Reponex Pharmaceuticals A/S

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(CVR-no. 30 08 23 46)

Forward-looking statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this presentation regarding Reponex' future operations, plans and objectives of management are forward-looking statements that are constantly evolving and being updated.

Background

Reponex Pharmaceuticals A/S is a clinical-stage biopharmaceutical company dedicated to the development of new, effective treatments for diseases that have significant patient and social impact and for which current therapy is lacking or in need of improvement. The diseases may be acute and life threatening, such as bacterial peritonitis or colorectal cancer, or may be chronic diseases that reduce the quality of life and may shorten it, such as inflammatory bowel diseases, or complications of chronic diseases such as the disabling non-healing skin ulcers in patients with diabetes or venous insufficiency. There is a continuing medical need to improve the treatment of these difficult conditions.

The business model is to bring the clinical programs to a stage with data showing the relevant clinical effect of the drug candidates. The clinical developments are performed in close collaboration with public research institutions and university hospitals.

Reponex' drug development is based on repositioning of established APIs (active pharmaceutical ingredients).

The key benefits of drug repositioning include:

- ✓ significantly accelerated time to bringing the drug to market
- ✓ significant decrease of the overall costs and development risks
- ✓ less restrictions on regulatory affairs and approvals because the safety and pharmacokinetic profiles of the repositioned drug candidates are already established
- ✓ possibilities of obtaining a strong intellectual property right (IPR) position, including patent protection
- ✓ providing the means for safer and more effective drugs to be made available to patients

Based on Reponex's proven ability to execute clinical studies and meet public authority requirements, as well as on the above-mentioned investment conditions with the relatively low cost of launching a successful repositioned drug, combined with the reduced risk in the development process and the reduced time to market, the Company has built up a diversified portfolio of clinical programs, which both individually and as a portfolio are expected to have a very attractive risk-reward ratio.

Company details

- **Company name**: Reponex Pharmaceuticals A/S
- **Address**: Slotsmarken 12, 1. th., DK-2970 Hørsholm, Denmark
- **CVR (Central Business Register) no.**: 30 08 23 46
- **Share capital**: DKK 829,540.90
- **Total no. of shares**: 8,295,409 shares of nominal value DKK 0.10
- **Number of shareholders**: >180
- **Board of Directors**: Søren Nielsen, chairman
  Troels Peter Troelsen, vice chairman
  Charlotte Pahl
  Christian Vinding Thomsen
  Lisbeth Thyregod
- **Management**: Klaus Snej Jensen, CEO
- **Accountants**: Grant Thornton, state-authorized accountancy partnership company
- **Accounting principles:** IFRS – international accounting standard
- **Bank:** Nykredit Bank

Professor Dr. Søren Nielsen, MD - Chairman of the Board

Scientific work: Cell and molecular biological, physiological and pathophysiological studies of aquaporin membrane water channels (aquaporins), sodium channels and transporters in the kidney and other organs to investigate their role in regulating water and sodium balance in health and disease. In close collaboration with Peter Agre (Nobel Prize 2003) of Johns Hopkins University School of Medicine and Mark Knepper of the NIH, the laboratory has been strongly involved in the development of this new research field since 1991. The main focus is on ischemia-reperfusion organ damage (kidney, heart, brain) including biotech and pharmaceutical drug development and role of mitochondrial dysfunction/lipid metabolism dysregulation in CNS and autoimmune diseases.

Innovation/community use of research/industrial financing: Co-founder and director of Action Pharma A/S (2001-2010 as CEO and 2010-2012 as COO). The lead program (AP214) has completed phase 2a and 2b clinical trials of renal protection in cardiac surgery patients in Europe and the United States. Has been responsible for raising over EUR 30 million for research and development. The AP214 asset (pharmaceutical drug candidate AP214) was acquired in May 2012 by Abbott, Chicago, for approximately EUR 100 million for marketing and patient use. CEO of SynAct Pharma ApS since 2012 (acquired part of the development programs from Action Pharma A/S).

