

Cinclus Pharma Q3 Report 2024

Webcast November 14, 2024, 10:00

Presenters:

Christer Ahlberg, CEO

Maria Engström, CFO

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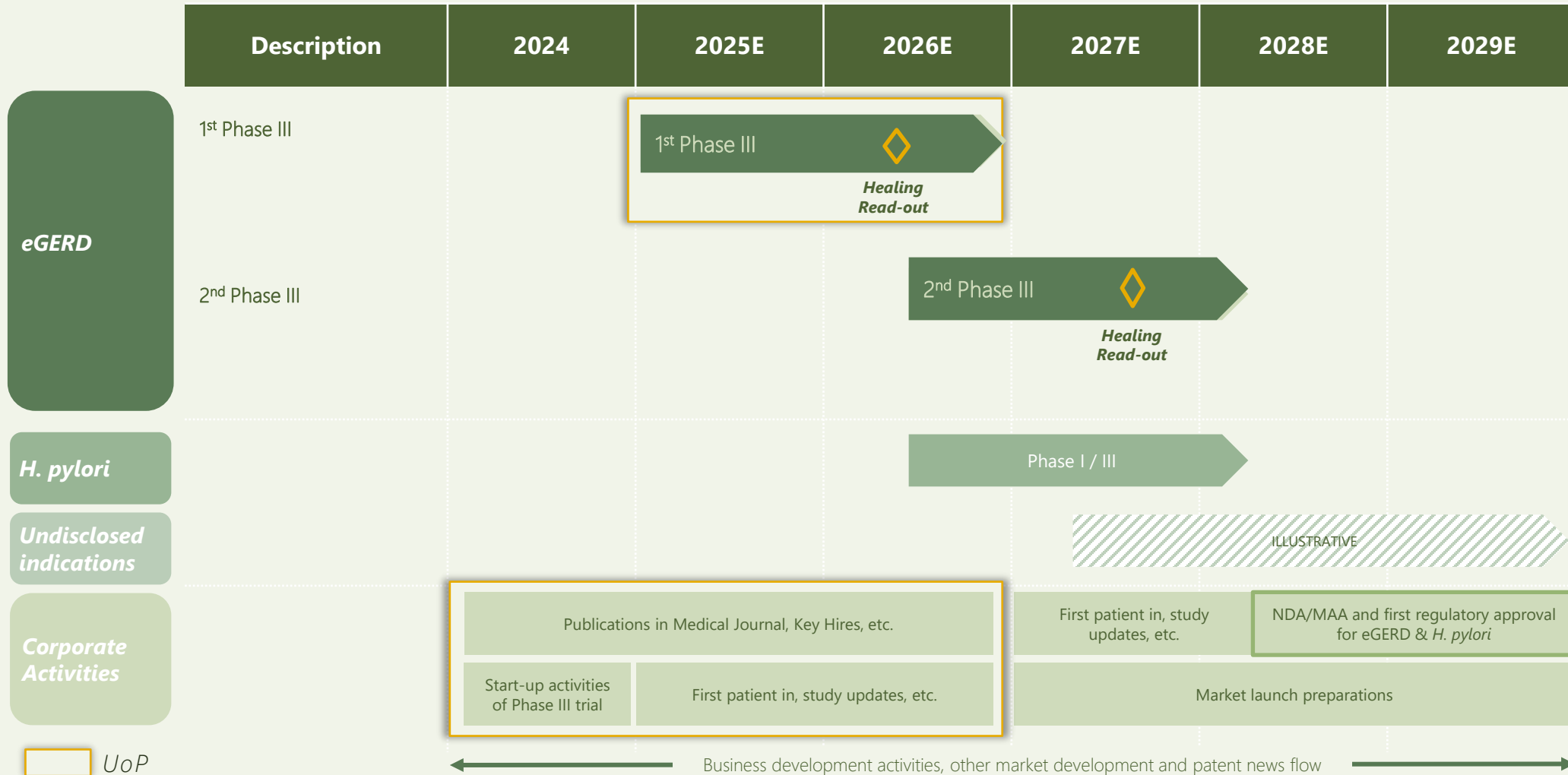
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Linaprazan Glurate: the next gold-standard in healing of severe erosive GERD

- 1 Next generation PCAB targeting healing in severe eGERD, *the* area of high unmet medical need
- 2 Superior acid control profile delivering fastest onset of action & time to steady state⁽¹⁾, crucial for healing of severe eGERD
- 3 In clinical trials, delivering 2x the healing effect difference vs active comparator (PPI) as compared to 1st generation PCAB
- 4 Phase III ready, clear FDA regulatory pathway, first phase III readout in 2026
- 5 Blockbuster market potential in healing of severe eGERD (LA grade C/D) patients
- 6 Strong IP protection beyond 2040 & 10 years data exclusivity upon market approval in EU and US

Strategic roadmap with dense upcoming news flow



Note: Illustrative guidance on timing, not exact dates. The information on this slide contains forward-looking statements based on estimates and assumptions and is subject to change. Timing of the second eGERD Phase III study as well as the H. pylori studies may be adjusted based on financing.

“The significant need for new alternatives to PPIs is evident as PCABs are making great progress worldwide”

- **Japan** – vonoprazan is market leader
- **South Korea** – Increasing significant sales
- **India** – Many different vonoprazan labels launched
- **USA** – High sales growth quarter to quarter

- Other markets where PCABs are launched:

LATAM:

*Mexico
Chile
Peru*

APAC:

*Japan
South Korea
China
India
Pakistan
Philippines
Malaysia
Bangladesh*

Summary of key events Q3, 2024

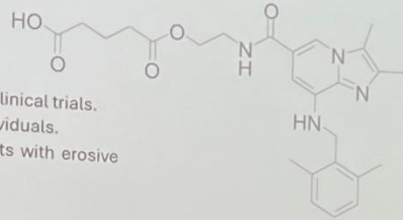
- PSI CRO was selected as the clinical research organization (CRO) for the phase III program.
- The PK/PD study was elected to be presented at UEGW, a scientific congress within the gastroenterology area.
- The manufacturing of the Investigational Medicinal Product (IMP), to be used for the company's upcoming phase III study of linaprazan glurate for eGERD, was successfully completed.
- During the period, the company received further national approvals for the formulation patent in Hong Kong and Mexico.

