



# **New Drug Development in Korea - Hanmi Case -**

1<sup>st</sup> Japan-Korea Joint Symposium on Medical Products, June 23<sup>rd</sup>, 2016, Tokyo

**Gwan Sun Lee**

President & CEO



## Company Overview



## R&D



## China Market



## Partnership & Alliance

**\$7B** — Record-breaking Deals\*

**28** — Pipelines on Track

**~700%** — Market cap. Growth\*\*

\*Sum of upfront and potential milestones from major deals in 2015

\*\*As of 30 December 2015

# Company Structure

**Hanmi**

Established	June 15 <sup>th</sup> , 1973
Employees	2,080 (as of Apr. 2016)
Researchers	523 (as of Apr. 2016)*
Total Sales	1.16 B USD (as of 2015)**
R&D Investment	165.4 M USD (14% of 2015 sales)

**Hanmi Science**  
Holding Company

**Hanmi Pharm**  
Established in 1973  
Pharmaceuticals in Korea

**Hanmi**  
Japan

**Hanmi**  
Europe

**Online Pharm**  
Medical Supplier

**Beijing Hanmi**  
Established in 1996  
Pharmaceuticals in China

**Hanmi FC**  
Established in 1984  
Mass Production of API

**Hanmi Medicare**  
Established in 2000  
Medicare Devices

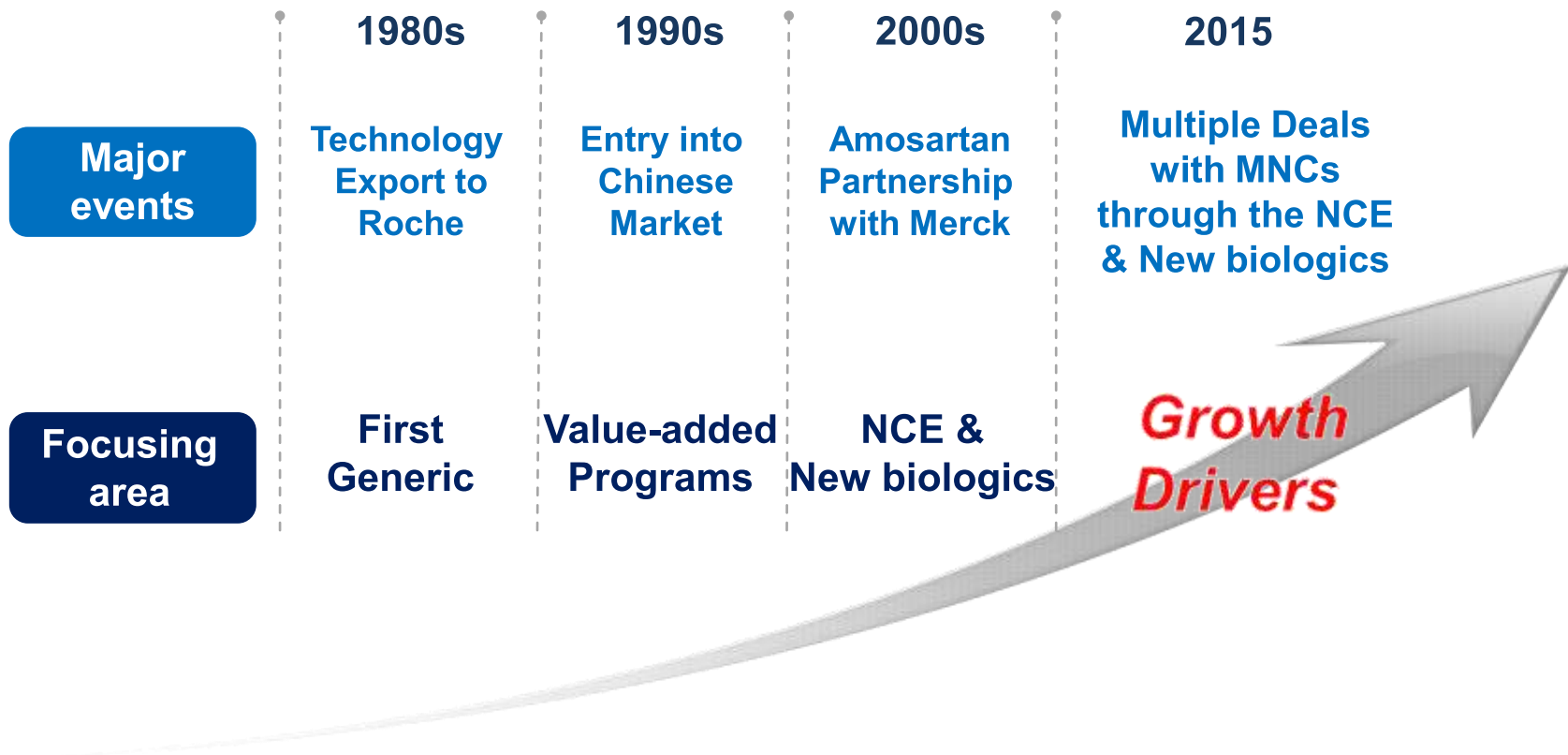
**Hanmi IT**  
Established in 2005  
Medical IT solution & RFID