Troels Peter Troelsen, MSc. Econ. – Vice chairman of the Board

Troels Peter Troelsen is chairman of the board of 6 companies and has over 20 years of experience as CEO and board member of larger companies and over 17 years of experience as Associate Professor at the Copenhagen Business School (CBS).
Troels Peter Troelsen has participated in 3 stock listings (IPO's) at Nasdaq OMX Copenhagen.
Troels Peter Troelsen has a broad national and international network.

Charlotte Pahl – Board member

Charlotte Pahl is a Director at Swedish Orphan Biovitrum AB (Sobi), Global Medical Affairs, Haematology. Charlotte Pahl has over 30 years of experience in the pharmaceutical industry gained while working for Sobi AB, Sweden. Sobi is listed at Nasdaq OMX Stockholm (SOBI). Charlotte Pahl has a wide range of international contacts and networks within the healthcare business, healthcare professionals and patients' organizations.

Lisbeth Thyregod, Master of Pharmaceutical Regulatory Affairs – Board member

Master of Pharmaceutical Regulatory Affairs 2011.
More than 40 year experience within the Life Science Industry
Head of Regulatory Affairs & Quality Assurance, Pharma Relations ApS
Lisbeth Thyregod has many years of experience from the life science industry as a specialist in regulatory affairs.

Christian Vinding Thomsen, attorney – Board member

Attorney-at-law, BKH Law P/S. Christian Vinding Thomsen is specialized within Regulatory Life Science & Healthcare, M&A and Corporate Law. With 20+ years' experience, Christian Vinding Thomsen is highly specialized in the legal issues facing the pharmaceutical industry. Christian Vinding Thomsen represents both Danish and non-Danish enterprises in issues relating to GCP, GMP, GDP, Market Access and Marketing Compliance. Further, Christian Vinding Thomsen advises on commercial contracts and corporate issues. In recent years Christian Vinding Thomsen has been team leader on a number of large successful transactions, including listings and mergers within the pharmaceutical industry.

CEO - Klaus Snej Jensen, MSc. Pharm.

Klaus Snej Jensen has over 30 years' experience in the pharmaceutical industry. He is a trained pharmaceutical researcher and comes from a position as CEO of NORD Pharma Partners and HB Medical Hørsholm. Klaus Jensen has been part of Drug Development since the early 1990s, when he was involved in the Novo Nordisk CNS Research Division and later as head of pharmaceutical development at NeuroSearch A/S, where he was a central part of the development program's activities, including the permanent due diligence set-up during negotiations with companies such as Novartis, Boehringer Ingelheim and GlaxoSmithKline. Most recently, he was appointed COO & Chief Pharmacist at Missionpharma A/S and has held various positions in Bavarian Nordic A/S, ALK A/S and Novo Nordisk A/S. Klaus Jensen has had significant global exposure in the pharmaceutical market, especially in the EU and the US as well as in India and China.

CFO/COO - Torsten Bjørn, BSc. Mech.

Torsten Bjørn has many years of experience in financial aspects of pharmaceutical companies. Torsten Bjørn has been responsible for accounting (ÅRL / IFRS), budgeting, financial calculations, consolidation of subsidiaries, internal controlling and reporting in Reponex as well as several other companies.
Documented experience base within administrative clinical project execution, IP, compliance and regulatory requirements.

CSO - Professor Dr. Lars Otto Uttenthal, MA, DPhil, BMBCh, MRCP(UK) – Responsible for IPR and clinical development

Professor Dr. Uttenthal is a former Research Fellow at the Universities of Oxford, London and Madrid and was Professor of Biochemistry at the University of Salamanca. He has over 45 years of experience in clinical medicine and biomedical research, as well as 18 years' experience in directing R&D in the medical industry. Dr. Uttenthal also has extensive experience with the conception of new patent applications and seeing them through the examination process.

Lasse Lindblad, Graduate Diploma in Business Administration (Finance) – International finance and business strategy

Lasse Lindblad is one of the primary founders of Reponex, and strategic advisor for Reponex in clinical, regulatory, IP and financial matters. With his extensive experience in business development, clinical, regulatory, and IP strategy and strategic value creation, Lasse Lindblad is a valuable consultant for Reponex.

He was trained in international economics, business administration and finance at the Copenhagen Business School and has extensive international experience in business development, investment banking, fundraising, mergers and acquisitions, exits and IPOs. He has an extensive relevant international network. Lasse Lindblad has been involved in biotech with both therapeutic developments and diagnostic applications for more than 20 years.