Post period highlights

- The PK/PD study was presented at UEGW, a scientific congress within the gastroenterology area, by the company's CMO, MD PhD Kajsa Larsson.
- Cinclus Pharma are in agreement with EMA regarding the paediatric study plan for eGERD.

Linaprazan glurate

- Prodrug of linaprazan.
- Treatment of acid related disease.
- Studied in 6 phase I and 1 phase II clinical trials.
- Safe and well tolerated in ≈ 500 individuals.
- Promising healing results in patients with erosive esophagitis.



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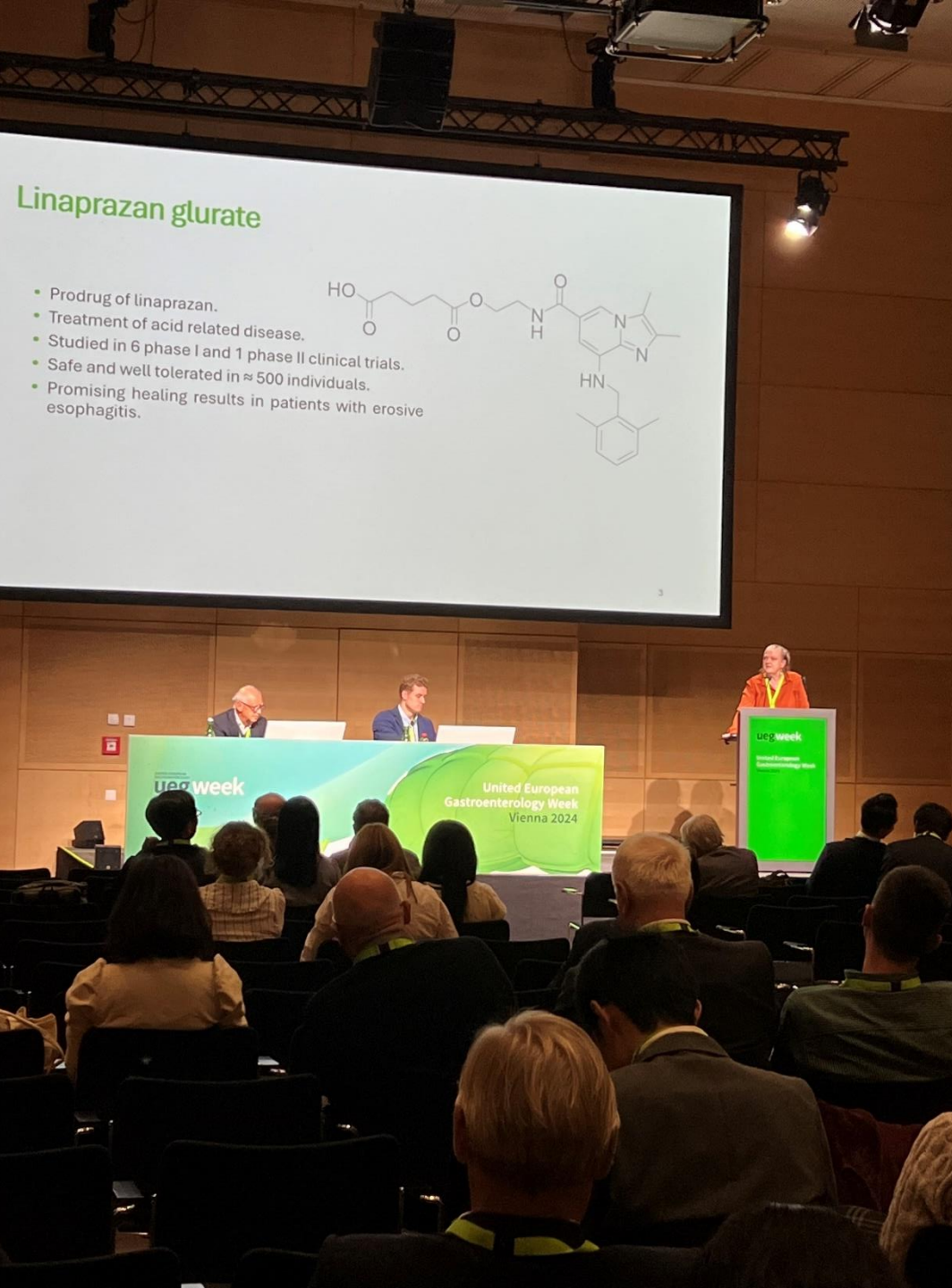
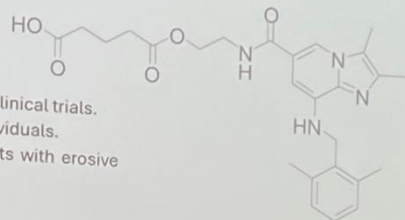
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PHARMACOKINETICS AND PHARMACODYNAMICS OF LINAPRAZAN GLURATE AFTER MULTIPLE ORAL DOSES UP TO 14 DAYS IN HEALTHY SUBJECTS

