



# First quarter results 2021

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**Audiocast presentation**  
6 May 2021



# 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

- First quarter 2021 overview
- Commercial development
- Pipeline update
- Key take-aways
- Q&A

## Company participants

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

**Eva Pinotti-Lindqvist**  
Chief Financial Officer

**Richard Jameson**  
Chief Commercial Officer



# Significant progress on key priorities

## Strong commercial development and progress with Buvidal

- Expansion of the commercial platform in Europe and Australia
- Successful life-cycle management and regulatory approvals
- Growing scientific evidence for Buvidal across treatment settings and geographies

## R&D and pipeline progress

- Two advancing Phase 3 studies of CAM2029 in acromegaly
- FDA allowance to start Phase 3 study in neuroendocrine tumors (NET)
- Scientific advice meeting with FDA for Phase 2/3 study in polycystic liver disease (PLD)
- Progress in our early projects and partnerships

## Positive financial performance

- Continued strong revenue growth
- Improved financial result and robust cash position
- Our full year 2021 financial outlook is unchanged<sup>1</sup>

Total revenue

**SEK 126 million**

**+155%** vs 2020

Operating results

**SEK -26 million**

**+66%** vs 2020

Cash position

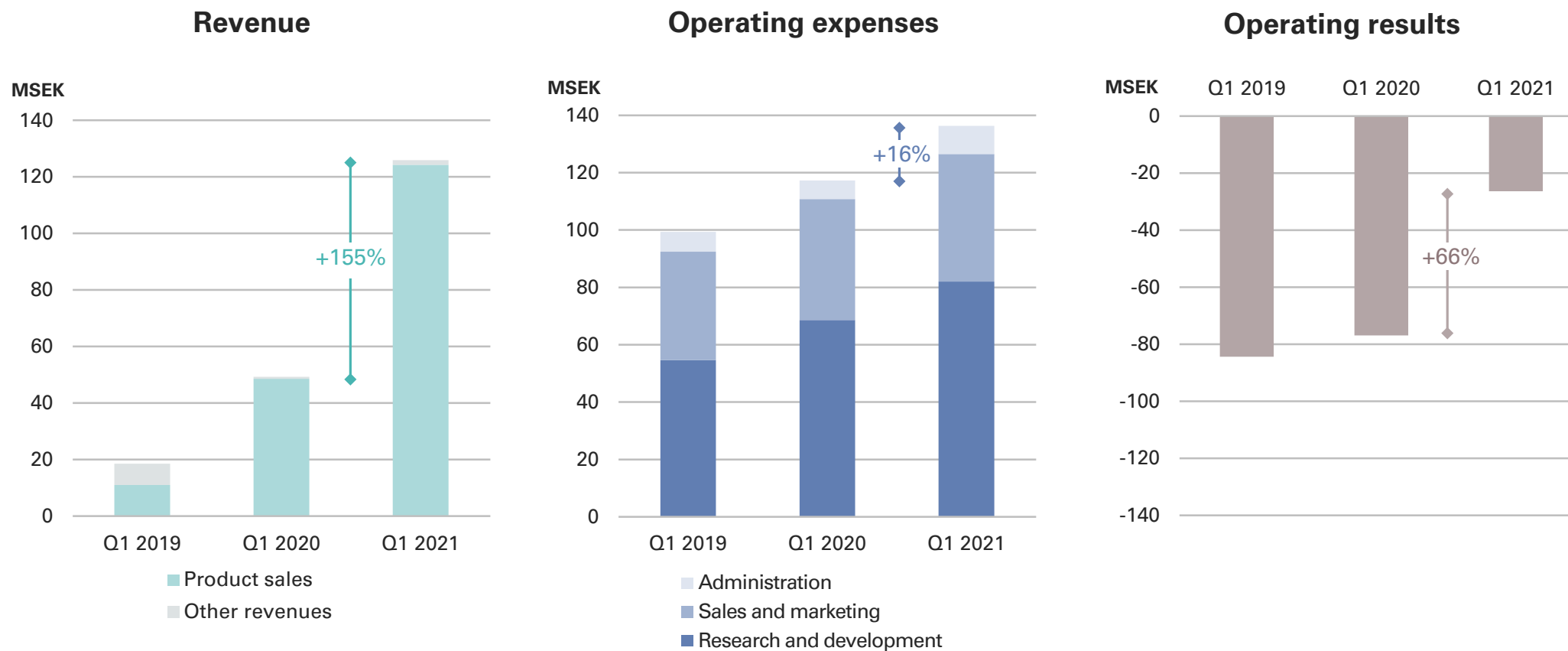
**SEK 428 million**

**+47%** vs 2020

# Q1

<sup>1</sup>Total revenue SEK 680 – 750 million, whereof product sales SEK 620 – 680 million, and the operating result SEK -120 – 0 million excluding a USD 35 million milestone payment on approval of Brixadi™ in the US

