



# Second quarter 2022 results

**Audiocast presentation**  
15 July 2022

A large, light blue circular graphic on the right side of the slide. Inside the circle, the letters "Q2" are written in a large, white, sans-serif font. The "Q" is partially cut off by the left edge of the frame.

Q2

# 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.

# Agenda

- Introduction and Q2 highlights
- Financial performance
- Commercial update
- R&D pipeline development
- Key take-aways
- Q&A

## Company participants

Fredrik Tiberg, PhD  
President & CEO, Head R&D

Jon Garay Alonso  
Chief Financial Officer

Richard Jameson  
Chief Commercial Officer





camurus®



Emerging leader in **opioid dependence treatment**



**Advancing late-stage pipeline** with blockbuster potential



Strong revenue growth towards **sustained profitability**

# Camurus' second quarter highlights



## Profitable in Q2 and H1

- ✓ Continued high double-digit YoY revenue growth
- ✓ Strong cash position, without debt providing financial flexibility
- ✓ FY 2022 result guidance raised



## Commercialization execution

- ✓ Increased patient shares and expanded our markets
- ✓ Strengthened leadership in opioid dependence treatment in Europe and Australia
- ✓ Accelerated investment in the organization and infrastructure

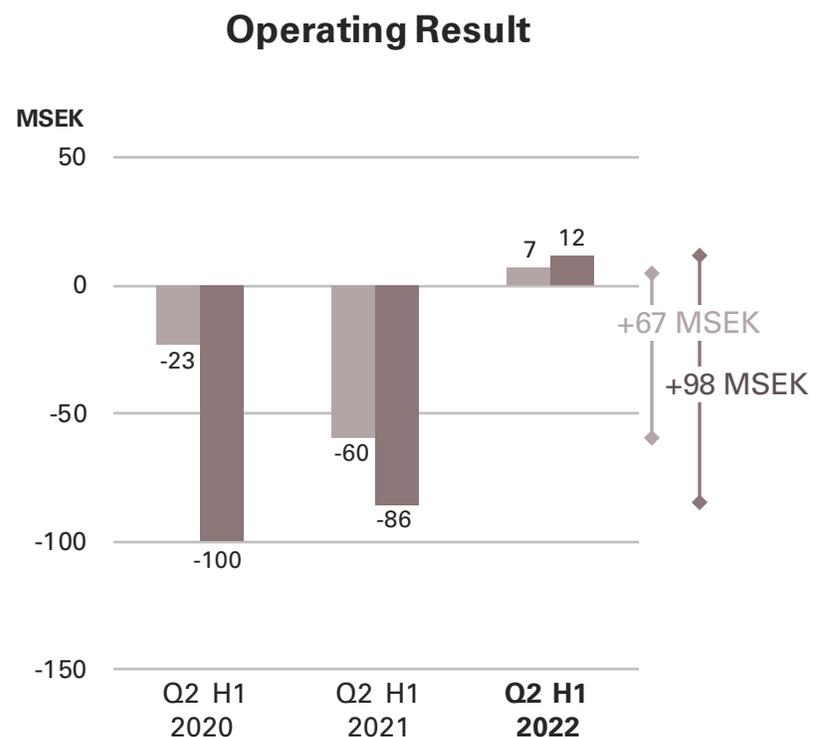
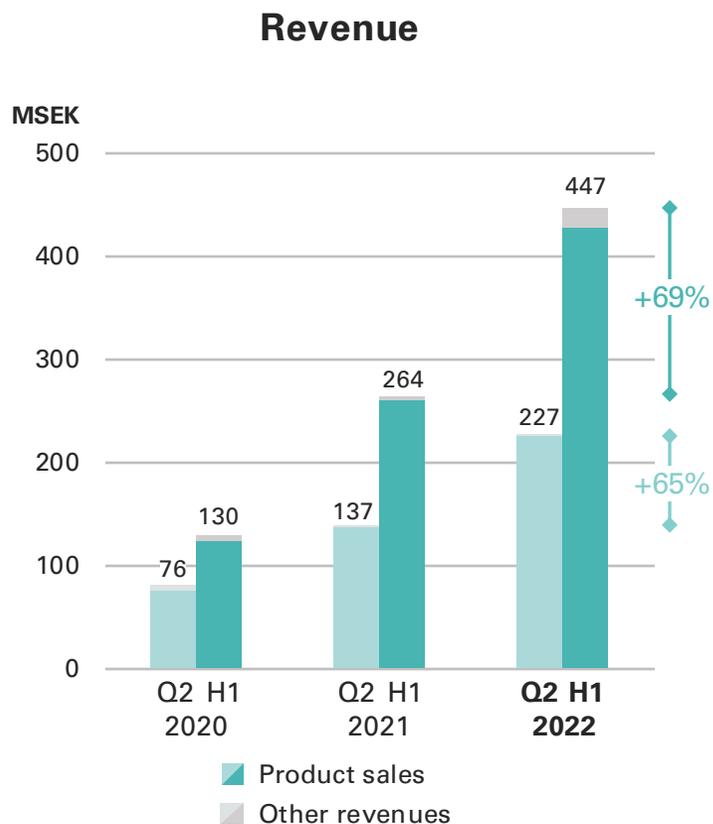