\*Number of Researchers = Dongtan + Seoul + Paltan + Hanmi FC + Beijing Research Center

# Hanmi Way – Evolution & Innovation

Hanmi

Continuously reinventing itself, Hanmi adapted to fast-changing global demand and provided innovative medical solutions





Company Overview



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*“ For the 10<sup>th</sup> year, our research demonstrates that **there’s no correlation between how much you spend on innovation and how well you perform.** You can’t just buy your way to the top.”*

*– Barry Jaruzelski, Sr. Partner of PWC*



Failure-tolerant Corporate Culture

Speed - Maximize Efficiency

Multinational Talents

Global Vision Statement

Innovative Approach

Focused Research



## Formulation Research Center

: Paltan, Gyeonggi-do

- Formulation, DDS Research
- R&D Staff: 63 (Ph.D 6, MS. 34)



## Hanmi R&D Center

: Dongtan, Gyeonggi-do

- NCE & NBE Drug Discovery
- R&D Staff: 147 (Ph.D 27, MS. 94)



## Seoul Research Center (HQ)

: Songpa-gu, Seoul

- eR&D, Clinical & Regulatory
- R&D Staff: 103 (Ph.D 12, MS. 47)



## Beijing Hanmi Research Center

: Beijing China

- NCE & NBE Drug Discovery
- Equipped with primate facility
- R&D Staff: 160 (Ph.D 14, MS. 88)



## Hanmi Fine Chem

: Shihwa, Gyeonggi-do

- Mass Production Research of APIs
- R&D Staff: 50 (Ph.D 3, MS. 39)

