# Second quarter and half-year results 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

- Strategic objectives
- Second quarter and half-year 2021 results
- Commercial development
- R&D 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





## Strategic objectives for continued growth



Establish Buvidal as preferred treatment choice and market leader in the long-acting opioid dependence segment



Bring new innovative medicines to market approvals to build and diversify our business



Strategic objectives

Drive commercial execution excellence, expand to new markets, and deliver sustainable profitability



Grow our clinical pipeline through patient-centric innovation, collaborations and acquisitions



Take advantage of our leading drug delivery technologies

## Continued strong operating performance

### Executing on commercial objectives

- Double-digit Q/Q sales growth limited by effects of the pandemic
- · Successful life-cycle management with approvals in three markets
- Publication of compelling clinical results in leading scientific journals
- Progress in market access processes, funding and preparation for new launches

### Advancing the pipeline to new market approvals

- Braeburn's NDA filing accepted by FDA with PDUFA date 15 December 2021
- Phase 3 programs advancing in acromegaly and neuroendocrine tumors
- Continued progress in the early pipeline and partnerships

### Long-term revenue growth towards profitability

- Total revenue in H1 increased to SEK 264 million, up 103% versus 2020
- The operating result for H1 was SEK -86 million, up 14% versus 2020
- Solid cash position and balance sheet

Total revenue

**SEK 138 million** 

+71% vs 2020

Operating results

**SEK-60** million

-156% vs 2020

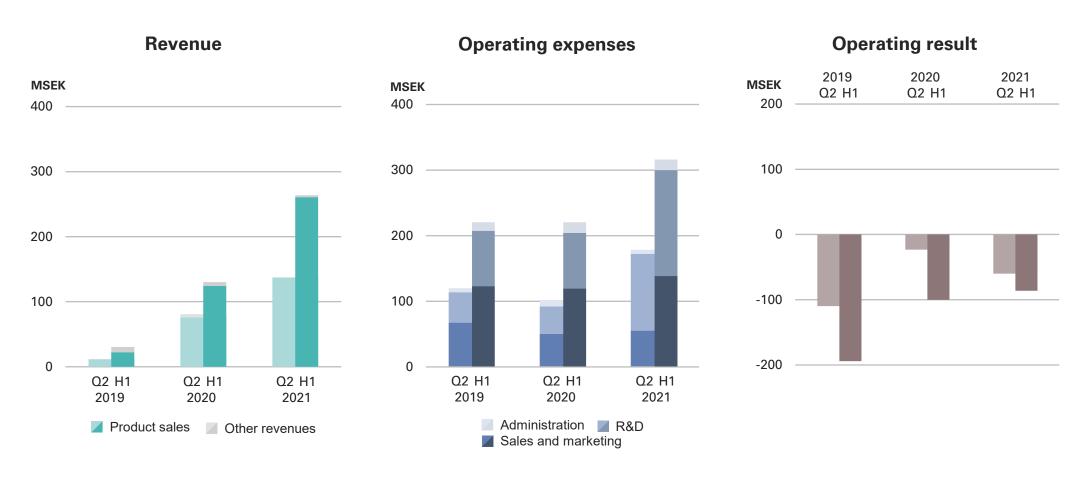
Cash position

**SEK 422 million** 

**+90%** vs 2020



## Second quarter and half-year results



The financial outlook for 2021 is maintained based on our expectations for product sales and revenue growth in the second half of the year as the impacts of COVID-19 continue to wane: Total revenue SEK 680 – 750 million, whereof product sales SEK 620 – 680 million, and an operating result SEK -120 – 0 million



# 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>





# Robust Buvidal sales growth continues under pressure by the pandemic

### High market penetration in Australia and the Nordics

Estimated patient market share >60% in Finland and ~10-20% in Scandinavia and Australia (~80,000 patients in ODT)

