

A woman with reddish-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 a distant shoreline with greenery. The entire image has a light blue-green tint.

camurus®

Company presentation

May 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® weekly and monthly depots



Unique FluidCrystal® technology platform

Commercially validated, with a broad range of applications



Advancing late-stage pipeline with blockbuster potential

Prospects for multiple new approvals in coming years in CNS and rare disease indications



Strong financial performance

Profitable with cash position over SEK 2 billion

LISTED ON NASDAQ STOCKHOLM
TICKER **CAMX**; EMPLOYEES: **215+**

Significant recent progress



Strong financial performance

- ✓ High year-on-year revenue growth
- ✓ Profitable since 2022
- ✓ SEK 1.1 billion directed share issue completed in January 2024
- ✓ Robust cash position
SEK 2.3 billion end Q1 2024
– no debt



Commercialization execution

- ✓ Strengthened leadership in opioid dependence treatment
- ✓ Continued strong Buvidal growth in Europe and Australia
- ✓ Accelerating Brixadi® growth in the US¹
- ✓ Camurus Inc. operational and preparing for US launch of Oclaiz™ in acromegaly



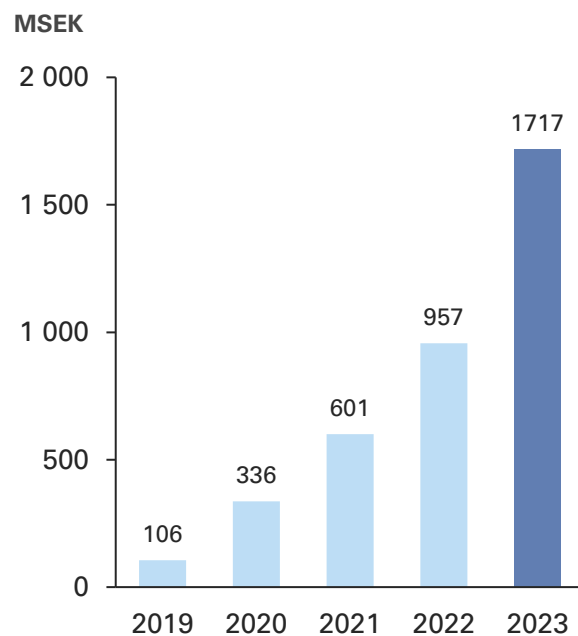
Pipeline advancement

- ✓ Four Phase 3 studies in rare disease indications
- ✓ FDA review of NDA for Oclaiz™ (CAM2029) in acromegaly ongoing – PDUFA date 21 October 2024
- ✓ Completed recruitment in SORENTO and POSITANO trials
- ✓ Positive assessment of novel monthly GLP-1 product candidate

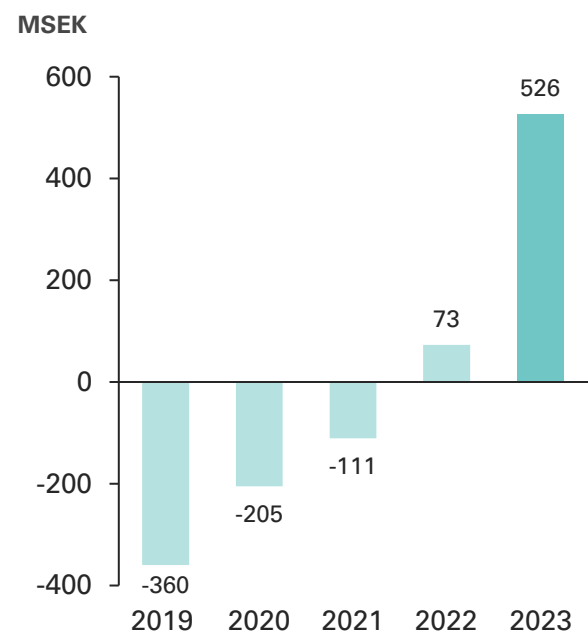
¹Brixadi® is the US brand name for Camurus' product Buvidal®; ²GEP-NET – gastroenteropancreatic neuroendocrine tumors; ³PLD – polycystic liver disease

