



camurus®

# Company presentation

August 2024

# 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



## Advancing late-stage pipeline with blockbuster potential

Prospect for multiple new approvals in CNS and rare disease indications



## Unique FluidCrystal® technology platform

Commercially validated with a broad range of applications



## Strong operational and financial performance

Sustainable profitability since 2022

LISTED ON NASDAQ STOCKHOLM  
TICKER **CAMX**; EMPLOYEES: **225+**

# Significant recent progress



## Commercial execution

- ✓ Establishing global leadership in opioid dependence treatment
- ✓ Robust growth of Buvidal sales in Europe and Australia
- ✓ Strong momentum for Brixadi in the US
- ✓ Building commercial organization in the US and preparing for launch of Oclaiz™ in acromegaly



## Advancing R&D pipeline

- ✓ US and EU regulatory applications for CAM2029 in acromegaly
- ✓ Completion of the 52-week Phase 3 ACROINNOVA 2 study with positive final results
- ✓ Completed recruitment in SORENTO and POSITANO Phase 3 studies
- ✓ Positive assessment of novel GLP-1 formulations, incl. once-monthly semaglutide

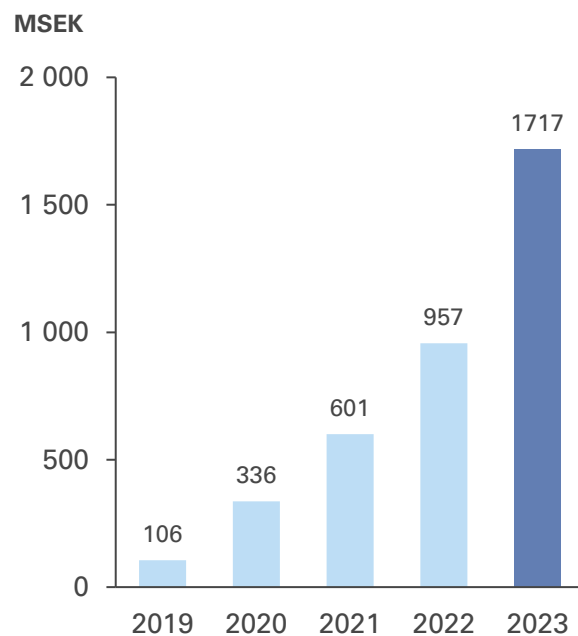


## Positive financial performance

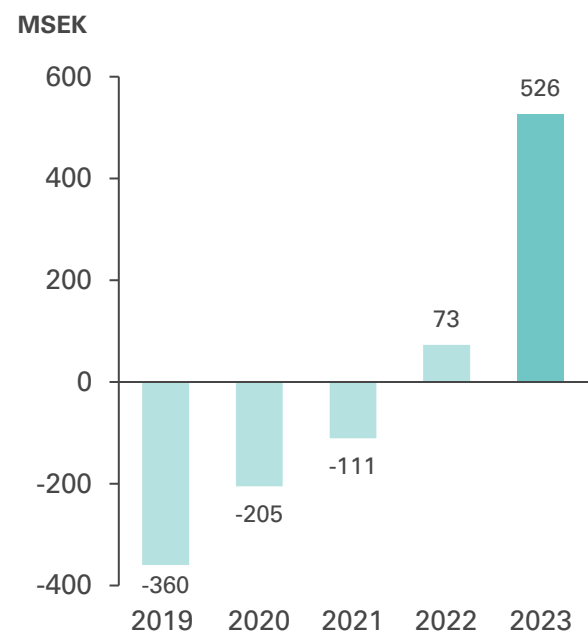
- ✓ Increasing revenues with improved margin
- ✓ Disciplined capital allocation
- ✓ Robust cash position of SEK 2.6 billion
- ✓ No debt

# Positive financial development

## Revenues



## Operating results



## Outlook 2024\*

Total revenue  
**SEK 1,740 – 1,860 million**  
 + 33 – 42% excl. one-time  
 milestones 2023

Profit before tax  
**SEK 330 – 450 million**  
 +131 – 215% excl. one-time  
 milestones 2023

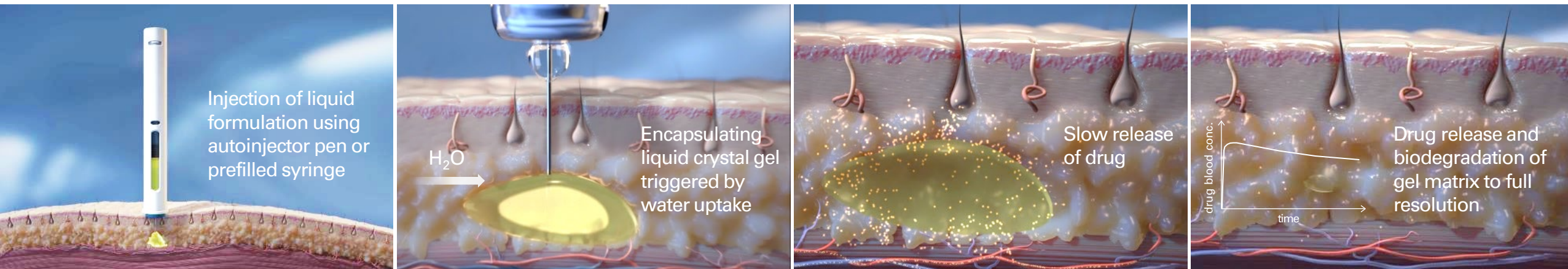
\*update July 2024: expected to finalize  
 in the mid to high end of the interval

