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Making a Healthier Future
with BIONEER

Making a Healthier Future for Humanity
with Genomic Technology

BIONEER

Innovation • Value • Discovery

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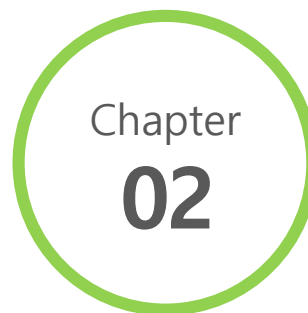
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Corporate Identity



Market Products



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Making a Healthier Future
with BIONEER

Chapter 01

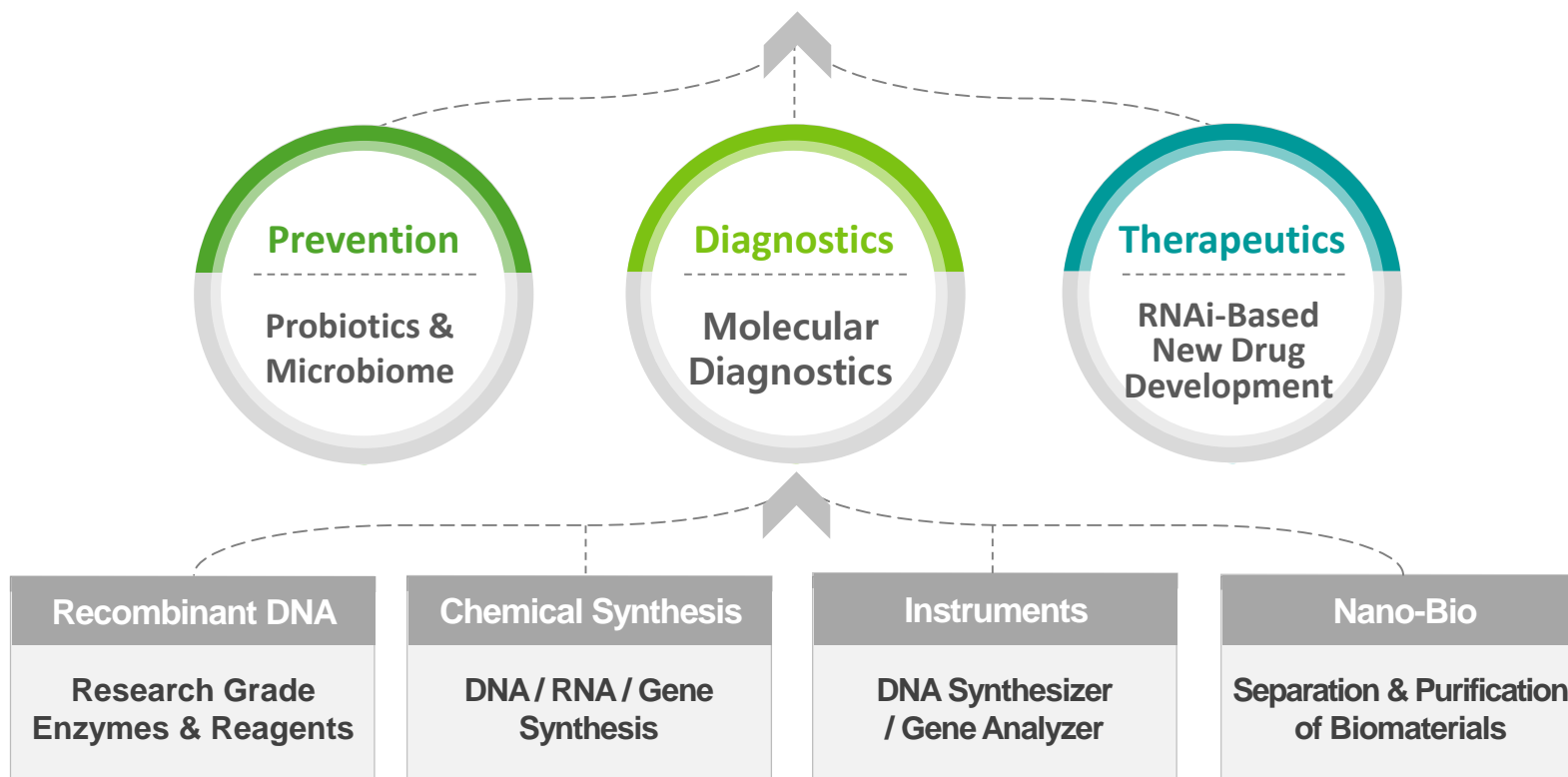
Corporate Identity



01 Key Technology Road Map

Translating Genomics Technology into Healthcare Solution!!