# Positive first quarter financial development




# Buvidal® – flexible long-acting treatment of opioid dependence

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>

## Buvidal provides significant benefits to patients and society

- Improved treatment outcomes and patient satisfaction<sup>1-3</sup>
- Reduced treatment burden and improved quality of life<sup>2</sup>
- Diminished diversion, misuse and pediatric exposure<sup>4</sup>
- Reduced treatment costs in the criminal justice system<sup>5</sup>



“Buvidal became my way out”

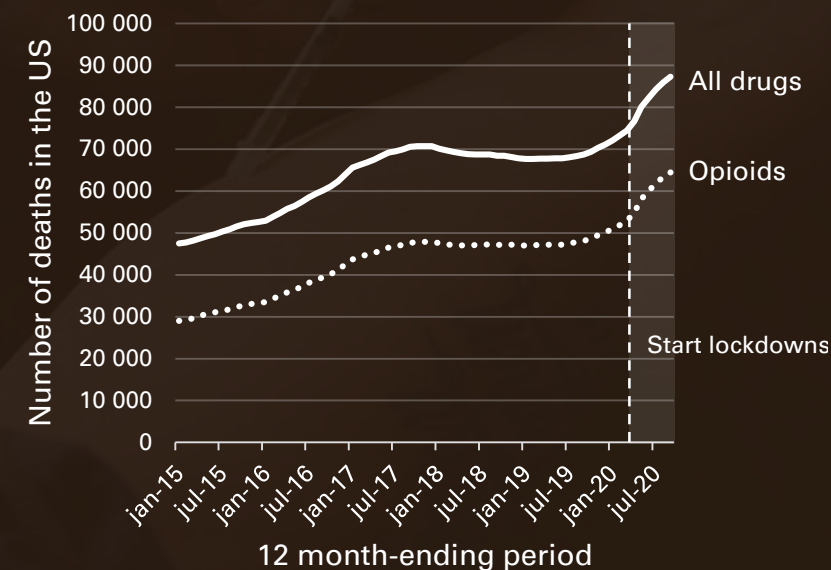
Justin, Buvidal patient in Australia

# Opioid dependence – worsened global health crisis during pandemic

- Largest society burden of all drugs<sup>1</sup>
  - 58 million opioid users worldwide
- High need for better access to care and new treatment alternatives
- Investment in treatment brings substantial value and saves lives
- New funding initiatives
  - President Biden recently issued a US\$1.5 billion grant for substance abuse treatment and prevention<sup>2</sup>
  - Scottish Government initiative £250m investment to tackle drug death crisis<sup>3</sup>
- Significant limitations with current daily medications
  - Diversion, misuse, risk of overdose, poor retention, burdens and stigma of daily buprenorphine and methadone medications