camurus®

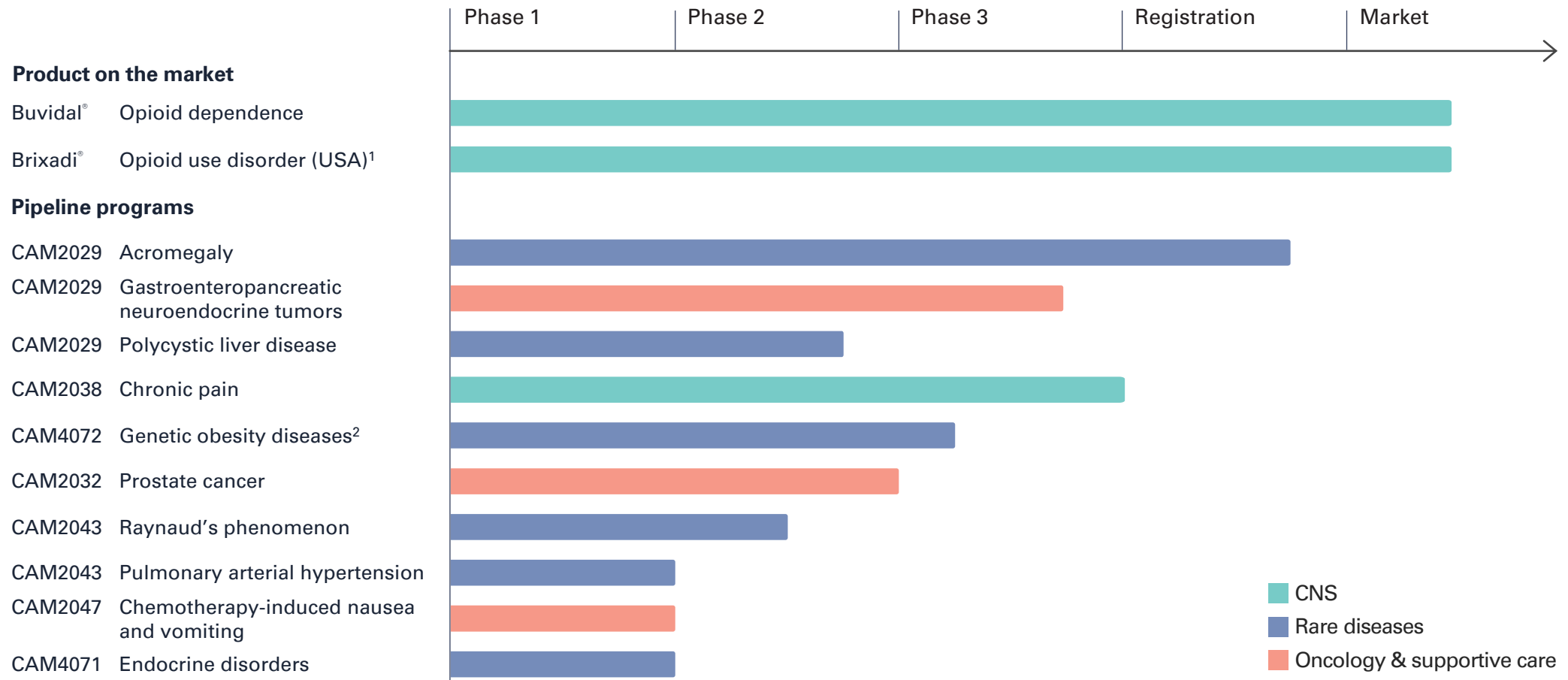


# FluidCrystal<sup>®</sup> extended-release technology

- ✓ 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



<sup>1</sup>Licensed to Braeburn in North America; <sup>2</sup>Licensed to Rhythm Pharmaceuticals worldwide

# 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 over<sup>1</sup>*

## Demonstrated benefits to patients and society

- Superior treatment outcome and patient satisfaction<sup>2-5</sup>
- Blocks subjective opioid effects from first dose<sup>3</sup>
- Reduces treatment burden and improved quality of life<sup>5,6</sup>
- Decrease risk of diversion, misuse and pediatric exposure<sup>7,8</sup>
- Provides cost savings<sup>9</sup>

“Buvidal became my way out”