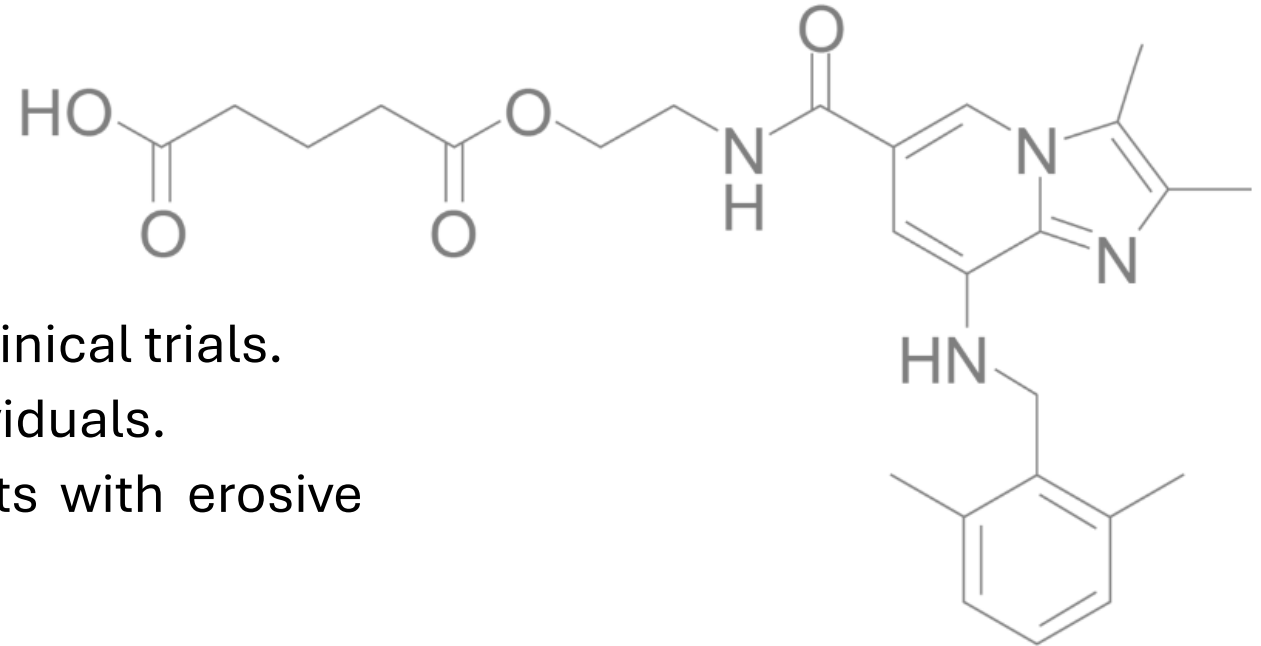
Matjaz Fležar ¹, Kajsa Larsson ², Kjell Andersson ², Gunilla Huledal ², Kristofer Katkits ², Elham Yektaei ², Peter Unge ²

1. University of Ljubljana, Ljubljana, Slovenia and University Clinic Golnik, Golnik, Slovenia,

2. Cinclus Pharma Holding AB (publ), Stockholm, Sweden

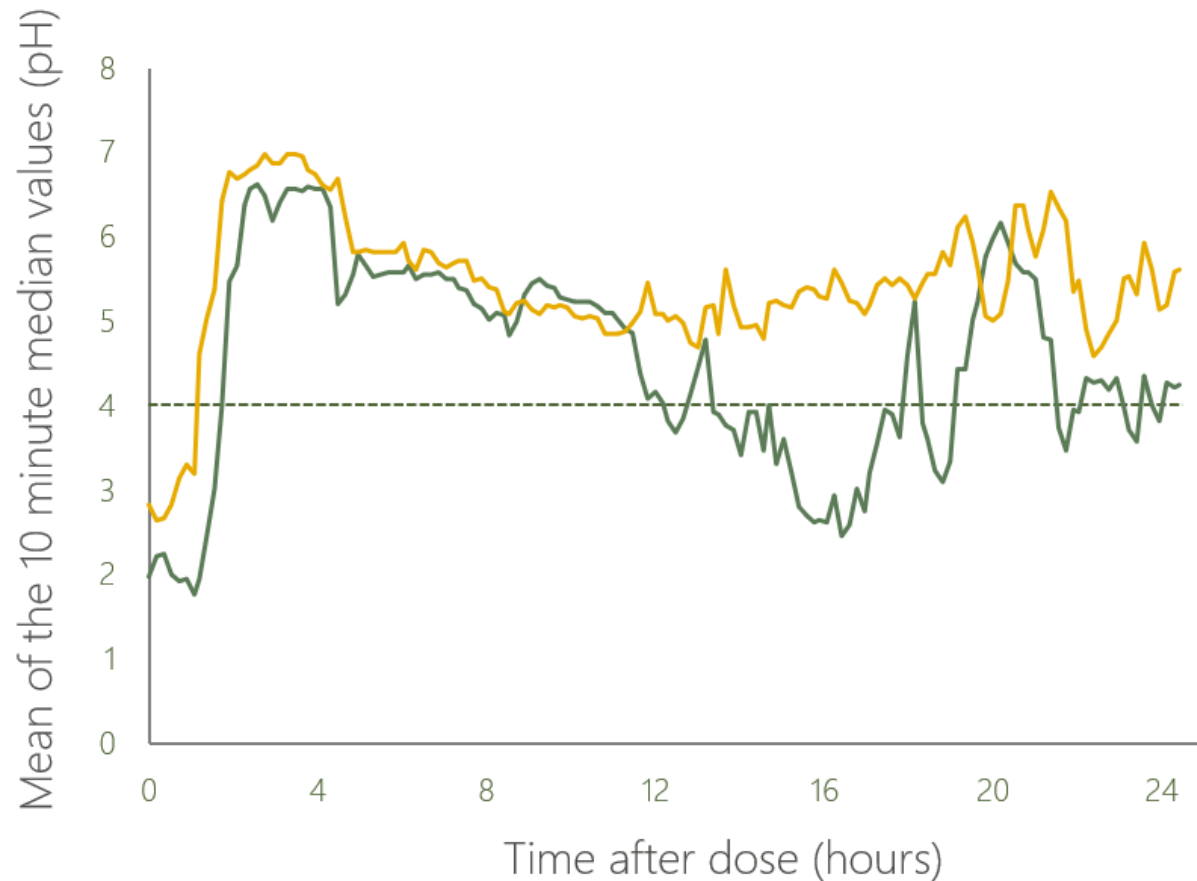
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Phase I SAD/MAD Study

- Holding time ratio pH>4 is a biomarker for healing of erosive esophagitis.
- Linaprazan glurate provides fast onset & full pH control.



2 mg/kg linaprazan glurate: Fast onset and close to 24 hours pH>4 (>90%).

1 mg/kg linaprazan glurate: Fast onset and 11 to 13 hours pH>4 (~45% to 55% pH >4 per 24 hours); similar to PPI.