Positive financial development

Revenues



Operating results

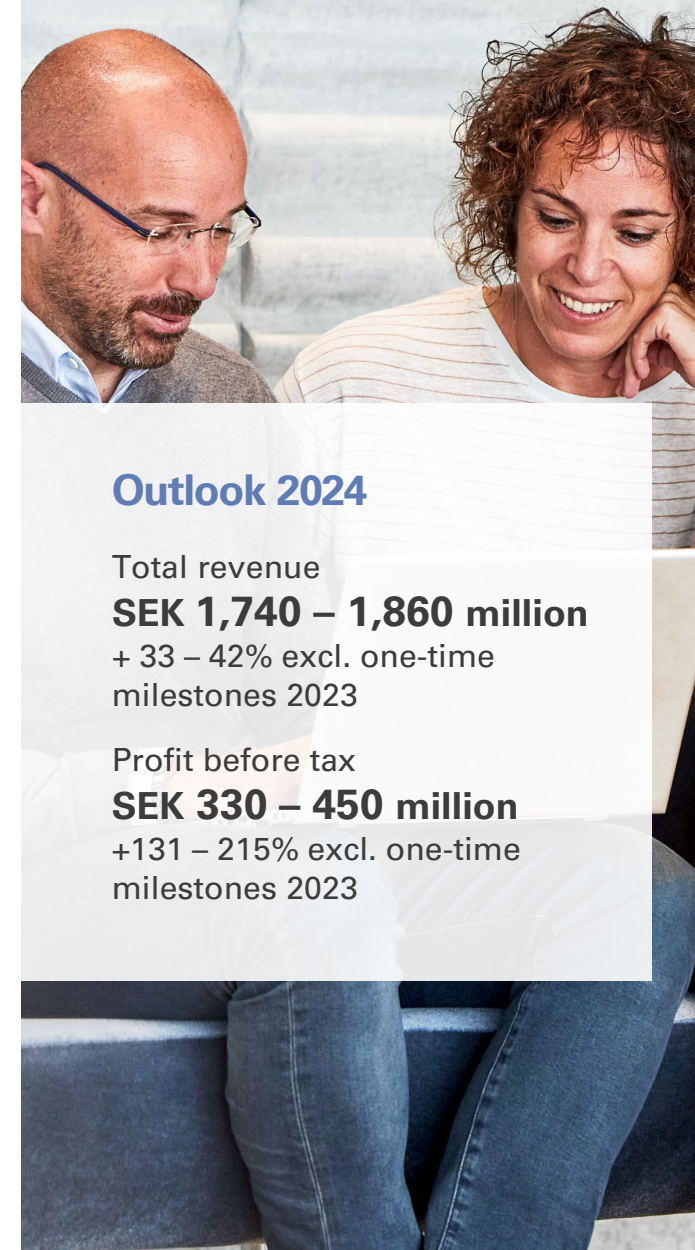


Outlook 2024

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

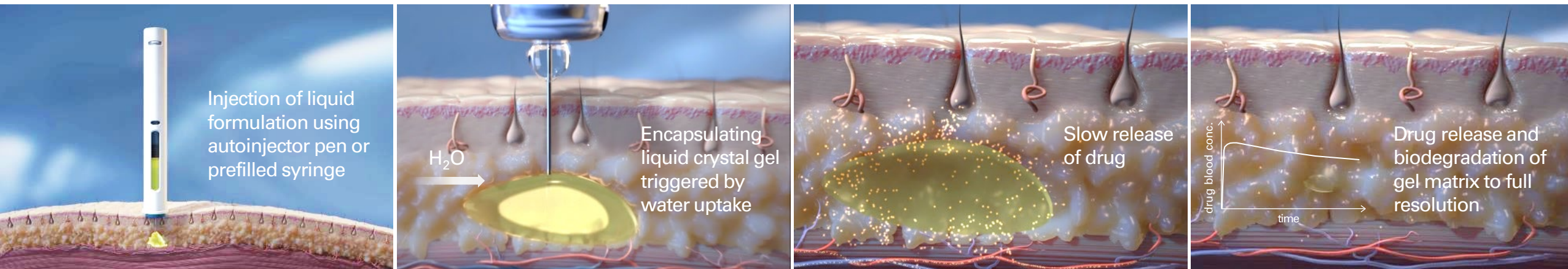
Profit before tax
SEK 330 – 450 million
 +131 – 215% excl. one-time
 milestones 2023