“Healthcare Innovator”





02 Company Overview

Location	Daejeon, South Korea
KOSDAQ Listed /Established	1992.08/2005.12
Key Products	MDx Instruments and Kits, Oligos and Research Products, siRNA Drug Development
Employees	380 (as of 2019.01)
Webpage	www.bioneer.com

Han-Oh Park, President & CEO



- B.S. Chemistry, Seoul National University (84')
- Ph.D. Biochemistry, KAIST (92')
- Vice President, Korea Biotechnology Industry Organization
- Adjunct Professor, KAIST
- Committee Member, Presidential Advisory Council on Science & Technology



Synergy in Business

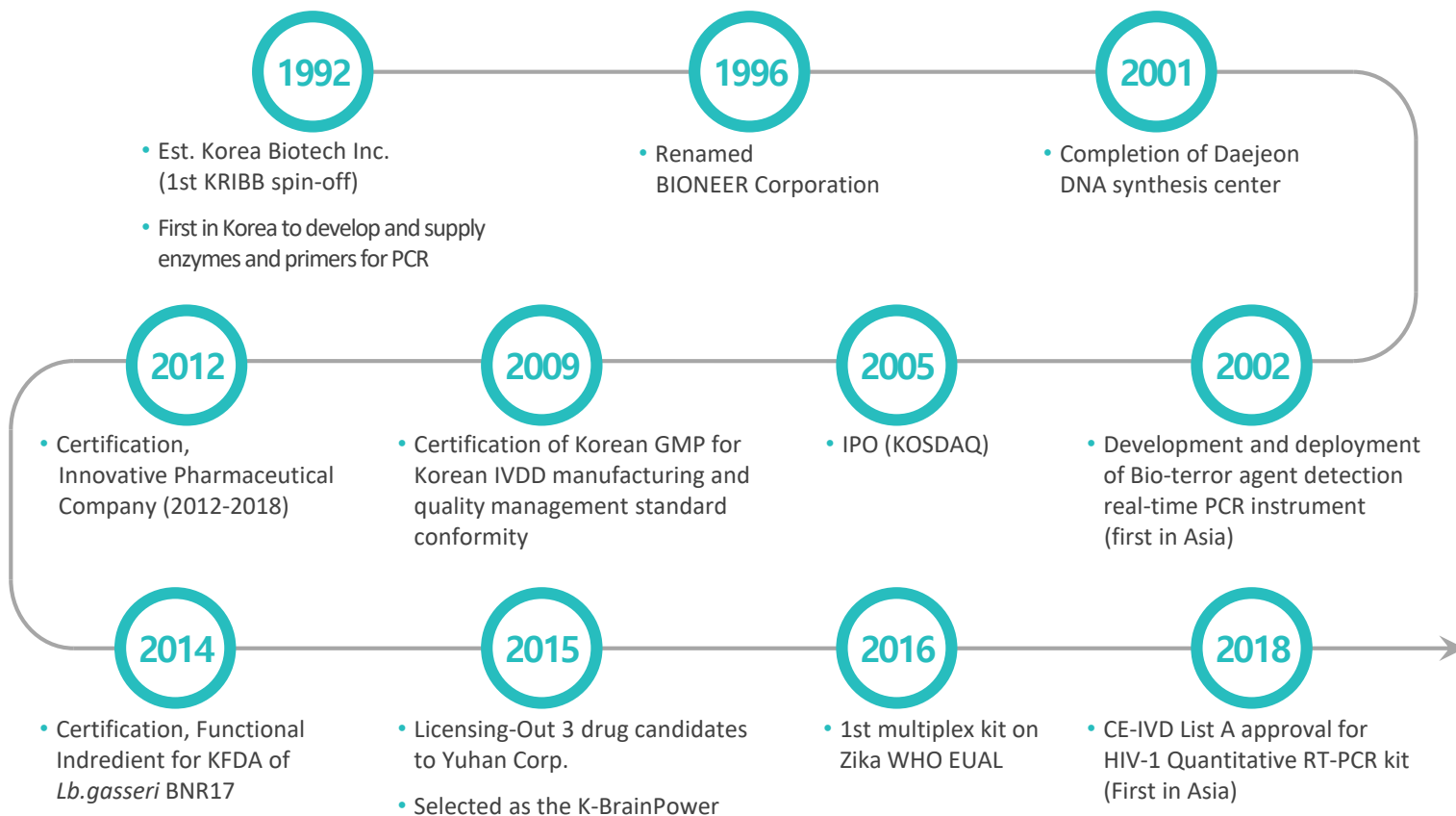
- The key technology of each division is organically integrated.
- Create and maximize synergy by Bioneer strategy.





03 Company History

Bioneer continues to challenge itself to become a global healthcare company.