Study Objective

To study the pH control and PK properties of a linaprazan glurate tablet for use in future clinical studies.

Primary Endpoints

- Percentage of time with gastric pH >4 at Day 1 and Day 14, following linaprazan glurate administration.
- Linaprazan glurate and linaprazan PK parameters after single and repeated after once (QD) or twice (BID) daily dosing administration of linaprazan glurate

Secondary Endpoint

- To assess the safety and tolerability after single and repeated doses of linaprazan glurate.

Dose Response with pH>4 HTR on Day 1 and Day 14

Percentage of time with intragastric pH >4, based on 10-minute medians of pH.

Day	Statistics	25 mg LG QD (N=12)	50 mg LG QD (N=12)	75 mg LG QD (N=13)	25 mg LG BID (N=9)	50 mg LG BID (N=11)	75 mg LG BID (N=10)
Day 1 pH >4 HTR	n	12	12	12	9	11	9
	Mean (SD)	48.0 (23.23)	64.6 (13.33)	68.1 (23.48)	76.0 (13.52)	87.4 (8.62)	94.5 (4.18)
Day 1 (1.5-24h) pH >4 HTR	n	12	12	12	9	11	9
	Mean (SD)	51.0 (24.91)	68.9 (14.02)	73.7 (24.78)	80.5 (14.12)	91.5 (8.98)	98.1 (3.10)
Day 14 pH >4 HTR	n	12	12	11	9	11	8
	Mean (SD)	48.5 (30.62)	63.9 (20.09)	87.2 (11.44)	76.9 (20.13)	95.7 (5.55)	99.0 (1.54)

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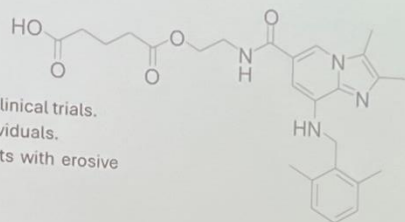
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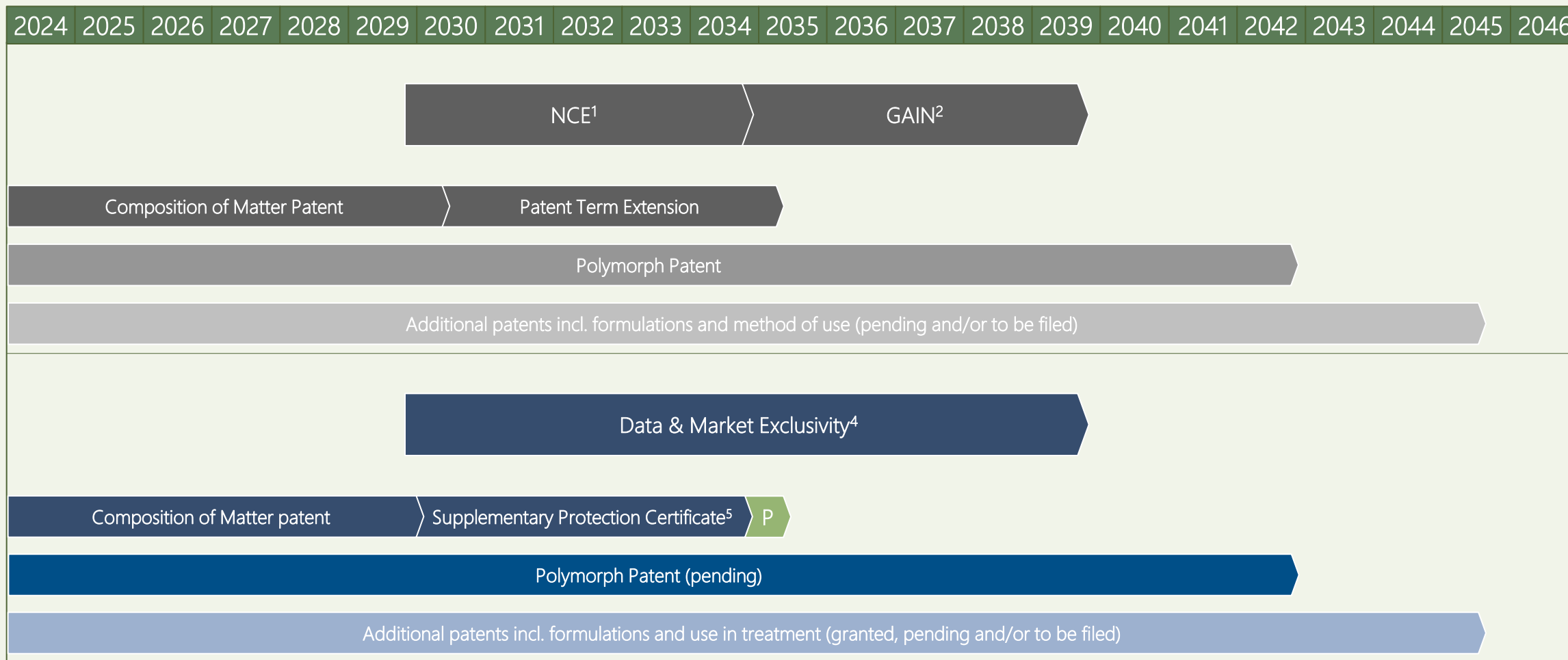
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Strong global IP protection and market exclusivity



Earliest possible generic competition in USA and EU in 2039 (depending on date for approval)

Note: Expected timeline relating to the Company's intellectual property for the coming years. This information contains forward-looking statements based on estimates and assumptions and is subject to change.

