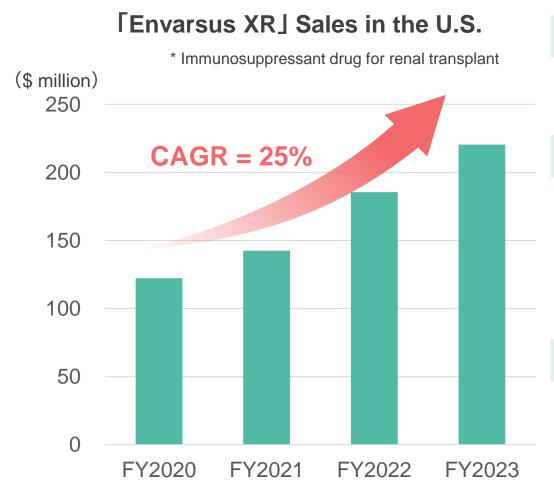
Aim for a sales scale and structure that can cover R&D and business development costs for continued growth





## **Achievements of Veloxis**

## Steady growth in market share, with a sales CAGR of more than 20% since acquisition



### Market

 Number of kidney transplants: Steady Increase (CAGR of over 6% between CY2020 and CY2023)

### **Achievements**

- Sales: Strong growth
- Share: The proportion of prescriptions in de novo kidney transplants is exceeding initial expectations. Also, market share in the tacrolimus market is steadily increasing (FY2019 5.2% ⇒ FY2023 Over 20%)

## **Development**

 VEL-101: Immunosuppressant for organ transplantation with potentially fewer side effects. Development progressing as planned; Ph1 study completed and Ph2 study planned.



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# Calliditas: expanding Global Specialty Pharma's scope in Nephrology and Rare Disease



#### **Market Leader**

 Tarpeyo: the first ever fully approved treatment for IgA nephropathy (currently approved in U.S., Europe, and China)



## **Expansion Opportunities**



 With the FDA granting full approval in December 2023, the patient population eligible for prescriptions expanded, leading to expectations of accelerated business growth



## **Strategic Fit**

 Expands our U.S. commercial footprint and builds on our existing expertise in immunology, renal transplantation and rare disease

## **Financial Impact**



- Revenues expected to >\$500 million by mid-2030s
- Accretive to FY25 operating income after amortization of goodwill and intangible assets



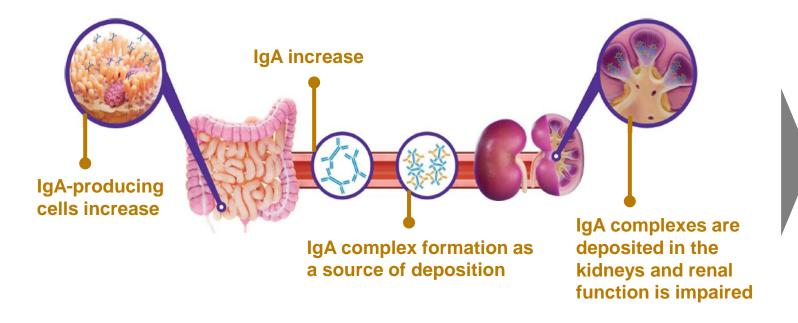
# IgA nephropathy is a rare disease resulting in sustained kidney damage and renal failure

## IgA nephropathy

Chronic kidney disease caused by the overproduction of the antibody IgA (immunoglobulin A) in the ileum that are deposited in the renal glomeruli leading to reduced kidney function

## **Symptoms**

Hematuria Edema Hypertension



20-40% develop renal failure



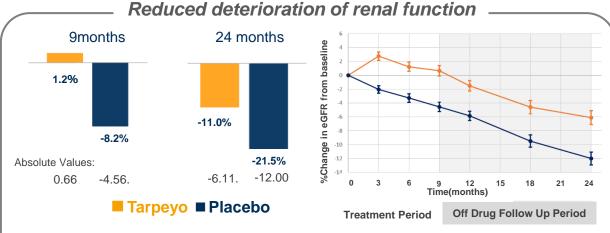


Dialysis or kidney transplantation required

# **Features of Tarpeyo**

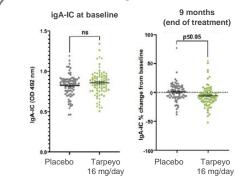


- Unique technological formulation of budesonide (steroid) for the treatment of IgA nephropathy
- Formulated to release in the ileum of the small intestine
- Inhibiting IgA production to prevent the worsening of renal function due to IgA nephropathy

