

A woman with long, wavy brown hair is shown in profile, looking out over a body of water. She is wearing a dark, patterned top. The background is a soft-focus view of water and distant land. The entire image has a light blue-green tint.

camurus®

Company presentation

January 2025

Forward looking statements

This presentation contains forward-looking statements that provide our expectations or forecasts of future events such as new product developments and regulatory approvals and financial performance.

Camurus is providing the following cautionary statement. Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include currency exchange rate fluctuations, delay or failure of development projects, loss or expiry of patents, production problems, unexpected contract, patent, breaches or terminations, government-mandated or market-driven price decreases, introduction of competing products, Camurus' ability to successfully market products, exposure to product liability claims and other lawsuits, changes in reimbursement rules and governmental laws and interpretation thereof, and unexpected cost increases.

Camurus undertakes no obligation to update forward-looking statements.

Camurus snapshot



Rapidly growing commercial stage company

Leader in opioid dependence treatment with Buvidal® and Brixadi® weekly and monthly depots



Unique FluidCrystal® technology platform

Commercially validated with a broad range of applications



Advancing late-stage pipeline with blockbuster potential

Prospect for multiple new approvals in CNS and rare disease indications



Strong operational and financial performance

Sustainable profitability since 2022

LISTED ON NASDAQ STOCKHOLM
TICKER **CAMX**; EMPLOYEES: **250+**

Strategy focused on growth and innovation

1. Grow Buvidal/Brixadi sales and expand to new markets
2. Advance R&D pipeline to new approvals and launches
3. Diversify and grow through business development
4. Drive operational excellence and sustainable profitability

Camurus' vision 2027

Sustainable value creation
for all stakeholders:

5x

**Five-fold
revenue growth**
to SEK 4.5 B



**Establish-
ment of US
commercial
infrastructure**

4

Approvals
for four R&D
pipeline
programs

~50%

Operating margin
around 50 percent

Exiting 2024 with positive momentum



Strong commercial performance

- ✓ Global leadership in long-acting treatment of opioid dependence
- ✓ Double-digit Buvidal sales growth in Europe, MENA and Australia
- ✓ Best-in-class launch of Brixadi® in the US
- ✓ Established US organization for Oclaiz™ launch readiness



Advancing R&D pipeline

- ✓ Positive results from 52-week Phase 3 ACROINNOVA 2 study in acromegaly
- ✓ CAM2029 NDA process in the US; CRL resolution ongoing
- ✓ SORENTO and POSITANO studies advancing in GEP-NET and PLD
- ✓ Clinical Trial Application approved for once-monthly semaglutide

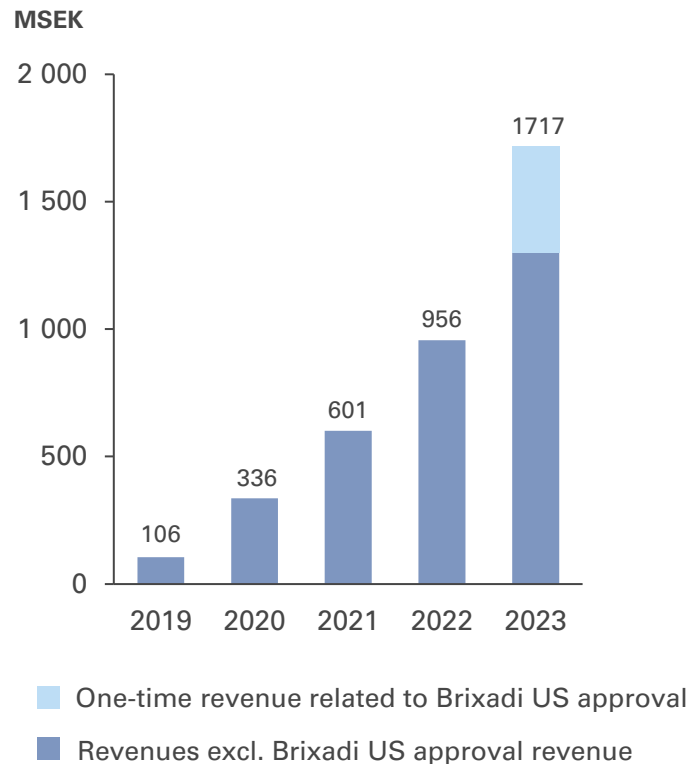


Corporate development

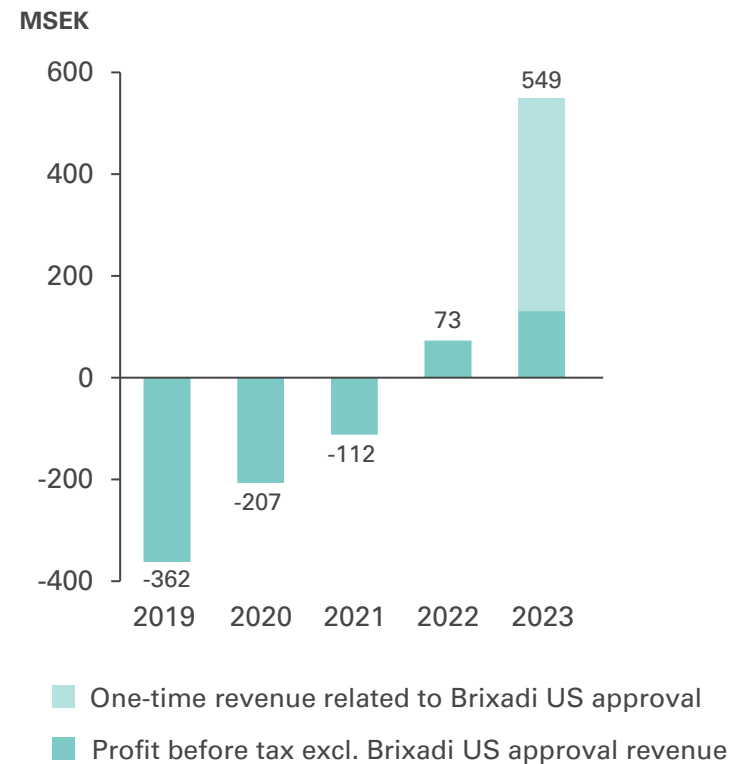
- ✓ Growing revenues and sustained profitability
- ✓ FY 2024 outlook raised
- ✓ Meaningful investment in R&D and US infrastructure
- ✓ Robust cash position ~ SEK 3 billion

Strong financial development

Revenues



Profit before tax



Raised 2024 Outlook*

Total revenues
SEK 1,810 – 1,880 million
 +38 – 43% excl. one-time
 milestones 2023