1) NCE = New Chemical Entity (5 years of regulatory exclusivity). 2) GAIN = 5 years extension of NCE because of QIDP designation. 3) P = Pediatric exclusivity (6 months). 4) 10 years of regulatory exclusivity (based on current legislation in the EU)

5) Supplementary Protection Certificate (SPC) = European equivalent of Patent Term Extension (PTE)

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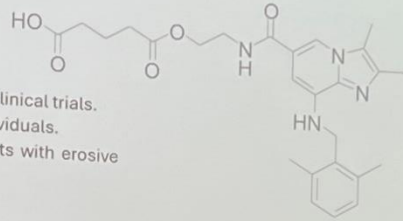
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- Cinclus Pharma, has reached an agreement with the European Medicines Agency's (EMA) Paediatric Committee (PDCO) on the company's Pediatric Investigation Plan (PIP).
- A regulatory agreement of a PIP must be obtained before a sponsor may submit a Marketing Authorization Application for approval to commercialize a new medicine for adult patients in Europe
- It also provides an opportunity for an expanded approval for use in children.
- Cinclus Pharma submitted its proposed PIP to EMA in December 2023 and has been going through the regulatory review processes since then.
- The company's agreed PIP mainly includes a clinical efficacy and safety trial where approximately 100 pediatric patients will be treated with linaprazan glurate on the same treatment schedule as in the company's phase III trials in adult eGERD patients.
- PIP includes a deferral under which the pediatric efficacy and safety trial is anticipated to be undertaken after a Marketing Authorization Application has been submitted.

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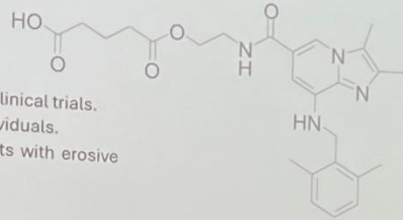
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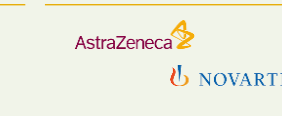
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Team with proven track-record within drug discovery and commercialization...

 <p>CHRISTER AHLBERG CEO</p>	 <p>MARIA ENGSTRÖM CFO</p>	 <p>KAJSA LARSSON CMO</p>	 <p>MARGIT MAHLÄPUU Executive R&D Director</p>	 <p>PETER WALLICH Commercial Director</p>	 <p>JESPER WIKLUND Director of Corporate and Business Development</p>
<p>Former experience in the pharmaceutical industry includes CEO at Sedana Medical Group (2017-2021) and CEO at Unimed Group (2010-2016), CEO at Eisai AB (2005-2010) and additional 10 years of experience in leading positions in sales and marketing at AstraZeneca (including launch of Nexium), Meda and Wyeth.</p>	<p>Former CFO of Sedana Medical Group (2017-2021) and Managing Director at Cross Pharma AB (2015-2016). Maria has also extensive experience from leading positions within finance for the past 25 years within Medivir, Biovitrum, Bristol Myers Squibb and Ericsson.</p>	<p>MD and Ph.D. in Medical Sciences, Consultant in internal medicine and hematology/hematooncology with more than 15 years' of clinical experience. From 2009 full time in the pharmaceutical industry at different positions within medical affairs and clinical development at national, regional and global levels in Genzyme, Roche, Alexion, Alnylam and Oncopeptides.</p>	<p>Senior manager with 20+ years of experience in R&D of novel pharmaceuticals overseeing cross-functional teams. Held leadership roles in publicly traded biopharmaceutical companies and privately owned biotech firms. Managed R&D portfolios with an emphasis on clinical and product development, regulatory affairs, and vendor management.</p>	<p>Over 30 years within pharmaceutical sales and marketing. Extensive experience in Gastroenterology (AstraZeneca) and the acid related diseases market – from early launch of Losec and development and launch of Nexium (1992–2008) in leading global roles for the business. Also worked in global commercial Novartis</p>	<p>More than 25 years experience from the pharmaceutical industry at companies such as AstraZeneca, Recipharm, etc. A broad experience from roles with responsibilities within analytical and product development, project management, and quality assurance, also worked as CMC consultant.</p>
					

Board of Directors

 <p>LENNART HANSSON Chairman of the board and member of remuneration committee</p>	 <p>WENCHE ROLFSEN Audit committee</p>	 <p>TORBJÖRN KOIVISTO Remuneration committee (chair)</p>	 <p>PETER UNGE</p>	 <p>ANDERS ÖHBERG</p>	 <p>HELENA LEVANDER Audit committee (chair)</p>	 <p>NINA RAWAL Audit committee</p>
<p>Ph.D. in Genetics and more than 25 years' experience in senior executive positions for R&D and business development in pharmaceutical- and biotech industry</p>	<p>Board of many life science companies, private, governmentally owned and publicly listed in Norway, UK and Sweden over the last 15 years</p>	<p>More than 20 years' experience as a business lawyer, focusing entirely on advising clients within the life sciences industry on matters of commercial and corporate law</p>	<p>Education and professional MD. Ph.D. Gastroenterologist and Internal Medicine with 25 years of Clinical experience</p>	<p>More than 15 years of experience within clinical development, pharmacovigilance, quality assurance and medical affairs at Pfizer, Ipsen, Shire and Novartis</p>	<p>More than 20 years of experience within asset management and equity markets from SEB, Nordea, Odin Funds and Neonet Securities</p>	<p>Ph.D. in Molecular Neurobiology from Karolinska Institute Partner and Co-Head at Trill Impact Ventures</p>

... supported by an experienced international advisory board



Professor Emeritus Richard Hunt, MD, Ph.D.

McMaster University, Hamilton, Canada

- Member of the Editorial Boards of 20 scientific journals, including Gastroenterology. Author of over 600 papers and abstracts



Professor Peter Malfertheiner, MD, Ph.D.

Otto v Guerlcke Univ, Magdeburg, Germany

- Founding member and past president of the European *Helicobacter* Study Group, Past President of the Eur Assoc of Gastroenterol and Endoscopy



Professor Nimish Vakil, MD, Ph.D.

Aurora Healthcare, Summit, Wisconsin, US

- Editor Am J of Gastroenterol. and Endoscopy, Board of Int Found Func Gastrointest Dis (patient organization). Author of more than 260 publications



Professor David Armstrong, MA, MB BChir

McMaster University, Hamilton, Canada

- Past Pres, Canadian Ass of Gastroenterol. and Gov, Am Coll of Gastroenterol. Editor Am J of Gastroenterol. Chair, Nati Colon Cancer Screening Network (Canada) and Vice-Chair, Guidelines Committee, World Gastroenterology Organization



Professor Michael Vaezi, MD, Ph.D., MSc

Vanderbilt University Medical Center, Nashville Tennessee, USA

- Ass. Chief and Clin. Dir., Division of Gastroenterol, Hepatol and Nutr. Dir, C. for Swallow. and Esophageal Dis. Past Editor, Gastroenterol



Professor Prateek Sharma, MD

University of Kansas School of Medicine, Kansas, USA

- President of the International Working Group for Classification of Oesohagitis. More than 400 publications related to UGI disease and cancer



Professor, Dr. Joachim Labenz, MD, Ph.D.