04 Business Portfolio

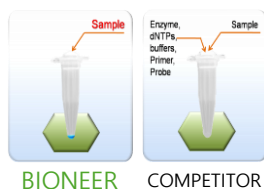
Life Science Research

- ✓ **Sustained and stabilized revenue growth**

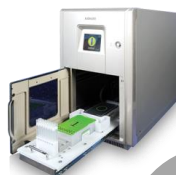
DNA/RNA
Synthesis



AccuPower®
PCR technology



DNA Synthesizer/
Gene Analyzer



Molecular Diagnostics

- ✓ **2017, Sales increased 80% year-on-year.**
 ✓ **2018, CE-IVD List A approval for HIV-1 Quantitative RT-PCR kit (First in Asia)**
 ✓ **2019, CE-IVD List A approval is expected (HBV, HCV MDx kits).**

Package closing system



MDx Instrument
(qPCR/Prep)



MDx Kits



Lb. gasseri BNR17

- ✓ **2018, Global licensing agreement**
- Isolation of *Lb. gasseri* BNR17 from human breast milk (2006.08)
 - Approved as functional ingredients with body fat reduction for functional foods by KFDA
 - Establish subsidiary: AceBiome Inc. (2017.04)
 - Global licensing agreement and supply contract

RNAi New Drug(SAMiRNA™)

- ✓ **2018, Preclinical tox study for IPF and keloid**
- Two-track approach for new drug and healthcare products development
 - Strong intellectual property position of siRNA and SAMiRNA
 - Powerful siRNA delivery platform technology for various diseases
 - Joint research partnership with Yuhan Corp. and global pharmaceutical companies





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Chapter 02

Market Products

- Life Science Research
- Molecular Diagnostics
- *Lb. gasseri* BNR17
- RNAi New Drug(SAMiRNA™)

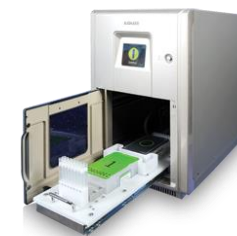


01-1 Life Science Research

Sustained and stabilized revenue growth

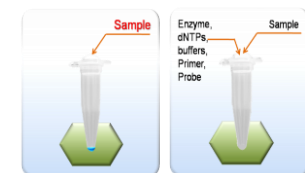
○ **ExiProgen™: Nucleic Acid Extraction & Protein Synthesis System**

- The world's first instrument for protein expression and purification, as well as nucleic acid extraction.
- Express and purify up to 16 proteins simultaneously for mutant screening, functional analysis, vaccine R&D, assay development and antibody development.
- Key Customers: Genentech, Stanford University, NPL, etc.



○ **AccuPower® PCR technology**

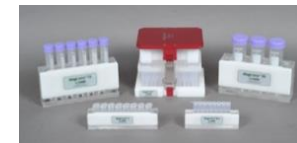
- Lyophilized room-temp-stable PCR premix, longer shelf life – more than one year.
- *Pyro-HotStart™* PCR: Enzyme -based HotStart PCR for the specific DNA amplification
- *Dual-HotStart™* RT/PCR : One-tube RT/PCR for more specific & sensitive RNA amplification



BIONEER **COMPETITOR**

○ **MagListo™ Nucleic acid extraction**

- Next Generation nucleic acid purification kits with magnetic silica Nanoparticle





01-2 Life Science Research

Sustained and stabilized revenue growth

○ DNA/RNA Synthesis

- Ensure High-quality & capacity Competitiveness with unique vertically-integrated DNA/RNA production
- The first developer of 384 parallel oligonucleotide synthesizer
- Raw material synthesis facility: Ton-scale phosphoramite capacity, >100 kinds of raw materials production
- Fully automated proprietary synthesis systems can produce over 30,000 oligonucleotides per day
- The state-of-art QC system: MALDI-TOF(7 systems), Capillary Electrophoresis system, LC-MASS

○ Gene Synthesis

- Fully automated and integrated Gene Synthesis technology
- With our oligo and molecular biology reagents, Bioneer offers the gene2protein™ service: codon optimization, gene synthesis, cloning and sequencing and protein synthesis.

