# **camurus**<sub>®</sub>

ANNUAL REPORT 2018

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## **camurus**

Camurus is a Swedish research-based pharmaceutical company committed to developing and commercialising innovative and differentiated medicines for the treatment of severe and chronic conditions. New drug products with best-in-class potential are conceived based on the proprietary FluidCrystal® drug delivery technologies and an extensive R&D expertise. Camurus' clinical pipeline includes products for treatment of cancer, endocrine diseases, pain and addiction, developed in-house and in collaboration with international pharmaceutical companies. The company's shares are listed on Nasdag Stockholm under the ticker "CAMX".

"First long-acting opioid dependence treatment launched in the EU"



CAM2029 has the potential to improve convenience and treatment outcomes for patients with acromegaly and NET





# "Buvidal approved for treatment of opioid dependence,

# **Approved medicines**

• Buvidal<sup>®</sup> approved for treatment of opioid dependence in the EU and Australia in November 2018

# Broad, late-stage R&D pipeline

• +10 clinical programs in addiction, pain, oncology, endocrinology, obesity and cardiovascular diseases

# Unique FluidCrystal® nano-technology

- Developed in-house with strong IP
- Next generation long-acting depot technology
- Proven in +20 clinical studies and approved products

# **Own commercial organization**

• Fully operational for 2019 Buvidal<sup>®</sup> launches in Europe and Australia

# **Multiple partnerships**

• Braeburn, Rhythm, Solasia...

# **Experienced management** and dedicated teams

• Broad experience and expertise across all disciplines of drug development



## FDA issued complete response letter regarding CAM2038 NDA

- Clinical milestone achieved in collaboration with Rhythm Pharmaceuticals in the development of a weekly setmelanotide depot for the treatment of genetic obesity disorders
- NDA for CAM2038 resubmitted to FDA

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- Positive Phase 1 results announced for CAM2043 for treatment of PAH
- Camurus entered into license agreement with Medison for commercialization of CAM2038 in Israel
- Directed share issue successfully completed with proceeds of SEK 102 million
- episil<sup>®</sup> oral liquid launched in Japan by Meiji Seika Pharma



- Camurus regained exclusive worldwide rights to CAM2029 and related product candidates from Novartis
- Positive topline Phase 3 results for CAM2038 in opioid experienced patients with chronic low-back pain
- CHMP adopted positive opinion recommending European approval of Buvidal<sup>®</sup> (CAM2038) for treatment of opioid dependence
- Successful transfer of CAM2029 from Novartis to Camurus

- Buvidal<sup>®</sup> approved by the European Commission as the first long-acting treatment for opioid dependence in the EU
- Buvidal<sup>®</sup> Weekly and Buvidal<sup>®</sup> Monthly approved in Australia as the first long-acting treatment of opioid dependence
- US FDA issues a tentative approval of Brixadi<sup>™</sup> for treatment of opioid use disorder
- Camurus Capital Markets and R&D Day held at IVA conference center in Stockholm

# Significant events after the period

- Buvidal<sup>®</sup> launched in the Nordics, UK and Germany
- Completion of a rights issue of SEK 403 million
- Braeburn initiated court proceedings to overturn the 3-year market exclusivity and seek immediate market approval of Brixadi<sup>™</sup> in the US

# Breakthrough year for Camurus with approvals of Buvidal<sup>®</sup> in the EU and Australia

2018 was a breakthrough year for Camurus. Buvidal<sup>®</sup>, our weekly and monthly buprenorphine depots, was approved in November for the treatment of opioid dependence – a severe and often chronic condition for which the need for new and improved treatments is enormous. With distribution, marketing and sales in place, the European launch is now accelerating with the first few hundred patients having initiated treatment. The response from physicians and patients has been very positive, which is encouraging as we continue the roll-out of Buvidal<sup>®</sup> on the European, Australian, and other global markets. During the year, we also delivered strong results in our product pipeline, including positive Phase 3 results with CAM2038 for the treatment of chronic pain and phase 1 data for CAM2043 for the treatment of pulmonary arterial hypertension (PAH). The approvals of Buvidal<sup>®</sup> by the European Commission and Australian Therapeutics Goods Administration was gratifying to us all at Camurus. After years of tireless development, we reached the finishing line with our first in-house developed medicine, which has the potential to transform opioid dependence treatment for hundreds of thousands of patients who have become dependent on illicit opioids or prescription painkillers. Our goal is now to give patients access as quickly as possible to this new effective treatment that can meaningfully improve their treatment outcomes and quality of life.

"Approvals of Buvidal" by the European Commission and Australian Therapeutics Goods Administration,,

#### GAME-CHANGING LONG-ACTING TREATMENT OF OPIOID DEPENDENCE

With its flexible weekly and monthly dosing options in multiple dose strengths, the treatment regimen with Buvidal<sup>®</sup> can be adjusted to the needs of individual patients, with improved treatment results versus standard daily treatment, as demonstrated in the pivotal Phase 3 study.<sup>1</sup> The need for daily, often supervised, medication – which can be burdensome and socially stigmatizing for patients – is avoided with weekly and monthly Buvidal<sup>®</sup>. Furthermore, since Buvidal<sup>®</sup> is designed for healthcare professional administration only, the risk of misuse and diversion and unintended exposure to children and teenagers is also largely avoided.

# DEDICATED COMMERCIAL INFRASTRUCTURE IN PLACE IN THE EU AND AUSTRALIA

During 2018, Camurus took the strategically important step to grow from an R&D focused company to a science-led, international pharmaceutical company with its own marketing and sales organization in the EU and Australia. By the end of the year we had grown from 71 to 94 employees, and are now already more than 100 employees, with an additional 20 consultants and contractor employees working from our Lund headquarters and regional offices in Cambridge, Mannheim, Paris and Sydney. About half of our people are directly involved with the launch of Buvidal®- working with everything from distribution, marketing and sales to medical information, education and safety monitoring. We are extremely pleased to have fantastic sales and marketing teams on board and we are convinced that we will succeed in our efforts to establish a strong position for Buvidal® on the global opioid dependence treatment market.

During the year we established commercial manufacturing of Buvidal<sup>®</sup> and an effective distribution network in Europe and Australia, which has enabled on-site delivery of Buvidal<sup>®</sup> to most clinics in the Nordics, UK and Germany within 24 hours of an order being placed.

"Establish a strong position for Buvidal<sup>®</sup> on the global opioid dependence treatment market,

## **BUVIDAL®**

# - the first long-acting injection treatment of opioid dependence in the EU and Australia



 Buvidal<sup>®</sup> is indicated (EU) for treatment of opioid dependence within a framework of medical, social and psychological treatment in adults and adolescents from 16 years

• Individualized dosing for use across treatment phases: initiation, switching from daily medications and long-term maintenance treatment

- Superiority claim versus daily standard treatment with daily buprenorphine/naloxone included in clinical outcomes
- Removes burden and stigma of daily medication
  - Administration by healthcare personnel safeguards against diversion, misuse and pediatric exposure

## **OPIOID DEPENDENCE**

is a chronic and relapsing medical condition diagnosed by signs and symptoms of compulsive opioid use causing significant mental, physical, and social problems, including transmission of infectious diseases, unintentional overdose, criminal activity, and incarceration.

## ESCALATING OPIOID CRISIS



#1 cause of deaths for people under 50 years in the US



With manufacturing and distribution secured, the European launch of Buvidal® began already in January 2019. A few hundred patients have initiated treatment in Finland, Sweden, Germany and the UK, and the feedback from patients and physicians has been very positive – which is in line with the experiences from the clinical program. Much of our attention is now focused on enabling patient access by having Buvidal® included in treatment plans, guidelines and formularies, and by working to secure reimbursement and the availability of appropriate resources for opioid dependence treatment at regional and national levels.

This work is greatly facilitated by the advantageous properties of Buvidal<sup>®</sup> and the results from its comprehensive clinical program, including the randomized, double-blind, double-dummy, active controlled phase 3 study against standard daily treatment with sublingual buprenorphine/ naloxone, which was published in JAMA Internal Medicine in 2018.<sup>1</sup>

During the year we continued building on the strong evidence base established for Buvidal<sup>®</sup>, and started two important new clinical studies:

- An open-label, clinical study of Buvidal<sup>®</sup> versus standard daily treatment with sublingual buprenorphine focusing on patient satisfaction, quality of life and health economic outcomes. The study was started in Australia in October 2018 and topline results are expected in the fourth quarter of 2019.
- A clinical study of Buvidal<sup>®</sup> and methadone treatments in the custodial setting, performed in seven correctional facilities in New South Wales (NSW), Australia. The study is sponsored by the NSW government and will include 120 opioid dependent patients, of which the Buvidal<sup>®</sup> patients will be followed for up to 1 year. Interim results are expected in the fourth quarter of 2019.

# "Feedback from patients and physicians has been very positive,,

Based on our own and independent external market research, the long-acting injectable market for opioid dependence in the EU and Australia is 200–300 million Euro per year.<sup>2-4</sup> With the strong product profile of Buvidal®, including the broad indication and demonstrated improved treatment outcomes – combined with the advantage of being first to market – we believe that Buvidal® could take a very significant share of this market.

# "Positive Phase 3 results for CAM2038 in chronic pain,,

#### **TENTATIVE APPROVAL IN THE US**

Our US partner Braeburn experienced unexpected setbacks during 2018. First, the Food and Drug Administration (FDA) issued a complete response letter requesting additional information for approval of Brixadi<sup>™</sup> (US tradename for Buvidal<sup>®</sup>). After diligently answering all questions and receiving a formal acceptance and new PDUFA date, Braeburn was issued a tentative approval of Brixadi<sup>™</sup> in December 2018. This meant that all regulatory requirements were fulfilled, but a final marketing approval of the monthly product was considered blocked by a market exclusivity granted by the FDA which extends to November 2020.

The decision took us by surprise and was disappointing, not only for Braeburn and Camurus, but also for physicians and patients, who had been anticipating the launch of Brixadi<sup>™</sup>. In view of the ongoing opioid epidemic in the US, the urgent need for new treatments, and the FDA's recent official statements and guidelines relating to the importance of depot medications for opioid dependence, the FDA decision to issue a tentative approval was confounding. The effect on Camurus was immediate, as the decision resulted in a delay of an expected 35 million USD milestone payment. In view of this, our Board of Directors initiated a rights issue to raise gross proceeds of 403 million SEK to finance key activities according to our business plan and long-term strategy. The rights issue has now been successfully completed. Since the FDA decision, Braeburn has been working intensively to give US patients access as soon as possible to this new treatment which fulfills critical unmet medical needs. Braeburn recently initiated court proceedings to overturn the 3-year exclusivity and obtain immediate market approval of Brixadi<sup>™</sup> in the US.

#### POSITIVE PHASE 3 RESULTS FOR CAM2038 IN CHRONIC PAIN

In September 2018, we reported positive results from a pivotal phase 3 study of CAM2038 in patients with chronic low back pain. The results show that CAM2038 provides clinically significant long-acting pain relief in patients who, prior to the study, were on daily medication with opioid painkillers.