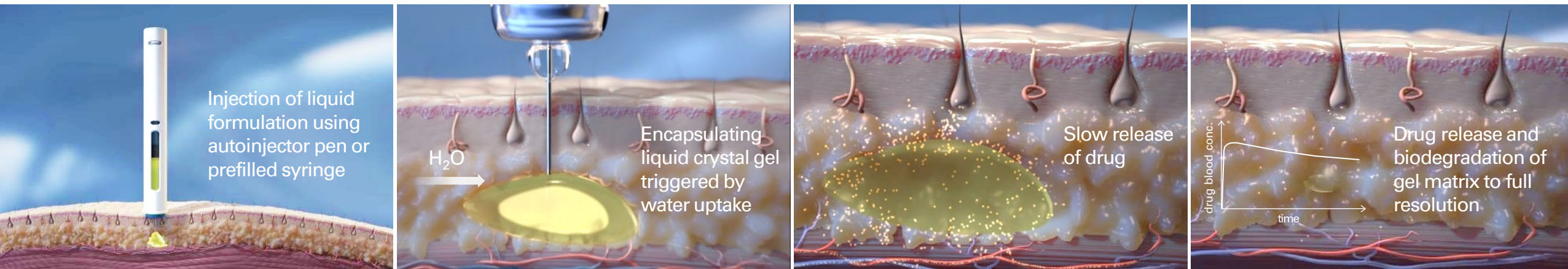
Profit before tax
SEK 450 – 510 million
 +214 – 256% excl. one-time
 milestones 2023

*updated 7 November 2024

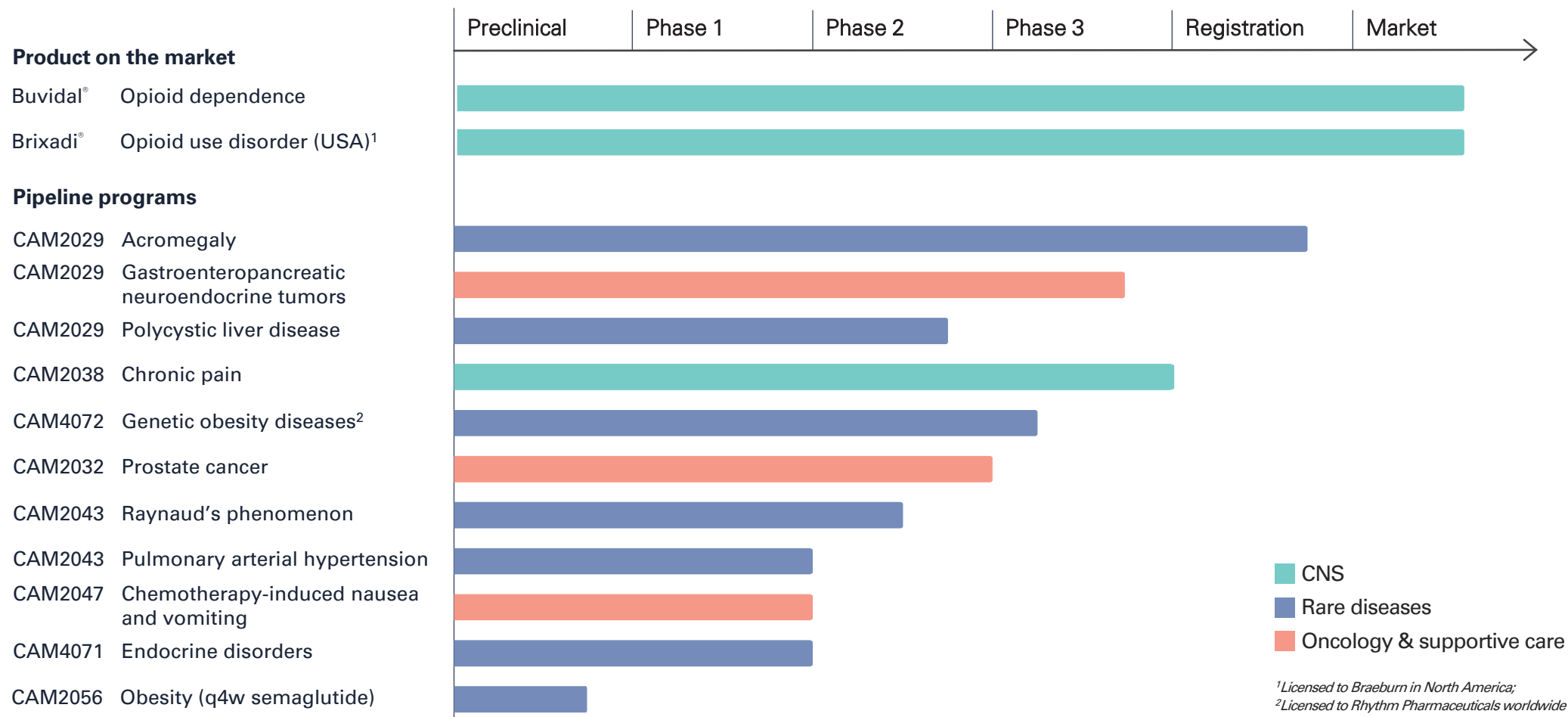


FluidCrystal[®] extended-release technology

- ✓ Easy and convenient administration
- ✓ Rapid onset & long-acting release
- ✓ Controlled by composition, liquid crystal phase structure and biodegradation
- ✓ Applicable across substance classes
- ✓ Compatible with prefilled syringes, autoinjector pens, and other advanced devices
- ✓ Manufacturing by standard processes



Broad and diversified product portfolio and pipeline



Buvidal – game changing opioid dependence treatment

Weekly and monthly, subcutaneous buprenorphine for individualized treatment of opioid dependence within a framework of medical, social and psychological treatment in adults and adolescents 16 years or over¹

Demonstrated benefits to patients and society

- Superior treatment outcome and patient satisfaction²⁻⁵
- Blocks subjective opioid effects from first dose³
- Reduces treatment burden and improved quality of life^{5,6}
- Decrease risk of diversion, misuse and pediatric exposure^{7,8}
- Provides cost savings⁹

“Buvidal became my way out”

Justin, Buvidal patient in Australia

¹ SmPC Buvidal Aug 2023; ²Lofwall et al. JAMA Int. Med. 2018;178(6): 764-773; ³Walsh et al. JAMA Psychiatry 2017;74(9):894-902; ⁴Frost, M., et al. Addiction. 2019;114(8):1416-1426. doi: 10.1111/add.14636; ⁵Lintzeris, N., et al. JAMA Network Open. 2021;4(5):e219041. doi:10.1001/jamanetworkopen.2021.9041; ⁶Barnett et al Drug and Alcohol Dependence 2021; <https://doi.org/10.1016/j.drugalcdep.2021.108959>; ⁷EPAR for Buvidal; ⁸Dunlop, A. J., et al. Addiction. 2021. <https://doi.org/10.1111/add.15627>; ⁹Dunlop, A. Oral presentation at CPDD June 2020.