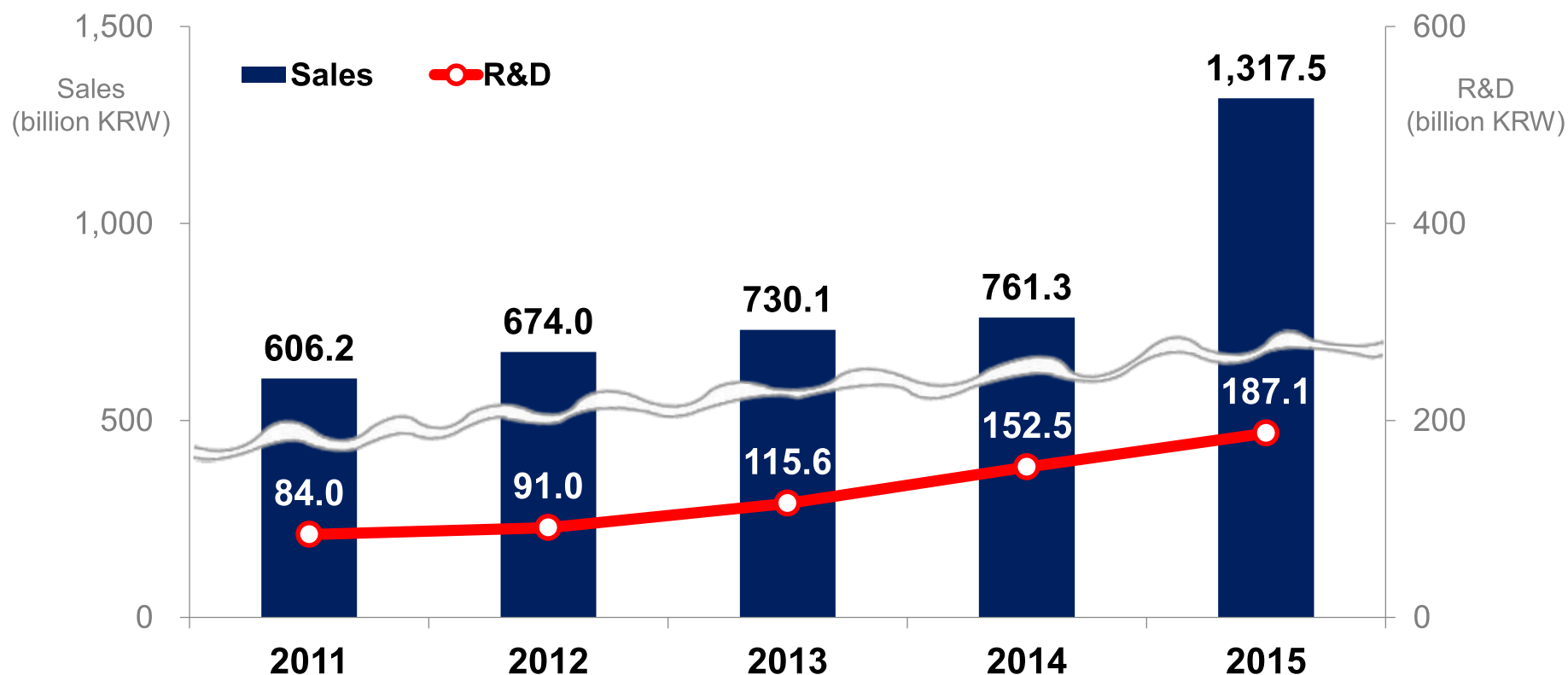
**Total R&D Staff : 520+**



# R&D Network



Ranked 1<sup>st</sup> in Korea for investing in New Drug Development



## Open innovation

Leveraging External Sources of Innovation



### Focus on 4 Therapeutic Areas

Diabetes

Obesity

Oncology

Auto-Immune

New Biologics based on  
the LAPSCOVERY Platform

New Chemical Entity focus on  
the Targeted Therapy

Value-added  
Programs

Formulation  
Technology



## *Global Development Strategy*

- Select candidates with best-in-class/first-in-class potential
- **Plan global development strategy from the beginning** and prioritize the program periodically based on competitive landscape
- Focus the resources on the high priority projects



## *Maximize the Internal/ External Human Resources*

- Continuous technology innovation through in house staffs
- **Recruitment of multinational talents in clinical science, business development, regulatory affairs, and CMC**
- Formulation of global advisory board in diabetes and oncology for the consultation of right developmental path