Significant collaborative partners

- **Zealand University Hospital**
- **Herlev University Hospital**
- **Bispebjerg University Hospital**
- **Savara ApS**
- **Ercros S.A.**
- **DB Lab A/S**
- **KLIFO A/S**
- **Zacco Denmark A/S**
- **Bioneer A/S**
- **CaRACS**
- **Granzer**
- **Lifecore Biomedical, LLC, USA**

Business model

It is Reponex's ambition to create value through the company's sustaining platform by bringing the clinical programs to a clinical stage with data documenting the relevant clinical effect of the drug candidates, that will be a strong starting point for the completion of an exclusive licensing of the company's drug candidates to global pharmaceutical companies, that can contribute to execution of the further clinical and regulatory process as well as having relevant distribution power.

Reponex' drug development is based on repositioning of established APIs (active pharmaceutical ingredients) with regard to new indications, new ways of administration and combination with other APIs. The clinical developments are performed in close collaboration with public research institutions and university hospitals, which in parallel obtain a research and publishing spin-off.

Reponex is organizationally effective, having adopted an aggressive commercial outsourcing strategy to be as agile as possible in order to meet a complex and continuously changing pharmaceutical industry. The strategy creates cost-effectiveness and the flexibility to scale up or down rapidly with respect to relevant human knowledge resources, which the company considers to a key factor and driver of success.

Reponex's drug development is based on a combination of:

- Repositioning of existing API (active pharmaceutical ingredient)
- Clinical strategy
- Effective regulatory pathway
- Aggressive outsourcing
- Intellectual Property Rights (IPR)

Repositioning

Repositioning means the finding of a new application for an active substance that is already being used for other treatments. In general, it means that the substance is used for another indication (i.e. for the treatment of a different disease) than that for which it was originally developed and registered. The advantage of this is that the active substance's basic toxicity and adverse events profile are known and documented.

Repositioning has the potential to impact a significant number of patients in which there is currently an unmet medical need. When repositioned therapies demonstrate improved efficacy, safety and/or cost over the current standard(s) of care, both patients and drug developers alike reap the benefits. Pharmaceutical companies can save both time and money in drug development by streamlining validation studies without the need to reproduce in-human safety studies, whereas patients gain access to novel, fast-tracked approaches aimed at treating their personal disease.

Through the innovative reuse of existing knowledge, Reponex seeks to execute its clinical development programs to the fullest possible extent and thereby achieve a low project risk. By combining effective drug development strategies, i.e. by repositioning in combination with a new route of administration, and in some cases by combination with various other active substances that act synergically on various aspects of the disease, the developments seek to achieve a potent therapeutic effect.

Clinical strategy

Reponex's clinical strategy is to establish collaborations with internationally leading experts in each of the company's specific clinical areas, and thereby execute Reponex's clinical programs in close interaction with the latest knowledge and research, that continuously are producing publications which directly or indirectly validate the height of Reponex's clinical development programs.

This means that Reponex carries out its clinical programs in the appropriate academic environment with direct access to patients, and keep abreast of the latest advances.

Through the innovative use of existing knowledge, its own experience base and the repositioning of drugs, Reponex seeks to design the company's clinical development programs under close assessment of relevant clinical endpoints, statistical significance of data outcomes and cost-effectiveness.

Reponex's clinical development programs generally meet a large unmet medical need within the individual indications.

It is Reponex's ambition to pursue the clinical programs to the stage of submission of relevant clinical data with statistical significance, which could form the basis of an industrial alliance or a sale based on industrial convergence.

Regulatory strategy

Reponex defines the regulatory strategy from corporative and clinical objectives, primary and secondary endpoints in correspondence with patent claims. Reponex will streamline the outcome of the clinical trials by pre-IND meetings with EMA and/or the FDA to align the strategy for a smooth registration pathway once relevant and strongly positive clinical data have been obtained.

Reponex's clinical pipeline opens access to a range of registration pathways provided by the EMA and the FDA by identifying the combination of a new indication and a new formulation based on well-known and characterized APIs with a safety and adverse events profile that allows for Reponex to refrain from conducting costly toxicological studies.