Towards global leadership in long-acting opioid dependence treatment

Wide and growing access to Buvidal and Brixadi

- Available across four continents
- More than 56,000 in treatment with Buvidal in Europe and Australia end-Sep 2024

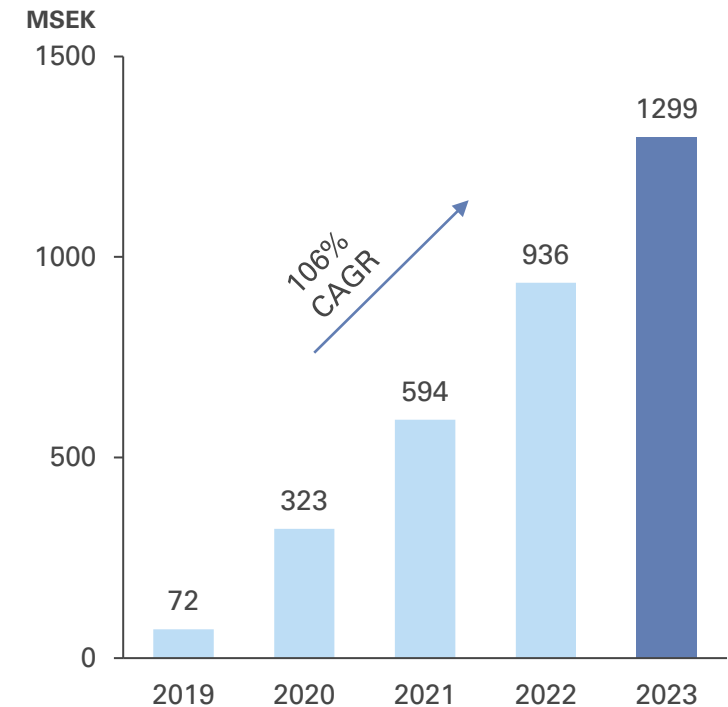
Robust Buvidal sales growth

- 106% CAGR since first launch in 2019
- Target more than 100,000 patients on Buvidal in 2027

Market expansion continues

- Four market authorization and several pricing and reimbursement applications under review

Strong growth of Buvidal sales



Accelerated growth of Brixadi in the US

Brixadi launched in the US in September 2023

- Camurus' licensee Braeburn responsible for US commercialization
- Focused commercial organization of over 100 people

Wide access to Brixadi for the treatment of OUD

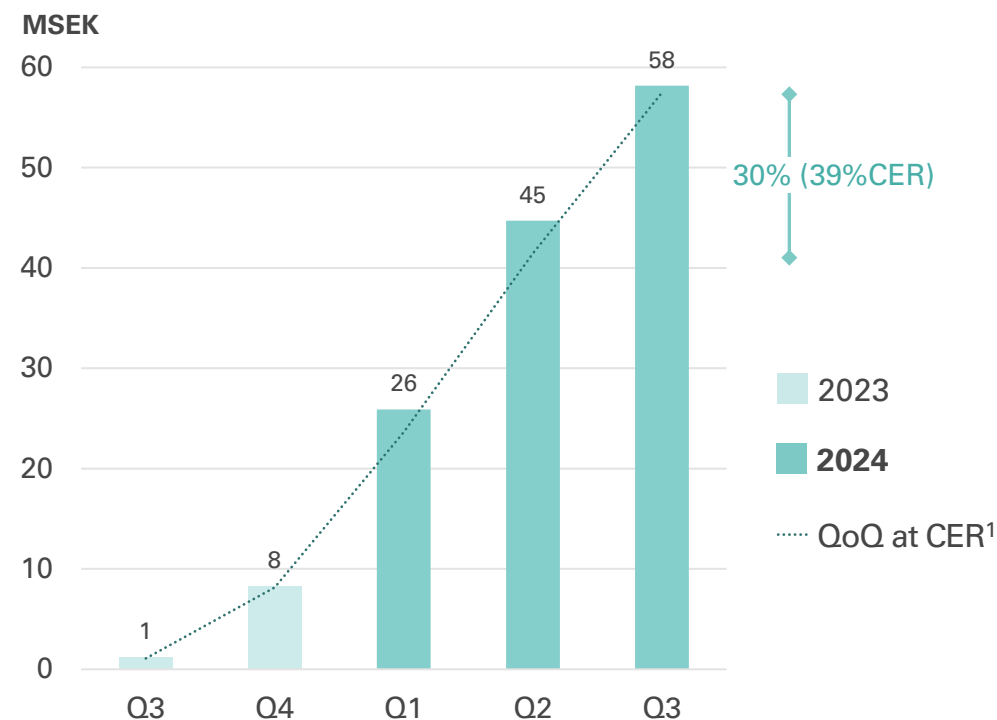
- High payer coverage – on par with competition for both Medicaid and commercial payers
- Broad and expanding distribution network

Accelerated sales growth

- Strong demand for Brixadi
- Accelerated net sales and royalty increase

Peak market potential > USD 1 billion¹

Brixadi royalty by quarter



Buvidal/Brixadi – well differentiated

Convenient and flexible administration

- Weekly and monthly dosing
- Multiple dose strengths (four weekly, three monthly)
- Choice of multiple injection sites
- Thin needle and small dose volumes
- Room temperature stability (no cold chain required)

Strong scientific evidence base

- Superior efficacy and patient reported treatment satisfaction vs daily standard of care

Competitive label¹

- Switch from daily sublingual buprenorphine using conversion table for dose equivalency
- Direct initiation of treatment following a single dose of transmucosal buprenorphine

LAI features²

	<small>ONCE-MONTHLY</small> Sublocade™	Vivitrol®	<small>Weekly/Monthly</small> Buvidal® Brixadi®
Weekly dosing	–	–	✓
Monthly dosing	✓	✓	✓
Multiple doses	–	–	✓
Choice of inj. sites	–	–	✓
Smallest needle	(19G)	(20G)	✓ (23G)
Lowest dose volume	0.5–1.5mL	3.4mL	✓ 0.16–0.64mL
Room temp. storage	–	–	✓
Day one initiation	–	–	✓
Clin. data vs active control	–	–	✓
Launched	US, CAN, DE, AUS, SE, FI, IL	US	US, EU, UK, AUS

LAI – long acting injectable

¹Brixadi US label; ²See product information

Growing scientific evidence base

Strong scientific support for Buprenorphine/Brixadi

- Documenting effectiveness in different treatment settings
- Positive health economical outcomes
- More than 160 scientific publications on Buprenorphine/Brixadi
- Ongoing clinical studies exploring new applications

Selected planned scientific conference participation in 2025

	Q1/Q2 2025			Q3/Q4 2025			
International	ASAM 24-27 Apr Denver, US	ISAM 26-28 May Hamburg, DE	ALBATROS 10-12 Jun Paris, FR	CPDD 14-18 Jun New Orleans, US	IMiA 29-31 Aug Sydney, AUS	ATHS 21-24 Oct Biarritz, FR	
National (selected)	RCGP & AP 16-17 January Manchester, UK	APSEP 27-28 March Paris, FR	Addiction Z April – May Gold Coast, AUS	Fed. Addiction 22-23 May Angers, FR	Suchtmedizin 3-5 July Munich, DE	Suchtsymp. Oct Grundsee, AT	APSAD 9-12 Nov Sydney, AUS
	APP Feb Gold Coast, AUS	Sigtunadagarna Apr SE	Subst. Forum. May Mondsee, AT	SEPD 4-7 Jun Madrid, ES	Prison Congr. Oct Montpellier, FR	RCPsych Addict Oct London, UK	Addiktum Nov/Dec Helsinki, FI

Recent key publications¹⁻³

JAMA Network | Open.