Manufacturing Infrastructure





02-1 Molecular Diagnostics

Competitive Edge

- Bioneer has developed and commercialized total solution of MDx including instruments and kits.
- Secured cost advantage through the in-house production of expensive raw-materials
- MDx Key technologies invention such as *Dual-HotStart™*, the most sensitive RNA detection technology

MDx Instruments

Real-time qPCR (*Exicycler™ 96*)



- First developer in Asia
- Patented **Light-Tunnel**-technology for more sensitive and uniform quantification
- Certified CE-IVD, sFDA(China), FSZ(Russia)

Gene Extraction (*ExiPrep™ 16 Dx*)



- Patented three protection devices against aerosol contamination enable high sensitive detection without noise signal.
- *AccuNanobead™* silica magnetic nanoparticles enables pure and high yield extraction of nucleic acid
- Compact and economical design

MDx Kits

MDx Kits (*AccuPower® PreMix Technology*)

- Ultra sensitive molecular diagnostics technology from *Pyro-HotStart™* and *Dual-HotStart™*
- Outstanding stability through patented lyophilized PreMix
- Superior sensitivity, specificity and convenience
- Detection of various pathogens and genetic mutations
- CE-IVD certified



Diagnosis

- Viral pathogens: Hepatitis B, C, HIV, Influenza, FMDV, CMV
- Tuberculosis, respiratory diseases, STIs

Plant /Animal Screening

- GMO screening
- Veterinary disease screening including bird flu, foot-and-mouth disease etc.

Food Screening

- Food poisoning, water screening for Norovirus, enterovirus etc.

02-2 Molecular Diagnostics System

○ *ExiStation*TM



- Automated MDx system consists of *ExiPrep*TM 16 Dx and *Exicycler*TM 96
- Completion of diagnosis from sample preparation to Real-Time PCR in only 3.5 hrs
- Simultaneous diagnosis allows earlier detection of superinfection, such as HIV and TB.
- Optimized for *ExiPrep*TM Dx Extraction Kits and *AccuPower*[®] MDx Kits

○ *ExiStation*TM 48/48A System



- Consists of *ExiPrep*TM 48 Dx, *Exicycler*TM 96 and/or *ExiLT*^{*}
- Advantageous when using same type of specimen.
- Nucleic acid extraction from 48 samples within an hour.
- Use primary tube directly
: decapping/capping of sample tube and sample transfer motions are all automated.*
- Sample information is inputted automatically using built-in barcoding system*

* Only apply to *ExiStation*TM 48A



02-3 Applications

Hepatitis & HIV

- HBV Kit
- HCV Kit
- HIV-1 Kit

Human Papillomavirus

- HPV 16&18 Kit
- HPV Genotyping Kit

Tuberculosis

- MTB Kit
- MTB & NTM Kit
- TB & MDR Kit
- TB & XDR Kit (launching soon)

Transplantation-related Disease

- CMV Kit
- EBV Kit
- BKV Kit

Sexually Transmitted Disease

- STI 8A Kit (CT, NG, UU, MG)
- STI 8B Kit (TV, MH, HSV1, HSV2)