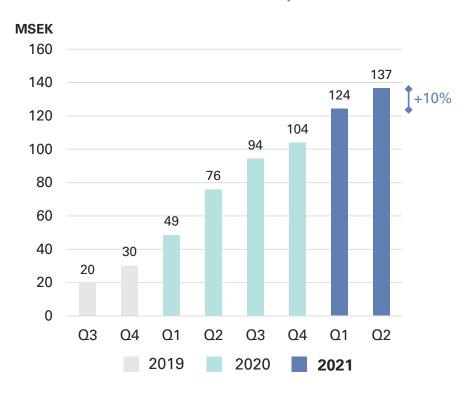
### Progress in UK, Germany, Spain and smaller markets

- Estimated patient market share ~2% in the UK and Germany
- Access limitations and funding being addressed
- High growth potential with about 330,000 patients in ODT

### Near-term launches prepared in seven new markets

- France, Switzerland, Benelux, Greece, Slovenia, Croatia and Portugal
- Additional 220,000 patients in ODT
- Pricing and reimbursement in final stages
- Additional markets in MENA

### Product sales SEK 137m; up 80% vs Q2 2020



# Increasing support for Buvidal and improved access to innovative ODT treatments

# Government initiatives to increase funding and improve treatment access

- Scottish government and Public Health England allocating funding for ODT and Buvidal<sup>1,2</sup>
- Recommendation for significant investments in ODT and innovations in England<sup>3</sup>
- Processes ongoing in Germany and Sweden to improve HCP remuneration system

### Adoption in the criminal justice system

- Expanding use of Buvidal with Australia,
   Germany and Scotland as forerunners
- Benefits of Buvidal clearly recognized, including cost savings
- Estimated >100,000 people with opioid dependence in European prisons<sup>4</sup>

### Growing scientific evidence base

- Positive results in peer-reviewed scientific journals
- Affirmative "real world" outcome studies
- Health-economical assessments demonstrating value of Buvidal to payors and society

### Increasing media attention

- Unmet medical need and positive impact of ODT
- Strong testimonials by patients and HCPs
- Buvidal identified as "game-changer"

### Drug used to treat heroin addiction in prison pilot scheme to go Scotland-wide

Buvidal has proved so successful behind bars, the Scottish





Additional drug treatment crime and harm reduction funding



The Daily Record says a "revolutionary" new drug treatment that aims to end the misery of methadone addiction has been given the green light in a £4m scheme approved by the Scottish government

# Growing scientific evidence base for Buvidal

#### Presentations at Scientific Conferences in 2021





#### Important publications in Q2 2021<sup>1-3</sup>



Original Investigation | Substance Use and Addiction

Patient-Reported Outcomes of Treatment of Opioid Dependence With Weekly and Monthly Subcutaneous Depot vs Daily Sublingual Buprenorphine

A Randomized Clinical Trial

Nicholas Lintzeris. MBBS. PhD: Adrian J. Dunloo. MBBS. PhD: Paul S. Haber, MD. FRACP: Dan I. Lubman, MB ChB, PhD: Robert Graham, MBBS. Sarah Hutchirson, Shalini Aurougiri, MBBS, PhD: Victorial Haber, MBBS, MPH: Peter Fjellmström, MD, PhD: Agreta Svedberg, MSc; Stefan Peterson, PhD: Fredrik Tiberg, PhD



Invited Commentary | Substance Use and Addiction

Extended-Release Buprenorphine and Its Evaluation With Patient-Reported Outcomes

Wilson M. Compton, MD, MPE: Nora D, Volkow, MD





tesearch Report

Treatment of opioid dependence with depot buprenorphine (CAM2038) in custodial settings

A. J. Dunlop 🕿 B. White, J. Roberts, M. Cretikos, D. Attalla, R. Ling, A. Searles, J. Mackson, M. F. Doyle, E. McEntyre, J. Attia, C. Oldmeadow, M. V. Howard, T. Murrell, P. S. Haber, N. Lintzeris