Original Investigation | Substance Use and Addiction

Extended-Release Injection vs Sublingual Buprenorphine for Opioid Use Disorder With Fentanyl Use
A Post Hoc Analysis of a Randomized Clinical Trial

Edward V. Nunes, MD; Sandra D. Comer, PhD; Michelle R. Lofwall, MD; Sharon L. Walsh, PhD; Stefan Peterson, PhD; Fredrik Tibergh, PhD; Peter Hjelmstrom, MD, PhD; Natalie R. Budilovsky-Kelley, PharmD

Research letters

The uptake of long-acting depot buprenorphine for treating opioid dependence in Australia, 2019–2022: longitudinal sales data analysis

Nicholas Lintzeris^{1,2}; Victoria Hayes^{2,3}; Adrian J Dunlop^{4,5}

JAMA Network | Open.

Original Investigation | Substance Use and Addiction

Extended-Release 7-Day Injectable Buprenorphine for Patients With Minimal to Mild Opioid Withdrawal

Gail D'Onofrio, MD; Andrew A. Herring, MD; Jeanmarie Perrone, MD; Kathryn Hawk, MD; Elizabeth A. Samuels, MD; Ethan Cowan, MD; Erik Anderson, MD; Ryan McCormack, MD; Kristen Huntley, PhD; Patricia Owens, MS; Shara Martel, MPH; Mark Schactman, MHS; Michele R. Lofwall, MD; Sharon L. Walsh, PhD; James Dzura, PhD; David A. Fiellin, MD

¹ Nunes et al. *JAMA Network Open*. 2024;7(6)

² Lintzeris et al. *MJA*. 2024

³ D'Onofrio et al. *JAMA Network Open*. 2024;7(7)

Octreotide SC depot, CAM2029

CAM2029 is a long-acting octreotide in development for three serious rare disease indications

- Acromegaly
- Gastroenteropancreatic neuroendocrine tumors (GEP-NET)
- Polycystic liver disease (PLD)

Designed for enhanced efficacy and patient convenience vs. current somatostatin receptor ligands (SRLs)



CAM2029 designed to address key limitations of current first-generation SRLs

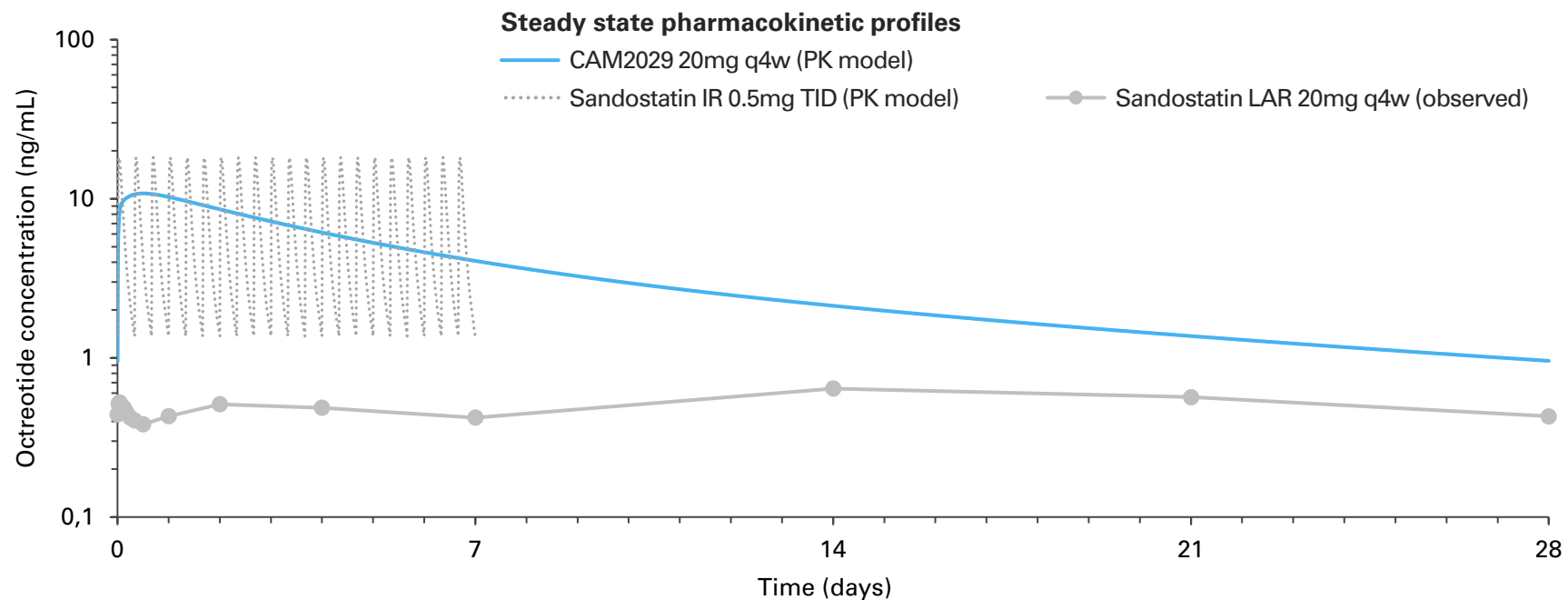
- ✓ Ready-to-use FluidCrystal® technology
- ✓ Rapid onset and long-acting octreotide release¹
- ✓ 5-fold octreotide bioavailability vs Sandostatin LAR with potential for improved efficacy¹⁻³
- ✓ State-of-the-art, pre-filled autoinjector pen enabling convenient patient self-administration
- ✓ Subcutaneous administration with thin needle (22-gauge, 12.5mm)
- ✓ Room temperature storage