The clinical development of CAM2038 in this indication continued during the year with a long-term safety study in a wider patient population. Topline results are expected in the second quarter of 2019. These will be followed by health authority discussions, before submitting applications for marketing authorization in early 2020.

The incidence of chronic pain in Europe and the US is about 20%. Depression, anxiety and opioid abuse are often linked to chronic pain, which makes it a major health issue with large negative consequences for both individuals and society. Treatment of patients with chronic pain and concomitant opioid misuse problems is particularly challenging. CAM2038 is designed for round-the-clock pain relief and an improved safety profile, as it minimizes the risks of developing opioid tolerance, addiction, misuse and overdose.

#### SIGNIFICANT OPPORTUNITIES WITH SUBCUTANEOUS OCTREOTIDE DEPOT

In July 2018, we regained the exclusive worldwide development and commercialization rights from Novartis to our octreotide depot, CAM2029, for the treatment of acromegaly

# **CHRONIC PAIN**

is often defined as pain lasting longer than three months or beyond the normal time for tissue healing. Common types of chronic pain include lower back pain, arthritis, headache, and face and jaw pain.



#### CAM2038 addressing unmet medical needs:

- Improved treatment adherence and potential for improved treatment outcomes
- Reducing the risk of misuse, abuse and diversion
  - Reducing risk of overdose

## ACROMEGALY

is a rare and chronic hormonal disorder that occurs when the pituitary gland produces excess growth hormone



# NET - NEUROENDOCRINE TUMOURS

Are a heterogenous group of rare tumours originating from regulatory hormoneproducing neuroendocrine cells



# "First long-acting octreotide product for subcutaneous dosing,,

and neuroendocrine tumors. CAM2029 may be the first long-acting octreotide product for subcutaneous dosing and is designed for easy self-administration by patients. Clinical studies also show that CAM2029 provides more than 500% higher bioavailability of octreotide than the market leading product Sandostatin® LAR®.<sup>7</sup> Recently published results from a phase 2 study indicate that CAM2029 can improve control of disease biomarkers in patients with acromegaly as well as decrease symptoms in patients with NET.<sup>8</sup>

During the second half of 2018, we finalized the phase 3 program design and completed GMP manufacturing preparations for upcoming phase 3 trials. A pivotal phase 3 study in acromegaly patients is planned to start mid-2019. We were also granted new patents for CAM2029 in the US and Australia, that strengthen our patent protection until 2032 or beyond.

With its patient-friendly dosing and the potential for improved treatment results, we believe that CAM2029 could take a significant share of the long-acting somatostatin analogue (SSA) market, which had sales of more than 2.5 billion USD in 2018.<sup>9</sup>

#### PROMISING CLINICAL RESULTS FOR OUR TREPROSTINIL DEPOT

In the second quarter of 2018, we announced promising phase 1 results for weekly treprostinil depot in development for treatment of pulmonary arterial hypertension (PAH).



Based on the pharmacokinetics and safety profile documented in the Phase 1 study, we have, together with opinion leaders and clinical experts, begun preparations for the continued clinical development of CAM2043. The goal is to start a phase 2 study in PAH patients in 2019 before beginning a pivotal phase 3 program.

"Promising phase 1 results for weekly treprostinil depot in development for treatment of PAH,,

#### **PROGRESS IN PARTNERSHIPS**

Partnership is an integral part of our business and has the potential for significant value generation from milestone payments and revenue from sales over the coming years. For example, we are developing a weekly setmelanotide

#### CEO STATEMENT

		Outlook 2019
DELIVERING ON STRATEGY	Achievements 2018	• Successful launch of Buvidal® in the EU and Australia
Commercialization	• Commercial infrastructure in place in the EU and Australia	
		<ul> <li>Preparations for market applications for CAM2038 in chronic pain</li> </ul>
Advancing product pipeline and launches of new products	<ul> <li>EU and Australian approvals of Buvidal<sup>®</sup> for opioid dependence</li> <li>Tentative US approval of Brixadi<sup>™</sup></li> <li>Positive phase 3 study in chronic pain</li> </ul>	<ul> <li>Start of phase 3 program for CAM2029</li> <li>Initiation of phase 2 study of CAM2043 in PAH</li> </ul>
Value creating partnerships	<ul> <li>Phase 1b clinical milestone and phase 2 start with weekly setmelanotide by Rhythm</li> <li>Partnership with Medison for Buvidal<sup>®</sup> in Israel</li> </ul>	New license partnerships for own product candidates
Leading drug delivery technology	<ul> <li>FluidCrystal<sup>®</sup> injection depot validated by product approvals</li> </ul>	<ul> <li>New technology licenses and research partnerships</li> </ul>

# **OPERATING EXPENSES**



#### Research and development MSEK 207.7 (222.9)

- Clinical studies with Buvidal® in Australia
- Phase 1 study of CAM2043
- Development of pivotal clinical programs for CAM2029 and CAM2043
- Establishment of commercial manufacturing of Buvidal®

#### Sales and marketing MSEK 100.9 (45.9)

 Establishment of marketing and sales organisation for Buvidal<sup>®</sup> in the EU and Australia





# "Validation of our innovative FluidCrystal<sup>®</sup> technology,,

(CAM4072) for the treatment of genetic obesity disorders in collaboration with Rhythm Pharmaceuticals. CAM4072 has shown promising results in clinical studies, including positive pharmacokinetics and safety results in Phase 1. In 2018, we received the first milestone payment from Rhythm, after completion of a successful Phase 1b. Thereafter, Rhythm has initiated a Phase 2 study of CAM4072 in patients with obesity. According to Rhythm, data for the weekly formulation are very promising and we expect a decision to enter pivotal Phase 3 studies in late 2019.

Several other collaborations based on our proprietary FluidCrystal® technology have been started, including with biotech and large pharmaceutical companies. These may become public after signing of license agreements.

#### CAMURUS WELL POSITIONED FOR GROWTH AND VALUE GENERATION

Apart from unforeseen events in our partnerships, 2018 was a strong year, where we delivered in accordance with our overall objectives. The approvals of Buvidal® in the EU and Australia was a breakthrough for the company and a validation of our innovative FluidCrystal® technology. After years of commitment and hard work, it is gratifying to us all to reach the goal of bringing a new important medicine to the market and receiving positive testimonials from patients and physicians.

With a newly launched medicine, a dedicated marketing and sales organization, a broad and diversified development pipeline of innovative products in late-stage development, multiple partnerships, and a unique drug-delivery technology platform, Camurus is well positioned to become a leading player in opioid dependence – as well as in other disease areas where our products and technologies can make a real difference to patients. With this foundation, we aim to deliver strong growth and value over the coming years.

I want to thank all employees for their exceptional efforts during the year and our shareholders for their confidence and patience.

Fredrik Tiberg, President & CEO

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## STRATEGY

# **OUR MISSION**

To improve treatment outcomes and patients' quality of life through simpler, smarter, and safer medications

# **OUR VISION**

To spearhead development of advanced drug delivery systems and innovative medical products to improve the treatment of patients with severe and chronic diseases

# **OUR VALUES**

# Innovation

We encourage innovation and new ways of thinking

# **Expertise**

We leverage the combined expertise of our employees and partners

## Passion

We are passionate about realizing our ideas and goals

# Quality

We strive for excellence in everything we do and produce

# Ownership

We take individual and collective ownership of what we do and how we do things

# **Business model**

We use our strong R&D expertise and world-leading drug delivery technologies to develop new treatments that have the potential to significantly improve the lives of patients with severe and chronic diseases. Innovative medicines are developed in-house or in partnerships with international pharmaceutical companies under technology or product licenses. To maximize the value of our pharmaceutical products, we have established an effective commercial organization with an initial focus on the opioid dependence markets in Europe and Australia, and other specialty markets with suitable dynamics and a concentrated prescriber base.

MODEL	<b>BUSINESS CONCEPT</b>	KEY REVENUE STREAMS	Own sales
Own product development and commercialization	Development and commercialization of innovative specialty pharmaceuticals	Product sales	
Product development in partnerships	Non-clinical and clinical development of novel pharmaceutical products	<ul> <li>Licence payments and development milestones</li> <li>Royalty and sales milestones</li> </ul>	
Technology collaborations	Product specific licenses to FluidCrystal® technology	Formulation design and early stage product evaluations	
			Partnerships

# **Products and Pipeline**

Our clinical pipeline represents a mix of in-house and partnered programs from early stage of development to registration phase and marketed products. We strive to address the needs of patients and healthcare providers by developing products that can truly make a difference in patients' everyday lives, improving treatment results and long-term recovery.





**BUVIDAL**<sup>®</sup>

A potential game-changer in the treatment of opioid dependence

# First long-acting treatment for opioid dependence in the EU and Australia

With the launch of Buvidal<sup>®</sup> in the EU and Australia, patients with opioid dependence have – for the first time – the possibility of a weekly or monthly individualized treatment, which aims to remove the risks, burden and stigma of daily medication, and help them in their recovery journey with improved treatment outcomes.

Opioid dependence is a serious, chronic, relapsing disease and a growing global public health crisis. In 2016, an estimated 34 million people misused opioids, and 127,000 people die each year from opioid overdoses.<sup>1</sup> In the US, opioid dependence is the number one cause of death for people under the age of 55.<sup>2</sup>

Daily sublingual buprenorphine and methadone, the established treatments of opioid dependence, have been proven to reduce illicit opioid use, limit the spread of blood-borne viruses and decrease mortality. The social functioning and quality of life for patients receiving this treatment can also be improved. Yet less than half of the 1.3 million people with opioid dependence in Europe receive medication therapy and 40-50% of these discontinue treatment within 6 months.<sup>3-6</sup>

#### TREATMENT ACCESS AND ATTRACTIVENESS

One reason why so few patients with opioid dependence receive medication is simply that access to treatment is often limited. Significant healthcare resources are required to provide a therapeutic program as patients must attend clinic every day to receive medication. If a program is available, the rules and regulations for patients to enter and remain in the program may also hinder the likelihood of a person receiving or continuing to receive treatment.

But it's not just availability of treatment that is an issue – it is also the attractiveness of the treatment program. Patients may shy away from the burden of a daily treatment, which can be seen as stigmatizing and which impacts their employability and personal lives: "With daily medication, patients are reminded every day of their opioid dependence," points out Antti Aivio, Country Lead for Finland and the Baltics, at Camurus. "And with daily medication, the drug stays in focus, even though the treatment program is trying to help patients think beyond their dependence on illicit drugs."

Sublingual administration also has a number of drawbacks – including the risk of diversion (the unlawful channeling of prescription drugs to the black market), misuse (use by people for whom the drug has not been prescribed or use of dose other than prescribed), and accidental ingestion by children. Trust between the patient and healthcare professional can become a barrier to treatment compliance, if the clinician questions whether the medication is being used as intended.