First published: 29 June 2021 | https://doi.org/10.1111/add.15627

<sup>1</sup>Lintzeris, N. et al.; JAMA Netw Open 2021 May 3;4(5):e219041. <sup>2</sup>Compton, Volkow, JAMA Netw Open. 2021 May 3;4(5):e219708.; <sup>3</sup>Dunlop, A. et al. Addiction. Published 29 June 2021



# Product and pipeline update

Phase 1	Phase 2	Phase 3	Registration	Market
CAM2043 Pulmonary arterial hypertension	CAM2029 Polycystic liver disease	CAM2029 Acromegaly	<b>Brixadi™</b> Opioid use disorder (US)¹	Buvidal® Opioid dependence
CAM2047 Chemotherapy-induced nausea and vomiting	CAM2032 Prostate cancer	CAM2029 Neuroendocrine tumors		episil® oral liquid Oral mucositis
CAM2048 Postoperative pain	CAM2043 Raynaud's phenomenon	CAM2038 Chronic pain		
CAM4071 Endocrine disorders	CAM4072 Genetic obesity disorders <sup>2</sup>			Opioid dependence & Pain Rare diseases Oncology & Supportive care

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

# Buvidal (Brixadi) lifecycle management and geographic expansion

### New market approvals

- Buvidal 160mg monthly dose in the EU,
   UK and Australia
- Label expansion for Buvidal in Australia (harmonizing with the EU label)

### 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

- NDA for treatment of opioid use disorder resubmitted to then US FDA
- FDA accepted the FDA as a complete response
- New PDUFA date 15 December 2021
- If approved, Brixadi will be available to US patients early 2022



### CAM2038 Chronic pain

- Pre-submission meeting held with EU Rapporteur
- Preparations ongoing for regulatory submission to EMA in H2 2021



# High unmet need for new treatment options in the US

# Opioid crisis worsened during COVID-19 pandemic

 Opioid overdose deaths has mounted during the pandemic and now exceed > 60,000 per year<sup>1</sup>

### High unmet need for treatment

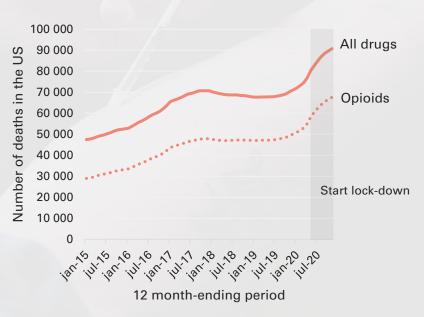
- More than 10 million Americans misuse opioids<sup>2</sup>
- About 2 million diagnosed with opioid use disorder<sup>2</sup>
- 1.4 million people in medication assisted treatment<sup>2</sup>
- Large need for new treatment options

#### New initiatives address the crisis

- President Biden recently issued US\$1.5 billion funding initiative for substance use treatment and prevention<sup>3</sup>
- Increased numbers of HCPs with waiver to administer medication assisted treatment

# Escalating overdose deaths during COVID-19

12 Month-ending Provisional Number of Drug Overdose Deaths in the US<sup>1</sup>





# Opportunity for long-acting injectables (LAIs) in US opioid use disorder (OUD) market

### US market expected to grow<sup>1</sup>

- Current US market size of USD ~2 billion<sup>1</sup>
- Expected to grow to USD >3 billion in 2028 mainly driven by transition to LAIs<sup>1</sup>
  - High price point of LAIs: \$1,500-1,800 per month<sup>2</sup>