## Progress in the pipeline

- ✓ Variation applications for Buvidal to include treatment of chronic pain in the EU and Australia
- ✓ Phase 3 studies in acromegaly and GEP-NET
- ✓ New Phase 2b study POSITANO in polycystic liver disease
- ✓ Clinical study operating milestones caught up in the quarter



# High growth resulted in profitability



Revenue growth

**+65%** vs Q2 2021

Improved result

**+67 MSEK** vs Q2 2021

Cash position

**SEK 428 million**

**+1%** vs Q2 2021

Q2

# Reported profit and loss and FY 2022 outlook

MSEK	Apr – Jun 2022	Change vs. 2021	CER Change vs. 2021
Total revenues	226.7	+64%	+56%
Gross margin	201.6	+38.8 bps	+265 bps
OPEX	-195.7	+10%	+6%
Other operating expenses	+1.0	-33%	-27%
Operating result	6.9	N/A	N/A

## Raised FY 2022 outlook<sup>2</sup>

Total revenue<sup>1</sup>  
**SEK 900 to 950 million**  
(same as previously)

Product sales<sup>1</sup>  
**SEK 875 to 925 million**  
(same as previously)

Operating results  
**SEK -20 to +40 million**  
(increased from SEK -60 to +10 million)

<sup>1</sup>At constant exchange rates in January 2022. <sup>2</sup>Guidance does not take account of potential \$35m development milestone on US approval of Brixadi.

# Commercial update



# Buvidal sales growth underscores potential

## 12<sup>th</sup> consecutive quarter of double-digit Q-on-Q growth

- SEK 225 million sales (+65% vs. Q2 2021, +11% vs. Q1 2022)
- Est. close to 30,000 patients in treatment at the end of Q2

## Strengthening market leadership in established markets

- Robust growth in the Nordics, UK, and Australia
- New funding allocated in England
  - About 60% of municipalities now have patient access to Buvidal
- 160mg strength and direct initiation reimbursed in Australia

## Improving access in future growth markets

- Strong growth in Spain, France and Middle East from low base
  - Over 90% of eligible patients in Spain now have access to Buvidal
- Expanded use in criminal justice settings across EU and AUS