Justin, Buvidal patient in Australia

<sup>1</sup> SmPC Buvidal Aug 2023; <sup>2</sup>Lofwall et al. JAMA Int. Med. 2018;178(6): 764-773; <sup>3</sup>Walsh et al. JAMA Psychiatry 2017;74(9):894-902; <sup>4</sup>Frost, M., et al. Addiction. 2019;114(8):1416-1426. doi: 10.1111/add.14636; <sup>5</sup>Lintzeris, N., et al. JAMA Network Open. 2021;4(5):e219041. doi:10.1001/jamanetworkopen.2021.9041; <sup>6</sup>Barnett et al. Drug and Alcohol Dependence 2021; <https://doi.org/10.1016/j.drugalcdep.2021.108959>; <sup>7</sup>EPAR for Buvidal; <sup>8</sup>Dunlop, A. J., et al. Addiction. 2021. <https://doi.org/10.1111/add.15627>; <sup>9</sup>Dunlop, 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 53,000 in treatment with Buvidal in Europe and Australia end-June 2024

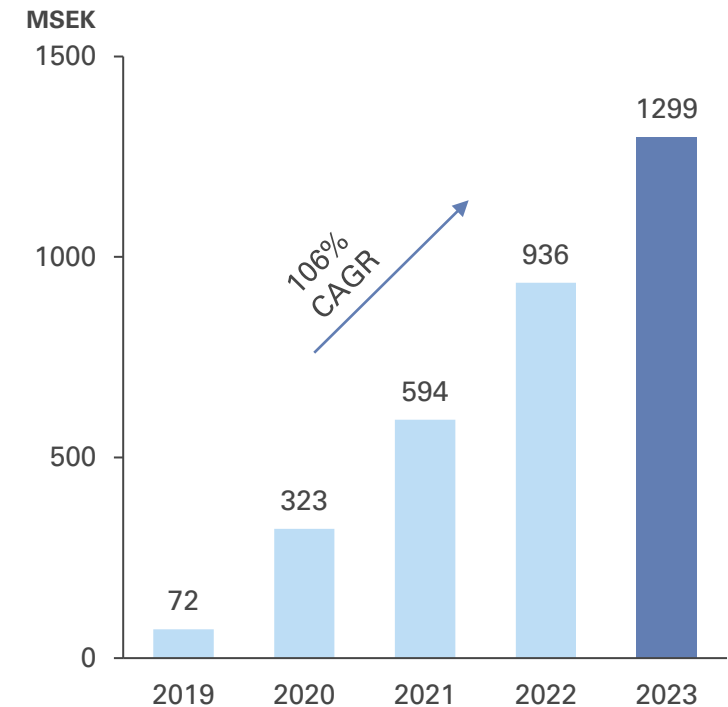
## Robust Buvidal sales growth

- 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

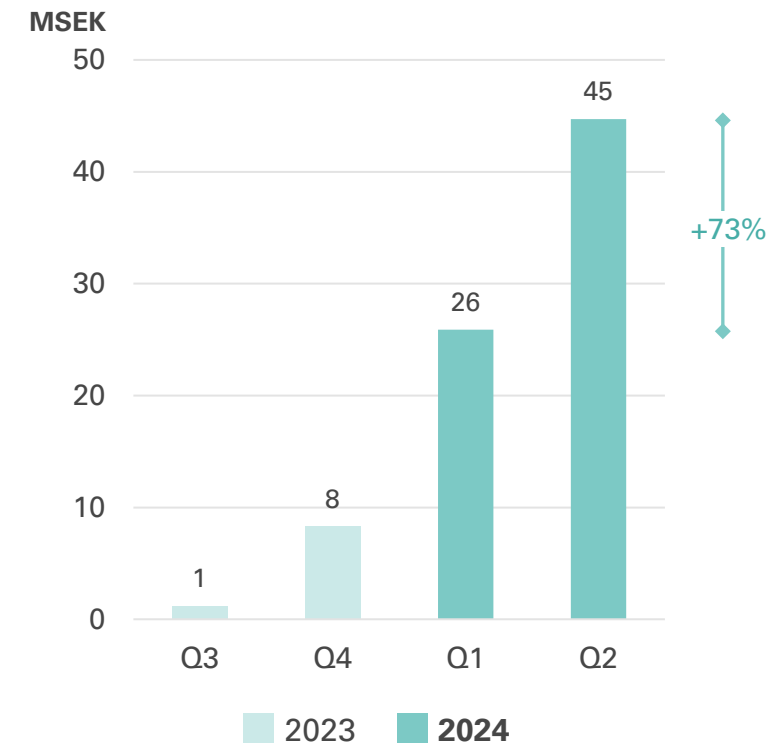
- High payer coverage – on par with competition for both Medicaid and commercial payers
- Broad and expanding distribution network