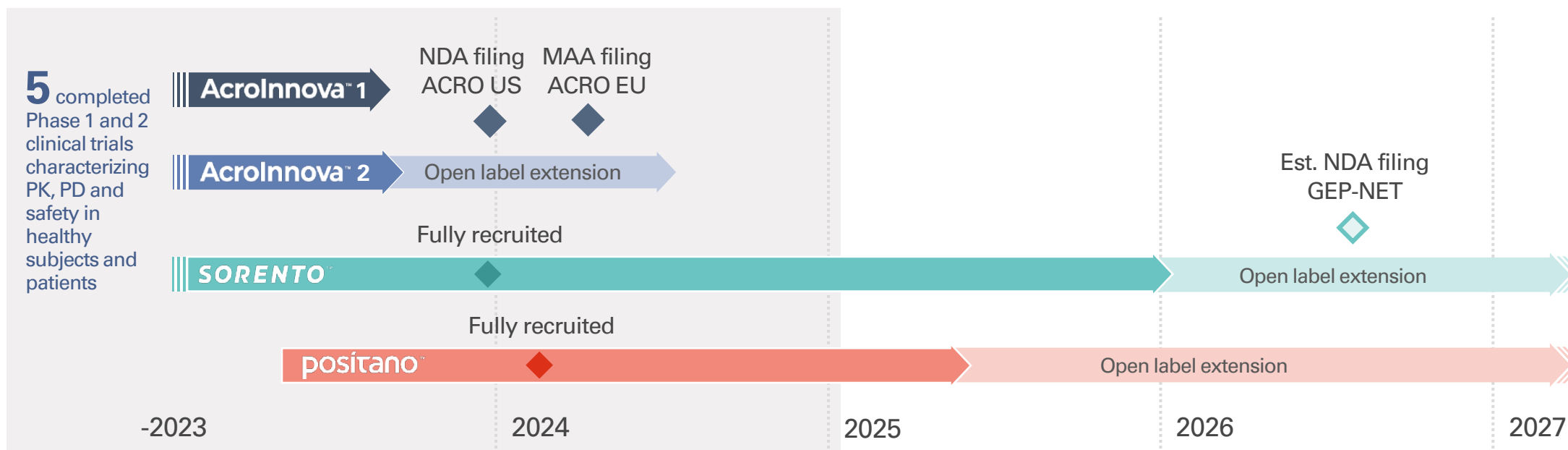
CAM2029 provides high SRL exposure

~5x higher octreotide plasma exposure for CAM2029 vs. Sandostatin LAR

– CAM2029 octreotide plasma levels in the range of immediate release octreotide



CAM2029 clinical program overview



ACROINNOVA 1 Phase 3 RCT
Randomized, double-blind, placebo-controlled trial in SRL responders

ACROINNOVA 2 Phase 3 LST
Open label, long-term safety and extension trial in partial and full SRL responders

SORENTO Phase 3 RCT
Active controlled Phase 3 trial in patients with metastatic/unresectable GEP-NET

POSITANO Phase 2/3 RCT
Randomized, double-blind, placebo-controlled Phase 2/3 trial in patients with PLD

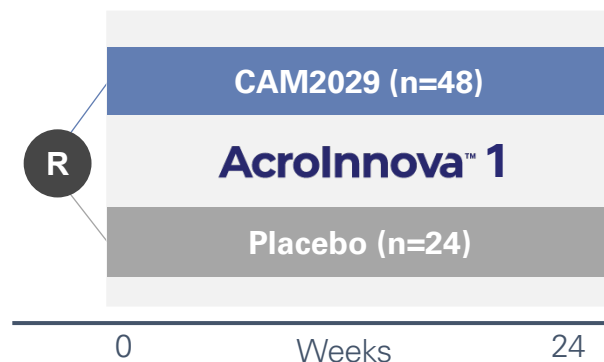
Positive results from ACROINNOVA 1 – CAM2029 provided robust biochemical control

ACROINNOVA 1 study design

- 24-week, randomized, double blind, placebo-controlled Phase 3 study

Patient population

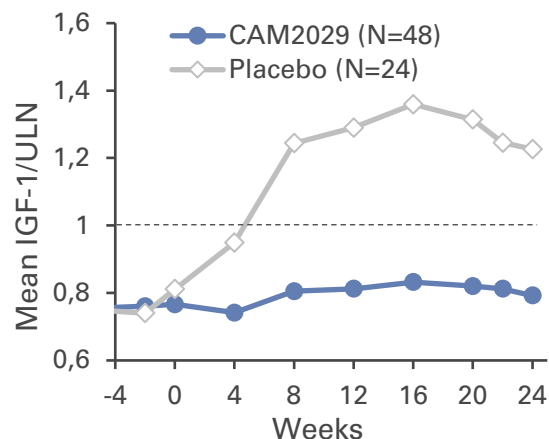
- Biochemically controlled on first-generation SRL*



Superiority achieved

- 77.2% vs. 37.5% patients with IGF-1 ≤ 1 ULN with CAM2029 versus placebo, $p=0,00018$

IGF-1 levels well controlled



CAM2029 improved

- Treatment convenience
- Acromegaly quality of life
- Patient satisfaction

CAM2029 was well tolerated

- Safety profile comparable to well established profile for first generation SRLs
- Most AEs were mild or moderate and transient injection site reactions and gastrointestinal side-effects
- No serious reactions related to CAM2029

*IGF-1 \leq ULN and mean GH < 2.5 μ g/L at screening, on stable octreotide LAR or lanreotide ATG for ≥ 3 months

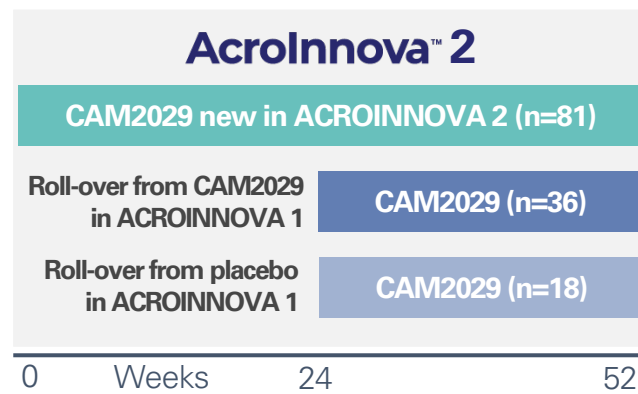
Positive topline results from ACROINNOVA 2

ACROINNOVA 2 study design

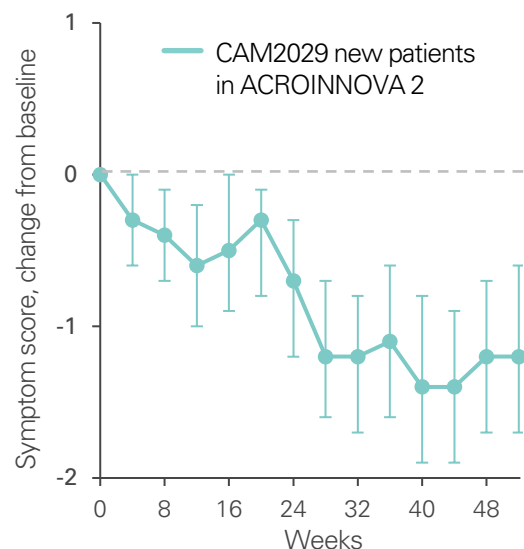
- 52-week, open-label safety study with further extension

Patient population

- New patients; uncontrolled or controlled with IGF-1 < 2xULN
- Patients who completed ACROINNOVA 1



Improved acromegaly symptoms with CAM2029



ACROINNOVA 2 results

- Reinforcing long-term safety and effectiveness in ACROINNOVA 1
- Increased response rate from SoC baseline in new recruited patients
- Roll-over placebo patients from ACROINNOVA 1 regained IGF-1 control with CAM2029