"The relationship between the patient and clinician is key to the success of the program, but the risks associated with sublingual medication put pressure on the patient/clinician relationship," explains Mr Aivio.

#### Of the 1.3 million high-risk opioid users in Europe, 76% live in five countries<sup>3</sup>





**BUVIDAL®** 

Antti Aivio Medical Science Lead Finland and Baltics





# Tentative approval of Brixadi<sup>™</sup> in the US

In December 2018, the FDA issued a tentative approval of Brixadi<sup>™</sup> (the US trade name for Buvidal<sup>®</sup>) for the treatment of moderateto-severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. With the tentative approval, Brixadi<sup>™</sup> met all regulatory standards for US approval, including safety, efficacy and quality, but final market approval of a monthly depot was determined subject to the expiration of an exclusivity period granted to Sublocade<sup>™</sup> until 30 November 2020. In April 2019, Camurus' US partner Braeburn filed a lawsuit to the federal district court for the District of Columbia seeking to overturn the market exclusivity and pled for immediate approval of Brixadi<sup>™</sup>. Add to these challenges the fact that opioid dependence impairs judgement, and that patients often have a chaotic lifestyle, and it is understandable why the risk of patients not returning for treatment each day is high.

Dr Ayana Gibbs, Head of Medical Affairs for Northern Europe at Camurus, explains: "A patient misses one day, then another and another until they eventually drop out of the program. But then they relapse and need to re-enter treatment. It's a revolving door which is detrimental to the patient's health and increases costs to payers and the healthcare system."

#### A NEW TREATMENT OPTION

Patients in Europe are in great need of new and more effective medications that can improve treatment outcomes and quality of life for patients has been long awaited by the opioid dependence community, says Professor Sir John Strang, Director of the National Addiction Centre, King's College, London, UK.

# "Patients in Europe are in great need of new and more effective medications,,

At the end of 2018 Buvidal® (prolonged-release buprenorphine), the first long-acting opioid dependence treatment, was approved in the EU and Australia, and received tentative approval in the US (see side bar).

Designed for once weekly or once monthly injection, Buvidal® delivers rapid and sustained suppression of withdrawal and cravings as well as opioid blockade from the first day of treatment. In clinical trials, Buvidal® was shown to improve treatment outcomes compared with sublingual buprenorphine/naloxone.

#### Limitations of current daily treatment

<ul> <li>Limited treatment adherence<sup>1,3-8</sup></li> <li>Increased risk of relapse/overdose, 40–50% of patients terminate treatment with buprenorphine in the first 6 months</li> </ul>	$\oslash$
<b>Burdens and stigma for patients</b> <sup>1,7</sup> – Daily and supervised administration – Limited access and strict controls	$\oslash$
Public health impact <sup>1,3</sup> <ul> <li>Exposure to children and teenagers</li> <li>Medication misuse, abuse and diversion</li> <li>Huge healthcare and societal costs</li> </ul>	$\odot$

Finland. "It gives the possibility to develop new treatment regimens and may enhance treatment adherence and outcomes. Importantly, it also offers flexible dosing options that meet the individual treatment needs of each patient."

#### OVERCOMING THE BURDEN AND STIGMA

Camurus hopes that Buvidal<sup>®</sup> will help patients to overcome the burden and stigma of daily opioid dependence treatment, and help strengthen the patient/clinician relationship – leading to better treatment adherence and outcomes.

"Buvidal<sup>®</sup> frees patients from needing to think about getting medication every day," Dr Gibbs says. "It frees clinicians from the worry that the medication is being misused. And it frees up their time, as rather than dispensing a medication every day they will have more time to offer other forms of support."

# "Buvidal<sup>®</sup> frees patients from needing to think about getting medications every day,

"As a psychiatrist I know the time and mental space Buvidal® opens up for patients to engage in psychosocial counselling and support for their dependence is very valuable," she adds. "Buvidal® has the potential to be a huge game-changer."

### A SIGNIFICANT MILESTONE

To prepare for the launch of Buvidal®, in 2018 Camurus established strong commercial teams within sales, marketing, medical affairs and market access across Europe and



Ayana Gibbs MBChB, MRCPsych, PhD Head of Medical Affairs NEU

"The first long-acting opioid dependence treatment, was approved in the EU and Australia,

Formulated with Camurus' FluidCrystal® injection depot technology, Buvidal® is a lipidbased solution containing buprenorphine in a prefilled syringe. The solution is injected subcutaneously once weekly or once monthly using a conventional syringe with a thin needle. On injection, a gel-like depot is formed, which is then biodegraded at a controlled rate over time, releasing the buprenorphine which blocks the drug-liking effect of opioids in the brain and reduces withdrawal, craving and the patient's use of illicit opioids.

Buvidal® has the potential to reduce the risks of diversion, abuse, misuse and accidental pediatric exposure, as the injection must be administered by a healthcare professional – so clinicians can be confident that the medication is being used by the person for whom it was intended. Furthermore, the different doses and strengths allow the treatment to be individualized to suit the needs of the patient.

"Buvidal® represents an important new medical treatment option for patients with opioid dependence," says Kaarlo Simojoki, Addiction Medicine Professor at University of Helsinki and Chief Physician of A-clinic Ltd, Buvidal<sup>®</sup> Key Features





# Compelling clinical data for Buvidal<sup>®</sup> versus daily standard treatment

- Non-inferior and superior efficacy shown in pivotal Phase 3 study versus standard daily SL BPN/NX<sup>9</sup>
- Sustained suppression of withdrawal and cravings<sup>9-11</sup>
- **Blockade** of opioid effects from the first dose<sup>10</sup>
- Safety profile comparable to SL BPN/NX except for mild and moderate injection site reactions<sup>9</sup>
- No opioid overdoses across clinical studies for participants treated with Buvidal<sup>® 9-12</sup>
- High patient satisfaction including versus SL BPN<sup>13</sup>

# "Encouraging response from patients and physicians,,

Australia, and expanded its global distribution network to ensure access to treatment.

To date, Buvidal® has been launched in Finland, Sweden, Denmark, the UK and Germany, with encouraging response from patients and physicians.

"The day before we launched in Finland, two doctors, from different clinics in Finland, called me as they had patients already waiting to start the treatment. And patients have been approaching the clinics spontaneously asking about this treatment – patients who haven't accepted the rules of daily medication programs but are now interested in weekly or monthly treatment," says Mr Aivio. Arnd Sprödefeld, Head of Marketing, Central Europe, at Camurus, agrees that the response from the market has been extremely positive. "Opioid dependence is a huge problem globally and in Europe, and the access to treatment is limited. Buvidal<sup>®</sup> is a completely new treatment option, that can improve both the access and the quality of treatment for opioid dependence. We are working intensively with clinicians and healthcare personnel to share experiences and improve treatment for patients." This is very exciting and rewarding, he says.

"We are motivated by the large medical need and the great opportunity to improve treatment results and quality of life for patients."

#### Weekly Buvidal<sup>®</sup>/Daily SL BPN<sup>14</sup>

#### Monthly Buvidal<sup>®</sup>/Weekly Buvidal<sup>®14</sup>



Population pharmacokinetic analysis and modelling based on data from four clinical trials

References 1. World Drug Report 2018 (United Nations publication, Sales No. E.18.XI.9). 2. Frazier et al, 2017, Journal of the American Medical Association. 3. European Drug Report 2018, EMCDDA. 4. Soyka M, et al. Int J Neuropsychopharmacol. 2008;11(5):641-653. 5. Apelt SM, et al. Pharmacopsychiatry. 2013;46(3):94–107.
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9. Lofwall MR, et al. JAMA Intern Med 2018; 178(6)764–773. 10. Walsh et al, JAMA Psychiatry 2017;74(9):894-902. 11. Haasen, C, et al, J Subst Abuse Treat. 2017;78:22-29. 12. Lintzeris et al., Drug and alcohol review. 2017;36(S1):47-48. 13. Study HS-14-499, data on file. 14. Albayaty M, et al, Adv Ther. 2017 34(2):560-575.
15. Market Access Dynamics in Opioid Addiction: Probing Prescriber Preferences and Payer Strategies for Current and Emerging Agents in the EU5, Decision Resources, 2015. 16. Camurus data Simon Kucher and Partners pricing research 2018. 18. Opioid Use Disorder (OUD): Opportunity Analysis and Forecasts to 2027, GlobalData, 2018. 19. Camurus data on file 2018 Patient qualitative study

#### Market potential of long-acting injectables (LAIs) in opioid dependence in EU and Australia<sup>15-17</sup>



# ~740,000 total addressable patient number for LAIs in EU and Australia



ESTIMATED MARKET SIZE FOR LONG-ACTING INJECTABLES





# Buvidal<sup>®</sup>–Scientific publications and presentations

In 2018, key results were presented at numerous international conferences and regional meetings as well as in leading publications:

#### Publications 2018:

- Lofwall MR, Walsh SL, Nunes EV, Bailey GL, Sigmon SC, Kampman KM, Frost M, Tiberg F, Linden M, Sheldon B, Oosman S, Peterson S, Chen M, Kim S. JAMA Intern Med. 2018;178(6):764-773
- ElKashef A, Alzayani S, Shawky M, Al Abri M, Littlewood R, Qassem T, Alsharqi A, Hjelmström P, Abdel Wahab M, Abdulraheem M, Alzayed A., Journal of Substance Use, 2019;24(1):4-7

#### Conferences and meetings 2018:

- AATOD American Association for the Treatment of Opioid Dependence, March 10-14, New York, USA
- ASAM American Society for Addiction Medicine. April 12-15, San Diego, USA
- **AMCP** Academy of Managed Care Pharmacy, April 23-26, Boston, USA
- **APA** American Psychological Association, May 5-9, New York, USA
- IOTOD Improving Outcomes in the Treatment of Opioid Depdendence, May 15-16, Madrid, Spain
- Europad European Opioid Addiction Treatment Association, May 25-27, Krakow, Poland
- Albatros Congrès International d'Addictologie de l'Albatros, June 6-8, Paris, France

- CPDD College on Problem Drugs and Dependence, June 9-14, San Diego, USA
- **CSAM** Canadian Society of Addiction Medicine, October 25-28, Vancouver, Canada
- **ISAM** International Society of Addiction Medicine, November 3-6, Busan, Republic of Korea
- **APSAD** Australasian Professional Society on Alcohol and other Drugs, November 4-7, Auckland, New Zealand
- SSA Society for the Study of Addiction, November 8-9, Newcastle upon Tyne, UK
- **ISPOR**, November 10-14, Barcelona, Spain
- AAAP American Academy of Addiction Society, December 6-9, Bonita Springs, USA





Nina Bladh Director CMC Regulatory Affairs

My role at Camurus is to ensure we are compliant with regulatory requirements within the so-called chemistry, manufacturing and control (CMC) area. Pharmaceutical development includes so many different dimensions, such as clinical effect, safety, functionality when administered by the user, and manufacturability. The development complexity arising from this combination of product characteristics is extremely interesting and exciting to work with.