camurus®

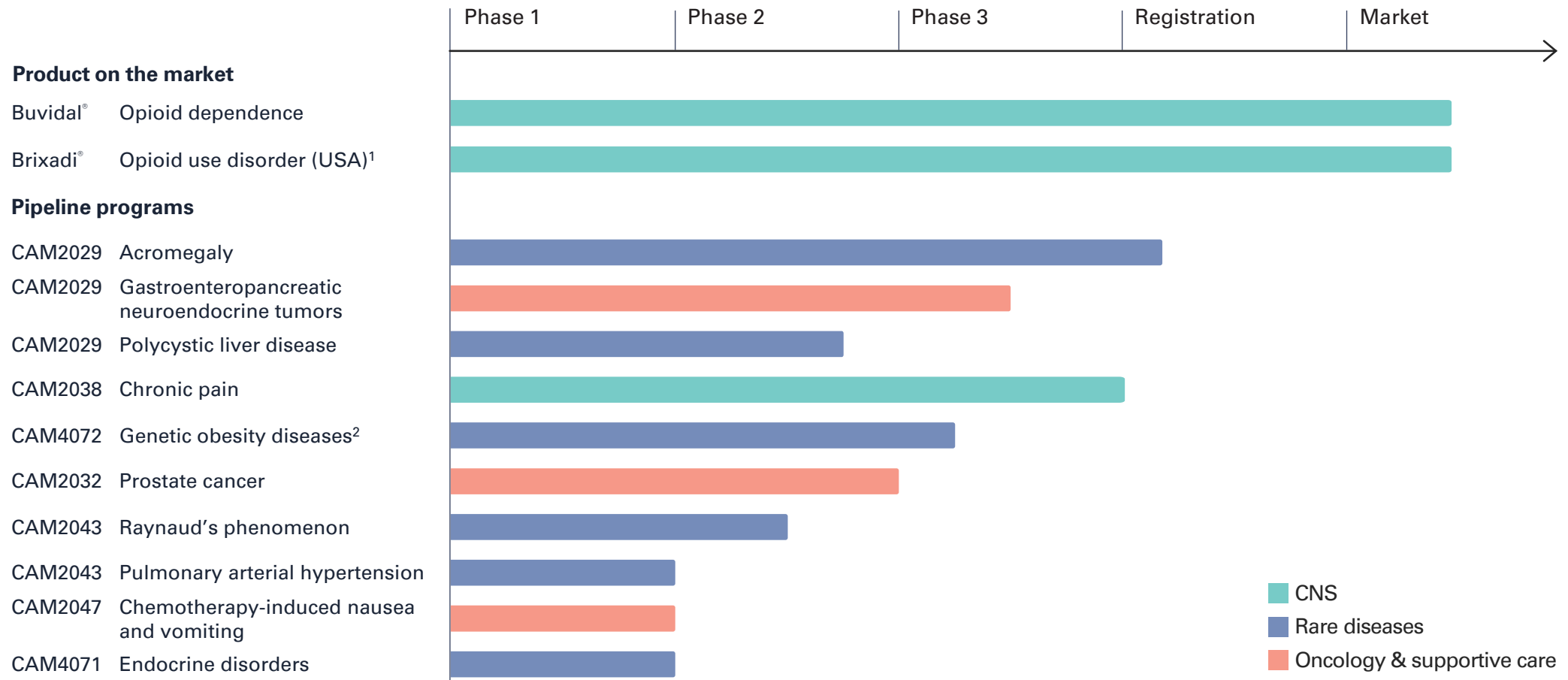


FluidCrystal[®] extended-release technology

- ✓ 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



¹Licensed to Braeburn in North America; ²Licensed 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 over¹

Demonstrated benefits to patients and society

- Superior treatment outcome and patient satisfaction²⁻⁵
- Blockade of subjective opioid effects from first dose³
- Reduced treatment burden and improved quality of life^{5,6}
- Decreased risk of diversion, misuse and pediatric exposure^{7,8}
- Reduced treatment costs⁹

“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 opioid dependence treatment

Wide and growing access to Buvidal and Brixadi

- Available across four continents
- More than 57,000 in treatment end-March 2024

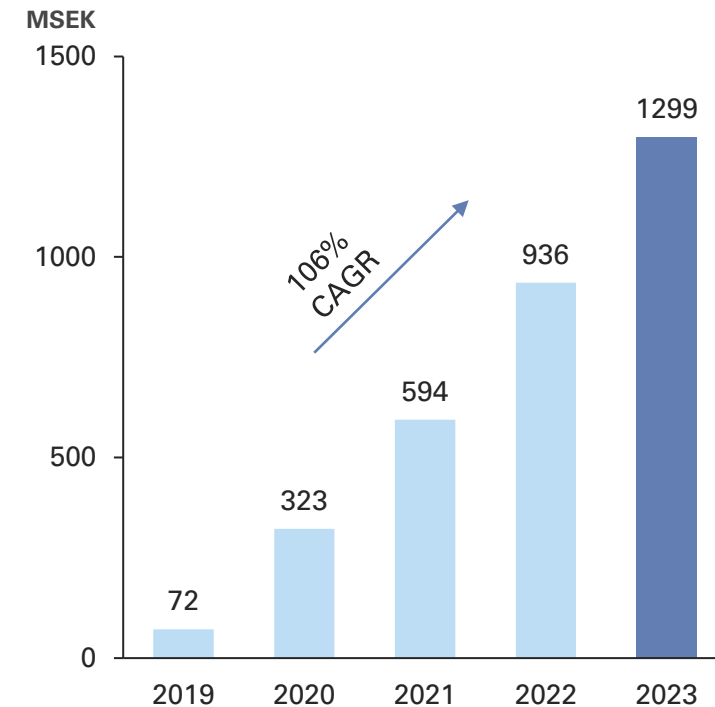
Robust Buvidal sales growth

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

Market expansion continues

- Recent pricing and reimbursement approval in Ireland
- 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