## *Long-Acting Protein/Peptide Discovery Technology (Fusion of Chemistry to Biologics)*

*“Monomeric Form and Aglycosylated Fc Enables Longest Duration”*

**Therapeutic Agent**

: e.g. Unnatural peptide



**Aglycosylated Fc**

: Increase solubility

### **Longest Duration by**

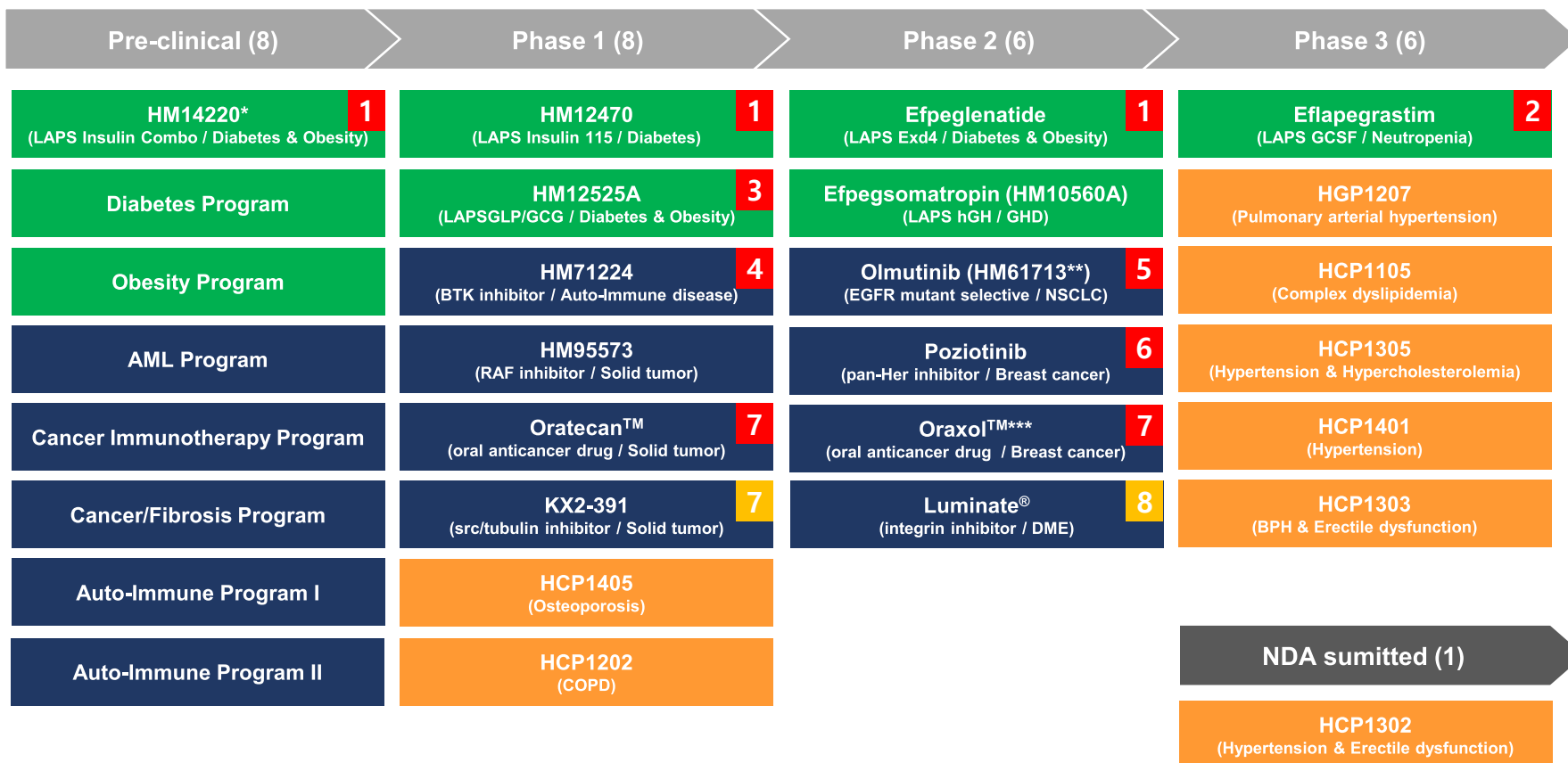
- Monomeric form helps to reduce receptor mediated clearance
- FcRn mediated endothelium recycling / Avoiding renal filtration

### **Strongest Efficacy by**

- Flexible linker minimizes loss of intrinsic activity
- Monomeric form helps to reduce RMC
- Highest bioavailability reduces dose level