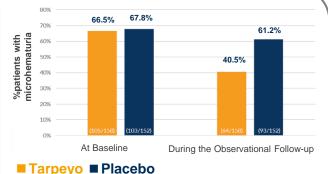


# Ph3 results: improved renal function at 24 months after 9 months of dosing

#### Improvement in IgA Nephropathy biomarkers



Tarpeyo resulted in a statistically significantly reduction in IgA-IC levels over the treatment period vs. placebo (p≤0.05)



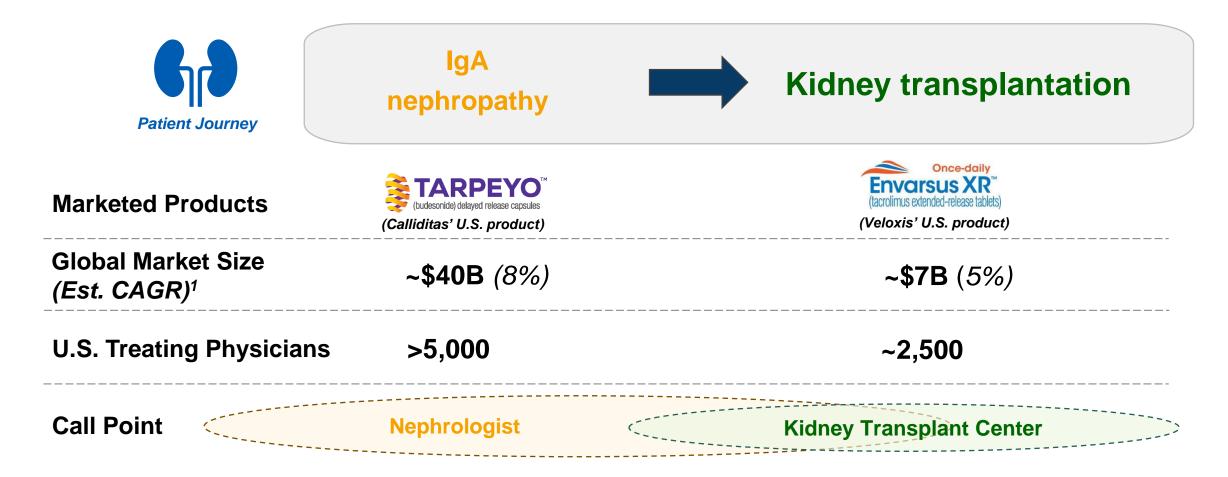
Tarpeyo resulted in a statistically significant improvement in the proportion of patients exhibiting microhematuria vs. placebo (p=0.0001)

9 months of dosing reduced blood IgA immune complex levels and microscopic hematuria



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## Calliditas expands our U.S. commercial footprint...



Leverage platform with new Business Development opportunities in the renal disease space

<sup>1</sup> Internal analysis



## **Reference: Overview of Calliditas Pharmaceuticals**

Company name	Calliditas Therapeutics AB	
Establishment	<ul> <li>2004: Established as Pharmalink AB</li> <li>2017: Changed to current company name</li> <li>2018: Listed on the NASDAQ Stockholm</li> <li>2020: Listed on the NASDAQ Global Select Market in the U.S., still takes the form of a dual listing</li> </ul>	
Location	Stockholm, Sweden	
CEO	Renée Aguiar-Lucander	
<b>Business overview</b>	Research, development, manufacturing and marketing of therapies primarily for kidney diseases	
Marketed product	Product Name: Tarpeyo (Generic name: Budesonide) Indication: Primary IgA nephropathy who are at risk for disease progression Merchandising right: U.S.: Launched in 2021 by Calliditas EU: Launched in 2022 by STADA Arzneimittel China: Launched in 2024 by Everest Medicines (Japan: Not yet launched, Viatris has exclusive rights to develop and market)	
Pipeline	Setanaxib: Under clinical development in primary biliary cholangitis, alport syndrome and solid tumors	
Revenue	2021: 229 million SEK / Approx 22 million USD 2022: 803 million SEK / Approx 75 million USD 2023: 1,207 million SEK / Approx 113 million USD	

# **AsahiKASEI**

## Creating for Tomorrow

#### THE COMMITMENT OF THE ASAHI KASEI GROUP:

To do all that we can in every era to help the people of the world make the most of life and attain fulfillment in living.

Since our founding, we have always been deeply committed to contributing to the development of society.

to contributing to the development of society,

boldly anticipating the emergence of new needs.

This is what we mean by "Creating for Tomorrow."