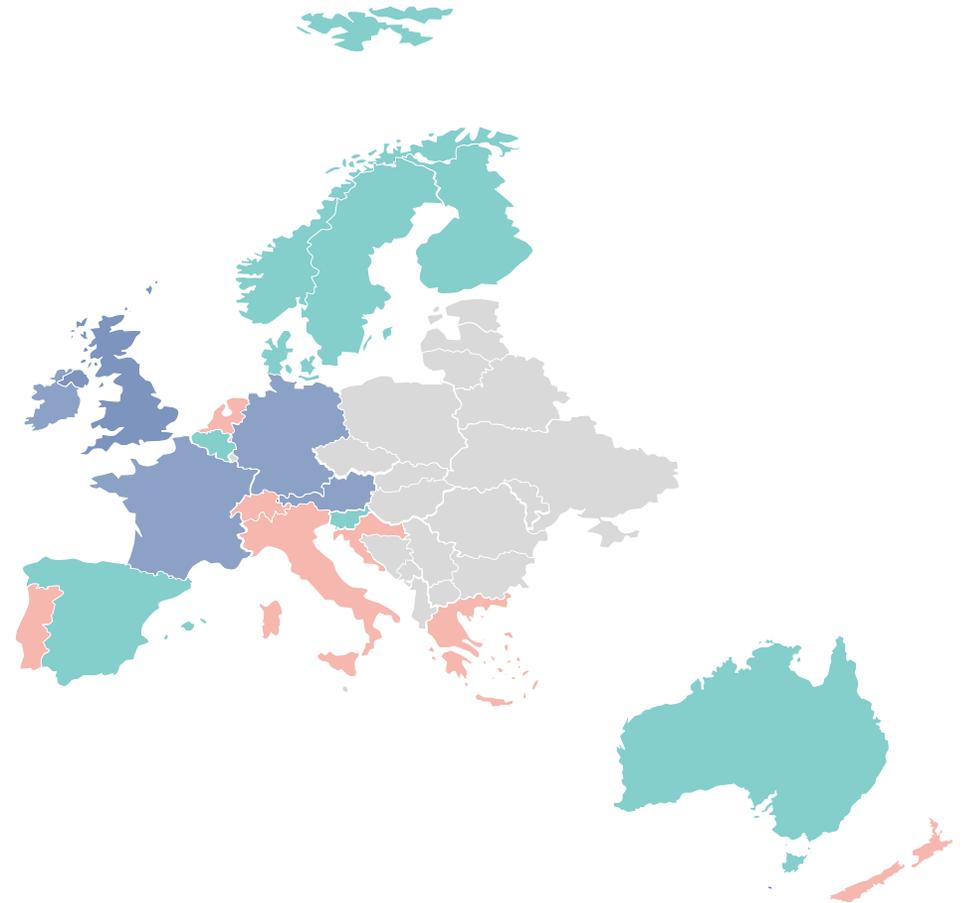
## Quarterly product sales



# Continued focus on commercial execution

- **Launched – full access**
  - Facilitating patient uptake
    - Educating on informed choice and the growing scientific evidence
    - Ensuring Buvidal offered as a first line treatment option
- **Launched – some restrictions on access**
  - Addressing funding needs and barriers
    - Communicating compelling value proposition
    - Supporting clinic applications/business cases to payers
- **Planned launches – awaiting P&R approvals**
  - Successfully complete reimbursement processes
    - Clear demonstration of value Buvidal brings

On track to achieve goal of more than 100,000 patients in treatment with Buvidal in 2026



# Regulatory processes provide further growth potential

## Brixadi™ tentatively approved in the US

- Braeburn issued with new Complete Response Letter (CRL) for the Brixadi NDA on 15 Dec 2021
- CRL due to quality related deficiencies at Braeburn's US contract manufacturer
- FDA inspections have been initiated of Braeburn's third-party manufacturer<sup>1</sup>
- ❑ Depending on the outcome, Braeburn will resubmit the Brixadi NDA as soon as practicable
- ❑ The review period is 2- or 6-month depending on FDA's classification of the NDA resubmission<sup>1,2</sup>

## Market authorization processes in MENA

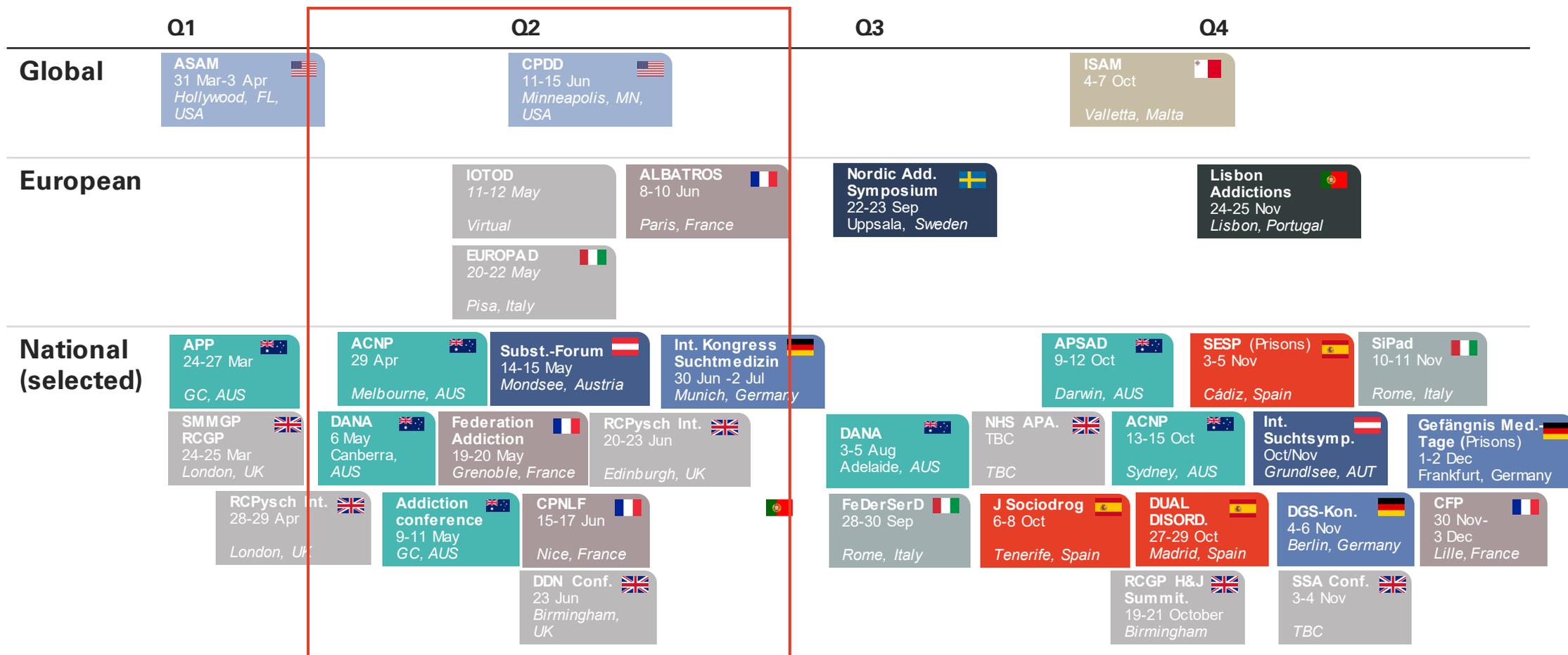
- Seven MAA applications under review in MENA
- ❑ Approval decisions expected in Q3 and onwards