Camurus is a relatively small company where you get involved in a broad scope of activities. This gives a great opportunity for new experiences and personal development. The atmosphere between colleagues at all levels at Camurus is fantastic.



Max Miller Research Scientist, Analytical Development

I come from Oregon in the US and was attracted to Camurus as it appeared to be an interesting and dynamic pharmaceutical company. It is very rewarding to take part in the development of a leading technology platform such as FluidCrystal<sup>®</sup>, and pharmaceuticals with the potential to help hundreds of thousands of people around the globe.

I work with the development and implementation of new analytical methods. At Camurus we work cross-functionally and everbody contributes with their knowledge and experience in the projects.

# FLUIDCRYSTAL® TECHNOLOGY PLATFORM

Mak

300

600

# FluidCrystal<sup>®</sup> – lipid-based nano-technologies

FluidCrystal<sup>®</sup> technologies have been designed to improve medication delivery and therapeutic performance.

# FluidCrystal® INJECTION DEPOT

Long-acting release with user-friendly administration

# FluidCrystal® TOPICAL BIOADHESIVE

Unique bioadhesion extends and reinforces treatment efficacy





# FluidCrystal® NANOPARTICLES

Nanoparticle carriers with high solubilizing capacity increase active pharmaceutical ingredient absorption and bioavailability



# FluidCrystal® INJECTION DEPOT

FluidCrystal<sup>®</sup> injection depot provides treatment efficacy over extended periods – from days to months – with a single injection. It can reduce the burden of daily medication while increasing adherence to therapy.

FluidCrystal® injection depot comprises a homogeneous lipid-based solution with a dissolved active pharmaceutical ingredient that can easily be injected subcutaneously using a conventional syringe with a thin needle.

Upon contact with fluids in the tissue, the lipid solution transforms into a liquid crystalline

gel, which effectively encapsulates the active ingredient. The pharmaceutical compound is then slowly released at a controlled rate as the depot gradually biodegrades in the tissue This release can be controlled, from several days to weeks or months, depending on the choice of lipid composition and other factors. The simplicity of the FluidCrystal® injection depot, including a spontaneous self-association to a functional structure in the body, eliminates complicated manufacturing procedures and the need for mixing (reconstitution) prior to administration.

Medicines based on the FluidCrystal® injection depot can be administered by the patients themselves or by healthcare professionals, without time-consuming and complicated reconstitution procedures. The prolonged action reduces the patient's burden of administering medication daily, improves treatment adherence and outcomes, and ultimately improves the patient's quality of life.

#### **KEY ATTRIBUTES**

- Easy and convenient administration
- Improved treatment adherence
- Adapted to pre-filled syringes and auto-injectors
- Long-acting release of active pharmaceutical ingredient
- Small injection volume with a thin needle
- Good safety profile
- Manufacturing by standard
   processes
- Suitable for biological peptides as well as small molecules



Pharmacokinetic profiles (plasma concentration of pharmaceutical substance over time) following the administration of pasireotide formulated in FluidCrystal® injection depot (left figure) compared to an immediate release formulation of pasireotide, (right figure). (Tiberg, F. et al, Poster presentation at ECF, Barcelona, May, 2018).



# FluidCrystal® TOPICAL BIOADHESIVE

FluidCrystal<sup>®</sup> topical bioadhesive slowly and precisely releases pharmaceutical substances systemically or locally, and can also provide protection of sensitive and inflamed tissues.

#### **KEY ATTRIBUTES**

- Strong adhesion to biological surfaces
- Protects sensitive tissues
- Relieves topical pain
- High solubilizing capacity for active pharmaceutical ingredients
- Extended local or systemic release of active ingredients
- Good local tolerability
- Manufacturing by standard processes

FluidCrystal® topical bioadhesive is a low-viscosity liquid product that forms a strong and thin bioadhesive film after administration on tissue surfaces. The nanostructure of the film can be controlled to achieve an optimal delivery profile and bioadhesive strength, making it suitable for prolonged local release of active pharmaceutical ingredients on the skin and on mucosal membranes of, for example, the mouth, nose and throat. The formulation has a high solubilizing capacity, which allows relatively small dosage volumes to achieve therapeutic effects with the active ingredient. FluidCrystal® topical bioadhesive can be administered using metered dose pumps, tubes, capsules and other primary packaging forms for liquids.



The commercial product episil® is based on FluidCrystal® topical bioadhesive. Read more about episil® on page 40.

# FluidCrystal® NANOPARTICLES

FluidCrystal<sup>®</sup> nanoparticles can resolve the issue of bioavailability for water and fat-soluble active pharmaceutical ingredients sensitive for biodegradation, e.g. peptides and proteins.



### **KEY ATTRIBUTES**

- Prolonged systemic active pharma ceutical ingredient circulation (parenteral administration)
- Enhanced delivery over mucosal and skin surfaces (topical administration)
- Protection of sensitive therapeutic substances
- High solubilization capacity for active ingredients
- Good systemic and local tolerability demonstrated in pre-clinical and clinical trials

FluidCrystal<sup>®</sup> nanoparticles are usually water based and comprise a stable emulsion of nanoparticles with a liquid crystalline structure. Products based on this technology are administered either parenterally via injections or as a liquid sprayed onto the skin or mucous membranes.



## CAM2038 PAIN

# An effective and potentially safer treatment of chronic pain

Chronic pain management is a difficult clinical challenge in medicine today, with limited treatment options available, a high unmet medical need and a risk of developing dependence. Weekly and monthly CAM2038 may deliver durable pain relief without the risks of tolerance development, dependence, abuse, diversion and overdose.

Chronic pain impacts the lives of one in five adults in Europe and the US – and a staggering 1.5 billion people globally.<sup>1</sup> Lower back pain, arthritis, headache, and face and jaw pain are the most common types of chronic pain. Moderate pain may prevent a person from participating in their daily activities, while severe pain typically stops a person from participating in those activities and prompts them to exhibit pain-avoidance behavior. With associated societal costs estimated to 560-635 billion dollar a year,<sup>2</sup> chronic pain represents a significant global health problem.

### **OPIOID TREATMENT**

Opioids are used for the management of moderate to severe acute and chronic pain that cannot be adequately controlled by other pain medications. However, use of opioid analgesics may result in dependence, overdose and death, which is drastically illustrated by the ongoing global opioid crisis. Furthermore, patients tend to become tolerant to full agonist opioids, requiring ever increasing doses, which ultimately can result in addiction, as well as risks of opioid prescriptions being diverted onto the black market, misused and exposed to children and teenagers.

> Global market for chronic pain USD 23.3 billion<sup>6</sup>



RUS ANNUAL REPORT

#### Registration program for CAM2038 in chronic pain targets opioid experienced patients

Completion of long-term safety extension study

> Scientific advice/ pre-MAA meetings

MAA submissions to EMA and TGA expected first half of 2020

# Focus on high risk, high need opioid experienced patients

Buprenorphine is an effective opioid analgesic at least 30 times more potent than morphine. However, as a partial agonist, it exhibits a maximal ceiling on some opioid effects which are less than those of full agonists like morphine and heroin.<sup>3</sup> Importantly, buprenorphine has a ceiling effect on respiratory depression and therefor remains one of the safest opioids. In addition, buprenorphine has a less significant effect on gastrointestinal activity, resulting in less constipation compared to full opioid receptor agonists.<sup>4</sup>

Buprenorphine is currently available in short-acting injectable formulations to treat

moderate to severe acute pain and transdermal patches for chronic pain. The patches provide stable but relatively low plasma concentrations of buprenorphine over a period no longer than 7 days. The low buprenorphine plasma concentrations result in inadequate analgesic effect for patients requiring high opioid levels.

#### CAM2038: DEVELOPMENT OF SAFER AND MORE EFFECTIVE TREATMENT OF CHRONIC PAIN

Weekly and monthly CAM2038 have been evaluated in a Phase 3 efficacy trial in opioid experienced patients with chronic low-back pain. The trial successfully met its primary efficacy endpoint of average pain intensity (API) demonstrating that patients with chronic low-back pain receiving treatment with CAM2038 experienced a statistically superior reduction in pain compared with patients treated with placebo (p<0.001). Furthermore, the key secondary endpoint of worst pain intensity also demonstrated statistically significant reduction (p<0.001).

# "Limited treatment options available,,

The development focus for CAM2038 in chronic pain has been on transferring patients treated with opioids at morphinedose equivalents of 40 mg/day or more to long-acting buprenorphine. CAM2038 may offer this patient group a safer treatment option as it is administered as a weekly or monthly subcutaneous injection by a health-

# "Treatment adherence may be improved,,

care professional, so treatment adherence may be improved and the known risks of tolerance development, dependence, misuse, diversion, and overdose are reduced.

The long-term safety of CAM2038 is currently being evaluated in a 52-week open label extension study, in which patients are either continuing from the randomized efficacy part of the Phase 3 study or are included directly in the open label extension phase. Marketing authorization application submissions are currently planned for the first half of 2020.

In the US, CAM2038 for the treatment of moderate to severe chronic pain in opioidtolerant patients is being developed in collaboration with Braeburn who has exclusive rights to North America. ESTIMATED TO AFFECT **1000** MILLION AMERICANS<sup>1</sup> **750** MILLION EUROPEANS<sup>2</sup>





References: 1. Global Industry Analysts, Inc. Report, 2011. 2. Gaskin D, Richard P. The Journal of Pain, 2012; 13 (8): 715–724. 3. Dahan A, et al. Br J Anaesth. 2005;94:825-34. 4. Tompkins DA, et al. J Pharmacol Exp Ther. 2014;348(2):217-26. 5. Pain Practice 2014, 14, 79–94. 6. Disease Landscape and Forecast Chronic Pain, Decision Resources 2015.

# CAM2029 for the treatment of acromegaly and neuroendocrine tumors

Acromegaly and neuroendocrine tumors are rare, chronic diseases that impact quality of life and cause premature death. CAM2029 has the potential to simplify treatment and improve treatment efficacy.

Acromegaly is a hormonal disorder, in which the pituitary gland produces excessive amounts of growth hormone. Often caused by benign tumors on the pituitary, acromegaly can lead to type 2 diabetes, high blood pressure, arthritis and increased risk of cardiovascular disease. Left untreated, acromegaly leads to serious illness and reduces life expectancy.

Neuroendocrine tumors (NET) are a group of rare tumors, originating from regulatory hormone-producing neuroendocrine cells, that can arise throughout the body. Like acromegaly, NET are frequently diagnosed late in the disease progression. Most NET are malignant and have often spread to other parts of the body by the time of diagnosis.

Dr Diego Ferone, Assistant Professor at the Department of Internal Medicine & Medical Specialties at the University of Genova and secretary of the Italian Endocrine Society, is involved in studies on the physiopathology and treatment of pituitary and neuroendocrine tumors and acromegaly. "I work in a large hospital unit both as a practicing physician and researcher. These are very complex diseases with major challenges in both diagnosis and treatment," he explains.

