Presentation Material

Expansion of DDS Business

November 20, 2024

Solution NOF CORPORATION

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Functions of DDS

To deliver

the required amount of drugs

to where they are needed

on a timely basis

Improvement of therapeutic effects by efficient transport of drugs to affected areas

 Reduction in dosing frequency by improving drug retention in the body (Improved Quality of Life)

Improvement of drug stability

DDS: Drug Delivery System



Expansion of NOF DDS materials in the pharmaceutical market (1)



1) Modality: Methods/means for fundamental pharmaceutical development technology

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Expansion of NOF DDS materials in the pharmaceutical market (2)



| | Main pharmaceutical area | | Market size | | |
|---|--|--|-------------------------------------|-------------------------------------|------|
| NOF DDS materials | | | 2023 (US dollars in millions) | 2028 (US dollars in millions) | CAGR |
| Phospholipids | Chemically synthesized pharmaceuticals | Small molecule drugs | 485,719 | 619,914 | 5% |
| Activated PEGs | | Protein drugs | 124.050 | 192,265 | 9% |
| | | Peptide drugs | 124,959 | | |
| Monodisperse PEGs, solubilizers | Biopharmaceuticals | Antibody drugs | 230,375 | 354,460 | 9% |
| Functional lipids (SS lipids, PEG lipids) | | Nucleic acid drugs, gene therapy drugs | 6,383 | 36,852 | 42% |

Prepared with reference to Arthur D Little document (2023) and Evaluate Pharma



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Activated PEGs for peptide/protein drugs

- Activated PEGs are highly water soluble and can greatly enhance the water solubility of peptide/protein drugs by chemical modification.
- Peptide/protein drugs modified by activated PEGs have very high retention in the body.
- NOF has the largest share of the global market for activated PEGs, and the number of marketed drugs incorporating NOF's products has been increasing in recent years.



Business environment for activated PEGs and NOF's strengths

- The CAGR of the market for peptide and protein drugs, which is the target of our initiatives to expand activated PEGs, is 9%.
- Strengths of NOF
 - In-house manufacturing of high-quality PEG materials based on manufacturing technologies for PEG derivatives that have been developed over many years
 - Advanced manufacturing and quality control systems that are GMP¹⁾-conformant
 - An extensive track record of adoption by U.S. and European pharmaceutical manufacturers
- NOF focuses on customized responses to suit customer requirements and biosimilar²) demand for PEGylated drugs.
 - 1) GMP (Good Manufacturing Practice)

Mandatory manufacturing/quality control standards to be followed by manufacturers and marketing authorization holders of pharmaceutical products, etc.

2) Biosimilar

A biologic drug that is almost identical to and has no clinically meaningful differences from an existing approved biologic drug that is already on the market (reference biologic product)

New manufacturing facilities for raw materials* for DDS drug formulations *Activated PEGs

- Start of operation: FY2025 (planned)
- Manufacturing capacity: about twice that of the DDS Plant at the Kawasaki Works (planned)
- > Characteristics
 - Able to manufacture on a larger batch scale than before with GMP-conformant facilities
 - Realize a smart factory through the digital transformation of manufacturing and quality control
 - Contribute to carbon neutrality by adopting solar panels and energy-saving design



Manufacturing Building (Under construction)



Aichi Works



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Nucleic acid drugs and gene therapy drugs



- Nucleic acid- and gene therapy-based drugs can effectively treat genetic disorders and are also used in the manufacture of vaccines
- However, since nucleic acids and genes are unstable within the body, DDS technologies are essential to allow their utilization in medical treatment

Functional lipids

- Lipid nanoparticles (LNPs) are used as part of DDS technologies for nucleic acid drugs and gene therapy drugs.
- > LNPs consist of ionizable lipids, PEG lipids, etc.

| Lipid NanoParticle (LNP) | | Constituent | Role |
|---|----------|---------------------------------|---|
| 2 A A A A A A A A A A A A A A A A A A A | | Ionizable lipids (SS lipids) | Facilitates the inclusion and intracellular delivery of nucleic acids/genes |
| | | PEG lipids | Improves drug retention in the body |
| | | Phospholipids | Formation of lipid membrane |
| | ~ | Cholesterol | Stabilization of lipid membrane |

- NOF has developed SS lipids as its proprietary ionizable lipids with enhanced bio-degradability in the body and is developing customers by proposing LNP prescriptions.
- NOF is promoting PEG lipids in the market by leveraging their track record of being adopted for COVID-19 vaccines.
- > NOF is promoting phospholipids broadly in the market as generic materials.

Business environment for functional lipids and NOF's strengths

The CAGR of the market for nucleic acid drugs and gene therapy drugs, which is the target of NOF's initiatives to expand functional lipids, is 42%.

Strengths of NOF

- In-house manufacturing of ionizable lipids and PEG lipids by combining manufacturing technologies for fatty acids, phospholipids, and PEG derivatives, which are NOF's core technologies
- Advanced manufacturing and quality control systems that are GMPconformant
- SS lipids, which are based on joint research with a university, and the capability to develop LNP formulations using these lipids

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New manufacturing facilities for SS lipids

- Start of operation: FY2023
- Characteristics
 - Advanced manufacturing and quality control systems that are GMPconformant
 - Facilities to produce functional lipid products for LNPs



Desolvation facilities (Rotary evaporator) Solvent tanks

Production facilities

Aichi Works

NOF

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Future sales strategies (1)



While customers demand LNPs optimized for each formulation, NOF's offerings have been limited to the provision of lipids and LNP prescription proposals.



NOF will expand a seamless solution business optimized for each development stage of its customers by combining NOF's lipid technologies and CDMOs' LNP technologies.

Future sales strategies (2)

- > NOF has chosen Phosphorex as its CDMO due to its advanced LNP technologies.
- NOF started collaborating with Phosphorex for development of LNP prescription and contract manufacturing in April 2024.
- NOF strengthened the partnership by making a capital contribution to the company in August 2024.

% phosphorex

Advancing Nanomedicines Together

Phosphorex, LLC

Address: Hopkinton, Massachusetts, U.S.A.

- Located in the Boston area where nucleic acid and gene therapy drugs are actively being developed
- Founded in 2005, Phosphorex specializes in the development of particle-based drug delivery systems
- Phosphorex has a track record of contract development of LNP formulations for NOF customers





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Research structure of DDS business

- Prompt implementation of customized responses to customer requirements for DDS materials
- Finding solutions for materials utilized in the production of nucleic acid drugs through MI¹
- > Development of new products, targeting modalities with high growth potential
- New technology development by expanding collaboration with external research institutes



¹⁾ MI: Materials Informatics

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Sales plan for raw materials for DDS drug formulations (index number)

*Expressed in index number form based on FY2019 (set equal to 100)



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- •This material is intended to provide an explanation of the company and its business, not to induce investment or any other action.
- •The results forecasts presented in this document are based upon currently available information and assumptions deemed rational. A variety of factors could cause actual results to differ materially from forecasts.
- •Please be aware that decisions regarding investments are the responsibility of the users themselves.
- •Please note that, in this material, amounts less than ¥100 million have been rounded off.
- •In the event of any discrepancy between the Japanese original and this English translation, the original shall prevail.

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