Gastro-intestinal Disease

- Norovirus Kit
- Enterovirus Kit

Respiratory Disease

- InfA Kit
- New InfA Kit
- CP Kit
- MP Kit
- MERS-CoV Kit

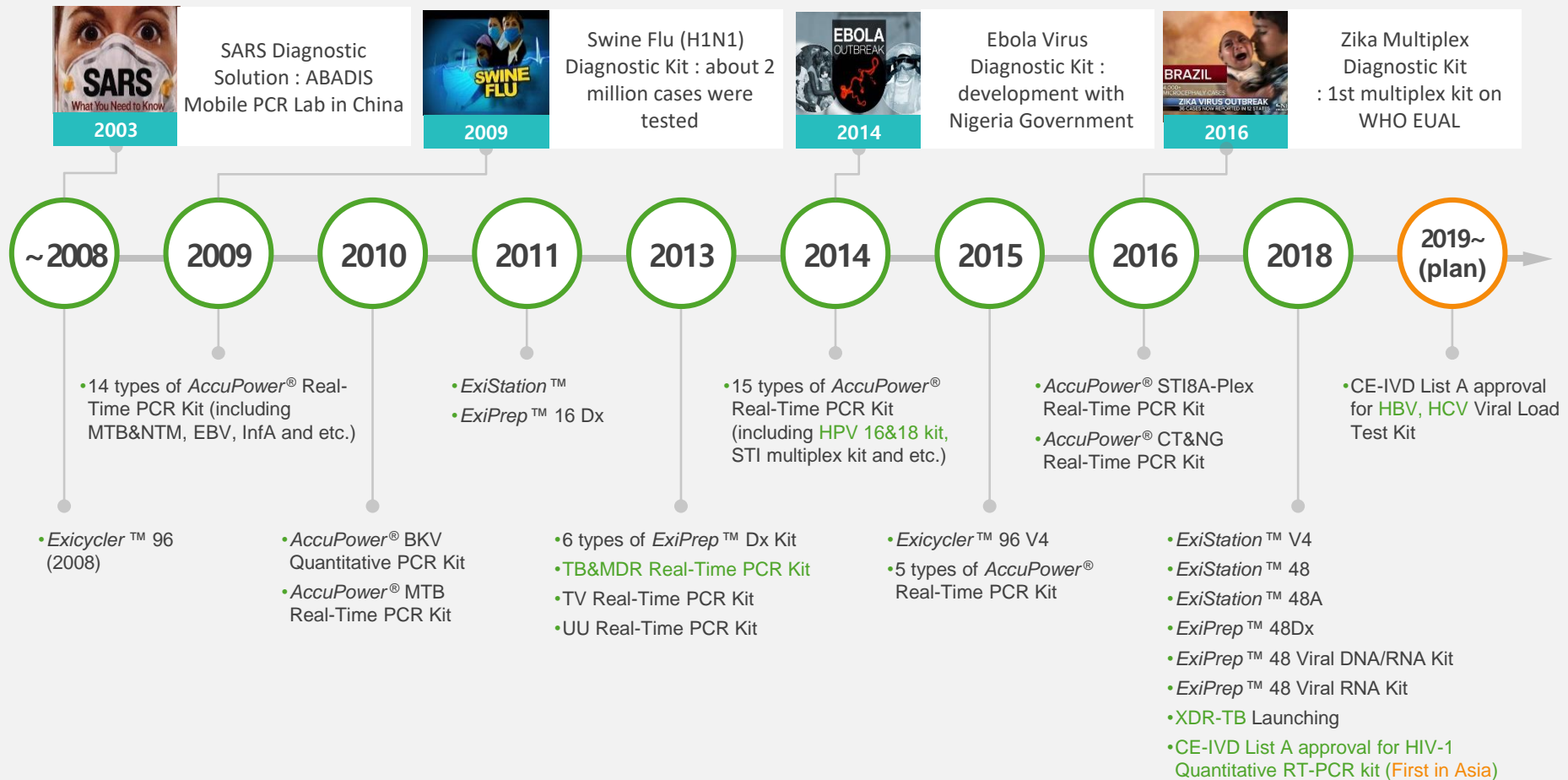
Mosquito-borne Disease

- ZIKV multiplex Kit (ZIKV, DENV, CHIKV)

Genotyping

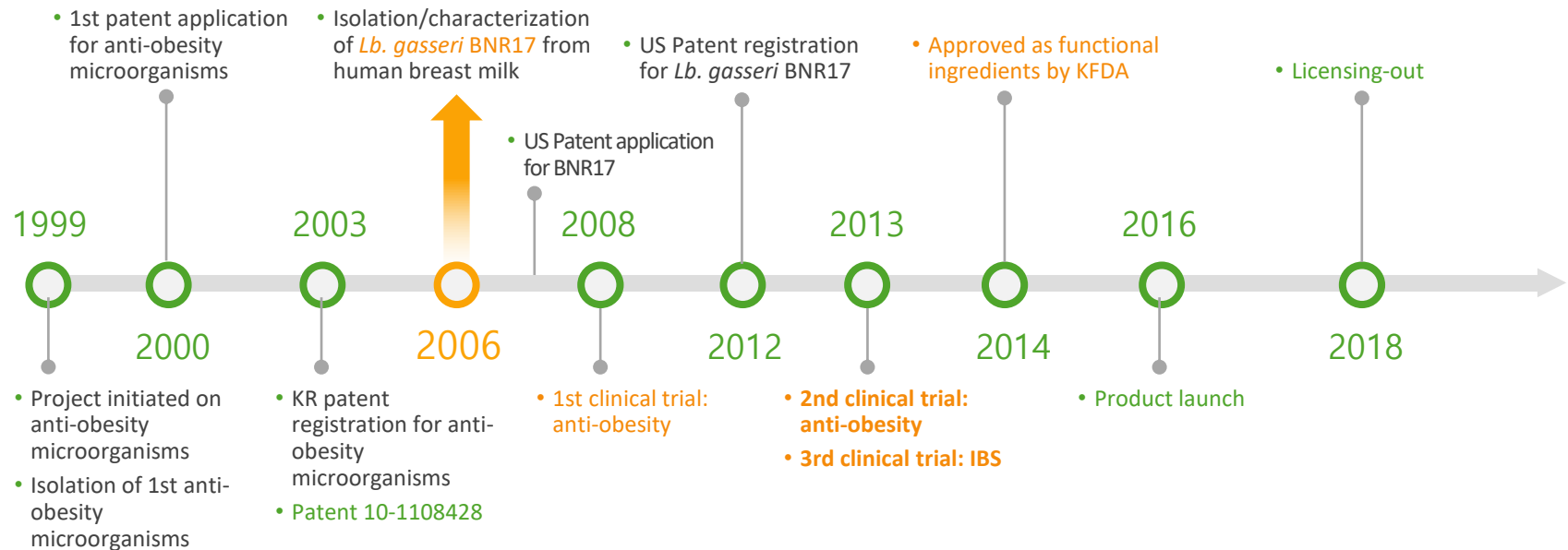
- ApoE Kit
- Warfarin Kit
- HLA-B27 Kit
- TPMT Kit
- MTHFR Kit
- JAK2 V617F Kit
- Factor V Leiden Kit

02-4 History of BIONEER's MDx Product



* This history is based on the year of achievement of CE mark.