# R&D Pipeline

Hanmi



**New Biologics (8)**

**NCE (13)**

**IMD/FDC (8)**

**Out-licensed (10)**

**In-licensed (2)**

\*Ready for IND submission 1. Sanofi 5. Boehringer Ingelheim / Zailab

\*\*NDA submitted in Korea 2. Spectrum 6. Spectrum / Luye

\*\*\*Phase 3 in South America 3. Janssen 7. Athenex

4. Eli Lilly 8. Allegro Ophthalmics



Company Overview



R&D



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Partnership & Alliance

# Beijing Hanmi : Overview

Hanmi

Fully integrated from R&D, manufacturing to sales and marketing in China



**Established**

**Mar. 27th, 1996**

**Shareholdings**

**Hanmi Pharm: 73.7%; China Resources Group: 26.3%**

**Employees**

**1,428 (as of Dec. 2015)**

**Total Sales**

**1,130 Mil. RMB (172 Mil. USD) (as of 2015)**

**R&D Investment**

**86.2 Mil. RMB (13.1 Mil. USD) (7.6% of 2015 sales)**

# Beijing Hanmi : Performance

Hanmi

## NO.1 Pediatric Market Share

No.1 probiotics product 'Mamiai' (for children)  
No.1 anti-cough and expectorant product  
'Yitanjing' (for children)