## Accelerated sales growth

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

## Peak market potential > USD 1 billion<sup>2</sup>

## Brixadi royalty by quarter



*OUD – opioid use disorder*

*<sup>1</sup>Company estimate*

# 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 label<sup>1</sup>

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

### LAI features<sup>2</sup>

			
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

<sup>1</sup>Brixadi US label; <sup>2</sup>See product information

# Growing scientific evidence base

## Strong scientific support for Buvidal/Brixadi

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

## Selected scientific conference participation in 2024

	Q1/Q2 2024			Q3/Q4 2024			
<b>International</b>	<b>ASAM</b> 4-7 Apr Dallas, US	<b>ALBATROS</b> 4-6 Jun Paris, FR	<b>CPDD</b> 16-19 Jun Montreal, CAN	<b>EUROPAD</b> 28-30 Jun Lisbon, PT	<b>ISAM</b> 5-8 Sep Istanbul, Turkey	<b>Lisbon Addict.</b> 23-25 Oct Lisbon, PT	
<b>National (selected)</b>	<b>CH Le Vinatier</b> 11 Jan FR	<b>WADD/SEPD</b> 17-20 Apr Mallorca, ES	<b>Hospital Croix</b> 17 May Lyon, FR	<b>WOWS</b> June Brisbane, AUS	<b>Suchmedizin</b> 4-6 Jul Munich, DE	<b>Suchtsymp.</b> Oct Grundlsee, AT	<b>APSAD</b> 30 Oct – 2 Nov Canberra, AUS
	<b>APP</b> 14-17 Mar Cold Coast, AUS	<b>Sigtunadagarna</b> 18-19 Apr SE	<b>Subst.Forum.</b> May Mondsee, AT	<b>DANA</b> 7-9 Aug AUS	<b>RCPsych Addict</b> Oct London, UK	<b>Gefängn.med</b> 5-6 Dec Frankfurt, DE	
	<b>GRAAP</b> 3 Apr Aix-en Prov, FR	<b>AUS/NZ Addict.</b> 29 Apr - 1 May Cold Coast, AUS	<b>Federation Add</b> 13-14 Jun Bordeaux, FR	<b>SOCIDROGA.</b> 26-28 Sep Valencia, ES	<b>Prison congr.</b> Oct Montpellier, FR	<b>Addiktum</b> Dec Helsinki, FI	

## Recent key publications<sup>1-3</sup>

**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<sup>1,2</sup>, Victoria Hayes<sup>2,3</sup>, Adrian J Dunlop<sup>4,5</sup>

**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

<sup>1</sup> Nunes et al. *JAMA Network Open*. 2024;7(6)

<sup>2</sup> Lintzeris et al. *MJA*. 2024

<sup>3</sup> 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

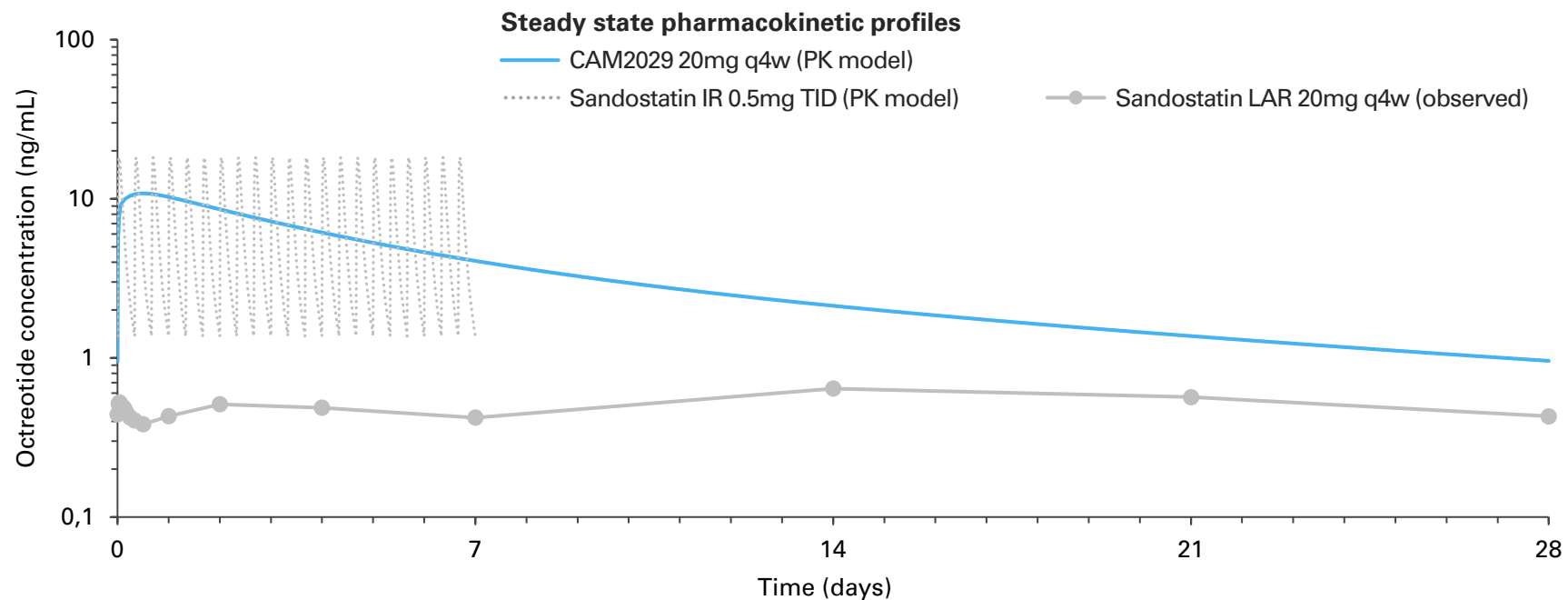
- ✓ Ready-to-use FluidCrystal® technology
- ✓ Rapid onset and long-acting octreotide release<sup>1</sup>
- ✓ 5-fold octreotide bioavailability vs Sandostatin LAR with potential for improved efficacy<sup>1-3</sup>
- ✓ State-of-the-art, pre-filled autoinjector pen enabling convenient patient self-administration
- ✓ Subcutaneous administration with thin needle (22-gauge, 12.5mm)
- ✓ Room temperature storage