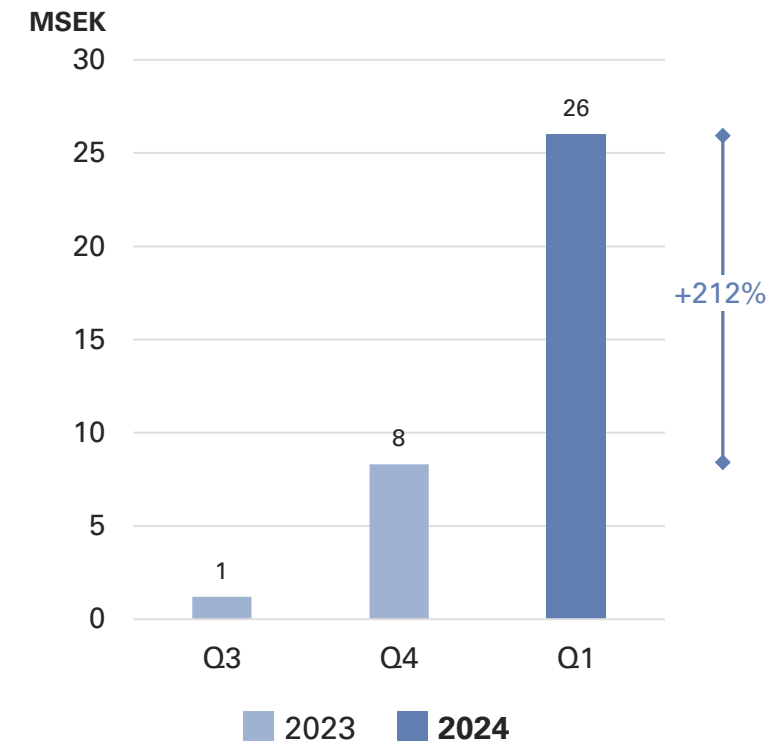
- High payer coverage – on par with competition for both Medicaid and commercial payers
- Broad and expanding distribution network

Accelerated sales growth

- Strong demand for Brixadi
- Est. more than 7,000 US patients in treatment with Brixadi end of March 2024¹
- Accelerated net sales and royalty increase

Peak market potential est. above USD 1 billion²

Brixadi royalty by quarter



OUD – opioid use disorder

¹Source: Braeburn Pharmaceuticals; ²Company 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 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

			
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 Buvidal/Brixadi

- Documenting treatment effectiveness
- Positive health economical outcomes
- About 160 scientific publications on Buvidal/Brixadi
- Ongoing clinical studies exploring new applications

Selected scientific conference participation in 2024

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

Recent key publications¹⁻³

www.nature.com/npp 

ARTICLE **OPEN** [Check for updates](#)

Pharmacokinetic-pharmacodynamic analysis of drug liking blockade by buprenorphine subcutaneous depot (CAM2038) in participants with opioid use disorder

Sharon L. Walsh¹, Sandra D. Comer², Jurij Aguiar Zdovic¹, Céline Sar³, Marcus Björnsson¹, Kerstin Strandgård⁴, Peter Hjalmsjö⁵ and Fredrik Tiberg^{6,7}

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MJA The Medical Journal of Australia
Australia's most trusted source of medical information

Research letters [Open Access](#) [CC BY](#)

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

Nicholas Linzeris¹, Victoria Hayes, Adrian J Dunlop

First published: 04 March 2024 | <https://doi.org/10.5694/mja2.52250>

Contents lists available at [ScienceDirect](#)

 **International Journal of Drug Policy**
Journal homepage: www.elsevier.com/locate/ijdrpgo

Research Paper

Trends in use of medicines for opioid agonist treatment in Australia, 2013–2022

Chrianna Bharat^{a,*}, Kendal Chidwick^a, Natasa Gisev^a, Michael Farrell^a, Robert Ali^{a,b}, Louisa Deegenhardt^a

^a National Drug and Alcohol Research Centre, UNSW Sydney, Randwick, NSW, Australia
^b Faculty of Health and Medical Sciences, University of Adelaide, Adelaide, Australia

¹ Walsh et al. *Neuropsychopharmacology*. 2024; ² Linzeris et al. *Med. J. Australia*. 2024; ³ Bharat et al. *Int. J. Drug Policy* 2024