### Mamiai

63 Mil. USD, 2015  
(450 Mil. RMB)

Modulator of  
intestinal flora



### 易坦静®



### Yitanjing

55 Mil. USD, 2015  
(360 Mil. RMB)

Expectorant  
cough medicine

## Nationwide Sales Network

1000 Sales force

32 Provinces

+300 Cities

+9,000 Hospitals

100% Children's Hospital

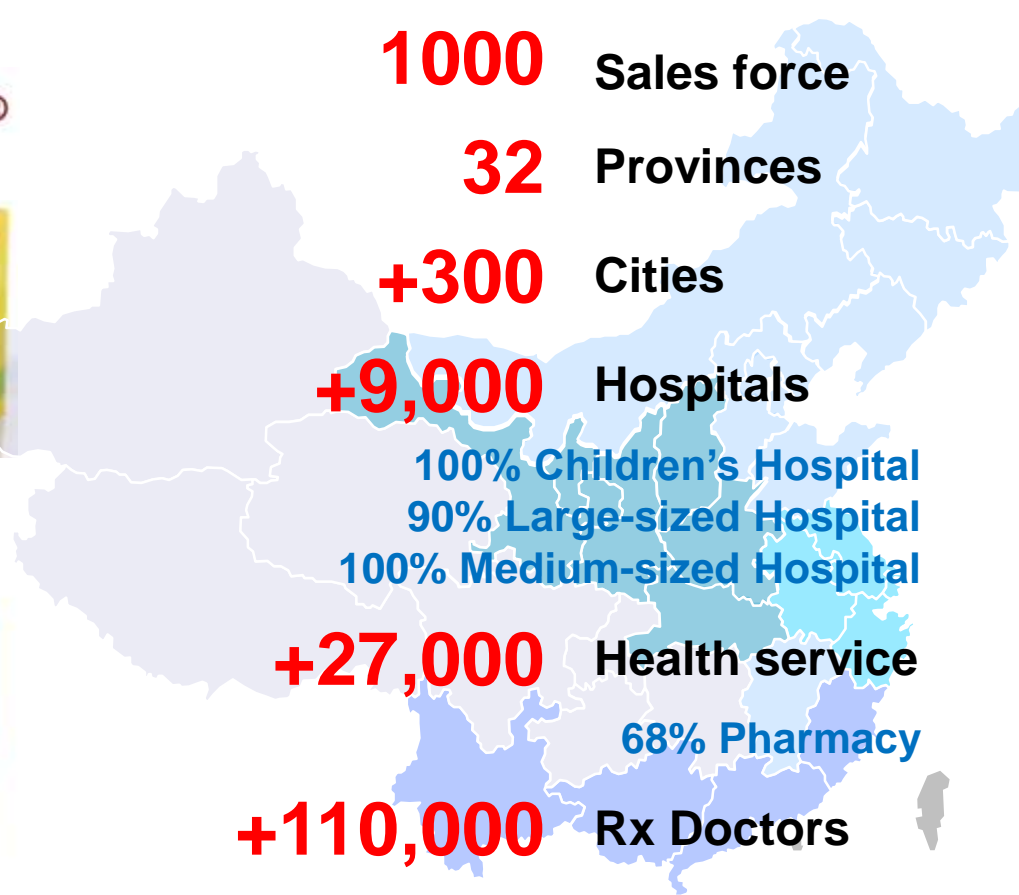
90% Large-sized Hospital

100% Medium-sized Hospital

+27,000 Health service

68% Pharmacy

+110,000 Rx Doctors





**Focus on the innovative** new drug discovery & development

**160** R&D staff

**7.6% Sales** to R&D Investment

Animal facility for rodents, beagles, and non-human primates

High-tech enterprise certification

## NCE

- ✓ Auto-immune
- ✓ Oncology
- ✓ First-in-class or Best-in-class

## New Biologics

- ✓ Oncology
- ✓ Auto-immune
- ✓ Next generation antibody

## BIO Production

- ✓ LAPScovary product
- ✓ Local manufacturing for China market access



# Hanmi's China Strategy and Partnership

Hanmi

## Open Innovation

- ✓ R&D Collaboration
- ✓ Marketing Collaboration
- ✓ Licensing
- ✓ Funding
- ✓ Acquisition
- ✓ ETC

## Local Partnerships & Collaborations

- ✓ **Fast & Successful Development**
  - Accommodate rapidly changing healthcare policy & environment
  - Collaboration with local partners with in-depth understanding of Chinese market

### ✓ Current Partners

**zaiLab™**

HM61713/ZL-2303 (2015)



poziotinib (2014)

## Beijing Hanmi & China Investment

- ✓ **Beijing Hanmi leading both R&D / Commercial growth in China**
- ✓ **Recent Investments**
  - Over \$200mil. investment for 10 years focused on R&D and manufacturing at Yantai site



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## *Maximize Value to Full Potential*

- Extensive development and commercialization capability
- Strong presence in the market with proven track record of success
- Portfolio fit with high priority

## *Good Working Chemistry*

- Positive interaction during course of discussion
- Openness and willingness to understand each other
- **Track record of sustainable partnership**

# Recent Global Partnership








Hanmi

Collaboration with global partners on various co-development and business opportunities for synergy effect



# Hanmi Have Reached New Heights in 2015

Hanmi

MAR	 Poziotinib		✓	Upfront payment	\$ 656 Mil.
MAR	 HM71224				
JUL	 HM61713		✓	Potential milestone payment	\$ 6,426 Mil.
NOV	 Quantum Project				
NOV	 HM12525A		✓	Royalties	Double Digit
NOV	 HM61713				

# New Model for New Drug Development – *Hanmi Way*

- **Focus the Resources into Core Research Area**

**New Chemicals:** Oncology & Autoimmune → Lead the world's new research trends

- **Efficient R&D through Platform Technology**

**New Biologics:** Rapid generation of candidates through **LAPSCOVERY Platform**

Focus the pipelines in Diabetes & Obesity → Strong Expertise in Metabolic Disease Area

- **Maximize the internal/external Human Resources**

Maintain the internal research leadership and recruit the external talents

Formulation of Global Scientific Advisory Board & Consultation for Development Path

- **Rapid Decision Process**

Decision through discussion between scientific leaderships and senior managements