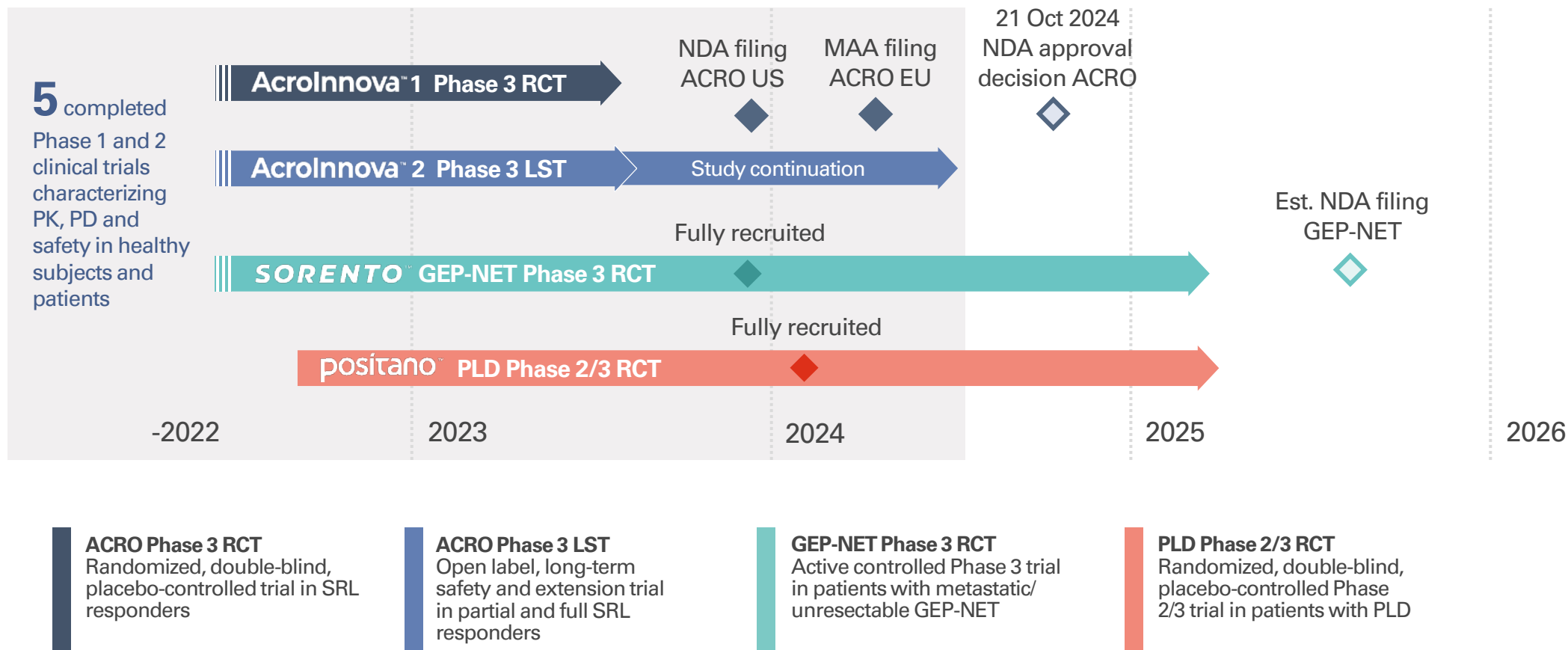
# CAM2029 provides high SRL exposure

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

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



# Comprehensive clinical study program for CAM2029





# 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

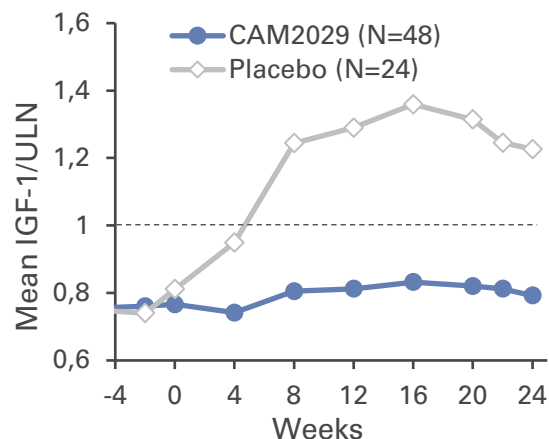
- Biochemically controlled on first-generation SRL\*