## Escalating overdose deaths during COVID-19

12 Month-ending Provisional Number of Drug Overdose Deaths in the US<sup>4</sup>



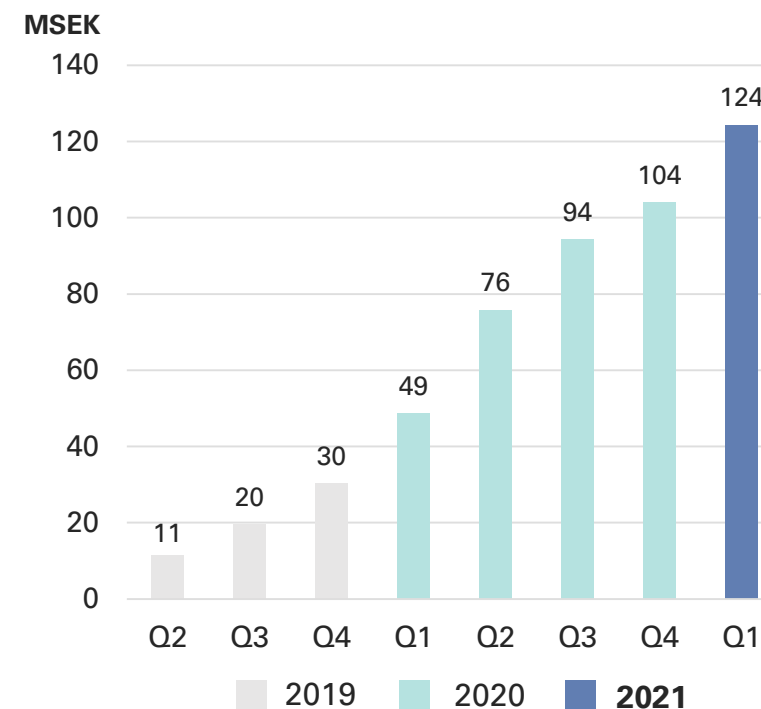
<sup>1</sup>United Nations: World drug report 2020; <sup>2</sup>[www.thenationalcouncil.org/wp-content/uploads/2021/03/American-Rescue-Plan-Act-MH-SUD-Provisions..pdf?daf=375ateTbd56](https://www.thenationalcouncil.org/wp-content/uploads/2021/03/American-Rescue-Plan-Act-MH-SUD-Provisions..pdf?daf=375ateTbd56); <sup>3</sup>[www.gov.scot/news/more-than-gbp-250-million-for-drug-deaths-emergency/](https://www.gov.scot/news/more-than-gbp-250-million-for-drug-deaths-emergency/)

<sup>4</sup> <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

# Strong growth for Buvidal during challenging period

- ✓ **Product sales 124m SEK; up 156% vs Q1 2020, 20% vs last quarter**
  - Exceptional market penetration in Australia & Nordics
  - Good progress in UK and Germany and smaller markets
  - COVID-19 remains barrier for uptake across most markets
- ✓ **About 18,000 patients in treatment end of quarter**
  - Excellent feedback on flexibility and ability to individualize treatment across settings and geographies
- ✓ **Buvidal market expansion continues**
  - Available in 15 countries in Europe, Australia and MENA
  - 8 new launches in wave 3 markets in 2021

Product sales by quarter





# Buvidal launches in Wave 3 markets being prepared

## Netherlands

- ✓ ~10,000 patients in opioid dependence treatment<sup>1</sup>
- ❑ Launch expected in Q2 2021

## France

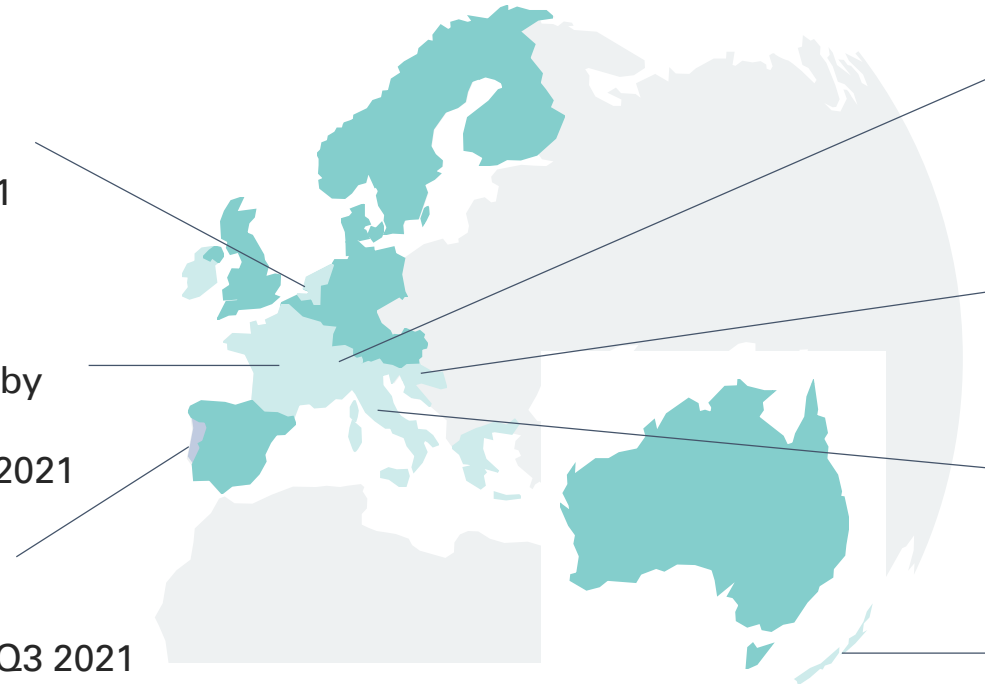
- ✓ >179,000 patients<sup>1</sup>
- ✓ Positive HEOR assessment by Haute Autorité de Santé
- ❑ Preparing for launch in Q3 2021