Improved patient reported outcomes for CAM2029 vs standard-of-care baseline

- Treatment satisfaction
- Quality of life
- Injection experience

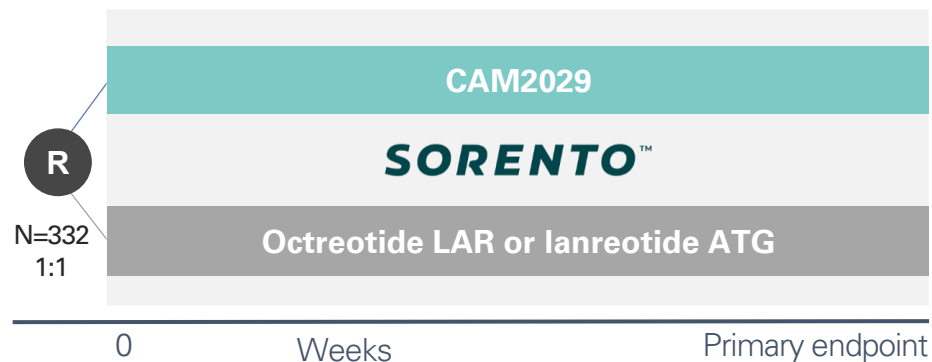
SORENTO assessing CAM2029 superiority in PFS vs SoC in patients with GEP-NET

Randomized, active-controlled Phase 3 study

- Randomized, multi-center, open-label, active-controlled Phase 3 study of CAM2029 vs. long-acting octreotide or lanreotide in patients with GEP-NET
- Single trial fulfilling regulatory requirements for safety and efficacy

Patient population

- Patients with confirmed, advanced and well-differentiated GEP-NET (grade 1 to grade 3)



Primary endpoint

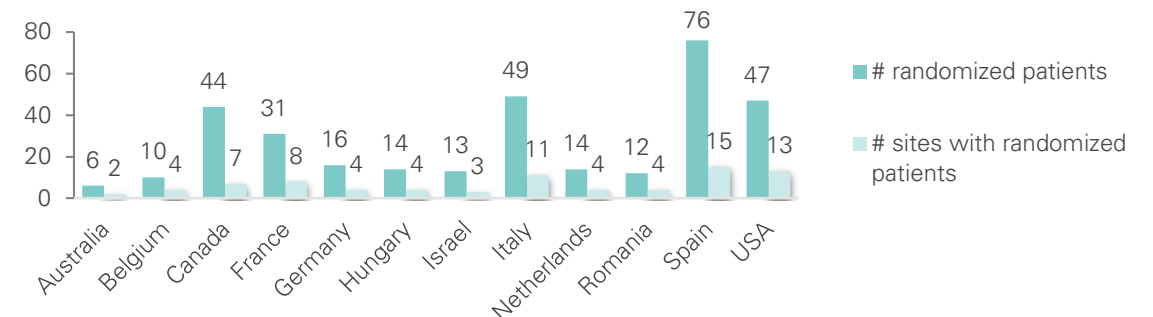
- Superiority in progression free survival, PFS, vs. standard of care (first-line medical treatment)
- Assessed after 194 documented PFS events

Secondary endpoints include

- Overall survival
- PROs (e.g., treatment satisfaction, quality of life)
- Safety

Recruitment completed Dec 2023

- Enrollment of 332 patients across 12 countries exceeding randomization target (302)



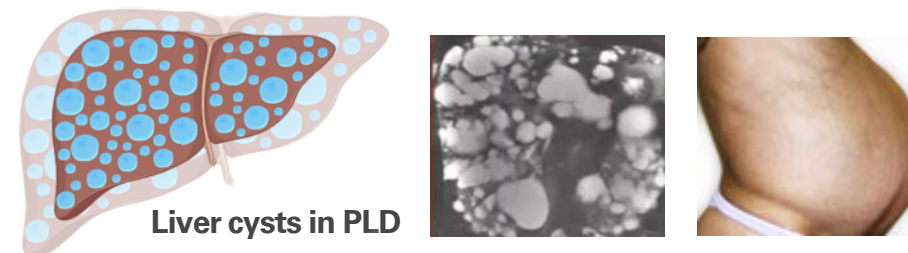
Clinical Phase 2/3 study in PLD fully recruited

POSITANO trial to assess efficacy and safety

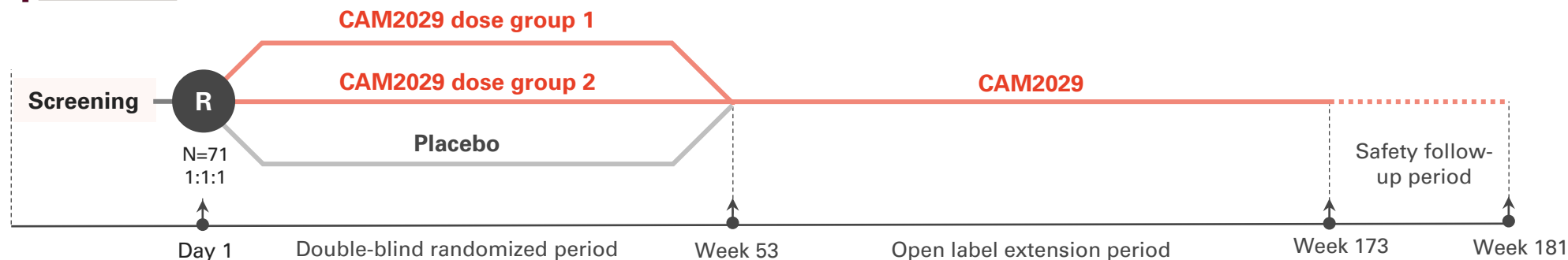
- 53-week randomized, placebo-controlled, three-arm study
 - Randomization of 71 patients completed in Q1 2024
 - Primary endpoint is liver volume change
 - Key secondary endpoint is Camurus' developed PRO, PLD-S
 - Multiple secondary endpoints, incl. quality of life, safety, etc.
- Open label extension extended to 120 weeks
 - Offer continued treatment in patients with expected benefits

Large unmet medical need in PLD

- Severe quality-of-life implications for patients with symptomatic PLD
- No labelled option available



positano[™]



CAM2029 progressing towards market with upcoming key milestones 2024/25

AcroInnova™

Pivotal randomized placebo controlled and long-term safety trials in acromegaly

- ✓ Positive ACROINNOVA 1 results
- ✓ NDA acceptance for review
- ✓ MAA submission to EMA
- ✓ Positive ACROINNOVA 2 complete core phase results
- ❑ CRL resolution ongoing
- ❑ US launch readiness for Oclaiz™
- ❑ MAA approval by EMA est. mid-2025

SORENTO™

Subcutaneous Octreotide Randomized Efficacy in Neuroendocrine Tumors

- ✓ SORENTO Phase 3 start Q4 2021
- ✓ SORENTO fully enrolled Q4 2023
- ❑ **Topline Phase 3 result est. late 2025 or early 2026**
- ❑ **NDA/MAA submission est. H2 2026**

positano™

Polycystic liver Safety and efficacy Trial with subcutaneous Octreotide

- ✓ POSITANO Phase 2/3 Q2 2022
- ✓ **POSITANO fully enrolled Q1 2024**
- ✓ Orphan drug designation
- ❑ **Topline result Q2 2025**