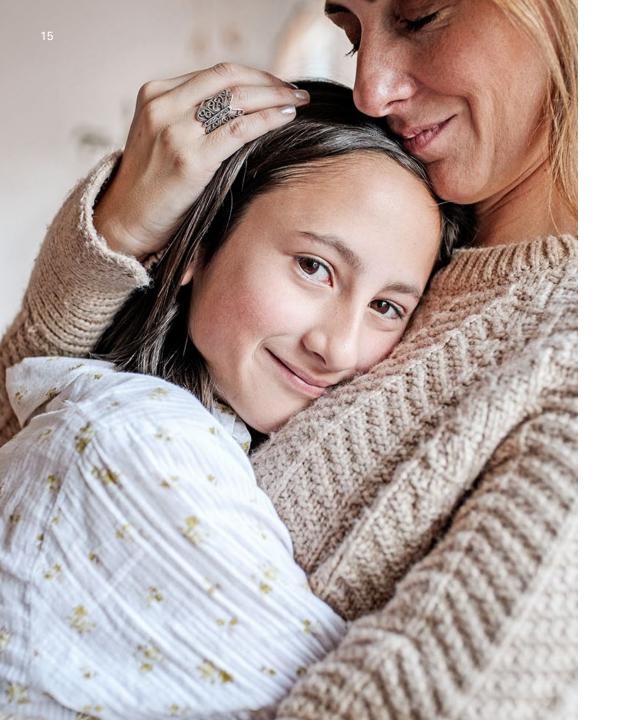
### LAIs projected to take over

- Number of patients treated with LAIs is still low, but growing
  - Around 3% LAI penetration in 2020
- On longer term, LAIs are projected to account for the majority of OUD market value<sup>1</sup>

### US LAI market approaching \$500 million<sup>3</sup>

- Extended-release buprenorphine (Sublocade™)
  - Current CAGR ~50%
- Extended-release naltrexone (Vivitrol)
  - Flat around \$300 million annual sales

LAI OUD PRODUCT	Weakly/Monthly BUPENORPHINE PROCOGO GELEASE SOLUTION FOR INJECTION	Sublocade (bupenophine extended-release) injection for subcutaneous use \$ 100mg-300mg	Vivitro l' (naltrexone for extended-release injectable suspension)
WEEKLY DOSING	✓	-	-
MONTHLY DOSING	$\checkmark$	<b>√</b>	$\checkmark$
MULTIPLE DOSES	$\checkmark$	_	_
CHOICE OF INJECTION SITES	$\checkmark$	_	_
SMALL NEEDLE	<b>√</b> (23G)	— (19G)	— (20G)
LOW DOSE VOLUMES	0.16 – 0.64 mL	— 0.5 – 1.5 mL	— 3.4 mL
ROOM TEMP. STORAGE	$\checkmark$	_	_
DAY ONE INITIATION	$\checkmark$	_	_
CLIN. DATA VS ACTIVE CONTROL*	$\checkmark$	_	_
LAUNCHED	EU, AUS	US, CAN, AUS	US



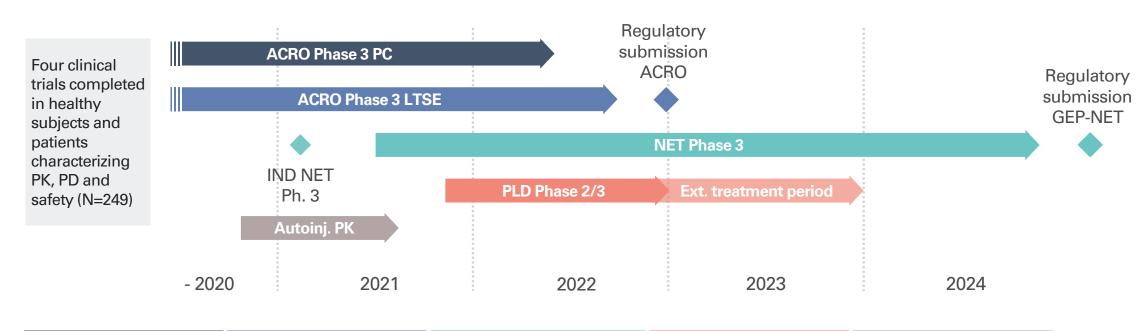
CAM2029 – octreotide subcutaneous depot in development

For treatment of acromegaly, neuroendocrine tumors (NET), and polycystic liver disease (PLD)