- **Pre-determined Internal Consensus for the Right Partner**

Extensive strategic analysis for the competing partner groups

Strategy for the maximization of deal value through multiple potential partners

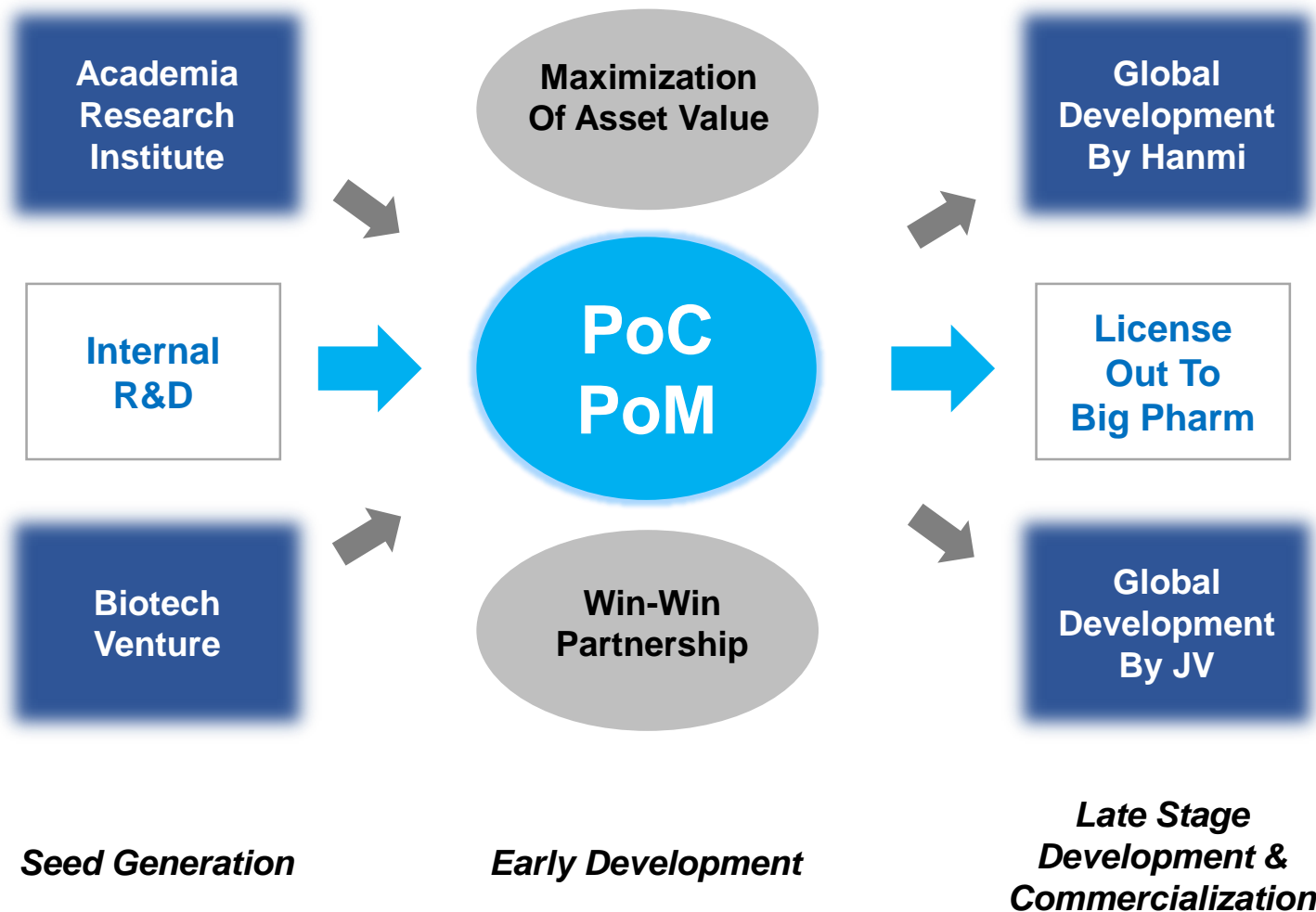
Execute the deal negotiation process focusing on the partner which can maximize the value of our asset

