

LIPIGON DEVELOPS FIRST- OR BEST-IN-CLASS TREATMENTS FOR ORPHAN INDICATIONS IN THE LIPID RELATED DISEASE AREA.



Market need and potential

Homozygote FH (HoFH) is an orphan indication that has a prevalence of 1 in 160,000 . This rare genetic disorder is strongly associated with CVD and premature death; untreated, it often causes heart disease in the early teen years . HoFH patients are largely unresponsive to conventional treatments. This is because these drugs are dependent on a specific receptor mechanism that is mutated in most FH patients (LDL receptor). Hence, there is a significant urgent demand on novel treatments that utilize a different mechanism of action. Sales predictions for HoFH drugs by 2023 are \$600 M.

Business idea

What distinguishes Lipigon to its competitors is the combination of lipid biology expertise combined with the advanced ASO platform. Lipisense is hitting two important targets at once is anticipated to target an LDLr independent mechanism lowering LDL in HoFH patients together with improving other important lipid moieties. This strategy is unmatched by current competitors. Furthermore, the effects on LDL-cholesterol are expected upon a single injection, which is a very attractive clinical development feature unique to Lipisense. Developing orphan therapies has a number of advantages, including less extensive clinical trials, support from authorities, advice and opportunities for market exclusivity in the EU (10 years) and the US (7 years), reduced fees for regulatory activities.

Advantages

- Genetic and clinical validation of targets
- Proven 3rd generation ASO technology
- De-risked pre-clinical safety/tox
- De-risked Phase 1 clinical trials (low number of subjects, effect on endpoint marker upon single injection)
- Experienced team and strong strategic partners
- Orphan indiciation
- Possibility to expand into broader indications product life cycle management

Current status

Lipisense is our front-runner program where we aim at selecting a candidate drug (CD) by Q2 2019. Our funding strategy are linked to the major milestones that the Lipisense program will reach during 2019 and 2020. The current plan is to raise funding via a pre-IPO and subsequent IPO as major inflection points are reached. Other funding options are also under consideration.

Competition

	Novelty: Mechanism of action	Efficacy: Suitable for all FH patients	Cost (EUR)	Ease of use: Route of administration
Statins	LDLr dependent	No	100	Oral
PCSK9 inhibitors	LDLr dependent	No	5-15K	Injection
Lomitapide	Non-LDLr dependent	Yes (but leads to liver lipid retention)	245K	Oral
Mipomersen	Non-LDLr dependent	Yes (but leads to liver lipid retention)	245K	Injection
Lipisense	Non-LDLr dependent	Yes	250K	Injection

Photos by Johan Gunséus

Lipigon's pipeline

Treatment	Preclinic	Preclinical		Clinical development			Partner
Identification	n Optimization	Safety	Phase 1	Phase 2	Phase 3		
Familial Hypercholesterolem							Secarna
Lipodystrophy							Ongoing
CVD/dyslipidemia	2019- 2020						Ongoing

COMPANY PROFILE

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IPR

ASO based treatment for HoFH filed November 2018

Capital need

20 MSEK pre-IPO Q2 2019 to cover pre-clinical safety/tox

50 MSEK IPO Q2 2020 to cover first-inman Phase 1 trials

Partnership

We are seeking contact with private and institutional investors, VC companies and pharmaceutical partners with an interest in metabolic disease

Management / Board

Carina Schmidt
Chairnerson – life science professional

Lars Öhman evelopment

Erik Lund ss development

Mikael Elofsson

Team

Stefan K Nilsson

Gunilla Olivecrona

Background

Lipigon was founded 2010 by Lipid biology experts. The company aims at building a sustainable research-based company with a rich pipeline of product candidates to bring major inflec-tion points alone or in collaboration with partners.