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

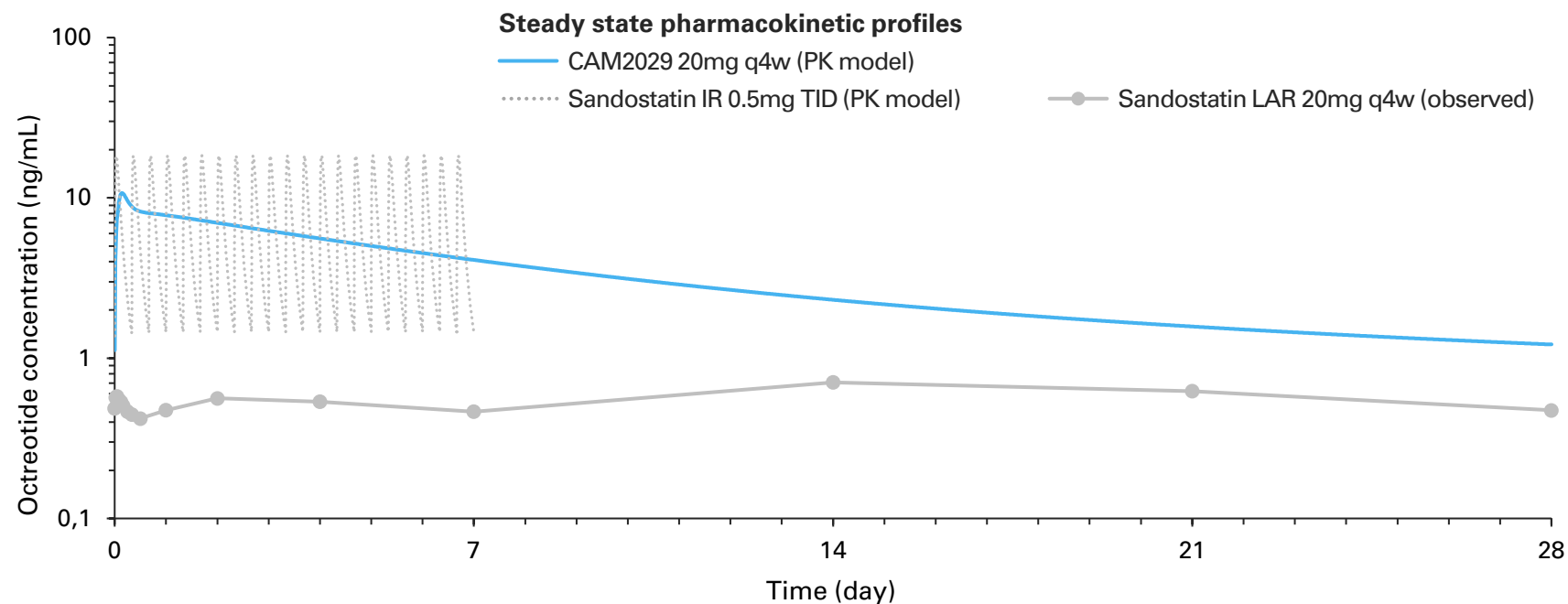
- ✓ Ready-to-use FluidCrystal® technology
- ✓ Rapid onset and long-acting octreotide release¹
- ✓ 5-fold octreotide bioavailability vs Sandostatin LAR with potential for improved efficacy¹⁻³
- ✓ State-of-the-art, pre-filled autoinjector pen enabling convenient patient self-administration
- ✓ Subcutaneous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