## Buvidal label extension to chronic pain

- Review ongoing of variation applications in EU and Australia to extend indication to chronic pain
- Responses being prepared for requests for supplementary information from CHMP
- ❑ CHMP opinion expected in Q4 2022
- ❑ Australian approval decision expected in H1 2023

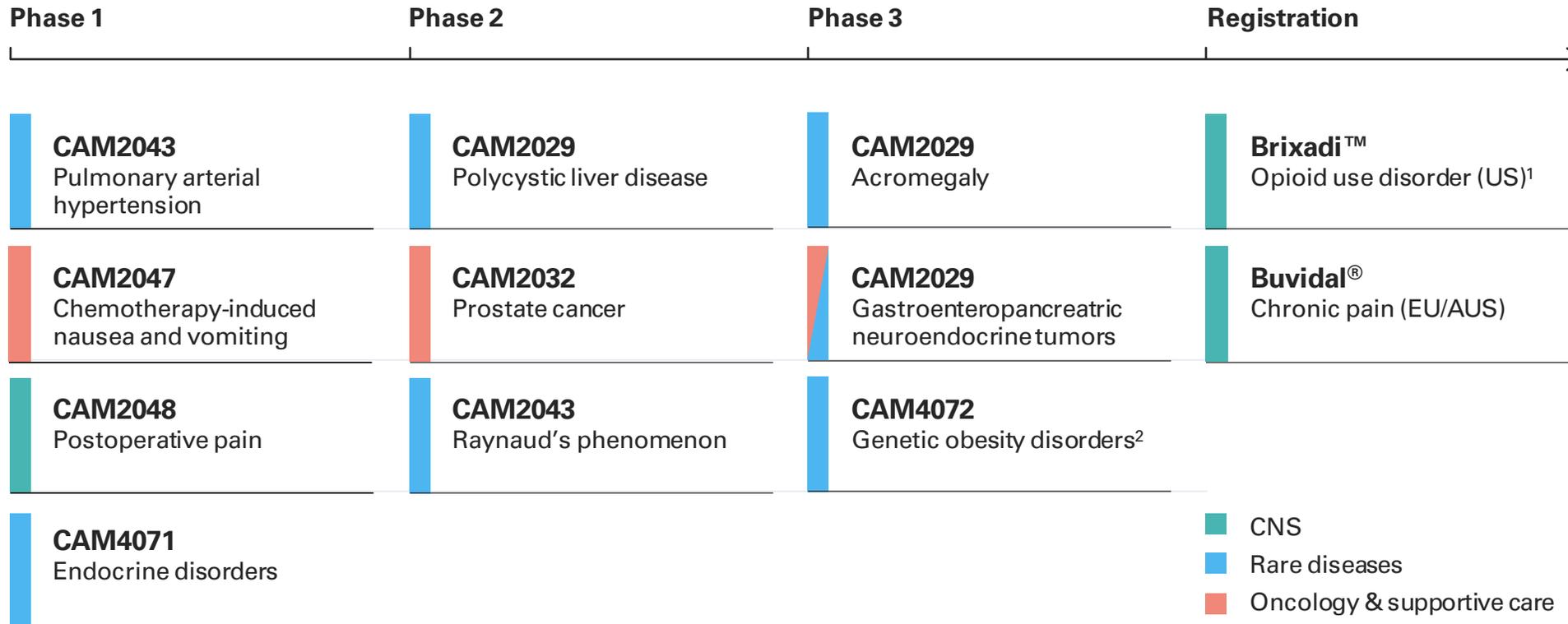
<sup>1</sup> Information provided by Braeburn; <sup>2</sup>CFR - Code of Federal Regulations Title 21  
Brixadi™ is the US trade name of Camurus product Buvidal®; NDA – New Drug Application; OUD – Opioid Use Disorder; FDA – US Food and Drug Administration; CHMP - EMA's Committee for Medicinal Products for Human Use.