## Portugal

- ✓ >17,000 patients<sup>1</sup>
- ❑ Preparing for launch in Q2/Q3 2021

## MENA

- ✓ Early access program in three countries
- ❑ Several regulatory submissions progressing



### Launch sequence

- Wave 1 & 2 Launched
- Wave 3 markets
- Wave 4 markets

## Switzerland

- ✓ 10,000 patients<sup>1</sup>
- ✓ Marketing approval received
- ❑ Launch expected in Q2/Q3 2021

## Croatia and Slovenia

- ✓ >8,000 patients<sup>1</sup>
- ❑ Preparing for launch Q3 2021

## Italy

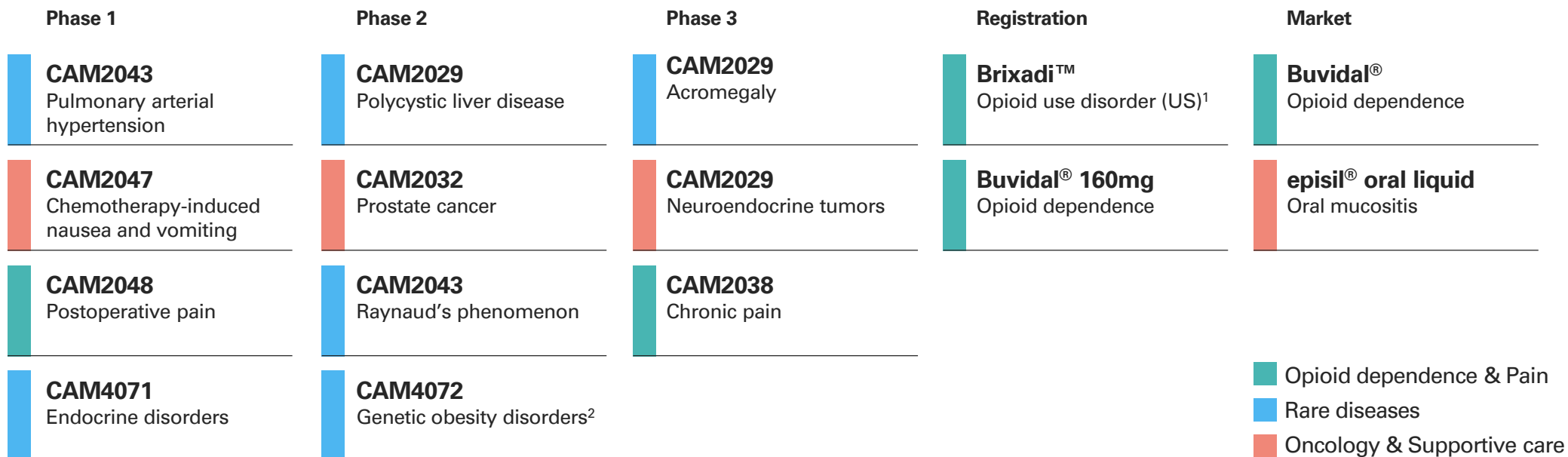
- ✓ ~70,000 patients<sup>1</sup>
- ❑ PMA ongoing

## New Zealand

- ✓ ~5,500 patients<sup>2,3</sup>
- ✓ Market authorization received
- ❑ PMA initiated

<sup>1</sup>EMCDDA 2020; <sup>2</sup>Office of the Director of Mental Health and Addiction Services Annual Report 2018 and 2019; <sup>3</sup>New Zealand Practice Guidelines for Opioid Substitution Treatment 2014

# Product and pipeline update



<sup>1</sup> Licensed to Braeburn. <sup>2</sup> Licensed to Rhythm Pharmaceuticals

# Buvidal (Brixadi) lifecycle management and geographic expansion

## New approvals

- Market authorization approval in New Zealand
- Approval of 160mg monthly dose and direct initiation in Australia in May 2021

## Regulatory filings

- Positive CHMP opinion for 160mg monthly dose

## Availability of Buvidal in MENA

- Early access programs ongoing in three countries
- MAAs under review in four MENA countries
- Further submissions planned in 2021

## Brixadi™ in the US

- Complete response letter (CRL) issued by FDA for the Brixadi NDA on 1 December 2020
- Braeburn are working with their contract manufacturer to address the CRL issues and resubmit the NDA
- A new PDUFA date for the Brixadi NDA is expected in H2 2021
- New US patent granted for Brixadi Weekly with expiry date July 2032