Gastroenterologist. Cons. Dir. For Diakonie Klinikum Stilling, Siegen and Centrum Gastroent Bethanien Krankenhaus, Frankfurt, Germany

- Member Medical Faculty University Duisburg-Essen, Sen. author of guideline of GERD 2023, Member EAGH, President DVGS 2015

Key figures

Q3

Q2

FY-23

Cash

644
MSEK

685
MSEK

88
MSEK

Co-workers

29

26

29

R&D spending
of total OPEX

81%

56%

81%

Financial overview

SEKm	Q3-24	Q3-23	YoY	Q2-24	Q1-24	Jan-Dec-23
Net sales	–	–	–	–	–	6,0
G&A	-7,3	-8,5	1,2	-16,7	-5,6	-39,6
R&D	-32,0	-54,5	22,5	-20,8	-30,5	-166,7
Other op exp/income	0,1	0,9	-0,8	0,2	-0,2	-0,7
EBIT	-39,1	-62,1	22,9	-37,3	-36,3	-201,0
Financial net	2,7	0,2	2,6	-2,8	-0,4	-13,6
Tax	-0,1	0,0	-0,1	-0,2	-0,2	-0,5
Net profit	-36,5	-62,0	25,4	-40,3	-36,9	-215,1
Cash flow from operating activities	-42,4	-46,0	3,7	-21,9	-35,5	-209,2
Cash flow from financing activities	1,9	89,4	-87,5	654,2	-0,3	122,9
Total cash flow	-40,5	43,4	-83,9	632,3	-35,8	-86,3
Cash at the beginning of the period	684,7	108,6	576,1	52,5	88,0	173,5
Cash at the end of the period	644,3	151,4	492,8	684,7	52,5	88,0

- Net sales – awaiting approval in China which will generate smaller milestone payment.
- The **operating expenses** were lower than last year but increasing due to start of ph I and III studies. G&A expenses are lower since Cinclus are past IPO.
- EBIT better than last year but lower than Q1 and Q2..
- Financial net increased due to positive interest gain of cash in bank.
- Tax concerned corporate and cantonal tax for our Swiss affiliate.
- Net profit better than last year but in line with past quarters of the year.

SEKm	Sep 30 2024	Sep 30 2023	YoY	Dec 31, -23
Fixed assets	0,9	0,6	0,6	0,3
Other Current assets	12,6	11,8	6,5	6,1
Cash	644,3	151,4	556,3	88,0
Total assets	657,7	163,8	563,3	94,4
Equity	606,3	-34,2	683,1	-76,8
Non-current liabilities	7,1	13,5	0,3	6,8
Current liabilities	44,4	184,5	-120,0	164
Total liabilities	657,7	163,8	563,3	94,4

- Cash – increase due to new share issue by the time of IPO
- Non-current liabilities – tax liability in swiss affiliate due to group internal move of IP back in 2022
- Current liabilities - lower due to share holder loan offset issue in connection with IPO.

Largest shareholders end of September 2024

	Number of shares	Share (%)
Trill Impact Ventures	3 721 221	8,0%
Fjärde AP-fonden	3 686 568	7,9%
Linc AB	2 318 322	5,0%
Peter Unge genom bolag	2 050 015	4,4%
Kjell Andersson genom bolag	1 908 000	4,1%
Mikael Dahlström Dödsbo	1 881 520	4,0%
Futur Pension	1 806 156	3,9%
Movestic Livförsäkring AB	1 791 878	3,9%
Nylof Holding	1 164 575	2,5%
Lennart Hansson genom bolag	1 084 771	2,3%
Nordnet Pensionsförsäkring	904 383	1,9%
Eir Ventures I AB	898 750	1,9%
Postamentet Holding AB	688 409	1,5%
MWP Management Consulting AB	680 000	1,5%
Irrus Investments	614 265	1,3%
Fifteen largest shareholders	25 128 423	54,0%
<i>Others</i>	21 409 366	46,0%
Total	46 537 789	100,0%
<i>Corner investors IPO</i>	11 239 126	24,2%
<i>Founders</i>	8 768 881	18,8%

IPO Cornerstone investors:

- Trill Impact Ventures
- 4th AP fund
- Linc AB
- Irrus Investments
- Eir Ventures
- Regulus Pharma

Founders:

- Peter Unge
- Kjell Andersson
- Mikael Dahlström estate
- Nylof Holding AB
- Lennart Hansson
- MWP Management Consulting AB

QA

Calendar



Year-End Report 2024, February 20, 2025
Annual report 2024, April 17, 2025
Q1 interim report, May 20, 2025
Annual General Meeting, May 22, 2025



IR contact

ir@cincluspharma.com

Indication aspiration

*Treatment of erosive
Gastro- esophageal
reflux disease
(eGERD) all grades
A-D*

*With focus on
healing of
severe eGERD
and ...*

... Accomplished 24hr pH
control in clinical studies

...Aiming to show superior
Healing in severe eGERD
(C&D)