# High visibility at scientific conferences 2022





# Broad and diversified pipeline for sustainable growth



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

# Octreotide SC depot – CAM2029

## Three registration programs in rare disease indications

- Acromegaly (ACRO), gastroenteropancreatic neuroendocrine tumors (GEP-NET), and polycystic liver disease (PLD)

## CAM2029 has favorable properties and potential benefits

- Rapid onset and long-acting octreotide release<sup>1</sup>
- Enhanced octreotide exposure ~500% increase vs. octreotide LAR<sup>1</sup>
- Maintained/improved biochemical and symptom control in ACRO and NET indicated<sup>2</sup>
- Ready-to-use with no need for reconstitution or conditioning
- Easy and convenient dosing by patients using pre-filled syringe or pen (“non-visible” needle)

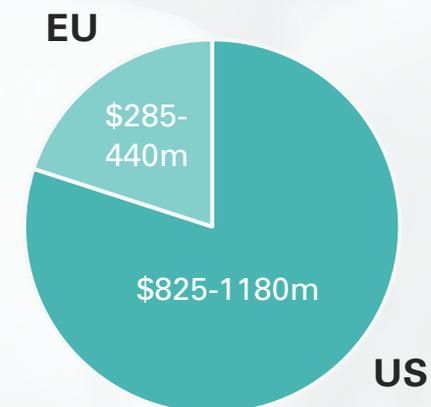


- Pivotal studies ongoing to demonstrate efficacy and safety across three indications

## Market potential

CAM2029 peak market sales estimate in acromegaly, NET, and PLD:<sup>1,2</sup>

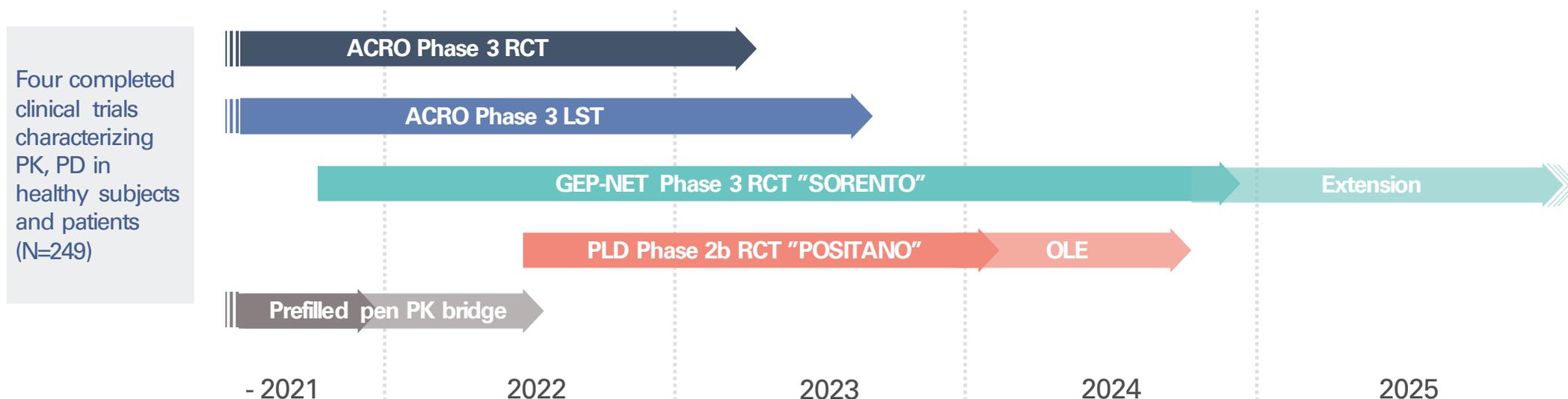
US\$ **1.1 – 1.6** billion



<sup>1</sup>Globe Life Sciences reports 2019/2020 and Company estimates .<sup>2</sup>Update ongoing

GEP-NET – Gastroenteropancreatic neuroendocrine tumors; PLD – Polycystic liver disease; IND – Investigational New Drug; HFE – Human Factor Engineering; PRO – patient reported outcomes

# CAM2029 – comprehensive clinical programs in three indications



ACRO Phase 3 RCT	ACRO Phase 3 LST	GEP-NET Phase 3 RCT	PLD Phase 2b RCT	Prefilled pen PK
Randomized, double-blind, placebo-controlled trial in SSA responders	Open label, long-term safety trial in partial and full SSA responders	Active controlled Phase 3 trial in patients with metastatic/unresectable GEP-NET	Randomized, double-blind, placebo-controlled Phase 2b study in patients with PLD	PK bridging study prefilled syringe and prefilled pen devices

# “POSITANO” Phase 2b study in PLD (HS-20-677)

## Study design

- A randomized, placebo-controlled, double-blind, multi-center trial to assess efficacy and safety of CAM2029 in patients with symptomatic PLD