## CAM2038 Chronic pain

- Pre-submission meeting held with EU Rapporteur
- Regulatory submission to EMA planned in H2 2021



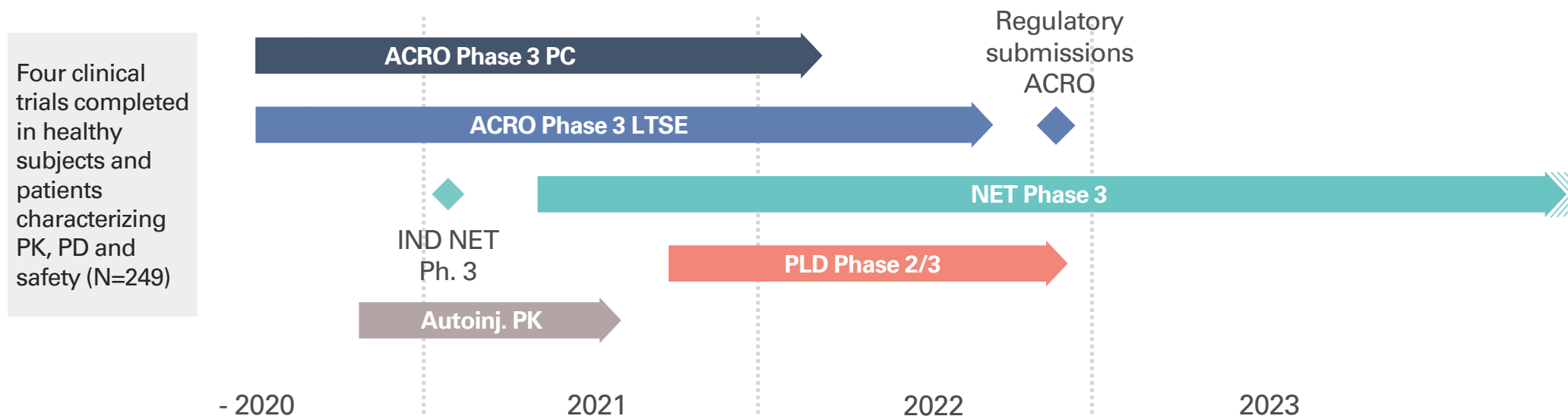


## CAM2029 – octreotide subcutaneous depot in Phase 3 development

Innovative medicine in late-stage development for the treatment of rare diseases; acromegaly, neuroendocrine tumors and polycystic liver disease

Designed for enhanced efficacy and patient convenience

# CAM2029 study program overview



| ACRO Phase 3 PC  | ACRO Phase 3 LTSE   | NET Phase 3  | PLD Phase 2/3  | Autoinjector PK   |
|--|---|--|--|---|
| Randomized, double-blind, placebo-controlled study in SSA responders | Open-label, long-term safety study in partial and full responders | Active controlled Phase 3 study in patients with metastatic, well differentiated GEP-NET | Placebo-controlled Phase 2 study in patients with polycystic liver disease (PLD) | PK bridging study of prefilled syringe and autoinjector devices |

# CAM2029 update status

## Acromegaly

- Two phase 3 studies ongoing
- On track for NDA/MAA submissions in late 2022
- Orphan drug designation in the EU
- Pre-launch activities initiated

## Neuroendocrine tumors

- Registration program for GEP-NET was aligned with FDA and EMA
- IND safe to proceed letter received from FDA for start of Phase 3 trial
- CTAs in progress

## Polycystic liver disease program

- FDA interactions ongoing about the clinical registration program for CAM2029 in PLD
- Patient reported outcome (PRO) questionnaire in development

## Autoinjector development

- Prefilled pen available for clinical trials
- Phase 1 bridging study ongoing
- Full validation ready in mid-2021

## New indications

- CAM2029 is being considered for additional indications
- Go / No Go decision and potential clinical study start in 2021



Estimated CAM2029 peak sales potential in the US and EU5:<sup>1</sup>

Acromegaly<sup>2</sup>

**US\$ 120-180 million**

Neuroendocrine tumors<sup>3</sup>

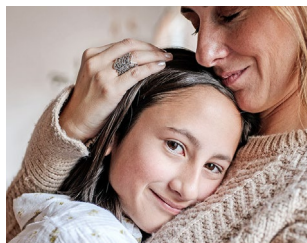
**US\$ 720-1015 million**

Polycystic liver disease<sup>4</sup>

**US\$ 265-415 million**

<sup>1</sup>Globe Life Science market research. Data on file. <sup>2</sup>Assuming CAM2029 autoinjector presentation and efficacy non-inferior to current long-acting SSA-products; <sup>3</sup>Assuming CAM2029 autoinjector presentation and efficacy superior to current long-acting SSA-products; <sup>4</sup>No currently available medical treatments