... Aiming to show superior
symptom control with focus on
night time symptoms

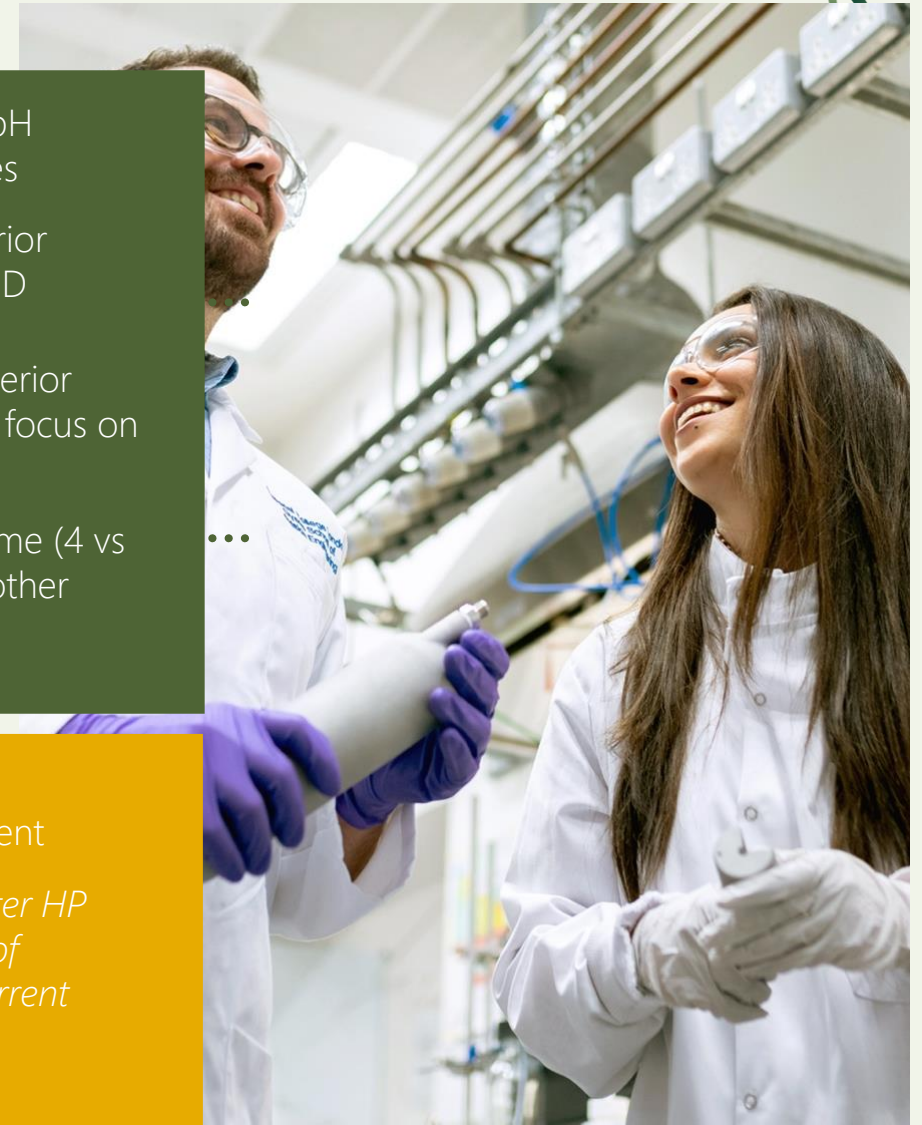
...Healing in half the time (4 vs
8 weeks) vs PPIs and other
PCABs

*Dual Treatment of
Helicobacter pylori
(Linaprazan glurate plus
amoxicillin)*

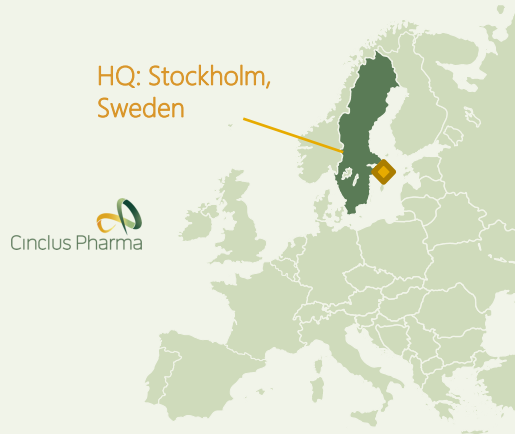
*With focus to
become ...*

..the new first line treatment

*Due to as good as or better HP
eradication with less risk of
antibiotic resistance vs current
standard of care*



Focus on the unmet medical need, where 24 hr acid control is most important



Linaprazan glurate

Potential to become **best in class** and the **first innovative MoA**¹⁾ in gastric acid related disorders in over 25 years



Focus on **Healing of Severe Patients**, the Unmet Medical Need in eGERD

Enables Specialty Commercial Focus

Greatest differentiation from PPIs²⁾ and 1st generation PCABs³⁾ → strong competitive position



Strong Phase II data point the way for phase III

Phase III studies to start in 2025, successful end of phase II meeting in the end of 2023