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 2/3 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
- Top-line results in 2022
- Pre-launch activities initiated
- Preparations for commercial manufacturing well under way

#### Neuroendocrine tumors

- IND safe to proceed letter received from FDA for start of Phase 3
- Pivotal Phase 3 study initiated

### Polycystic liver disease program

- Type B meeting held with the FDA
- IND submitted to the FDA
- Phase 2/3 study planned to start H2 2021

### Prefilled pen development

- Phase 1 bridging study ongoing
- Results in H2 2021
- Validation for Phase 3 and commercial use ready in Q3 2021
- Will be implemented in all clinical programs



Estimated CAM2029 peak sales potential in the US and EU5:1

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



## Recent and anticipated news flow 2021/22

### H1 2021

- ✓ Buvidal market approval in New Zealand
- ✓ Line-extension approvals of Buvidal in EU and Australia
- ✓ Publication of DEBUT and UNLOC-T study data



 ✓ Brixadi NDA resubmitted by Braeburn – new PDUFA date
 15 Dec 2021

### H2 2021

- Start CAM2029 Phase 3 in NET
- □ Results CAM2029 bridging PK study with prefilled pen
- ☐ Start CAM2029 Phase 2/3 in PLD
- ☐ Start CAM4072 Phase 3 study (Rhythm)
- MAA submission CAM2038 in chronic pain
- Results Phase 2 results CAM2043 in Raynaud's phenomenon
- NDA approval for Brixadi in opioid use disorder

### 2022

- Results CAM2029 Phase 3 efficacy study
- Results CAM2029 Phase 3 long-term safety study
- MAA approval and launch of CAM2038 in chronic pain



NDA/MAA submission CAM2029 for acromegaly



## Key takeaways Q2 2021



#### **Commercialization**

- Continued significant sales growth of Buvidal in Europe and Australia
- Successful Buvidal life-cycle management
- Strengthened evidence base for Buvidal
- New government funding initiatives



### **Pipeline advancement**

- Potential for US approval of Brixadi in December 2021
- Phase 3 programs advancing in acromegaly and neuroendocrine tumors
- Progress in the early pipeline and partnerships



### **Corporate development**

- Financed to execute on our strategic objectives and reach profitability
- Cash position SEK 422 million and total assets SEK 1 046 million

**Q&A** 



## Financials - second quarter and first half 2021

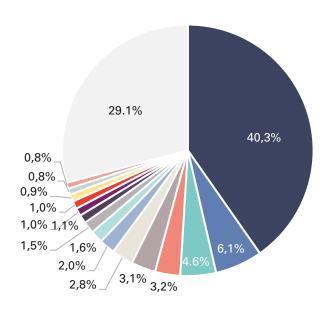
MSEK	Apr – Jun 2021	Apr – Jun 2020	Change	Jan – Jun 2021	Jan – Jun 2020	Change	Jan – Dec 2020
Total revenues	138	81	+70%	264	130	103%	336
whereof product sales	137	76	+80%	261	124	110%	323
Operating expenses	179	102	+75%	315	219	44%	508
Operating result	-60	-23	-156%	-86	-100	14%	-205
Result for the period	-48	-20	+142%	-70	-82	14%	-167
Result per share, before and after dilution, SEK	-0.89	-0.39	-130%	-1.29	-1.58	+18%	-3.18
Cash position	422	222	+90%	422	222	90%	462