High market potential for CAM2029 – largest opportunity in GEP-NET

Attractive specialty pharma opportunity

- Highly concentrated target audiences
- Differentiated product features
- Switch from established first-line treatments
- Blockbuster potential in GEP-NET alone

CAM2029 peak sales estimates from third party market research¹⁻⁴

	TERRITORY	PATIENT POPULATION	EST. PEAK PATIENT SHARE	EST. PEAK SALES
ACRO	EU/AUS	16,500 ⁴	20 – 35%	€30 – 65 million
	US	10,000	25 – 40%	\$150 – 280 million
NET ¹	EU/AUS	68,000 ⁴	30%	€300 – 400 million
	US	37,000	40%	\$1,200 – 1,500 million
PLD ¹	EU/AUS	15-18,000 ⁴	30 – 40%	€80 – 100 million
	US	12-13,000	30 – 40%	\$200 – 300 million

¹Globe Life Science Aug 2022, data on file; ²Globe Life Science 2020, data on file; ³Assuming €10-12.5k (EU/AUS) and \$60-70K (US) per year net pricing in acromegaly, €15-20k (EU/AUS) and \$80-100K (US) per year net pricing in NET, and €17.5k (EU/AUS) and \$60K (US) per year net pricing in PLD; ⁴Patient numbers extrapolated from 5EU estimates by assuming same prevalence across European countries and Australia



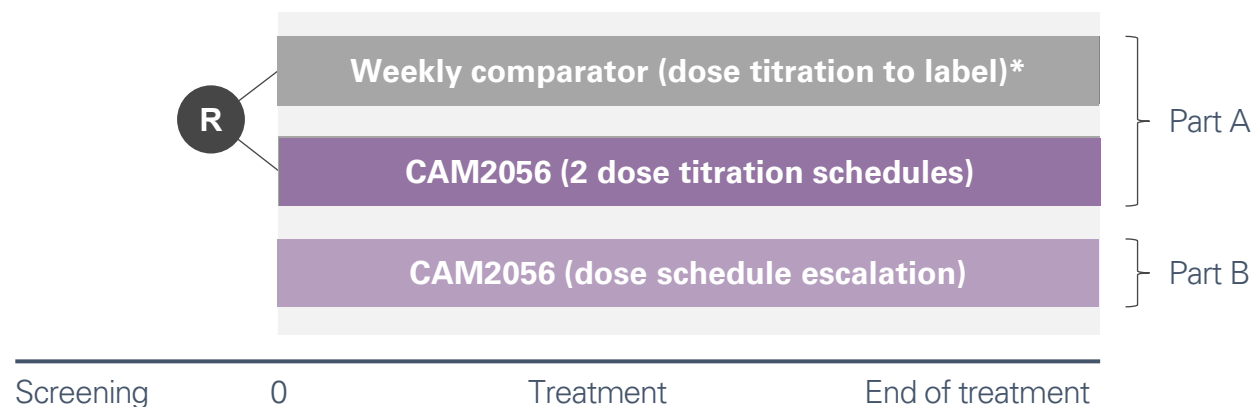
Once-monthly semaglutide entering clinical development

CAM2056 – once monthly FluidCrystal semaglutide

- Completed preclinical program met target profile for pharmacokinetics, pharmacodynamics (incl. weight management) and tolerability

Clinical study under initiation

- Phase 1 study assessing pharmacokinetics, pharmacodynamics (incl. weight loss), tolerability and safety of CAM2056 in overweight or obese people who are otherwise healthy
- Clinical Trial Application approved in December 2024



* Wegovy®



Significant near-term opportunities

- ❑ Strengthening leadership in treatment of opioid dependence
- ❑ US and EU market approval decisions for CAM2029 in acromegaly
- ❑ US launch of Oclaiz™ in acromegaly
- ❑ Topline results from POSITANO and SORENTO studies of CAM2029 in GEP-NET and PLD
- ❑ Advancing early pipeline programs in attractive indications, including semaglutide and other long-acting incretins
- ❑ Inorganic growth and diversification through business development



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Shareholders and analyst coverage

Shareholders as of 30 December 2024	Number of shares	% of capital	% of votes
Sandberg Development AB	20,530,692	34.9	35.0
Fjärde AP-fonden	2,808,776	4.8	4.8
JP Morgan Chase Bank	2,341,984	4.0	4.0
Swedbank Robur Fonder	2,181,347	3.7	3.7
State Street Bank and Trust	2,008,381	3.4	3.4
Fredrik Tiberg, CEO	1,615,000	2.7	2.8
Handelsbankens fonder	1,331,085	2.3	2.3
Avanza Pension	1,245,689	2.1	2.1
The Bank of New York Mellon	877,810	1.5	1.5
Afa Försäkring	816,153	1.4	1.4
Norges bank	704,848	1.2	1.2
JP Morgan SE	643,206	1.1	1.1
SEB Investment Management	642,193	1.1	1.1
CS Client Omnibus	631,048	1.1	1.1
Camurus Lipid Research Foundation	480,150	0.8	0.8
Other shareholders	20,020,656	34.0	33.7
In total	58,808,768	100.0	100.0

Analysts

Carnegie
Erik Hultgård

DNB
Patrik Ling

Handelsbanken
Mattias Häggblom

Jefferies
Brian Balchin

Nordea
Viktor Sundberg

Pareto
Dan Akschuti

Bryan Garnier
Oscar Haffen Lamm

SEB
Christopher Uhde

Experienced and committed management team



Fredrik Tiberg, PhD
President & CEO, CSO
In Company since 2002
Holdings: 1,615,000 shares, 42,000 employee options and 4,000 PSP units

Education: M.Sc. in Chem. Eng., Lund Institute of Technology, PhD and Assoc. Prof. Physical Chemistry, Lund University.
Previous experience: More than 20 years executive leadership experience from the pharmaceutical industry. Prof Physical Chemistry, Lund University; Visiting Prof at Oxford University; Section Head, Inst. for Surface Chemistry.



Jon Garay Alonso
Chief Financial Officer
In Company since: 2022
Holdings: 1,450 shares, 24,000 employee options and 2,300 PSP units

Education: Bachelor in Business Administration by Universidad Comercial de Deusto. Executive MBA by IESE Business School.
Previous experience: More than 20 years experience from Finance within pharmaceutical and medtech companies, incl. Baxter, Gambro, Convatec, Bristol Myers Squibb.



Richard Jameson
Chief Commercial Officer
In Company since: 2016
Holdings: 29,193 shares, 24,000 employee options and 2,300 PSP units

Education: B.Sc. in Applied Biological Sciences from University West of England
Previous experience: General Manager, UK & Nordics for Reckitt Benckiser (2010 – 2013) and Area Director Europe, Middle East and Africa for Indivior (2013 – 2016).



Fredrik Joabsson, PhD
Chief Business Dev. Officer
In Company since 2001
Holdings: 40,170 shares, 16,000 employee options and 1,500 PSP units

Education: M.Sc. in Chemistry, PhD in Physical Chemistry, Lund University
Previous experience: More than 20 years of experience in pharmaceutical R&D, business development, alliance management and investor relations.