## Primary endpoint

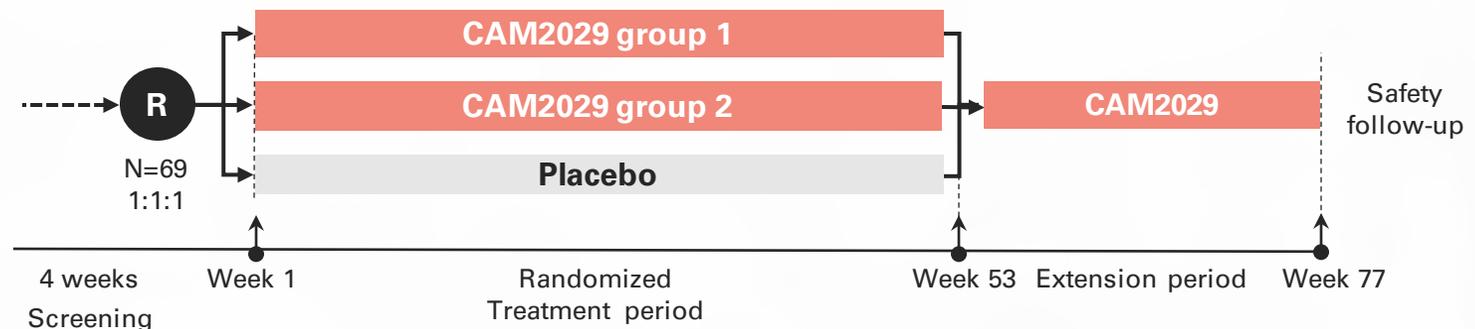
- Change from baseline to Week 53 in height-adjusted total liver volume (htTLV)

## Key secondary endpoint

- Change from baseline to Week 53 in the Polycystic Liver Disease Symptoms (PLD-S) outcome score

## Patient population

- Adult patients  $\geq 18$  years old with a diagnosis of symptomatic PLD, either in isolation as in ADPLD or in association with ADPKD



# CAM2029 status and expected milestones

## Acromegaly

- ✓ Two phase 3 studies ongoing
- ✓ Orphan drug designation in the EU
- ❑ Target completion of recruitment Sept./Oct. 2022
- ❑ Topline Phase 3 efficacy results H1 2023
- ❑ NDA and MAA submissions 2023/24

## Neuroendocrine tumors (GEP-NET)

- ✓ GEP-NET program aligned with FDA and EMA
- ✓ IND/CTA approvals in 10 countries
- ✓ 50 of 94 sites activated
- ❑ Target recruitment completion H1 2023
- ❑ Completion of efficacy part after 194 PFS events

## Polycystic liver disease (PLD)

- ✓ IND safe to proceed letter
- ✓ Orphan Drug Designation (US)
- ✓ PRO developed and aligned with FDA
- ✓ FPFV in Phase 2b trial June 2022
- ❑ Target recruitment completion H1 2023

## Prefilled pen device

- ✓ Pre-filled pen fully validated in Q3 2021
- ✓ Positive topline Phase 1 results (48 subjects)
- ✓ Implemented in all clinical programs

# Topline results from CAM2043 Phase 2 in Raynaud's Phenomenon

## Explorative Phase 2 study of weekly SC treprostinil in patients with Raynaud's Phenomenon secondary to systemic sclerosis

- The primary endpoint of statistically significant effect on finger temperatures after cold challenge 6 h post-dose was not met
- Several secondary endpoints were met, incl. a positive treatment difference for the primary measure 24 h post-dose, and a significant improvement of the Raynaud's Condition Score Day 8 and Day 15
- The safety profiles were comparable to that reported in the Phase 1 of CAM2043 and for approved treprostinil products for injection

## Next steps of the CAM2043 program

- Completion of clinical study report in Q3
- Review of results and overall development program with the study investigators and external experts



# Welcome to Camurus' Capital Markets and R&D Day 2022

When: Tuesday 6 September, 1 – 5 pm

Where: IVA Conference Center,  
Grev Turegatan 16, Stockholm

During the event, members of Camurus' senior management will provide an update on the company strategy, business progress and key R&D pipeline programs. Further insights will be provided by leading clinical experts within Camurus' therapeutic focus areas.

Please register no later than 30 August at [CMD@camurus.com](mailto:CMD@camurus.com)

A detailed program will be provided at Camurus website [www.camurus.com](http://www.camurus.com) two weeks ahead of the event.