## Superiority achieved

- 77.2% vs. 37.5% patients with IGF-1  $\leq 1$  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  $< 2.5$   $\mu$ g/L at screening, on stable octreotide LAR or lanreotide ATG for  $\geq 3$  months

# Positive topline results from 52-week Phase 3 ACROINNOVA 2 study announced 15 July 2024

## ACROINNOVA 2 study design

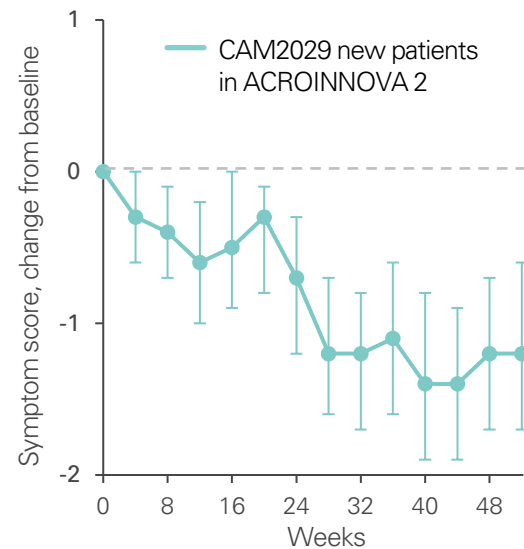
- 52-week, open-label safety study with further extension

## Patient population

- New patients; uncontrolled or controlled with  $\text{IGF-1} < 2 \times \text{ULN}$
- Patients who completed ACROINNOVA 1



## Improved acromegaly symptoms with CAM2029



## ACROINNOVA 2 results

- Reinforcing long-term safety and effectiveness observed 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

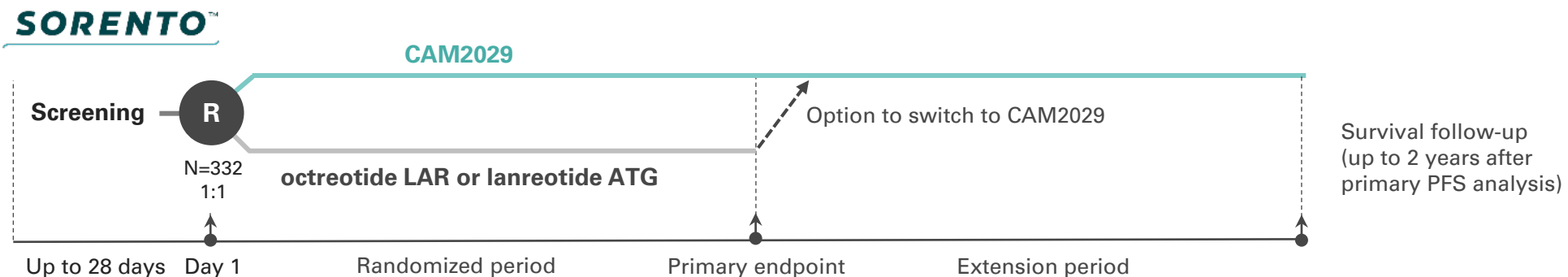
- Patients with confirmed, advanced and well-differentiated GEP-NET (grade 1 to grade 3)