# Recent and anticipated news flow 2021/22



Start CAM2029 Phase 3 study in GEP-NET

Start CAM2029 Phase 2/3 in PLD

Phase 3 efficacy results CAM2029 in acromegaly

Results CAM2029 autoinjector PK study

Start CAM4072 registration study program (Rhythm)

Results CAM2029 Phase 3 long-term safety study in acromegaly

Buvidal EU/AU line extension approvals

Start new in-house clinical program

Phase 2 results CAM2043 in Raynaud's



NDA/MAA submissions CAM2029 for acromegaly



Publication of DEBUT and UNLOC-T data

MAA submission CAM2038 chronic pain

Buvidal third wave market expansion

Brixadi US approval

MAA approval CAM2038 chronic pain

2021

H1

H2

2022

# Key strategies for value creation in short and medium term



## Pipeline advancement

- Late-stage development and new regulatory approvals for CAM2038 and CAM2029
- Grow our pipeline of innovative medicines and expand the use of our FluidCrystal® technology in areas of high unmet need and market potential



## Commercialization

- Establish leadership in opioid dependence treatment in Europe and Australia
- Continued RoW expansion
- Market approval and launch of Brixadi™ in the US
- Pre-launch activities in acromegaly and chronic pain



## Corporate development

- Continue to build our commercial infrastructure and add new products
- Develop sustained growth and profitability through own sales, partnerships, business development and M&A



# Q&A

# Key figures first quarter 2021

| MSEK  | Jan – Mar<br>2021 | Jan – Mar<br>2020 | Change | Jan – Dec<br>2020 |
|---|-------------------|-------------------|--------|-------------------|
| Total revenues                                      | 126               | 49                | +155%  | 336               |
| whereof product sales                               | 124               | 49                | +156%  | 323               |
| Operating expenses                                  | 136               | 117               | +16%   | 508               |
| Operating result                                    | -26               | -77               | +66%   | -205              |
| Result for the period                               | -22               | -62               | +64%   | -167              |
| Result per share, before and<br>after dilution, SEK | -0.40             | -1.19             | +66%   | -3.18             |
| Cash position                                       | 428               | 291               | +47%   | 462               |

# Reiterated Outlook 2021

## Key assumptions: Revenue

- Excludes a potential \$35m milestone for final approval of Brixadi in the US
- Product sales estimate based on end of 2020 Buvidal patient numbers, a similar uptake as in 2020, and market expansion
- Uncertainty relating to Covid-19 impacts

## Expenses

- Incremental R&D investments, including in CAM2029 Phase 3 programs
- Investments in market expansion for Buvidal with launches in Wave 3 markets
- Limited organizational expansion

## Full year 2021 guidance\*

Revenue

**SEK 680 – 750 million**

whereof product sales

**SEK 620 – 680 million**

Operating result

**SEK -120 – 0 million**

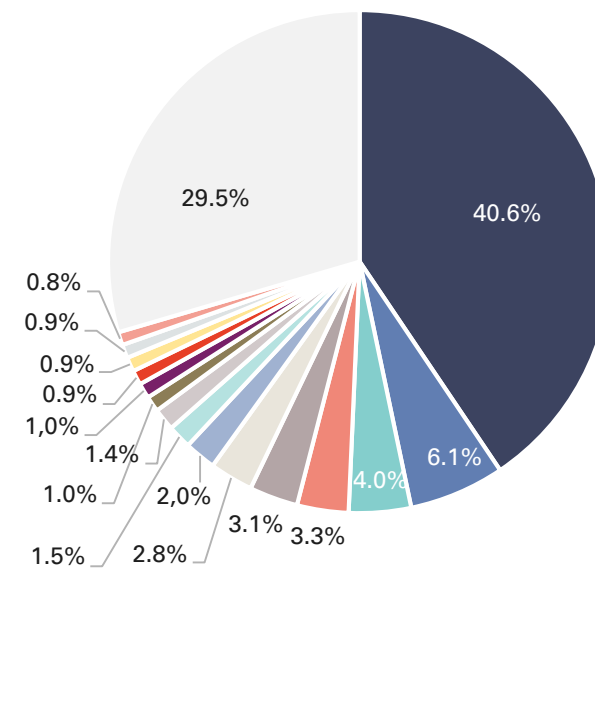
\* Constant exchange rates from January 2021