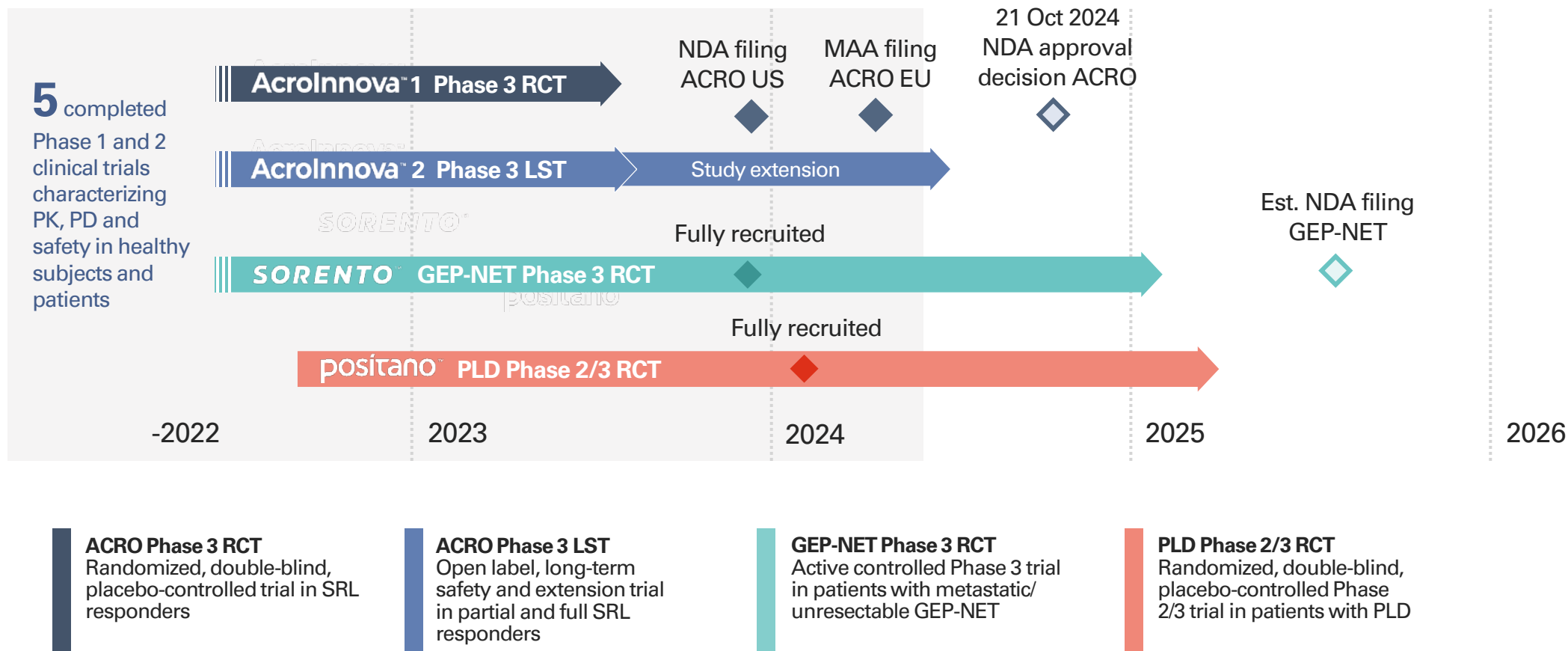
CAM2029 provides high SRL exposure

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

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



Comprehensive clinical study program for CAM2029



Timelines are indicative. PK – pharmacokinetic; PD – pharmacodynamic; RCT – randomized control trial; LST – long-term safety trial; ACRO – acromegaly, GEP-NET – gastroenteropancreatic neuroendocrine tumors; PLD – polycystic liver disease

Positive results from ACROINNOVA 1 – CAM2029 provided robust biochemical control

ACROINNOVA 1 study design

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

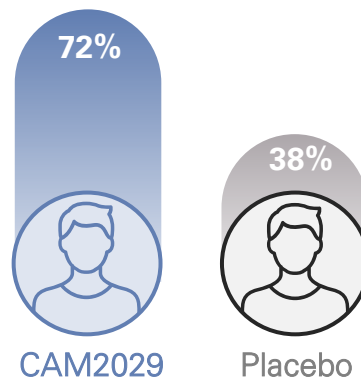
Patient population

- Biochemically controlled on first-generation SRL*



Superiority achieved

- Significantly more patients achieved IGF-1 control with CAM2029 than with placebo



Proportion of patients mean IGF-1 \leq ULN at Week 22 and Week 24

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 \geq 3 months

Positive interim results from ACROINNOVA 2

ACROINNOVA 2 study design

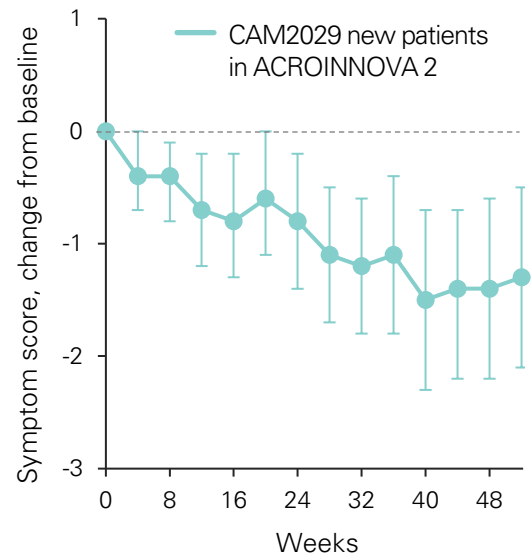
- 52-week, open-label safety study with further extension

Patient population

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



Improved acromegaly symptoms with CAM2029



ACROINNOVA 2 interim results

- Reinforcing long-term safety and effectiveness observed in ACROINNOVA 1
- Roll-over placebo patients from ACROINNOVA 1 regained IGF-1 control with CAM2029

Improved patient reported outcomes vs standard-of-care

- 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

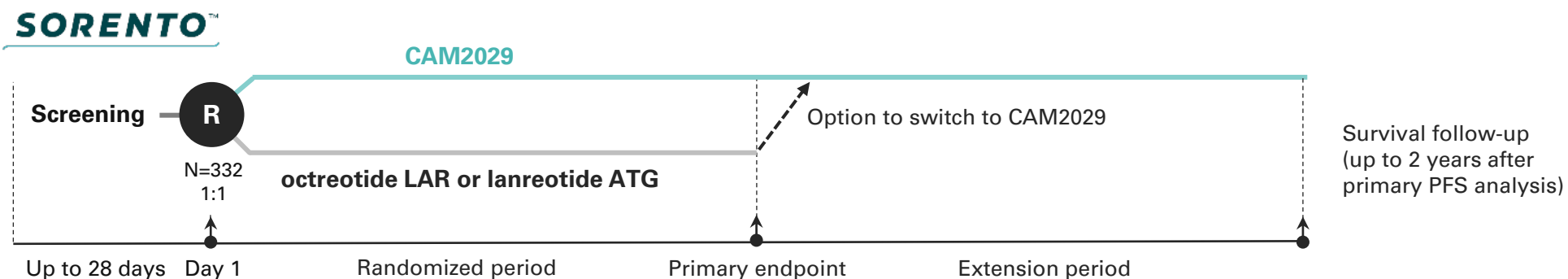
- Patients with confirmed, advanced and well-differentiated GEP-NET (grade 1 to grade 3)