Acromegaly and NET are rare diseases, with an estimated prevalence of 8 per 100,000<sup>1-3</sup> and 54 per 100,000<sup>4</sup>, respectively. However, incidence rates in NET have increased in recent years and there is an unmet medical need for a treatment that is more convenient and less painful for patients with these chronic diseases.

#### **CURRENT THERAPEUTIC OPTIONS**

The most rapid and effective option for complete cure of acromegaly and NET is surgery. However, for the majority of patients surgery is not possible and for those the somatostatin analogues (SSAs), such as octreotide and lanreotide, are the standard medical therapy. These stop the body from producing too much growth hormone, thereby reducing





The annual growth of the SSA market has increased by a CAGR of 13 percent over the last 20 years Dr Ferone explains the limitations of current treatments, and that "patients are intolerant to medical treatment because of the mode of administration of current medications and so adherence is poor".

#### CAM2029 CAN SIMPLIFY AND IMPROVE TREATMENT

CAM2029 is a long-acting octreotide solution formulated with Camurus' FluidCrystal® injection depot technology, for the treatment of acromegaly and NET.

CAM2029 is being developed as a prefilled syringe, ready-to-use and not requiring reconstitution prior to subcutaneous administration. The formulation is also compatible with autoinjectors which could further enhance the ease of administration. Furthermore, CAM2029 is administered subcutaneously with a thinner needle than currently marketed therapies, which may lead to less painful injections.

# "Patients find subcutaneous administration so much more acceptable,,

"CAM2029 is very interesting because it is based on a known active ingredient which we already use, but delivered in a different way," explains Dr Ferone. "Adherence and tolerance to treatment may improve, because patients find subcutaneous administration so much more acceptable. The possibility of self-injection is an important achievement, which puts

#### CAM2029 – KEY TARGET ATTRIBUTES

- Subcutaneous long-acting octreotide
- Fast onset and one month duration of therapeutic plasma-levels
- Provided ready-for-use in prefilled syringes for easy self-administration
- Compatible with autoinjectors
- High bioavailability 500% higher than Sandostatin<sup>®</sup> LAR<sup>®</sup>, with potential for better treatment effects in some patients





### a totally different perspective on treatment for patients." "In fact, patients in clinical trials who have experienced treatment with CAM2029 have expressed their willingness to continue on this treatment – this underlines the acceptability and tolerance for a treatment that can be self-administered at home," he continues. CAM2029 for the treatment of acromegaly has been granted orphan designation by the European Commission. This status is given to

#### **IGF-1** concentrations



## Octreotide plasma concentrations

"CAM2029 has the

potential to simplify

treatment efficacy.

severity of symptoms and slowing disease

progression. Current long-acting SSAs are

administered either via an intra-muscular or

deep subcutaneous injection once a month.

These medications must be refrigerated, and

so require conditioning to room temperature

before administration. They also have a com-

administration by a specially trained healthcare

plex reconstitution procedure and/or a long

injection time with a relatively thick needle.

These long-acting SSAs therefore require

professional - and the treatment burden for

patients is significant.

treatment and improve



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# "May improve treatment efficacy for patients not responding satisfactorily to current therapies,,

medicines of significant benefit to patients with rare diseases and provides several benefits during product development, such as scientific advice and protocol assistance, and additional market exclusivity once the medicine is approved. The pharmacokinetics, safety and efficacy of CAM2029 have been documented in Phase 1 and 2 clinical trials. Following administration, CAM2029 has been shown to give rapid and long-acting release of octreotide to therapeutic concentrations – and has 500% higher bioavailability of octreotide compared to the market-leading product (Sandostatin<sup>®</sup> LAR<sup>®</sup>)<sup>5</sup>, which may improve treatment efficacy for patients not responding satisfactorily to current therapies.

The results of the Phase 2 trial demonstrated that CAM2029 provides well maintained or improved biochemical control in patients with acromegaly and symptom control in patients with functioning NET after switching from Sandostatin<sup>®</sup> LAR<sup>®</sup> (see figure).<sup>7</sup>

"CAM2029 has a much more favorable profile than current medications, and in some cases we have seen an improvement in treatment efficacy, which is extremely interesting," Dr Ferone says.

# "Planning a phase 3 trial for CAM2029 for the treatment of acromegaly in mid-2019,,

# FURTHER DEVELOPMENT AND POTENTIAL OF CAM2029

Camurus is planning a Phase 3 trial for CAM2029 for the treatment of acromegaly in mid-2019, to assess the superiority of CAM2029 compared to placebo in maintaining biochemical response. The long-term safety, pharmacokinetics and patient satisfaction for CAM2029 will also be evaluated. In addition, Phase 3 trials for CAM2029 for the treatment of patients with NET and also other potential indications are being planned. In July 2018, Camurus regained the global development and commercialization rights to CAM2029 and related assets from Novartis.

Novartis had been responsible for the development of CAM2029 since October 2013. The company returned the rights to Camurus due to commercial reprioritization among its different programs. According to Novartis, this decision did not reflect a change in the view of the development of CAM2029.



Time average IGF-1 concentration for acromegaly patients treated with Sandostatin<sup>®</sup> LAR® and switched to CAM2029 (left). Average number of symptoms per day for NET patients treated with Sandostatin<sup>®</sup> LAR<sup>®</sup> and switched to CAM2029 (right)

References: 1. Lavrentaki A, et al. Pituitary. 2017; 20(1):4-9. 2. Burton T, et al. Pituitary. 2016;19(3):262-7.
3. Broder MS, et al. Endocrine practice : official journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists. 2016;22(11):1327-35. 4. Dasari A, et al. JAMA Oncol. 2017;3(19):1335-42. 5. Tiberg F, et al. Br J Clin Pharmacol. 2015;80:460-72. 6. GlobalData 2019. 7. Analysis of data from Pavel M, et al. Cancer Chemotherapy and Pharmacology. 2019; 83:375–385.

#### CAM2029 scientific publication:

Pavel M, et al. Cancer Chemotherapy and Pharmacology. 2019; 83:375–385



## CAM2043 PAH

# CAM2043 for the treatment of pulmonary arterial hypertension

Pulmonary arterial hypertension is progressive, life-threatening, and commonly diagnosed only when the disease is at an advanced stage. CAM2043 has been designed to overcome the drawbacks of current therapies, including the burden of complicated and potentially painful administration and the associated risks of infection.

"Without therapeutic intervention, median overall survival is less than 3 years,

Pulmonary arterial hypertension (PAH) is caused by thickening of the walls of the pulmonary arteries, thereby narrowing the passage for blood to pass through with increased vascular blood pressure and resistance as result. This may in turn lead to right ventricular failure and premature death. The early symptoms of PAH – such as shortness of breath, dizziness and fatigue – are often mild and similar to many other conditions, such as cardiovascular and respiratory diseases. As a result, time from symptom onset to disease diagnosis is on average more than 2 years and without therapeutic intervention, median overall survival is less than 3 years from diagnosis.

The cause of PAH has been linked to several factors and may develop due to imbalances in the endothelial, nitric oxide and prostacyclin pathways. With a prevalence of 6.6 to 26 per million adults in developed countries, it is estimated that about 35,000 patients within the EU have PAH.<sup>1</sup>

# CURRENT THERAPIES HAVE DRAWBACKS

PAH is incurable but specialist treatments are available which reduce symptoms and slow disease progression.

Prostanoids are the most potent treatment for PAH. Treprostinil, a prostacyclin analogue,

ESTIMATED NUMBER CURRENTLY DIAGNOSED PATIENTS WITH PAH' **24,000** IN THE US **35,000** IN EU



"CAM2043 – a single weekly dose which can be self-administered by patients,,

has been used to treat PAH since its approval by the US FDA in 2002. It works by dilating the narrowed vessels in the lungs, so that more blood can flow through, resulting in a reduction of the pulmonary arterial blood pressure. This leads to improved oxygen transportation, increased cardiac output and, over time, less strain on the heart.

Treprostinil is available as subcutaneous and intravenous infusions, and as an inhalation and oral product. The most effective treatment has been shown to be infusion products, but, as treprostinil only lasts for a few minutes

#### **Treprostinil Product Sales**<sup>2</sup>

Million USD





in the bloodstream, it must be continuously pumped 24 hours a day into the body using an external catheter or pump. This makes administration complicated, often painfully intolerable and burdensome for the patient. In addition, the administration procedures are associated with risks of serious bloodstream infections. This type of treatment is therefore primarily used in patients with more severe PAH. Oral and inhaled treprostinil are used to treat less severe cases of PAH. But factors such as poor bioavailability and variability of the

# "Reducing the risk of infusion-related infections and pain,

active ingredient, complex dosing schedules (inhaled treprostinil may be taken 6-9 times a day) and handling of the inhalation device, are limiting their use.



Repeated dose pharmacokinetic profiles<sup>3</sup>

#### CAM2043 - A NEW TREATMENT FOR PAH

Based on Camurus' proprietary FluidCrystal® technology, CAM2043 is a long-acting treprostinil formulation for subcutaneous administration via a pre-filled syringe, currently in development for the treatment of PAH.

CAM2043 is patient-friendly, offering convenience in terms of a single weekly dose which can be self-administered by patients at home, helping to alleviate their treatment burden by also reducing the risk of infusionrelated infections and pain, and eliminating the need to carry an external pump.

# "Phase 2 trial expected to start in the second half of 2019,,

CAM2043 has a favorable pharmacokinetic profile, providing a steady release of treprostinil with a profile suitable for weekly or less frequent dosing. CAM2043 is being developed as a small dose volume, allowing dose titration for efficacy and tolerability. CAM2043 therefore has the potential to be a treatment alternative not only to infusion products but also oral and inhaled products for patients over the full range of disease severities in PAH.

#### **CLINICAL DEVELOPMENT**

The pharmacokinetics and safety of CAM2043 have been evaluated in a Phase 1 trial in 60 healthy subjects. The pharmacokinetic profile met the target specification for once-weekly dosing. The tolerability of CAM2043 was

#### POTENTIAL BENEFITS OF CAM2043 IN PAH

- Possibility for earlier introduction of parenteral treprostinil treatment
- Steady plasma profiles may improve efficacy versus oral and inhaled prostacyclin products
- Improved convenience for patients with no need for infusion pumps.
- No risk of infusion-related blood stream infections
- Enhanced quality of life for patients

generally acceptable and injection site reactions were tolerable and resolved over time.

Camurus is currently preparing a flexibledose Phase 2 trial of CAM2043 in patients with PAH. The trial, which is expected to start in the second half of 2019, will assess efficacy, pharmacokinetics, safety and tolerability of CAM2043.

References: 1. GlobalData EpiCast Report:
Pulmonary Arterial Hypertension, 2017.
2. GlobalData, 2019. 3. Camurus data on file 2018.