03 Anti-obesity probiotic, isolated from human breast milk



Discovery of Lactobacillus strain for body weight control

- Screening of probiotic lactic acid bacteria from various sources and selection of *Lb. gasseri* BNR17 from human breast milk (August 2006)

Functional recognition and commercialization

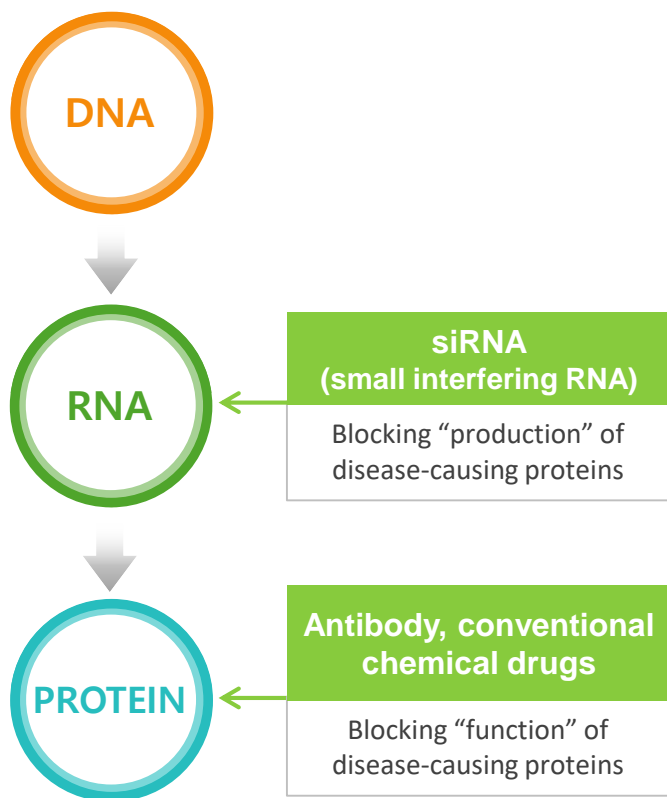
- 2nd clinical trial to study anti-obesity activity supported by Korean government fund in progress
- 3rd clinical trial to study bowel function improvement in Irritable Bowel Syndrome and anti-diabetic activity supported by Korean government fund in progress
- Approved as functional ingredients for Functional Foods by KFDA
- Global licensing agreement and supply contract



04-1 RNAi New Drug

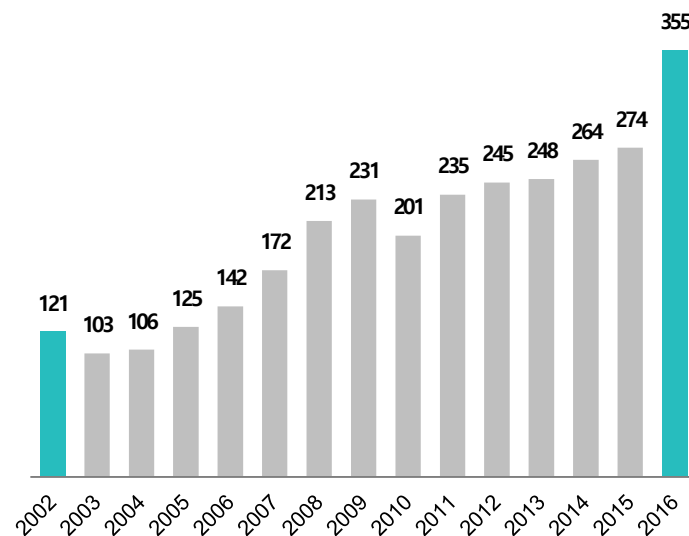
New drug modalities are mainly based on sequence.

Central Dogma



Oligo Therapeutics Programs

Number of total therapeutic oligo programs has almost tripled since early 2000.



Source : Gary Carter, The Oligo Therapeutics Market Landscape, TIDES 2016 presentation



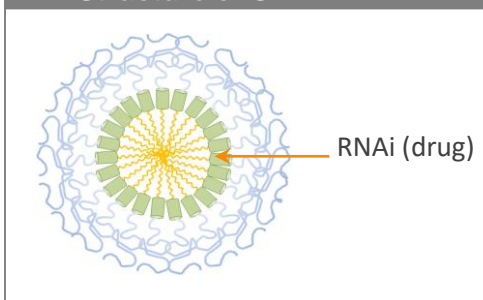
04-2 Competitive Edges

SAMiRNA™ solves the unmet needs in RNAi drug development.