# Shareholders

| Shareholders as of 30 April 2021  | Number of shares  | % of capital | % of votes   |
|-----------------------------------|-------------------|--------------|--------------|
| Sandberg Development AB           | 22,000,692        | 40.6         | 40.6         |
| Fjärde AP-fonden                  | 3,330,676         | 6.1          | 6.1          |
| Gladiator                         | 2,167,026         | 4.0          | 4.0          |
| Avanza Pension                    | 1,794,547         | 3.3          | 3.3          |
| Fredrik Tiberg, CEO               | 1,696,788         | 3.1          | 3.1          |
| Didner & Gerge Fonder             | 1,517,016         | 2.8          | 2.8          |
| Svenskt Näringsliv                | 1,100,000         | 2.0          | 2.0          |
| Backahill Utveckling              | 826,491           | 1.5          | 1.5          |
| Lancelot Avalon                   | 775,000           | 1.4          | 1.4          |
| State Street Bank and Trust       | 545,591           | 1.0          | 1.0          |
| Afa Försäkring                    | 531,000           | 1.0          | 1.0          |
| Camurus Lipid Research Foundation | 505,250           | 0.9          | 0.9          |
| Cancerfonden                      | 500,000           | 0.9          | 0.9          |
| CBNY – Norges Bank                | 470,780           | 0.9          | 0.9          |
| Enter fonder                      | 457,561           | 0.8          | 0.8          |
| Other shareholders                | 16,017,018        | 29.5         | 29.5         |
| <b>In total</b>                   | <b>54,235,190</b> | <b>100.0</b> | <b>100.0</b> |

Shareholder distribution



# Experienced and committed management team



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

**In Company since:** 2002  
**Holdings:** 1,696,788 shares & 165,000 warrants

**Education:** M.Sc. in Chemical Engineering, PhD in Physical Chemistry, Lund University

**Previous experience:** Professor in Physical Chemistry at Lund University, Visiting Professor at Oxford University, Institute for Surface Chemistry (Section head).



**Eva Pinotti-Lindqvist**  
*Chief Financial Officer*

**In Company since:** 2014  
**Holdings:** 45,124 shares & 17,009 warrants

**Education:** Bachelor's of Science in Economics, Lund University

**Previous experience:** Chief Financial Officer at EQL Pharma, Nordic Market Analyst at Nordic Drugs, Finance Consultant at Poolia



**Richard Jameson**  
*Chief Commercial Officer*

**In Company since:** 2016  
**Holdings:** 20,490 shares & 88,000 warrants

**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 Hjelström, MD, PhD**  
*Chief Medical Officer*

**In Company since:** 2016  
**Holdings:** -

**Education:** MD, PhD and Associate Professor from Karolinska Institutet, Postdoctoral fellowship at 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:** 45,463 shares & 35,000 subscription warrants

**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.



**Maria Lundqvist**  
*Head of Global HR*

**In Company since:** 2021  
**Holdings:** -

**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.



**Annette Mattsson**  
*VP Regulatory Affairs*

**In Company since:** 2017  
**Holdings:** 12,000 subscription warrants

**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.



**Torsten Malmström, PhD**  
*Chief Technical Officer*

**In Company since:** 2013  
**Holdings:** 45,363 shares & 8,000 subscription warrants

**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 Zealande Pharma, Director of Development at Polypeptide, Team Manager at AstraZeneca.



**Andrew McLean**  
*VP Corporate Development & Senior Counsel*

**In Company since:** 2021  
**Holdings:** -

**Education:** Bachelor of Laws (LL.B (Hons)), Aberystwyth University and College of Law, Guildford (Law Finals)

**Previous experience:** General Counsel, Company Secretary & Chief Compliance Officer at Kyowa Kirin International, International Business Lawyer at Recordati SpA, Head of Legal Affairs at Shire Pharmaceuticals