# **Partnerships**

Our clinical pipeline contains innovative formulations developed in-house, based on the FluidCrystal<sup>®</sup> injection technology, for treatment of severe and chronic conditions. To maximize the value creation, we are retaining the rights to product and candidates in opioid dependence and other specialty markets, while other products or development programs are available for out-licensing to global or regional partners.



overall development capacity and is an important source of future revenues in the form of potential development and commercialization milestones and royalties on sales. Camurus is currently performing several feasibility studies assessing partner drug compounds formulated with FluidCrystal® technology.



# **Partnerships**

**b** braeburn

Braeburn holds the rights to Brixadi<sup>™</sup> (CAM2038) for treatment of opioid dependence in North America and optional rights to China, Japan, Korea and Taiwan.

Braeburn also holds the North American rights to CAM2038 for treatment of chronic pain (Phase 3), and CAM2048/58 for treatment of postoperative pain and PONV (Phase 2).

MEDISON Medison has exclusive rights to CAM2038 in Israel. Expected launch in Q1 2020. rhythm

Rhythm Pharmaceuticals holds the global rights to CAM4072, a once-weekly formulation of setmelanotide for treatment of genetic obesity (Phase 2).

Solasia

Solasia has exclusive distribution rights to episil® in Japan and China. episil® was launched in Japan in May 2018 by Solasia's partner Meiji Seika and registered in China in February 2019 with expected launch in mid-2019.

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#### CAM2032

The well-established hormone therapies for prostate cancer, based on gonadotropin releasing hormone agonists such as leuprolide, aim to reduce testosterone levels and thereby impede the growth of cancer cells. CAM2032 is a long-acting subcutaneous leuprolide depot for the treatment of prostate cancer. Based on our FluidCrystal® injection depot technology, CAM2032 is being developed for self-administration with a prefilled syringe as a small dose volume which does not require any reconstitution or temperature conditioning. The pharmacokinetic, pharmacodynamic, and safety profiles following repeated administration of CAM2032 in prostate cancer patients have been evaluated with positive results in two Phase 2 trials. Additional potential indications for CAM2032 include precocious puberty and endometriosis.

#### CAM2047

Granisetron is a 5-HT3 receptor antagonist used for the treatment of acute chemotherapyinduced nausea and vomiting (CINV), a side effect experienced by the majority of cancer patients undergoing chemotherapy treatment.

CAM2047 is being developed as a Fluid-Crystal®-based long-acting subcutaneous depot providing prolonged exposure of granisetron for the treatment of acute as well as delayed CINV. Results from a Phase 1 trial demonstrated that CAM2047 is well tolerated locally and systemically, with pharmacokinetic profiles meeting the target specifications.

#### Mean granisetron plasma concentration after single doses of CAM2047 (Phase 1 data)



#### CAM2048 AND CAM2058

Post-operative pain and post-operative nausea and vomiting are common adverse effects of surgery but many patients receive inadequate pain therapy. Opioid therapy is among the most effective treatments for postoperative pain, and buprenorphine offers a superior safety profile compared with full opioid receptor agonists.<sup>1</sup>

CAM2048 is a buprenorphine depot formulation based on the FluidCrystal® technology providing rapid onset of action and sustained plasma levels of buprenorphine for the treatment of post-operative pain. CAM2058 is a unique combination of buprenorphine and granisetron, which not only addresses postoperative pain, but also the symptoms of nausea and vomiting that often co-occur with the pain. CAM2048 and CAM2058 are being developed in collaboration with Braeburn and have been evaluated in a Phase 1 trial with positive results.

#### CAM4071

CAM4071 is a long-acting formulation of pasireotide based on our FluidCrystal® injection depot technology, which has been investigated in a completed Phase 1 trial. The results from the study were presented at the European Congress of Endocrinology in Barcelona in May 2018.

#### CAM4072

CAM4072 is a weekly formulation of the MC4 agonist setmelanotide based on our Fluid-Crystal® technology and is being developed by our partner Rhythm Pharmaceuticals for the treatment of rare genetic obesity disorders. Results from Phase 2 clinical trials of setmelanotide demonstrated significant reductions in hyperphagia and body weight for patients with POMC and LepR deficiency obesity. Phase 3 clinical trials are ongoing for each of these indications while the long -acting formulation of setmelanotide, CAM4072, is being developed in parallel. Rhythm has successfully completed Phase 1 studies of single and repeat doses of CAM4072 and continued clinical studies of CAM4072 in patients with rare genetic obesity disorders are currently being prepared.

References: Khanna IK, Pillarisetti S. J Pain Res. 2015;8:859-75

## DEVELOPMENT MODEL & EARLY R&D PROJECTS

# Unique and validated technology platform – FluidCrystal®

Camurus' development model and pipeline are based on identifying and developing innovative treatments using its FluidCrystal<sup>®</sup> technologies to help patients with serious and chronic diseases live better lives.

FluidCrystal<sup>®</sup> is Camurus' unique patent-protected technology that, when combined with marketed active pharmaceutical compounds or new chemical entities, creates innovative and convenient treatments. The technology offers an effective barrier against generics and can prolong a product's life cycle.

#### **NEW PIPELINE PROJECTS**

Camurus continuously assesses new opportunities where its FluidCrystal<sup>®</sup> technology and expertise can be used to develop innovative and improved medicines. The Company's new pipeline projects are generated in-house as well as in partnership with international biotech and pharmaceutical companies.

Every new product candidate is carefully evaluated with a focus on five key criteria (see figure):

- 1. Clear unmet medical needs
- 2. Technology match
- 3. Streamlined clinical development
- 4. Market exclusivity and patent protection
- 5. Market potential

If these criteria are met, the product candidate is evaluated in preclinical studies against the target product profile in terms of drug loading, manufacture, stability and drug release in vitro and in vivo.

#### STREAMLINED DEVELOPMENT

Following a positive preclinical evaluation, planning and initiation of the clinical development program and technology transfer for manufacturing of the product candidate begins. New products are usually protected by existing technology patents and supplemented by additional product-specific patent applications. An initial freedom-to-operate analysis is normally conducted when the product candidate's properties have been identified; preliminary market analyses take place early in the project and are refined during clinical development.

Using established pharmaceutical compounds with welldocumented clinical efficacy and safety profiles streamlines development and facilitates the use of abbreviated regulatory pathways such as the 505(b)(2) process in the US, and hybrid application in the EU. Time-consuming and costly development phases can therefore be shortened substantially, and the risks associated with clinical development are significantly reduced.





Time and cost-effective development of innovative and differentiated medications - combining clinically documented APIs with leading and proven technologies

#### IMPROVED TREATMENT OUTCOMES

The method of administration of existing medications may result in suboptimal exposure profiles and poor treatment compliance, which negatively affect treatment outcomes. FluidCrystal® technologies are designed to address these limitations and improve therapeutic performance and treatment adherence, thereby improving treatment outcomes, benefiting patients and the healthcare system.

#### Unmet medical need

- Patients and prescribers in focus
- Better treatment outcomes; convenience, compliance, healthcare cost savings
- **Technology match**
- Value creation by use of FluidCrystal<sup>®</sup> technology platforms
- Technology fit (solubility, stability, and *in vitro* and *in vivo* release)

#### Attractive market

- Potential for pricing and reimbursement
- Concentrated customer base, prescribers
- Large market potential
- Commercial synergies

Expeditious clinical development and market registration

- 505(b)(2) registration pathway
- Accelerated approvals

#### **Patent protection**

- Existing platform patents
- Product patent opportunities

Key criteria for evaluation and selection of new product candidates

## Active intellectual property strategy

Camurus has an active patent strategy covering all major geographic markets, including the US, EU5, Japan and China. Our patent portfolio covers our technology platforms as well as our specific product candidates and currently consists of about 330 issued patents.

In addition, we are actively prosecuting about 135 pending patent applications worldwide and we are continuously filing new patent applications extending the protection of the technology and products. The duration of our patents for our FluidCrystal® technology and our product candidates vary, depending on the aspect, application and geography. The earliest patent expirations are expected in 2025-27, while several patents and patent applications extend until 2033 and longer. We also have extensive know-how of all critical aspects of our formulation technology, including the components, manufacturing, devices, packaging and stability. This continues to grow and creates new IP opportunities as we and our partners further develop our different product candidates and obtain market approvals.

Products marketed under the brand name Buvidal® are protected by issued patents or optional provisional patent protection. Aspects of the marketed Buvidal® products are currently covered by 30 issued patents, including patents in AUS, EU5 and US. EMPLOYEES



#### Personnel distribution





# Highly-skilled and creative employees are the core of our operations

At Camurus, we value diversity, equality and responsibility. We are an agile organization with a shared ambition for growth and an innovative and collaborative culture. During 2018 the number of employees increased as we continued to build our European and Australian commercial organization. With the continued development of the organization, Camurus is dedicated to anchoring our unique culture across new geographies and markets to support continued success. Our operations are conducted from modern, state of the art laboratories and offices at our headquarters in Lund, Sweden.



#### ENTREPRENEURIAL COMPANY CULTURE

Camurus is a workplace where all employees' knowledge, passion, creativity, and skills are key to success. During 2018 we have welcomed new employees in Sweden, Germany, UK, France and Australia. Approximately half of the employees work in research and development and Technical Operations, many of which hold advanced university degrees. The other half work within the commercial organisation and HQ support functions. Working in dynamic teams, employees strengthen our innovative corporate culture through collaboration and knowledge sharing. Active transfer of knowledge throughout our international network and through intense collaborations with academia and industrial partners supports employee development. And so does the continued expansion of our organization, which offers employees a unique opportunity to develop their expertise, leadership and possibility to make a difference, every day.





**Daria Bove** Brand Manager

I work as Brand Manager and in my role, I am primarily responsible for the development, maintenance and implementation of global Buvidal® product branding, marketing toolkits and activities in accordance with the defined strategies. Right now, Camurus is in the midst of an exciting transition from being an R&D-based company to becoming a commercial one, and I am looking forward to seeing and taking an active part in this development and transformation.

At Camurus, I find it inspiring and motivating to have colleagues who are engaged, dedicated and ready to go the extra mile to reach not only their personal goals and objectives but also work as a team.



Ruari Macdonald Business Unit Head Australia

I am the Business Unit Head in Australia and I've been given the responsibility to build the commercial team and bring Buvidal® to the patients and physicians of Australia. It is an amazing opportunity to be part of an organisation that has developed a game-changing medication in an area of medicine that I'm very passionate about, and also an opportunity to work with fantastic people.

Camurus' culture is dynamic, agile and people focused, and everyone is committed to working together to solve challenges. I know that I have the support of all my colleagues in building Camurus' future success.



Patient quote

MEDICAL DEVICE - EPISIL®

## episil<sup>®</sup> oral liquid – for effective oral pain relief

Formulated using Camurus' FluidCrystal<sup>®</sup> topical bioadhesive technology, episil<sup>®</sup> provides fast pain relief and protection of sore and inflamed mucosal surfaces.