SAMiRNA Description

- **SAMiRNA™ (Self-Assembled-Micelle-inhibitory-RNA)** is a novel class of RNAi molecule developed by Bioneer, which provides the solution for virtually all major difficulties in the development of RNAi-based therapeutics including siRNA delivery.
- Using this novel RNAi prodrug technology, Bioneer is currently advancing clinical development of pipeline programs for previously non-druggable diseases through our own pipeline efforts as well as through partnerships with major global pharmaceutical companies.

Structure of SAMiRNA™



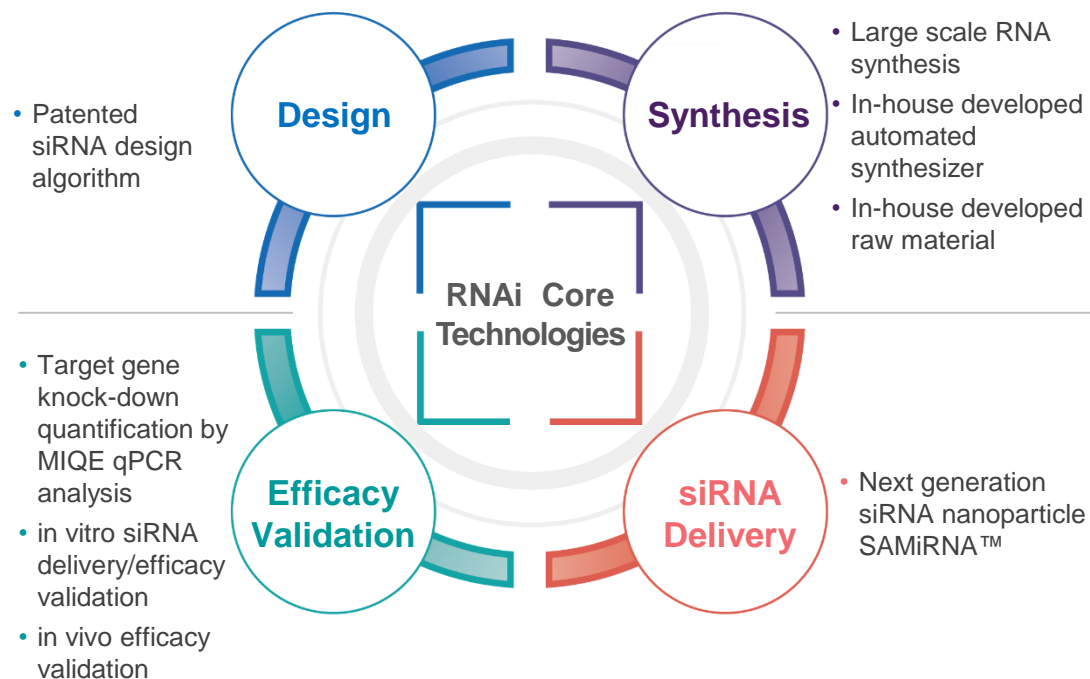
Summary

- The world's first **siRNA prodrug** technology: highly stable in circulation and siRNA is released and active only within the target cells
- **Strong intellectual property** position around SAMiRNA's unique structure and manufacturing processes
- **in vivo efficacy validated** in animal disease models via low dose I.V. injection
- Superb **serum stability** (PK/PD validated)
- Extremely **low toxicity** and cytokine induction
- Fully automated solid phase chemical synthesis of siRNA conjugates; **advantage of manufacturing & QC processes** for large scale production of siRNA drug
- Powerful siRNA delivery **platform technology**: Flexibility to incorporate siRNA sequences against any disease target