Aggressive outsourcing

Reponex has chosen an aggressive commercial outsourcing strategy in order to be as well prepared as possible for change to meet the challenge of a complex and continuously changing pharmaceutical industry, just as the strategy creates both cost-effectiveness and the flexibility rapidly to scale relevant knowledge resources up or down, which is considered a key factor for success.

Reponex’s IP strategy

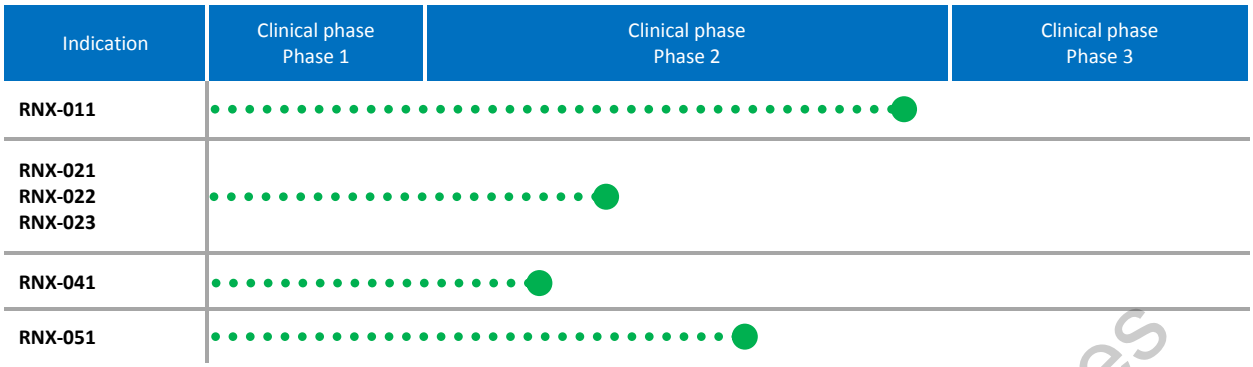
Reponex seeks to attend to IP protection through a purposeful patent strategy. This is carried out with strict observance of the costs associated with the patenting process, especially in the national phase when Reponex's starting point is to protect the largest pharmaceutical markets, such as the USA and the EU.

Reponex endeavors to draft its patent application so that the description and claims can be expected as far as possible to cover the anticipated new indications and the corresponding clinical trial endpoints. The process has an element of reciprocity, in that allowed claims can influence the prioritization of clinical endpoints, just as unexpected benefits discovered at clinical trial may lead to a new patent application.

Reponex Pharmaceuticals A/S

Reponex's clinical overview

Pipeline



Patient base and global market

Drug candidate and indication	Clinical phase	Patient base	Global market
RNX-011 Prevention and treatment of bacterial peritonitis	II	Approx. 1.2 million new cases per year in the EU, USA and Japan	Estimated with some uncertainty at USD 1.5 – 2 billion.
RNX-021 , RNX-022 Treatment of chronic skin ulcers	II	Approx. 16 million patients in the EU, USA and Japan	USD 19 billion (2019) USD 25 billion (expected for 2025)
RNX-023 Treatment of infected chronic skin ulcers	II	Approx. 2.5 million patients in the EU, USA and Japan	
RNX-041 Treatment of Crohn's disease and pouchitis	II	Approx. 2 million patients in the EU and USA with Crohn's disease. Chronic pouchitis affects up to 10% of patients following total proctocolectomy for ulcerative colitis.	USD 3.6 billion (2016) USD 4.7 billion (expected for 2025)
RPNX-051 Prevention and treatment of colorectal cancer	II	Approx. 1.5 million new cases per year in the western world	USD 9.4 billion (2020)
RNX-42 Administration platform		New drug delivery platform for drugs targeted to the intestine.	

Clinical development programs

RNX-011 - Reponex's medicinal product for the intraperitoneal treatment of bacterial peritonitis

Reponex is, as the only company with strong data for a completed clinical phase 2 study, a global leader in clinical trials of drugs for the treatment of peritonitis.