#### **ORAL PAIN AND CANCER THERAPIES**

Oral mucositis is a painful inflammation and ulceration of the oral mucosa. It is a common side effect of radiotherapy and chemotherapy affecting the majority of head and neck cancer patients who receive radiotherapy, and 30-75% of patients undergoing chemotherapy for other types of cancer, including breast cancer.1 In severe cases, oral mucositis may restrict primary cancer treatment, requiring a reduction in dosage or postponement of therapy. Advanced stages of oral mucositis can be extremely painful, preventing the patient from eating and leading to hospitalization for rehydration, nutrient supply and opioid analgesia. Destruction of the protective oral mucosa also leaves patients with an increased risk of infection.2

#### **EPISIL® FOR ORAL PAIN RELIEF**

episil<sup>®</sup> is applied as a liquid which transforms into a thin bioadhesive film when in contact with the buccal membrane, alleviating pain by protecting mucous membranes. In clinical trials, episil® has been proven to reduce pain in the mouth by up to 40%, with a long-lasting effect of up to 8 hours.<sup>3,4</sup> episil® is CE-marked and registered as a medical device class 1 in Europe and under a 510k clearance for medical device in the US. episil® is currently being marketed in Europe, the US, United Arab Emirates and Japan. Recently, episil® was also approved in China by the National Medical Products Administration (NMPA, formerly CFDA).

Sales and distribution are conducted via in-house marketing in Sweden, Denmark, Norway, and the UK, and by a number of distribution partners in various countries. In 2018, episil® was launched in Japan 2018 by Camurus' partner Solasia and is sold through Meiji Seika Pharma. Furthermore, a distribution agreement was signed with BTC Health Ltd for the exclusive rights to distribute episil oral liquid in Australia and New Zealand where episil® was approved in February 2019 with an estimated launch in mid-2019..



Japanese product packaging

#### EPISIL® KEY ATTRIBUTES

- Rapid pain relief within 5 minutes
- Effective oral pain relief lasting up to 8 hours
- Convenient, ready-to-use, pocket-sized device
- Food and drinks can be consumed 5 minutes after application

**Reference 1**. Carulli et al, Hematol Rep. 2013 Jan 25; 5(1): 21–25. **2**. Al-Ansari S, et al. Curr Oral Health Rep. 2015;2:202-11. **3**. Tiberg F, et al. Support Care Cancer. 2009;17:918. **4**. Cheng Y, et al. OncoTargets and Therapy. 2018:11:8555-8564.



# Driving business success through sustainable development

Working towards sustainable results with our social and environmental actions is an integral aspect of Camurus' Code of Conduct and the way we operate. We believe that living up to our responsibilities will ensure the long-term success of the Company and thereby benefit the patient communities we serve.

In 2015, leaders from 193 countries of the world came together and created the United Nations Sustainable Development Goals (SDGs). These 17 Goals aim to rid the world of poverty and hunger and reduce the effects of climate change by 2030.

At Camurus, we are playing our part towards achieving the third SDG, to "Ensure healthy lives and promote well-being for all at all ages", which includes making sure everyone has health coverage and access to safe and effective medicines. Our mission is to improve the lives of patients suffering from serious and chronic diseases by providing innovative treatment solutions. Furthermore, a target of the third SDG is to strengthen the prevention and treatment of substance abuse. Our focus on long-acting treatment options for opioid dependence can make a significant contribution towards this goal. Sustainable development is only possible if we continue to embrace our social and environmental responsibilities, and in so doing help to ensure the long-term health of people and our planet.

#### SOCIAL RESPONSIBILITY

Social responsibility at Camurus focuses on three main areas: employee development and wellbeing, patient safety and business ethics.

## Employee development and wellbeing

At Camurus, our single greatest asset is our employees. We value diversity, equality and responsibility. It is employees' knowledge, passion, creativity and skills which drive our success and build our innovative corporate culture.

During 2018 the number of our employees increased as we continued to build our Euro-

pean and Australian commercial teams. With the continued development of the organization, Camurus is dedicated to anchoring our unique culture across new regions and markets and providing a secure and safe workplace, opportunities for development and a positive working environment. Guidelines and procedures have been implemented to integrate health and safety aspects in all business activities, and to prevent employees from being exposed to unnecessary risks.

#### Patient safety

Patient safety will always remain our highest priority. We adhere to our internal guidelines and procedures, which have been implemented to protect patient safety and to ensure the high quality of products. Furthermore, we follow all relevant laws and regulations in our research and development, manufacture, storage and distribution activities, including the disclosure of information regarding the safety of our pharmaceutical products. We report any side effects related to compounds in clinical development as required by relevant laws and regulations. We track and monitor products already on the market for side effects and new and unexpected safety signals and notifying regulators about relevant data in accordance with applicable regulations.

#### **Business ethics**

We are committed to upholding the highest standards of integrity and honesty. We operate within a strictly regulated industry, where government bodies routinely demand information through audits, evaluations and inspections. We adhere to all relevant laws and guidelines with regard to all of our interactions with regulatory bodies and healthcare professionals. We utilize the services of healthcare professionals or organizations when there is a justifiable need. Compensation, if relevant, is in line with local legislation.

Clinical research to evaluate the safety and efficacy of medicines is a necessary component of pharmaceutical development. We are committed to protecting the patients and healthy volunteers who participate in our clinical trials, upholding the highest ethical, scientific, and clinical standards in all our research, and communicating clinical trial results in a timely, accurate and transparent way. All data from clinical research is registered, processed and stored in a manner that facilitates thorough reporting, interpretation and verification. We are committed to providing accurate and non-misleading information about our products. The Company's Code of Conduct guides our efforts against corruption and bribery.

Our suppliers play an important role in our research, development and pharmaceutical sales. We select our suppliers based on objective criteria with the expectation that they act in a manner that corresponds to our commitment to adhering to relevant laws and ethical business practices.

#### **ENVIRONMENTAL RESPONSIBILITY**

We strive to continually reduce waste and energy consumption, and to minimize the environmental impact of our research and development work and products. Environmentally friendly ingredients and transportation are chosen whenever possible, and regional supply chains are established wherever practicable. Furthermore, we expect our suppliers to strive towards reducing their environmental footprint.

To read our Code of Conduct, visit camurus.com

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## **Share development**

Camurus' share is listed on Nasdaq Stockholm Mid Cap list under the ticker CAMX. At the end of 2018, the closing price of Camurus' share was SEK 66.90.

The stock listing in December 2015 was a crucial step in the strategic move to make Camurus a long-term profitable pharmaceutical company. A well-organized in-house marketing and sales organization is now being established to promote medical products within our commercial focus of specialty pharmaceuticals. The successful listing on the stock exchange enables financing of the expansion of the Company's project portfolio and the advancement of early stage projects to clinical development, and for Buvidal® prolonged-release buprenorphine, all the way to market.

#### SHARE PRICE TREND

Camurus' shares decreased by 52 percent during the year, and the closing price on December 28, 2018 of SEK 66.90. The Nasdaq Stockholm 30 index (OMXS30) decreased by 11 percent during the same period. The highest price paid for the Camurus share was SEK 147.80 (January 8, 2018) and the lowest was SEK 66.80 (December 27, 2018). At the end of the year, market capitalization was MSEK 2,570.

#### **DIRECTED SHARE ISSUE**

In June 2018, the Company completed a directed share issue of 1.1 million shares, raising proceeds of approximately SEK 102 million before issuance cost. The Issue entailed a dilution of approximately 2.9 percent of the share capital and voting rights. Total number of shares after the Issue was 38,381,486.

#### SHARE DATA

On December 31, 2018, Camurus had 38,381,486 registered common shares, corresponding to 38,381,486 votes.

#### **OWNERSHIP STRUCTURE**

At the end of 2018, Camurus AB had 5,260 shareholders, of whom 452 comprised financial and institutional investors with holdings amounting to 83 percent of the share capital and votes, and 4,807 comprised private individuals with holding totalling 17 percent of the share capital and votes. Foreign shareholders accounted for 4.4 percent of the capital and votes. The ten largest shareholders accounted for 77 percent of the capital and votes.





### SHARE CAPITAL AND CAPITAL STRUCTURE

At the year's end, the share capital was SEK 959,537; distributed among 38,381,486 shares with a quota value of SEK 0.025. In accordance with the Articles of Association, the share capital shall comprise a minimum of SEK 500.000 and a maximum of SEK 2,000,000, divided among a minimum of 20,000,000 shares and a maximum of 80.000.000 shares. Camurus' Articles of Association contains a record day provision, and the Company's shares are registered with Euroclear Sweden AB who administer the Company's shareholder register and registers the shares of individuals and organizations. All shareholders are entitled to an equal share in the Company's profits and a percentage of the surplus in the event of liquidation.

#### **INCENTIVE PROGRAM**

Presently Camurus has three long-term incentive programs active. In accordance with a decision by the Annual General Meeting in May 2016, May 2017 and May 2018, subscription warrant programs for the Company's employees, has been introduced. The warrants are valued by an independent institute in accordance with the Black&Scholes model and were acquired by the participants at market value. As part of the program, the participants receive a three-piece stay-on bonus in the form of gross salary addition from the Company, equivalent to the amount paid by the participant for its subscription warrants. As the stay-on bonus is conditional on continued employment, costs including social security fee, are expensed over the vesting period and a liability is calculated at

each balance sheet date based on how much has been earned. Expenses are recognized as personnel expense in the income statements. All three programs vest in three years. In total they represent a total maximum of 1,625,632 shares, or 4.2 per cent of the total number of shares in the Company. For more information, see Note 24. folio further and pursuing commercial operations, and the available financial resources will be utilized to finance this strategy. Consequently, the Board of Directors does not intend to propose any dividend to shareholders until Camurus generates sustainable profitability. The Board of Directors proposes that the Annual General Meeting pass a resolution to not issue any dividends for the fiscal year.