# What's next?

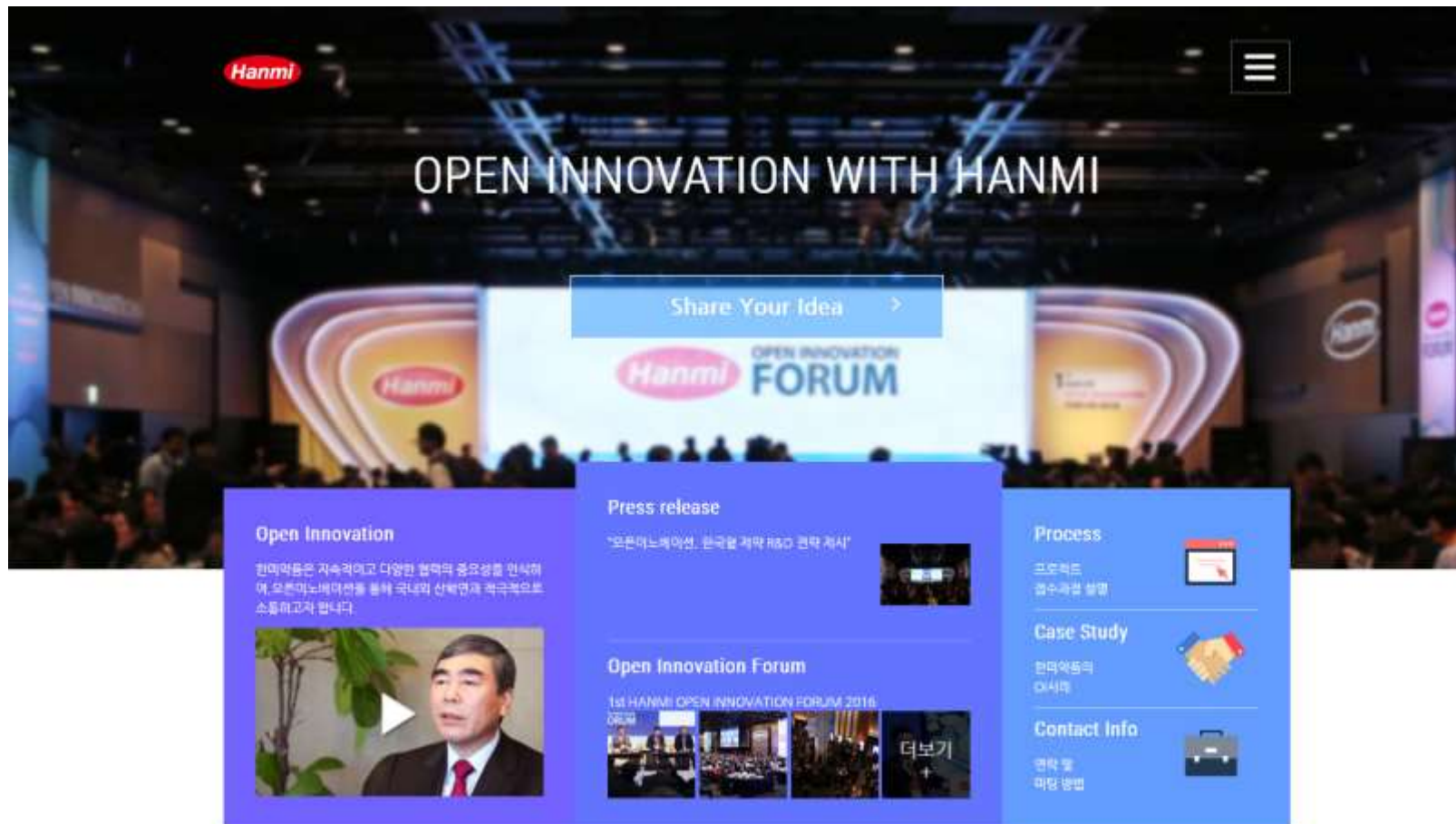




# Future Strategy- *Outsourcing Seeds by Open Innovation*



Hanmi Open Innovation Home Page(<http://oi.hanmi.co.kr>)





**“Creating the future together”**

***Hanmi***

***Thank you!***