## 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

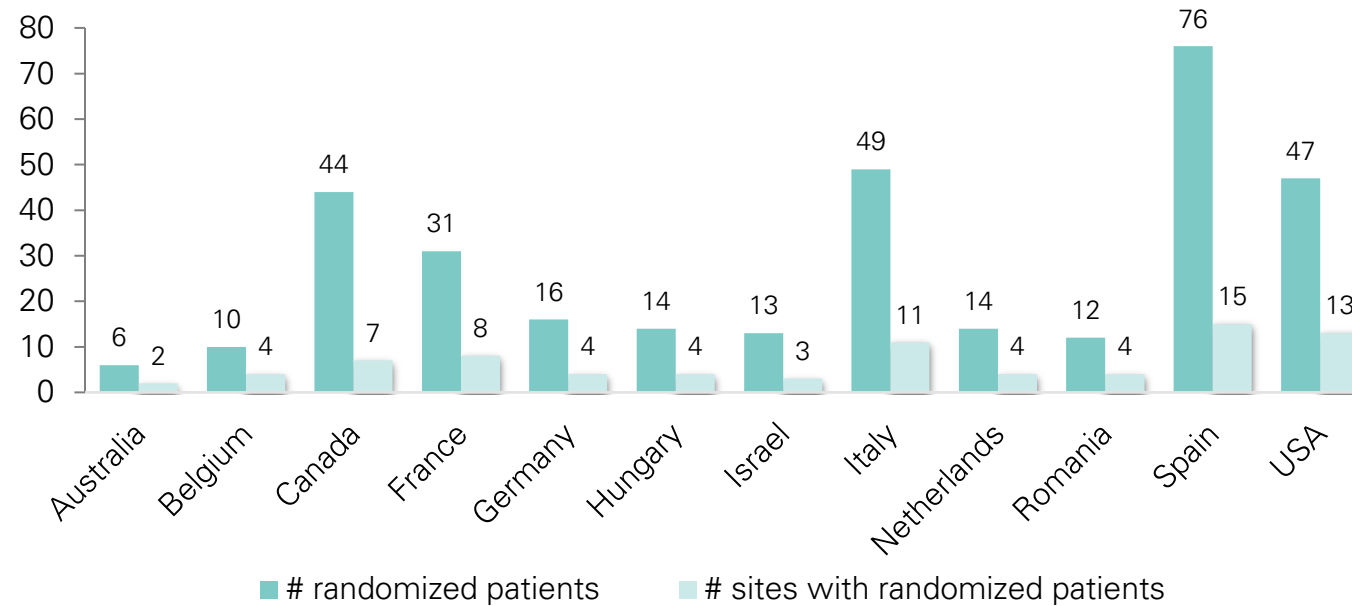
- Overall survival
- PROs (e.g., treatment satisfaction, quality of life)
- Plasma concentrations of octreotide
- Safety



# Completed patient recruitment in SORENTO

- ✓ Enrollment of 332 patients across 12 countries **exceeding randomization target (302)**
- ✓ **Largest ever controlled clinical study** with somatostatin receptor ligand

**332**  
patients  
randomized



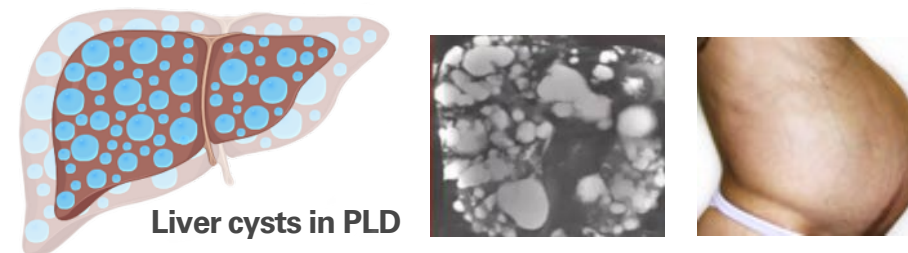
# Clinical Phase 2/3 study in PLD fully recruited

## POSITANO trial to assess efficacy and safety

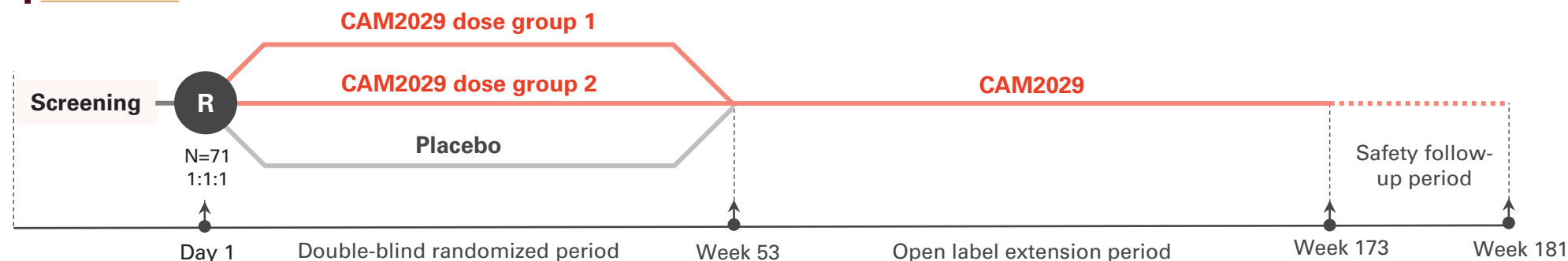
- 53-week randomized, placebo-controlled, three-arm study
  - Randomization of 71 patients completed in Q1 2024
  - Primary endpoint is liver volume change
  - Key secondary endpoint is Camurus' developed PRO, PLD-S
  - Multiple secondary endpoints, incl. quality of life, safety, etc.
- Open label extension 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**<sup>™</sup>



# 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
- ❑ **NDA PDUFA date 21 Oct 2024**
- ❑ **US launch readiness for Oclaz™ around year end 2024**
- ❑ **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 result est. H1 2025**
- ❑ **NDA/MAA submission est. H2 2025**

## positano™

Polycystic liver Safety and efficacy Trial with subcutaneous Octreotide

- ✓ POSITANO Phase 2/3 Q2 2022
- ✓ POSITANO fully enrolled Q1 2024
- ❑ **Topline result H1 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 research<sup>1-4</sup>