A scientifically de-risked development program

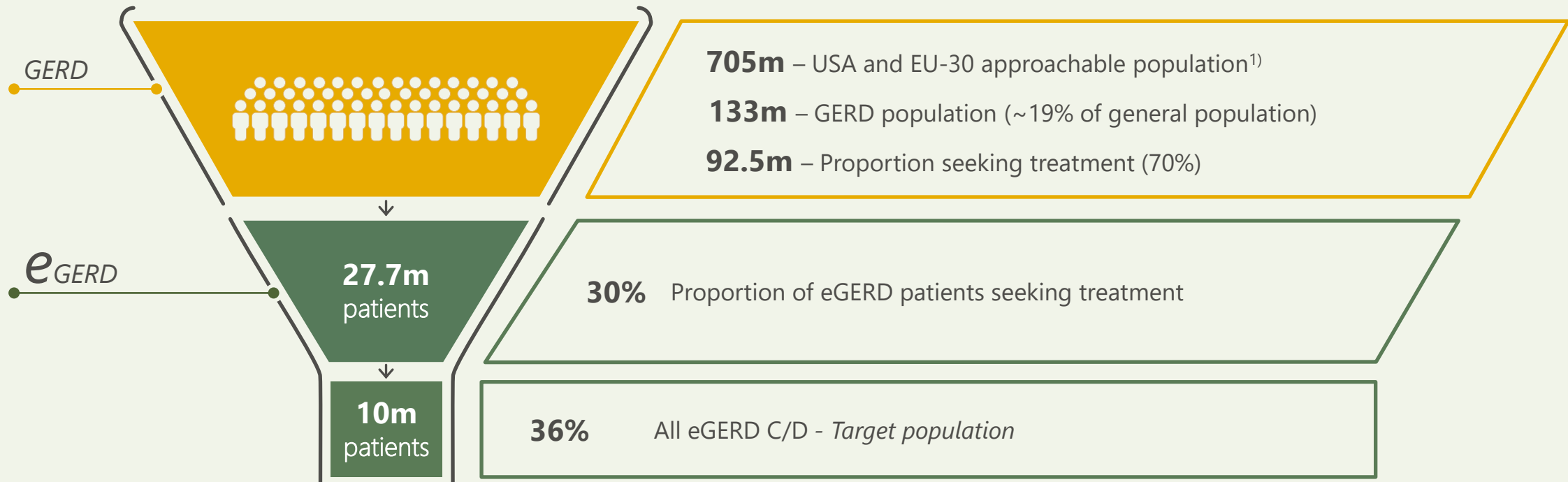


Strong Investor Base

Backed by **life science focused institutional investors** Trill Impact Ventures, AP4, Linc and Eir Ventures

Appendix

Blockbuster market potential in severe eGERD in USA & EU



*Assuming Gross Price per tablet: USA \$21,7 EU €3 - Healing b.i.d²⁾ - Maintenance q.d.³⁾
Cost of healing of eGERD patients c. USD 1,215 per healing cycle – c. 1-2 cycles per year*

Linaprazan glurate: Potential to be best in class 2nd generation PCAB

PHARMACOLOGICAL (PRODRUG) ADVANTAGES PROVIDES...

... CLINICAL ADVANTAGES AND SUPERIORITY PROFILE

	DOSING INDEPENDENT OF MEAL	TIME TO PH>4 After 1 st dose	TIME TO FULL EFFECT PH>4 24hrs/day	24 HOURS ACID CONTROL	HEALING EFFECT DIFFERENCE VS. PPIs (Lansoprazole)	TIME TO HEALING Weeks	SUPERIORITY IN HEALING PHASE vs. PPIs	SUPERIOR DAY-TIME SYMPTOM RELIEF vs. PPI	SUPERIOR NIGHT-TIME SYMPTOM RELIEF vs. PPI
PPIs (e.g., Lansoprazole FDA label)	✗	+4 hrs	3-5 DAYS ¹⁾	~40-70% ²⁾	✗	8	✗	✗	✗
Vonoprazan (FDA label) (1 st generation PCAB)	✓	2-4 hrs	up to 7 days	~63-85% ³⁾	18-20%p in 2 & 8 weeks	8	✗	✗	✗
Linaprazan glurate (Expected FDA label) (2nd generation PCAB)⁴⁾	✓	1-2 hrs <i>Fastest symptom relief</i>	1-2 hrs <i>Fastest healing</i>	92-96%	52%p in 4 weeks	4 <i>Healing in half the time</i>	✓	✓	✓

Linaprazan glurate is, unlike 1st generation PCABs, developed for healing of patients with severe eGERD - aiming to become superior compared to existing medication

Specialist GI targeted commercialization approach maximizes Cinclus Pharma optionality post-data

Specialist GI approach

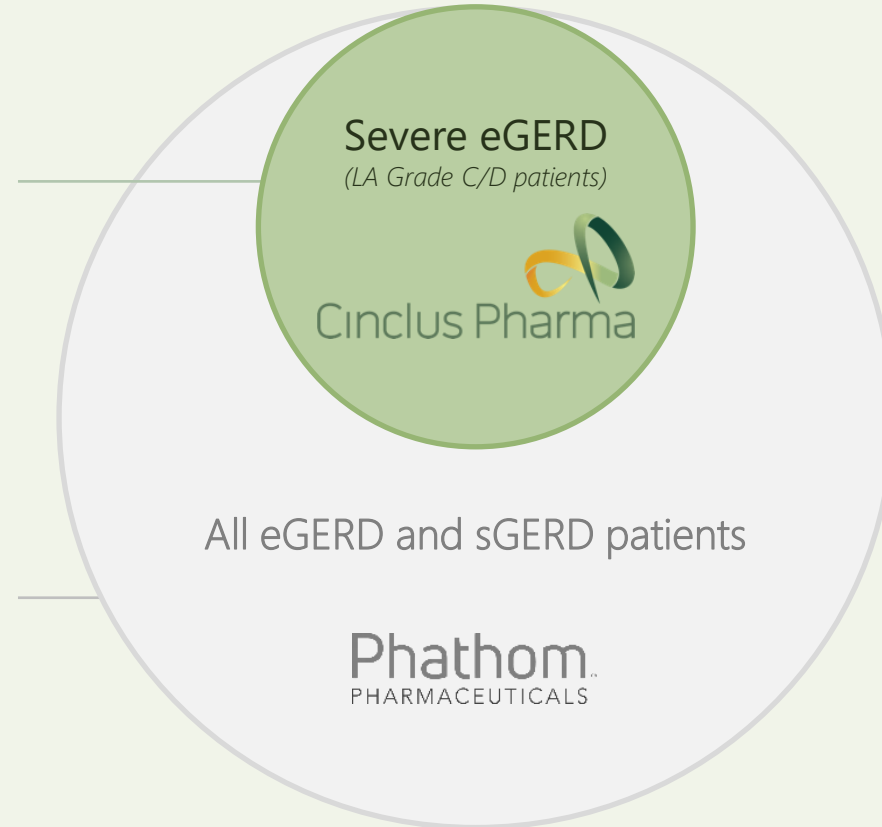
Effective market entry

Accessible with a highly focused sales & marketing team

Non-targeted approach

Requiring Big Pharma reach

Requires significant sales & marketing resources; large primary care sales force, DTC campaigns, etc.



Effective go-to-market approach

- Specialist GI approach...

The concentrated Specialist GI prescribers' community can be targeted with a lower number of sales reps - a specialty pharma approach targeting science driven specialist

- ...enabling faster market penetration...

Patients are already identified and treated by specialist GI prescribers, enabling faster market penetration post approval

- ...with high post-data optionality

All the commercial rights are still in the company, creating high go-to-market and business development optionality post first data in 2026