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

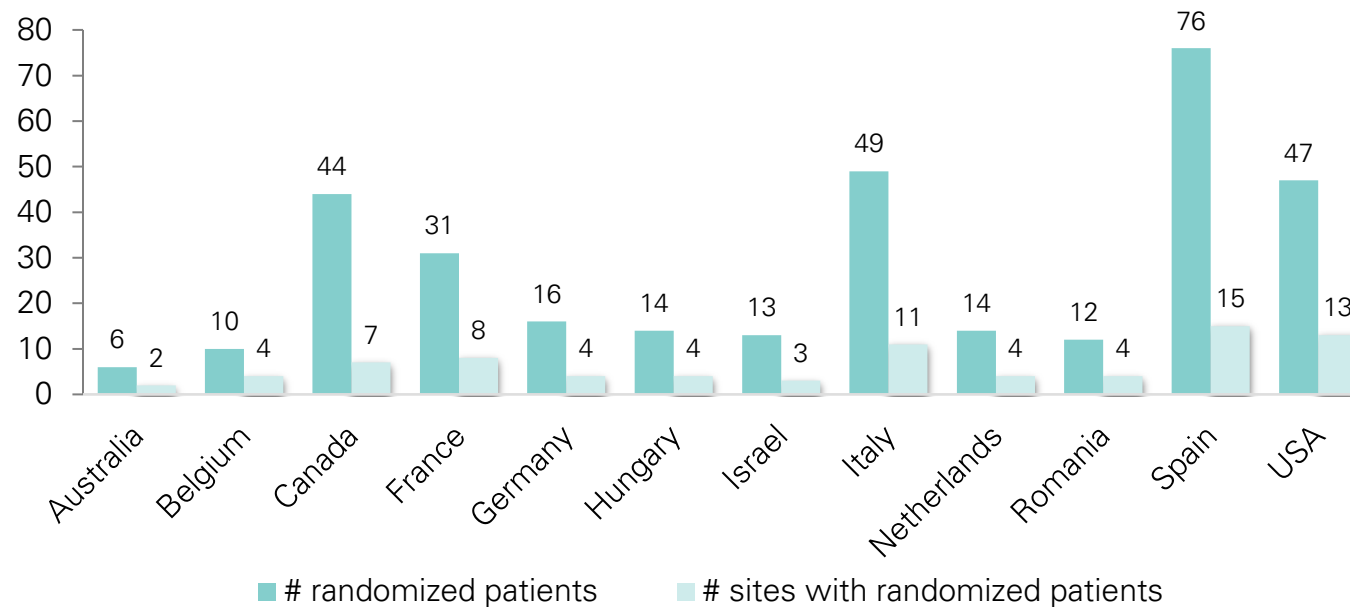
- Overall survival
- PROs (e.g., treatment satisfaction, quality of life)
- Plasma concentrations of octreotide
- Safety



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



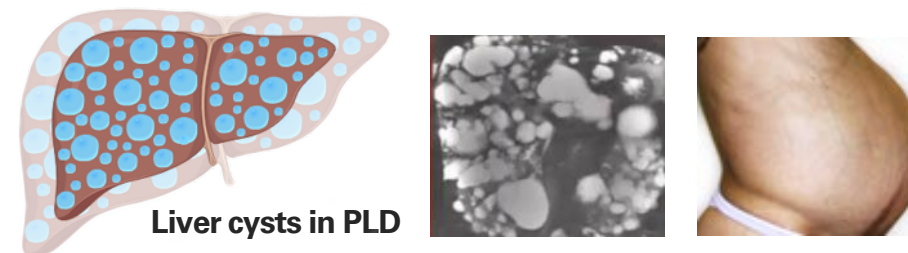
Clinical Phase 2/3 study in PLD fully recruited

POSITANO trial to assess efficacy and safety

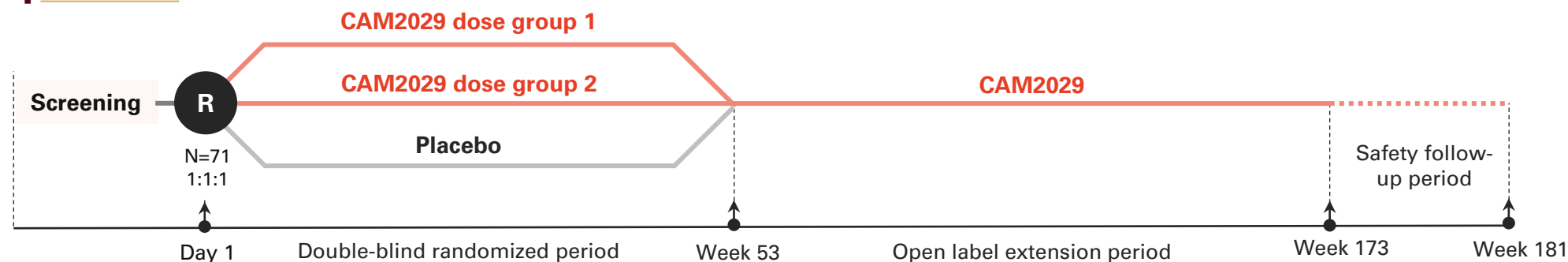
- 53-week randomized, placebo-controlled, three-arm study
 - Randomization of 71 patients completed in Q1 2024
 - Primary endpoint is liver volume change
 - Key secondary endpoint is Camurus' developed PRO, PLD-S
 - Multiple secondary endpoints, incl. quality of life, safety, etc.
- Open label extension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