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

<sup>1</sup>Globe Life Science Aug 2022, data on file; <sup>2</sup>Globe Life Science 2020, data on file; <sup>3</sup>Assuming €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; <sup>4</sup>Patient numbers extrapolated from 5EU estimates by assuming same prevalence across European countries and Australia



# Establishing US organization for launch of Oclaiz™

Estimated ~ \$1.5 billion market opportunity

## Key activities

- US office established in Princeton, New Jersey
- President Camurus US, Behshad Sheldon
- Key positions onboarded
- In-depth market research
- High medical affairs activity
- Payor engagement
- Distribution model



US office location at Carnegie Center, Princeton

## Regulatory timeline:





# Significant near-term opportunities

- ❑ Establish global leadership in opioid dependence treatment
- ❑ US market approval decision for Oclaiz™ (CAM2029) in acromegaly
- ❑ Topline results from SORENTO and POSITANO studies of CAM2029 in GEP-NET and PLD
- ❑ Advancement of new pipeline programs in attractive indications
- ❑ Inorganic growth and diversification through business development
- ❑ US commercial readiness for own launch of Oclaiz™



A photograph on the left side of the slide shows three business professionals walking together. A man in a grey sweater and glasses is in the foreground, looking down at a document he is holding. Behind him, two women are smiling and looking towards him. They are in a bright, modern office environment with large windows in the background.

# Strategy for continued value creation

- 1. Grow Buvidal/Brixadi and expand to new markets
- 2. Grow and advance R&D pipeline to new approvals
- 3. Diversify through business development and partnerships
- 4. Strengthen organization and sustainability agenda

**Camurus' vision 2027**

Sustainable value creation  
for all stakeholders:

5x

Five-fold  
revenue growth



Establish-  
ment of US  
commercial  
infrastructure

4

Approvals  
for four R&D  
pipeline  
programs

~50%

Operating margin  
around 50 percent

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P +46 46 286 57 30 | [info@camurus.com](mailto:info@camurus.com) | [camurus.com](http://camurus.com)

# Shareholders and analyst coverage

Shareholders as of 31 July 2024	Number of shares	% of capital	% of votes
Sandberg Development AB	20,530,692	35.0	35.2
Fjärde AP-fonden	2,610,766	4.5	4.5
JP Morgan Chase Bank	2,154,190	3.7	3.7
Swedbank Robur Fonder	1,980,728	3.4	3.4
Avanza Pension	1,680,214	2.9	2.9
State Street Bank and Trust	1,661,724	2.8	2.9
Fredrik Tiberg, CEO	1,615,000	2.8	2.8
Handelsbankens fonder	1,505,697	2.6	2.6
JP Morgan SE	821,115	1.4	1.4
The Bank of New York Mellon	750,080	1.3	1.3
Norges bank	724,131	1.2	1.2
Afa Försäkring	689,293	1.2	1.2
CS Client Omnibus	612,684	1.0	1.1
SEB Investment Management	573,317	1.0	1.0
Svenskt Näringsliv	519,000	0.9	0.9
Other shareholders	20,208,287	34.5	34.2
<b>In total</b>	<b>58,636,918</b>	<b>100.0</b>	<b>100.0</b>

## 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, 102,000 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.

# 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:

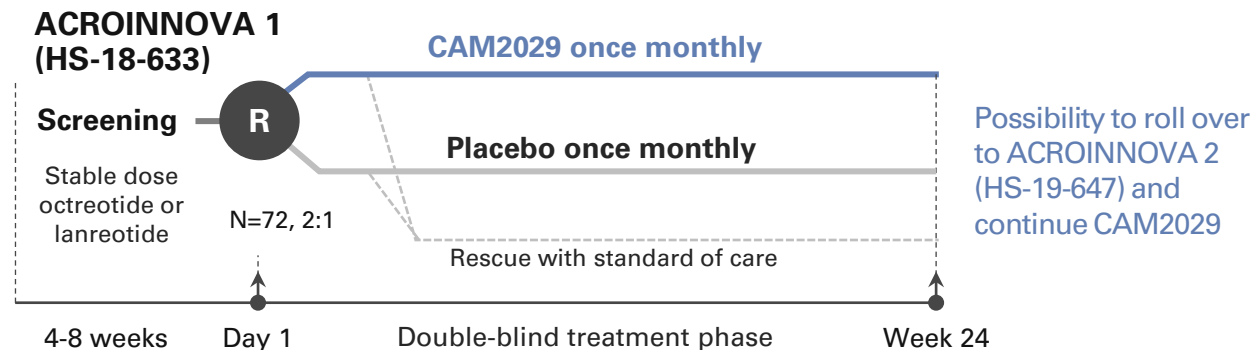
- Proportion of patients with mean IGF-1  $\leq 1 \times \text{ULN}$  (week 22 and 24)

### 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)