**Agneta Svedberg**  
*VP Clinical & Regulatory Dev.*

**In Company since:** 2015  
**Holdings:** 12,000 shares & 50,000 subscription warrants

**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.

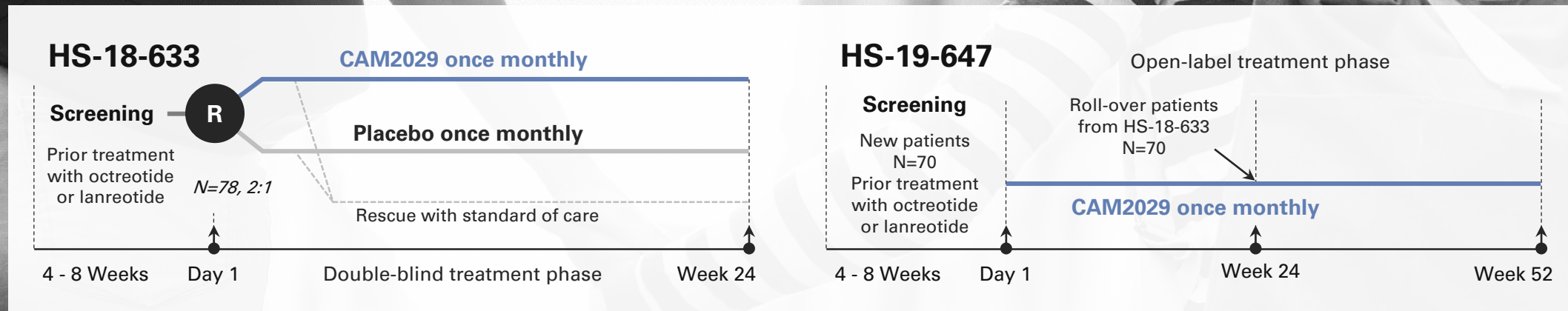
# Two ongoing pivotal Phase 3 studies of CAM2029 in acromegaly

## Efficacy trial

- Phase 3, randomized, double-blind, placebo-controlled, multi-center trial to assess efficacy and safety of CAM2029
- 78 patients, full SSA responders
- Regulatory requirements for efficacy data met
- **Primary end-point:** Proportion of patients with mean IGF-1 levels  $\leq 1x$  upper limit of normal (ULN) at w22 and w24
- Study ongoing and recruiting

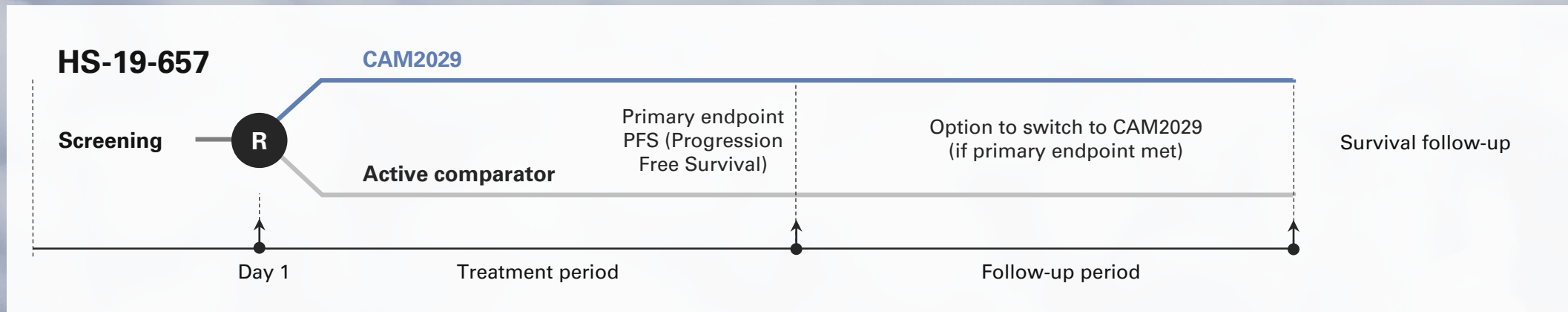
## Long-term safety trial

- Phase 3, open-label, single arm, multi-center trial to assess the long-term safety and efficacy of CAM2029
- $\geq 100$  patients exposed to CAM2029 for 12 months
  - Roll-over patients from HS-18-633 and
  - 'New patients' (partial SSA responders, irradiated patients, and full SSA responders)
- **Primary end-point:** Safety profile (adverse events)
- Study ongoing and recruiting



# GEP-NET Phase 3 trial under start-up

- ✓ Phase 3, randomized, open-label, active-controlled multi-center trial to assess efficacy and safety of CAM2029 versus octreotide LAR or lanreotide ATG in patients with GEP-NET
  - Approximately 300 patients with GEP-NET randomized 1:1
  - **Primary endpoint:** superiority of treatment with CAM2029 versus standard of care, as determined by progression free survival in patients with GEP-NET
  - Study starting



\* GEP – gastroenteropancreatic; NET – neuroendocrine tumors