## Key takeaways Q2 2022



Profitability reached in the quarter and first half of the year



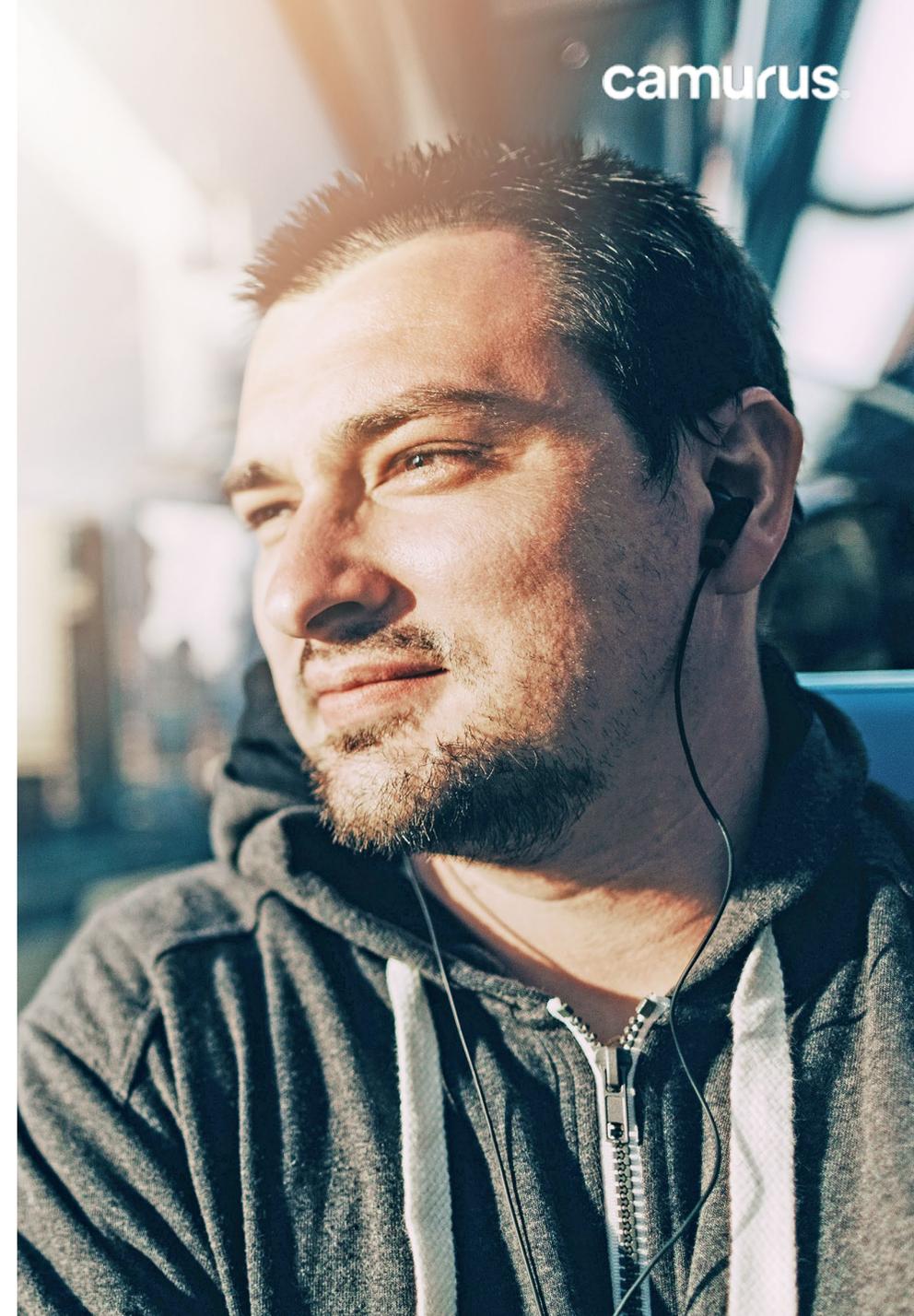
Strong commercial execution



R&D pipeline progress towards new approvals



Full year 2022 result guidance raised



# Q&A

# Recent and expected news flow 2022/23



## H1 2022

- ✓ First dosing in Ph. 3 switch study of CAM4072 (Rhythm)
- ✓ Buvidal chronic pain label expansion submitted in AUS
- ✓ Reimbursement in Belgium



- ✓ Launch of Buvidal 160mg and direct initiation in Australia
- ✓ Positive operating results reported in Q1

## H2 2022

- ✓ Divestment of episil® oral liquid to Solasia
- ✓ Topline Phase 2 results for CAM2043 in RP
- ❑ First dosing in POSITANO Phase 2b study in PLD
- ❑ [Brixadi US resubmission]
- ❑ Completed enrollment in CAM2029 Phase 3 ACRO study
- ❑ CHMP opinion for Buvidal in chronic pain
- ❑ Start Phase 3 *de novo* study CAM4072 (Rhythm)