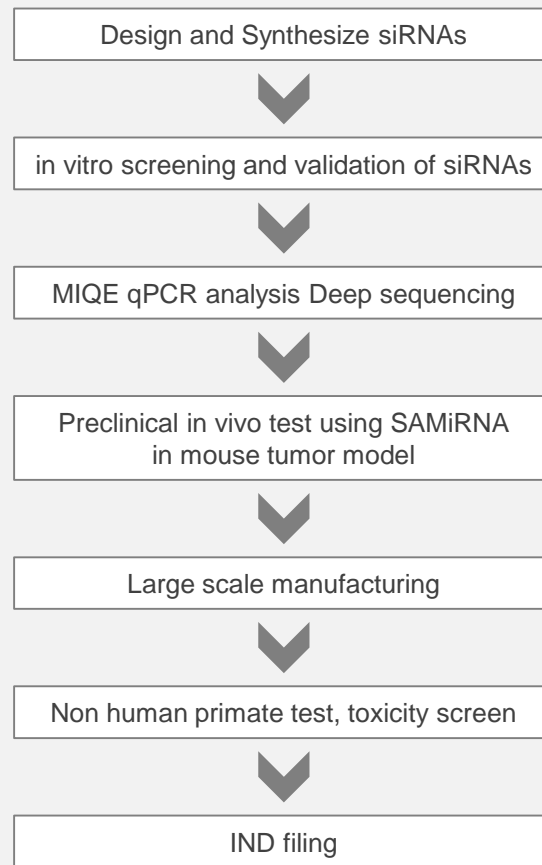


04-3 RNAi New Drug

Bioneer has vertically integrated siRNA drug development processes from high throughput siRNA synthesis to screening of SAMiRNA™.



Drug Development Roadmap

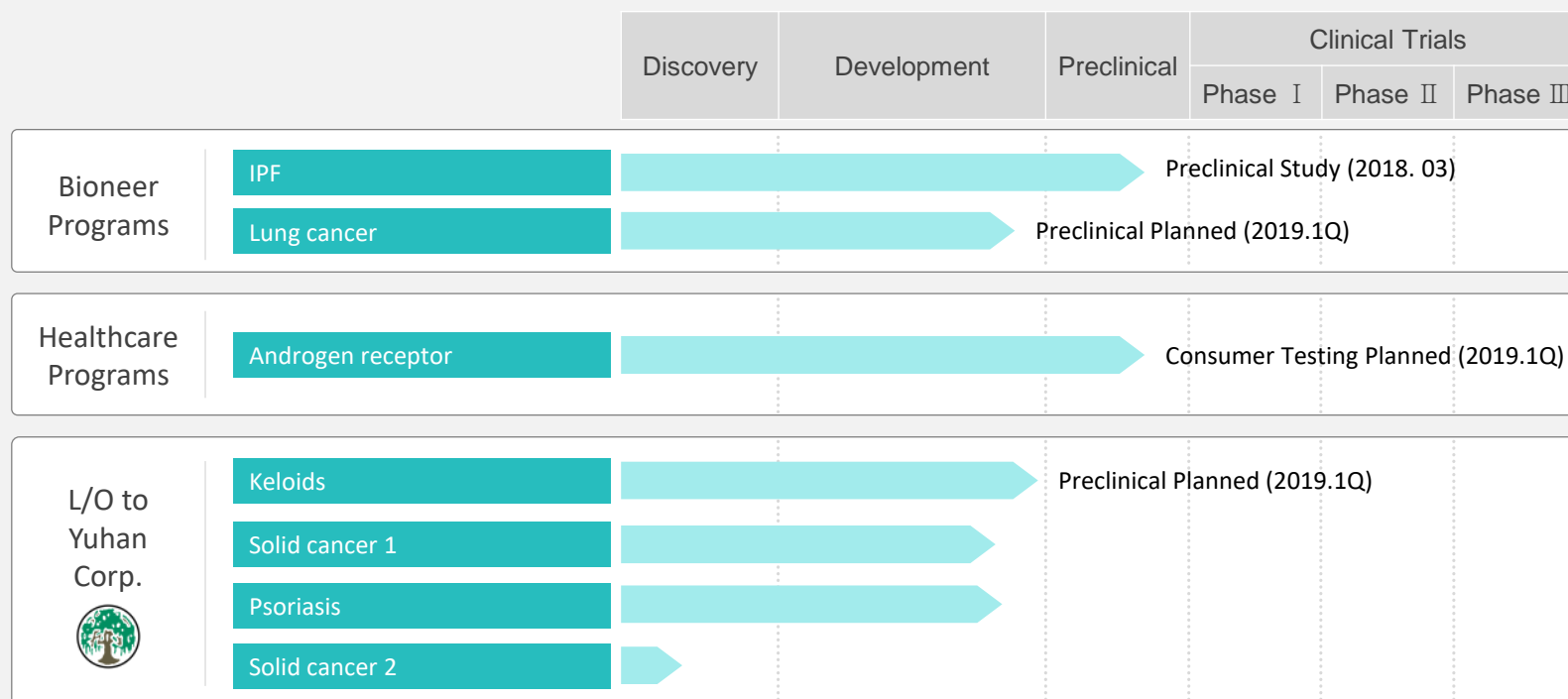




04-4 SAMiRNA™ Programs and Pipeline

Major fields of development

- New Drug : Lung cancer, Liver cancer, IPF, COPD, Immuno-oncology drug
- Healthcare : Hair loss prevention product



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