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
- ✓ Positive ACROINNOVA 2 interim results
- ✓ NDA acceptance for review
- ✓ MAA submission to EMA
- ❑ **ACROINNOVA 2 complete core phase results end-Q2 2024**
- ❑ **NDA PDUFA date 21 Oct 2024**
- ❑ **Est. US launch of Oclaiz™ around year end 2024**

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

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

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 €10-12.5ks (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



Building US infrastructure for launch of Oclaiz™

Estimated ~ \$1.5 billion market opportunity

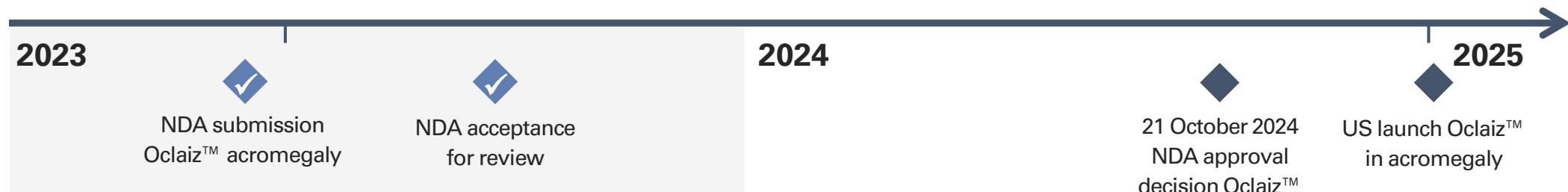
Key activities

- 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™



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Shareholders and analyst coverage

Shareholders as of 30 April 2024	Number of shares	% of capital	% of votes
Sandberg Development AB	21,875,692	38.0	38.0
Fjärde AP-fonden	2,610,766	4.5	4.5
Avanza Pension	1,835,773	3.2	3.2
Swedbank Robur Fonder	1,799,360	3.1	3.1
Fredrik Tiberg, CEO	1,615,000	2.8	2.8
JP Morgan Chase Bank	1,561,012	2.7	2.7
State Street Bank and Trust	1,324,791	2.3	2.3
Handelsbankens fonder	1,309,942	2.3	2.3
The Bank of New York Mellon SA/NV, W8IMY	963,860	1.7	1.7
The Bank of New York Mellon, W9	658,292	1.1	1.1
Norges bank	624,070	1.1	1.1
Afa Försäkring	614,293	1.1	1.1
CS Client Omnibus	585,939	1.0	1.0
SEB Investment Management	551,681	1.0	1.0
SEB, Luxembourg branch	512,979	0.9	0.9
Other shareholders	19,171,168	33.3	33.3
In total	57,614,618	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 and 102,000 employee options

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. Professor Physical Chemistry, Lund University; Visiting Professor at Oxford University; Section Head, Institute for Surface Chemistry.



Jon Garay Alonso
Chief Financial Officer
In Company since: 2022
Holdings: 1,450 shares & 57,750 employee options

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 and 57,750 employee options

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: 50,170 shares and 38,500 employee options

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 Johnsson
Senior VP R&D
In Company since: 2003-2017, 2019-
Holdings: 21,000 shares & 23,500 employee options

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: 38,500 employee options

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: 45,363 shares and 38,500 employee options

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 and 38,500 employee options

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 and 20,000 employee options

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

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



Agneta Svedberg
VP Clinical & Regulatory Dev.
In Company since: 2015
Holdings: 22,987 shares and 38,500 employee options

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:

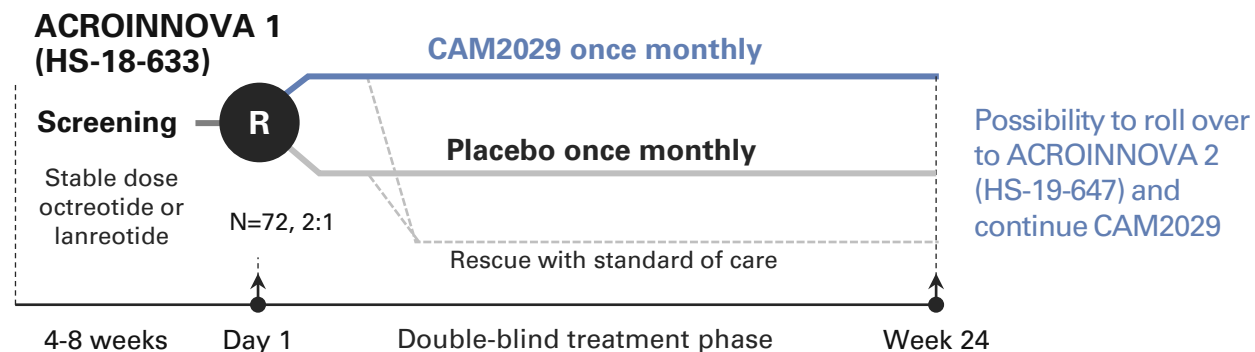
- Proportion of patients with mean IGF-1 $\leq 1 \times \text{ULN}$ (week 22 and 24)

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)