## 2023

- ❑ Completed enrollment in CAM2029 SORENTO Phase 3 NET
- ❑ Phase 3 RCT results CAM2029 ACRO



- ❑ TGA approval decision Buvidal chronic pain
- ❑ Phase 3 LST results CAM2029 ACRO
- ❑ Pipeline expansion new clinical program
- ❑ NDA/MAA submission CAM2029 ACRO

## Key figures second quarter 2022

MSEK	Apr – Jun 2022	Apr – Jun 2021	Change	Jan – Jun 2022	Jan – Jun 2021	Change	Jan – Dec 2021
Total revenues	227	138	+64%	447	264	+69%	601
whereof product sales	225	137	+65%	427	261	+64%	594
Operating expenses	196	179	+10%	384	315	+22%	628
Operating result	7	-60	N/A	12	-86	N/A	-111
Result for the period	8	-48	N/A	7	-70	N/A	-90
Result per share, before and after dilution, SEK	0.14	-0.89	N/A	0.13	-1.29	N/A	-1.66
Cash position	428	422	+1%	428	422	+1%	412

# Experienced and committed management team



**Fredrik Tiberg, PhD**  
*President & CEO, Head R&D*  
**In Company since:** 2002  
**Holdings:** 1,672,788 shares,  
 90,000 warrants & 60,000  
 employee options

**Education:** M.Sc. in Chemical Engineering, Lund Institute of Technology, PhD and Assoc. Prof. Physical Chemistry, Lund University.

**Previous experience:** More than 20 years leadership experience from the pharmaceutical industry. Professor Physical Chemistry at Lund University, Sect. Head Institute for Surface Chemistry, Visiting Professor at Oxford University



**Jon Garay Alonso**  
*Chief Financial Officer*  
**In Company since:** 2022  
**Holdings:** 1,450 shares &  
 33,750 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.



**Maria Lundqvist**  
*Head of Global HR*  
**In Company since:** 2021  
**Holdings:** 22,500 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.



**Richard Jameson**  
*Chief Commercial Officer*  
**In Company since:** 2016  
**Holdings:** 25,193 shares,  
 58,000 warrants and 33,750  
 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).



**Peter Hjelmsström, MD, PhD**  
*Chief Medical Officer*  
**In Company since:** 2016  
**Holdings:** 22,500 employee  
 options

**Education:** MD, PhD and Assoc. Prof. Karolinska Institutet, Postdoc. Yale University

**Previous experience:** More than 15 years of experience from the pharmaceutical industry, including as Medical Director at Orexo and Head of Clinical Science at Sobi



**Fredrik Joabsson, PhD**  
*Chief Business Dev. Officer*  
**In Company since:** 2001  
**Holdings:** 49,170 shares,  
 15,000 subscription warrants  
 & 22,500 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 and alliance management.



**Torsten Malmström, PhD**  
*Chief Technical Officer*  
**In Company since:** 2013  
**Holdings:** 46,858 shares &  
 22,500 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:** 1,504 shares,  
 7,000 subscription warrants &  
 22,500 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.



**Agneta Svedberg**  
*VP Clinical & Regulatory Dev.*  
**In Company since:** 2015  
**Holdings:** 17,987 shares,  
 37,500 subscription warrants &  
 22,500 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.

# Shareholders and analyst coverage

Shareholders as of 30 June 2022	Number of shares	% of capital	% of votes
Sandberg Development AB	21,875,692	39.9	39.9
Fjärde AP-fonden	3,502,450	6.4	6.4
Avanza Pension	2,712,571	4.9	4.9
Didner & Gerge Fonder	2,572,977	4.7	4.7
Fredrik Tiberg, CEO	1,672,788	3.0	3.0
Svenskt Näringsliv	1,150,000	2.1	2.1
Lancelot Avalon	900,000	1.6	1.6
Backahill Utveckling	826,491	1.5	1.5
State Street Bank and Trust	759,194	1.4	1.4
JP Morgan Chase Bank	675,010	1.2	1.2
Öhman Fonder	587,940	1.1	1.1
Afa Försäkring	545,660	1.0	1.0
Camurus Lipid Research Foundation	495,250	0.9	0.9
Adrigo Small & Midcap L/S	428,234	0.8	0.8
Carl-Olof and Jenz Hamrins Stiftelse	425,000	0.8	0.8
Other shareholders	15,877,686	28.7	28.7
<b>In total</b>	<b>55,006,943</b>	<b>100.0</b>	<b>100.0</b>

## Analysts

### Carnegie

Erik Hultgård

### DNB

Patrik Ling

### Handelsbanken

Suzanna Queckbörner

Mattias Häggblom

### Jefferies

James Vane-Tempest

### Nordea

Viktor Sundberg

### Pareto

Peter Östling