The aim of this project is to improve the treatment of incipient or established peritonitis (inflammation of the peritoneum) as a consequence of appendicitis or other intestinal perforations, thereby significantly reducing the length of hospitalization in favor of patients' convenience and healthcare costs. Following a successful Phase 2 clinical acceptability and safety study, the second Phase 2 clinical trial in patients with ruptured appendix has also been successfully completed with strong data.

Reponex wants its effective RNX-011 to have as broad indications as possible for its marketing authorization, so that it is not merely authorized for the prevention and treatment of peritonitis due to a perforated appendix. RNX-011 is expected to be highly effective for treating all forms of secondary bacterial peritonitis, which is typically caused by perforations or leakage from the gastrointestinal tract due to many different causes. Therefore Reponex is planning, together with its abdominal surgical collaborators, to conduct additional clinical trials on the use of RNX-011 in operative intervention in these other cases.

Reponex wants to be able to offer the drug combination to all patients during surgery if bacterial peritonitis is expected as a risk (prophylactic) or if the patient develops post-operative peritonitis.

RNX-021, RNX-022, RNX-023 - Reponex's dermatological products for the topical treatment of chronic skin wounds and ulcers

Chronic ulcers in the form of venous leg ulcers and diabetic ulcers are a worldwide problem to the great inconvenience of the affected patients.
Reponex has formulated two gels for topical application to accelerate the healing of chronic skin wounds and ulcers, one with a single active substance (RNX-021) and another with the addition of two other wound healing agents (RNX-022).
A randomized, placebo-controlled clinical phase 2 trial of RNX-021 is in active progress at Bispebjerg Hospital, with similar trial of RNX-022 to follow.

Up to 16% of patients with chronic leg ulcers will at some point in the course of treatment experience infection in the wound that requires treatment.
Reponex has formulated a drug (RNX-023) in the form of a dusting powder that combines an active substance with an antibiotic for use on severely infected chronic wounds. The formulation work with RNX-023 in the laboratory is ongoing at Reponex's formulation partner.

RNX-041 - Reponex's medicinal products for intra-intestinal administration to treat Pouchitis

A special group of previously operated ulcerative colitis patients, having complete colon resection, suffer from a chronic, Crohn's-like inflammation of the pouch constructed from the terminal ileum to allow normal defecation. This inflammatory condition is called "pouchitis". Pouchitis causes great pain, very frequent toilet visits and often significantly reduced quality of life for the patients.

A clinical phase II trial on RNX-041 for the treatment of pouchitis is ongoing at Zealand University Hospital. The study will provide invaluable data for the design and execution of the subsequent placebo-controlled trial of RNX-041 for Crohn's Disease.

RNX-041 - Reponex's medicinal products for intra-intestinal administration to treat Crohn's disease

Crohn's disease is an immune-mediated disease in which parts of the digestive tract come under destructive attack. Recurring intestinal ulceration, narrowing and fistula formation are frequent manifestations, which i.a. causes great pain, frequent toilet visits and generally very reduced quality of life for the patients.

Reponex has developed an innovative drug combination, RNX-041, and route of administration from the intestinal cavity via endoscope in order to improve on the positive but moderate results achieved by systemic administration of similar substances while reducing the risk of systemic adverse events. Reponex is preparing a placebo controlled phase II study on RNX-041 for Crohn's Disease.

RNX-051 - Reponex's medicinal product for intra-intestinal administration to eradicate cancer-promoting colonic bacteria

It has recently been discovered that generation, growth and spread of colorectal cancer tumors are promoted by certain bacteria in the large intestine, including fusobacteria, toxin-producing enterococci, coliforms and *Bacteroides spp*. These may exist in biofilm which invades the surface mucous layer of the colon and some can also infect the tumors, promoting growth and resistance to radio- and chemotherapy.

Reponex has designed a pharmaceutical composition for an innovative method of eradicating or reducing these cancer-promoting bacteria in the colon and eliminate the bacterial biofilm, by the intraintestinal administration of RNX-051. A clinical phase II trial on RNX-051 is ongoing at Zealand University Hospital.

With successful data, Reponex wants to further develop the project in combination with the company's innovative oral drug administration platform for a more appropriate route of administration.