Markus Johansson
Senior VP R&D
In Company since: 2003-2017, 2019-
Holdings: 21,000 shares, 9,500 employee options and 1,500 PSP units

Education: Ph.D. in physical chemistry and M.Sc. in chemistry from Uppsala University.
Previous experience: More than 20 years of experience from pharmaceutical development and project management



Maria Lundqvist
Head of Global HR
In Company since 2021
Holdings: 16,000 employee options and 1,500 PSP units

Education: B.Sc. in Business and Economics, Uppsala University.
Previous experience: More than 20 years of experience of leadership roles within Human Resources, including HR Director Nordics at Teva Pharmaceuticals and HR positions at Tetra Pak, Vestas and AstraZeneca.



Torsten Malmström, PhD
Chief Technical Officer
In Company since 2013
Holdings: 35,363 shares, 16,000 employee options and 1,500 PSP units

Education: M.Sc. in Chemistry, PhD in Inorganic Chemistry, Lund University
Previous experience: More than 20 years of experience from pharmaceutical R&D including Director Pharmaceutical Development at Zealand Pharma, Director of Development at Polypeptide, Team Manager at AstraZeneca.



Annette Mattsson
VP Regulatory Affairs
In Company since: 2017
Holdings: 2,004 shares, 16,000 employee options and 1,500 PSP units

Education: Bachelor of Pharmacy, Uppsala University and Business Economics, Lund University
Previous experience: More than 25 years of experience within regulatory affairs, including European RA Director/Global RA Lead at AstraZeneca and Global RA Lead at LEO Pharma.



Alberto M. Pedroncelli
Chief Medical Officer
In Company since 2023
Holdings: 1,000 shares, 20,000 employee options and 1,500 PSP units

Education: MD University of Milan. Ph. D. endocrinology post-graduate school University of London
Previous experience: Head of Clinical Development and Medical Affairs Recordati, Senior Leadership positions Novartis, clinician and research fellow Dept. Endocrinology, University Hospital Bergamo, Italy



Behshad Sheldon
President Camurus Inc.
In Company since 2024
Holdings: 1,000 shares, 2,000 employee options and 1,500 PSP units

Education: B.Sc. in Neuroscience from University of Rochester
Previous experience: More than 25 years of experience from the international pharma industry, including President & CEO of Braeburn Pharmaceuticals and senior positions within Smithkline Beecham, Bristol-Myers Squibb and Otsuka Pharmaceuticals.



Agneta Svedberg
VP Clinical Dev.
In Company since: 2015
Holdings: 22,987 shares, 16,000 employee options and 1,500 PSP units

Education: M.Sc. In Radiophysics and B.Sc. In Medicine from Lund University, Executive MBA from Executive Foundation Lund
Previous experience: More than 25 years of experience in drug development, incl. as COO at Zealand Pharma, CEO of Cantargia, Senior VP Clinical Development at Genmab.



Bo A. C. Tarras-Wahlberg
VP Legal & Group General Counsel
In Company since 2024
Holdings: 1,500 PSP units

Education: LLM from Lund University and studies at Queen Mary College
Previous experience: More than 20 years of experience as lawyer and from international senior legal positions, incl. as Assoc. General Counsel at Baxter, Gambro, legal private practice and as law clerk at District Court.

ACROINNOVA 1

Phase 3 RCT efficacy and safety trial

ACROINNOVA 1 trial design

- 24-week, randomized, double blind, placebo-controlled trial

Key eligibility criteria:

- Patients with acromegaly on treatment with a stable dose of octreotide LAR or lanreotide ATG for at least 3 months with
- IGF-1 levels $\leq 1 \times \text{ULN}$ at screening

Primary endpoint:

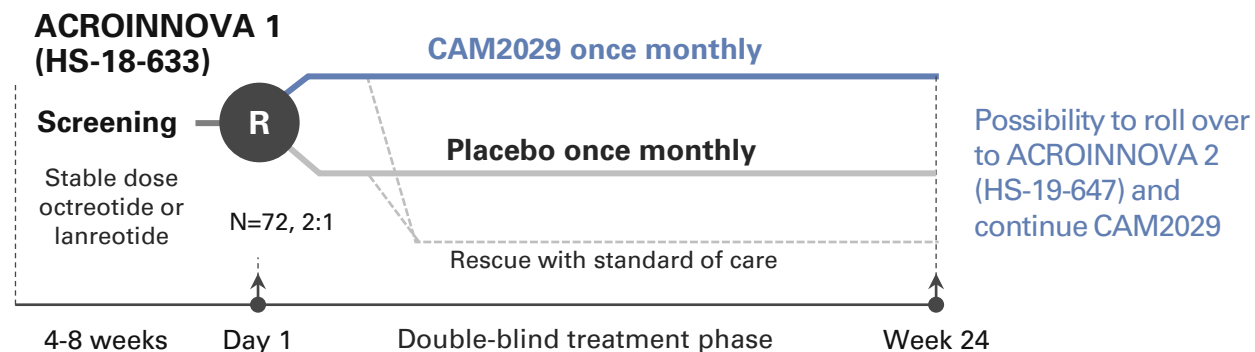
- Proportion of patients with mean IGF-1 $\leq 1 \times \text{ULN}$ (week 22 and 24)

Key secondary endpoints:

- Proportion of patients with mean IGF-1 levels $\leq 1 \times \text{ULN}$, incl. patients with decreased dose
- Proportion of patients with mean IGF-1 levels $\leq 1 \times \text{ULN}$ and GH cycle levels $< 2.5 \mu\text{g/L}$

Secondary endpoints, e.g.:

- Time to loss of IGF-1 response
- IGF-1 and GH over time and change from baseline
- Clinical signs and symptoms (AIS score)
- Patient satisfaction and treatment satisfaction (PSS and TSQM)
- Acromegaly quality of life (AcroQoL)
- Self-injection assessments (SiAQ)
- Plasma concentrations of octreotide
- Safety and tolerability



Statistical assumption primary endpoint:

- 90% power to show treatment difference with 80% response for CAM2029 vs 40% response for placebo, based on Chi-squared test (with continuity correction)

ACROINNOVA 2

Phase 3 long-term safety and extension trial

ACROINNOVA 2 trial design

- 52-week, open-label, long-term safety and extension trial

Patient population

- New patients in trial; IGF-1 < 2xULN (n=81)
- Roll-over CAM2029 patients; IGF-1 ≤ 1xULN (n=36) from ACROINNOVA 1
- Roll-over placebo patients; IGF-1 ≤ 1xULN (n=18) from ACROINNOVA 1

Primary endpoint:

- Long-term safety and tolerability

Secondary endpoints:

- Biochemical response (IGF-1, GH)
- Mean IGF-1 and GH over time
- Clinical signs and symptoms (AIS)
- Patient and treatment satisfaction (TSQM)
- Quality of life (AcroQoL, EQ-5D-5L)
- Self-Injection Assessment Questionnaire (SiAQ)
- Octreotide concentrations

ACROINNOVA 2 (HS-19-647)