### Shareholders

Shareholders as of 30 June 2021	Number of shares	% of capital	% of votes	
Sandberg Development AB	22,000,692	40.3	40.3	
Fjärde AP-fonden	3,330,676	6.1	6.1	
Avanza Pension	2,506,313	4.6	4.6	
Gladiator	1,762,953	3.2	3.2	
Fredrik Tiberg, CEO	1,706,788	3.1	3.1	
Didner & Gerge Fonder	1,517,016	2.8	2.8	
Svenskt Näringsliv	1,100,000	2.0	2.0	
Lancelot Avalon	875,000	1.6	1.6	
Backahill Utveckling	826,491	1.5	1.5	
State Street Bank and Trust	572,208	1.1	1.1	
Cancerfonden	550,000	1.0	1.0	
Afa Försäkring	545,660	1.0	1.0	
Camurus Lipid Research Foundation	505,250	0.9	0.9	
CBNY Norges Bank	435,657	8.0	0.8	
Carl-Olof and Jenz Hamrins Stiftelse	425,000	0.8	0.8	
Other shareholders	15,878,867	29.2	29.2	
In total	54,538,571	100.0	100.0	

#### **Shareholder distribution**





## Experienced and committed management team



Fredrik Tibera, PhD President & CEO, Head R&D In Company since: 2002 Holdings: 1,706,788 shares,

90,000 warrants & 60,000

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).

Education: B.Sc. in Applied Biological Sciences from

Middle East and Africa for Indivior (2013 - 2016).

University West of England



Richard Jameson



Fredrik Joabsson, PhD

In Company since: 2001

Holdings: 49,170 shares,

Chief Business Dev. Officer

15,000 subscription warrants

& 22,500 employee options



Previous experience: General Manager, UK & Nordics for

Reckitt Benckiser (2010 – 2013) and Area Director Europe.

**Previous experience:** More than 20 years of experience in pharmaceutical R&D, business development and alliance management.



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.



Andrew McLean VP Corporate Development & Senior Counsel

In Company since: 2021 Holdings: 22,500 employee 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



**Eva Pinotti-Lindqvist** Chief Financial Officer

In Company since: 2014 Holdings: 46.744 shares. 9.009 warrants and 33.750 emplovee options



Peter Hjelmström, MD, PhD Chief Medical Officer

In Company since: 2016 Holdings: 22,500 employee options



Maria Lundqvist Head of Global HR

In Company since: 2021 Holdings: 22,500 employee options



Torsten Malmström, PhD Chief Technical Officer

In Company since: 2013 Holdings: 46.858 shares & 22,500 employee options



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

In Company since: 2015 Holdings: 16.087 shares. 37,500 subscription warrants & 22.500 employee options

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

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

Education: B.Sc: in Business and Economics, Uppsala

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.

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.

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.



# CAM2029 has potential for best-in-class, offering clear advantages over current long-acting SSAs

i	Key Brands			
	Sandostatin® LAR® (octreotide) Somatuline® Autogel® (lanreotide)		Signifor® LAR (pasireotide)	CAM2029
Presentation	Powder in a vial, requiring multi-6-step preparation	Pre-filled syringe	Powder in a vial, requiring multi-6-step preparation	Convenient device, Ready-to- use pre-filled syringe, autoinjector
Needle Size	19G 40mm	18G 20mm	20G 40mm	Thin needle - 22G 12.5mm
Storage	Intramuscular	Deep subcutaneous	Intramuscular	Subcutaneous
Injection Route	Refrigerated, requires 30 – 60 minutes warm-up time prior to reconstitution	Refrigerated, requires warm-up before injection	Refrigerated, requires at least 30 minutes warm-up time prior to reconstitution	No refrigeration, Room temperature storage, no warm-up time
Administration	Administration by trained healthcare provider	Not approved for partner and self injection in the US	Administration by trained healthcare provider	Self-administration at home, No need for clinic dosing visits
Price (US)	\$50,000 - 80,000 / year1	\$70,000 – 115,000 / year <sup>1</sup>	\$175,000 / year <sup>1</sup>	-
Global Sales	~\$1.4 bn in 2020 <sup>2</sup>	~\$1.3 bn in 2020 <sup>2</sup>	N/A	Not yet approved

### Outlook 2021 maintained

### Key assumptions<sup>1</sup>: 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
- Maintained financial outlook based on our expectations for product sales and revenue growth in the second half of the year as the impacts of COVID-19 continue to wane

### **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