Other Development programs

RNX-042 - New drug delivery platform

In parallel with the development of RNX-041, it has been important for Reponex to develop a concept for administration of the active substances for the treatment of intestinal lesions in the form of an oral drug, so that patients can receive treatment daily comfortably and without significant inconvenience.

Reponex has been developing a new concept and technology that entails the targeting of the active ingredients in RNX-041 and possibly other biological agents directly to the intestinal lesions, by binding the agents to known and approved substances that in themselves bind selectively to the lesions and prolong the contact of the biological agents with the ulcer bed. RNX-042 is to be administrated orally by a gel forming substance protecting the biological agents until reaching the terminal ileum where the gel dissolves and releases the active ingredients.

Two main concepts are being studied that can be used individually or in combination to target the drugs to the intestinal lesions in Crohn's Disease:

1. Adsorption (surface binding) of the fragile but important active protein in Reponex's medicinal drug, which builds the integrity of the intestinal mucosa, into a known ulcer-treating particle product that binds the protein, protects it from the breakdown of stomach acid and digestive enzymes, binds to defects in intestinal mucosa and enhances the action of the adsorbed protein.

2. Dissolve the active substances in a small amount of a thin liquid containing substances which form a soft gel lump when the liquid is swallowed and comes into contact with the stomach acid. The drugs remain significantly inside the gel, thereby protecting against the full effect of stomach acid and digestive enzymes. The gel is transported down the intestine, but is broken down again in the transition from the small intestine to the large intestine, thus triggering the drugs. This could prove to be suitable for the treatment of Crohn's lesions in the terminal small intestine and / or the subsequent part of the large intestine. Preliminary studies so far indicate a satisfactory incorporation of the API into the gel when it is formed in contact with simulated gastric acid.

Reponex attaches great importance to the development of these possible oral treatments for intestinal lesions, as thy are expected to enable the performance of what is actually a local treatment that would most often require invasive endoscopy, as a convenient oral treatment for daily use.

Through the development work with RNX-042, this dynamic gel concept has proven to be particularly suitable for the delivery of particle preparations further down the intestine, including probiotic bacteria, which is also specified in the filed patent application.

Reponex's innovative drug administration platform opens up completely new possibilities for local targeted treatments in the gut, which go far beyond Reponex's current development program.

Overview of IPR

Application No	Priority date	Title	Indication	Status
WO2016020530A1 (priority DK PA2014 70473)	**07.08.2014**	"Compositions for treatment of peritonitis"	RNX-011	**Granted in EU, US and JP**
Priority DK PA2019 70266	**28.04.2019**	"Composition for the intraperitoneal treatment of secondary bacterial peritonitis with reduction of complications"	RNX-011	Awaiting national phase
WO2015177379A3 (priority DK PA2014 70300)	**23.05.2014**	"Compositions for promoting the healing of wounds"	RNX-021, RNX-022	National phase in EU, US
WO2015118069A1 (priority DK PA2014 70059)	**05.02.2014**	"Compositions for promoting the healing of skin ulcers and wounds"	RNX-023	**Granted in EU and RU** National phase in US
WO2016012608A1 (priority DK PA2014 70461)	**25.07.2014**	"Compositions for treatment of IBD"	RNX-041	**Granted in US** National phase in EU
Priority DK PA2019 70266 Priority DK PA2019 70324	**20.03.2019 22.05.2019**	Targeting biological agents to mucosal defects of the gastrointestinal tract	RNX-042	Awaiting national phase
PCT/EP2019/050798 (priority DK PA2018 70030)	**17.01.2018**	"Compositions for eliminating bacterial promotors of colorectal cancer by intraluminal application"	RNX-051	National phase in EU, US, JP and RU

Control by regulatory authorities

Reponex Pharmaceuticals A/S is a regulated company subject to a number of laws and executive orders as well as Eudralex vol. 4, part I-III with annexes. Reponex has obtained the below authorizations and certificates.

Authorizations according to the Danish Medicines Act §39

Manufacturing and Importation Authorization

Wholesale Distribution Authorization regarding Medicinal Products

Certificates

GMP: Certificate of compliance - Good Manufacturing Practice

GDP: Certificate of compliance - Good Distribution Practice

Regulations

GCP: Good Clinical Practice