## DIVIDEND POLICY AND PROPOSED DIVIDEND

In accordance with the dividend policy adopted by the Board of Directors, Camurus will continue to focus on its strategy of developing and expanding the Company's clinical project port-

#### **Ownership Distribution size classes as of 28 December 2018**

	Number of shareholders	Number of shares	% of capital	% of votes
1 - 500	3,843	600,262	1.56	1.56
501 - 1,000	622	526,285	1.37	1.37
1,001 - 5,000	573	1,345,619	3.51	3.51
5,001 - 10,000	83	615,096	1.6	1.6
10,001 - 15,000	39	470,474	1.23	1.23
15,001 - 20,000	20	347,195	0.9	0.9
20,001 -	80	34,476,555	89.83	89.83
Total	1,421	38,381,486	100.0	100.0

#### Shareholders as of 28 December 2018

	Numbers of shares	% of capital	% of votes
Sandberg Development AB	20,014,978	53.2	53.2
Gladiator	2,480,000	6.5	6.5
Tiberg, Fredrik	1,512,551	3.9	3.9
Catella Fondförvaltning	958,425	2.5	2.5
Fjärde AP-Fonden	896,116	2.3	2.3
Backahill Utveckling AB	877,193	2.3	2.3
Försäkringsbolaget Avanza Pension	712,729	1.9	1.9
Swedbank Robur fonder	706,456	1.8	1.8
Camurus Lipid Research Foundation	445,000	1.2	1.2
Enter Fonder	405,877	1.1	1.1
Other shareholders	8,972,161	23.4	23.4
	38,381,486	100.00	100.00

#### **Ownership Distribution as of 28 December 2018**

	% of votes	% of capital	Number of shareholders	Number of shares
Swedish Institutions	79.1	79.1	251	30,341,222
Foreign Institutions	3.5	3.5	202	1,334,774
Swedish private shareholders	16.6	16.6	4,768	6,364,200
Foreign private shareholders	0.9	0.9	39	341,290
	100.0	100.0	5,260	38,381,486

#### GLOSSARY

**505(b)(2)** US submission which contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use

**Acromegaly** A disorder caused by overproduction of growth hormones resulting in abnormal body growth

Agonist A drug or other substance that binds to and blocks a receptor and thereby stimulates the activity of the receptor

Analogue Similar molecular structure

Antagonist A drug or other substance that binds to and blocks a receptor without stimulating the activity of the receptor

API Active pharmaceutical ingredient

**Bioadhesive** A substance that is adhesive to biological surfaces

**Bioavailability** The degree and rate at which a substance (as a drug) is absorbed by the body

**Buprenorphine** Active ingredient that is strongly analgesic and that may be used for treatment of opioid dependence

**CE marking** CE marking of a product is used within the EU/EEA to show that the manufacturer or importer has followed the essential requirements regarding safety, health, performance etc. that are outlined in the applicable EU directives

**CINV** Chemotherapy-induced nausea and vomiting

**Clinical trials** Investigations performed in humans in order to study the properties of an investigational product

**EMA** European Medicines Agency, a decentralized agency of the EU, responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the EU

Endocrine diseases Diseases affecting the endocrine system, i.e. the body's production, secretion and response to hormones

**Endogenous** Produced within the body

Endometriosis A disease in which tissue that normally grows inside the uterus (endometrium) grows outside the uterus

**EU5** France, Germany, Italy, the United Kingdom and Spain

**FDA** Food and Drug Administration, the US food and drug authority

**Gauge** The dimension of the outer diameter of an injection needle. The gauge value decreases when the outer diameter increases

**Generic drug** A drug that has the same active ingredient as a brand name drug

GMP Good Manufacturing Practice GnRH Gonadotropin-Releasing Hormone

IGF-1 Insulin-like Growth Factor 1

*In vitro* Biological process that takes place outside a living cell or organism

**Incidence** Number of new cases per population at risk

**IND** Investigational New Drug, classification that is required for development of a new drug in the US

**Intramuscular injection** Injection of a drug in a muscle, e.g. the gluteal muscle

Intravenous injection Injection of a drug into a vein

LAIs Long-acting injectables

Leuprolide Active ingredient used for treatment of e.g. prostate cancer

**Lipids** Group of compounds consisting of fat or fat-like substances

MAA Marketing Authorisation Application, application for marketing authorization of a drug within the EU/ EAA

Milestone payment Economic compensation obtained within a framework of a partner program when a specific goal has been achieved

**Mortality** The incidence of death or number of deaths within a population

Naloxone Active ingredient used as an antidote to reverse respiratory depression after opioid or opiate overdoses

Nanoparticle Microscopic particle that behaves as a whole unit

NDA New Drug Application, application for approval from the FDA to commercialise a new drug in the US

**NET** Neuroendocrine tumors, a group of different kinds of hormone producing tumors

NEU Northern Europe

Octreotide Active ingredient used for treatment of e.g. cancer

**Oral mucositis** Inflammation of the oral mucosa that leads to ulcers and pain in the oral cavity

**Orphan drugs** Drugs intended to treat serious or life-threatening diseases that are so rare that pharmaceutical companies are reluctant to develop them for economic reasons

**PAH** Pulmonary arterial hypertension

**Peptide** Molecule consisting of a chain of amino acids

**Pharmacodynamics** The biochemical and physiological effects of a drug on the body

**Pharmacokinetics** The fate of a drug within the body (i.e. the absorption, distribution, metabolism and excretion)

**Pharmacovigilance** System for detection, assessment, understanding and prevention of adverse effects and other drug-related problems

**PONV** Postoperative nausea and vomiting

**Pre-clinical studies** Studies performed in model systems, i.e. not in humans

**Prevalence** The proportion of a population that is affected with a particular disease or condition

**Reconstitution** Preparation of a drug before administration, often addition of a diluent to a powder

**Setmelanotide** A MC4 receptor agonist peptide for the treatment of rare genetic disorders of obesity **SSA** Somatostatin Anologues, the standard for safe and effective medical therapy for acromegaly and symptom control in NETs

**Subcutaneous injection** Injection of a drug under the skin

Sublingual Under the tongue

**TGA** Therapeutic Goods Administration, the regulatory body for therapeutic goods (including medicines and medical devices) in Australia

**Toxicity** The degree to which a substance is toxic

**Transdermal** A route of administration wherein active ingredients are delivered across the skin for systemic distribution, e.g. via patches or ointments

**Viscosity** A measure of how viscous or thick a fluid is

WHO World Health Organization

## **Financial Reports**

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450

400

500

450

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#### **GROUP AND PARENT COMPANY**

The Board of Directors and Chief Executive Officer of Camurus AB (publ), with its registered office in Lund and company registration number 556667-9105, hereby present the Annual Report for the 2018 financial year, for the Group and the Parent Company. The annual accounts and the auditor's report are presented on pages 48-91. The earnings from the year's activities and the Parent Company's and the Group's financial position are presented in the director's report and the subsequent income statement and balance sheet, comprehensive income statement, statement of cash flow, statement of changes in equity as well as supplementary disclosures and notes, all of which collective-ly constitute the annual accounts.

#### **CAMURUS' OPERATIONS**

Camurus is a research-based pharmaceutical company committed to developing and commercialising innovative and differentiated pharmaceuticals for the treatment of serious and chronic conditions, where there are clear medical needs and the potential to significantly improve treatment. For the development of new drug candidates Camurus utilizes its unique proprietary formulation technology, FluidCrystal® injection depot. New proprietary medicines with improved properties and treatment outcomes are developed by combining the company's patented drug delivery technologies with active ingredients with documented safety and efficacy profiles. These are developed with significantly lower cost and risk, compared with the development of completely new pharmaceuticals. Camurus' development pipeline contains product candidates for the treatment of cancer and the side effects of cancer treatment, endocrine diseases, pain and addiction.

The company's shares are listed on Nasdaq Stockholm under the ticker "CAMX".

2018 was a breakthrough year for Camurus. In November Buvidal® weekly and monthly buprenorphine depots was approved for the treatment of opioid dependence – a severe and often chronic condition for which the need for new and improved treatments is enormous, by the European Commission and Australian Therapeutics, Goods, Administration. Strong results in the product pipeline, including positive Phase 3 results with CAM2038 for the treatment of chronic pain and phase 1 data for CAM2043 for the treatment of pulmonary arterial hypertension (PAH) were also delivered.

#### DEDICATED COMMERCIAL INFRASTRUCTURE IN PLACE IN THE EU AND AUSTRALIA

During 2018, Camurus took the strategically important step to grow from an R&D focused company to a science-led, international pharmaceutical company with its own marketing and sales organization in the EU and Australia. By the end of the year the organisation had grown from 71 to 94 employees, working from Lund in headquarters and regional offices in Cambridge, Mannheim, Paris and Sydney. Furthermore, employees are also present in Norway, Finland and Denmark. About half of the employees are directly involved with the launch of Buvidal<sup>®</sup> - working with everything from distribution, marketing and sales to medical information and education. Camurus has attracted many knowledgeable and highly engaged coworkers to the commercial teams and look forward to establish a strong position for Buvidal<sup>®</sup> on the global opioid dependence treatment market.

During the year commercial manufacturing of Buvidal® and an effective distribution network in Europe and Australia was establishing this enables on-site delivery of Buvidal® to most clinics in the Nordics, UK and Germany within 24 hours of an order being placed.

The advantageous properties of Buvidal® and the results from its comprehensive clinical program, including the randomized, double-blind, double-dummy, active controlled phase 3 study against standard daily treatment with sublingual buprenorphine/naloxone, was published in JAMA Internal Medicine in 2018.

Building on the strong evidence base established for Buvidal<sup>®</sup> continued during the year and two important new clinical studies was started:

- An open-label, clinical study of Buvidal® versus standard daily treatment with sublingual buprenorphine focusing on patient satisfaction, quality of life and health economic outcomes. The study was started in Australia in October 2018 and topline results are expected fourth quarter of 2019.
- A clinical study of Buvidal<sup>®</sup> and methadone treatments in the custodial setting, performed in seven correctional facilities in New South Wales (NSW), Australia. The study is sponsored by the NSW government and will include 120 opioid dependent patients, of which the Buvidal<sup>®</sup> patients will be followed for up to 1 year. Interim results are expected in the fourth quarter of 2019.

#### **TENTATIVE APPROVAL IN THE US**

Camurus' US partner Braeburn experienced unexpected setbacks during 2018. First, the Food and Drug Administration (FDA) issued a complete response letter requesting additional information for approval of Brixadi<sup>™</sup> (US tradename for Buvidal<sup>®</sup>). After diligently answering all questions and receiving a formal acceptance and new PDUFA date, Braeburn was issued a tentative approval of Brixadi<sup>™</sup> in December 2018. This meant that all regulatory requirements were fulfilled, but a final marketing approval of the monthly product was considered blocked by a market exclusivity granted by the FDA which extends to November 2020.

The decision was a disappointment, not only for Braeburn and Camurus, but also for physicians and patients, who had been anticipating the launch of Brixadi<sup>™</sup>. In view of the ongoing opioid epidemic in the US, the urgent need for new treatments, and the FDA's recent official statements and guidelines relating to the importance of depot medications for opioid dependence, the FDA decision to issue a tentative approval was confounding. The effect on Camurus was immediate, as the decision resulted in a delay of an expected MUSD 35 milestone payment. In view of this, Camurus' Board of Directors initiated a rights issue in February 2019 to raise gross proceeds of MSEK 403 to finance key activities according to the business plan and long-term strategy. The rights issue was successfully completed in March 2019.

Since the FDA decision, Braeburn has been working intensively to give US patients access as soon as possible to this new treatment which fulfils critical unmet medical needs. Braeburn recently initiated court proceedings to overturn the 3-year market exclusivity for Sublocade<sup>™</sup> and seeks immediate market approval of Brixadi<sup>™</sup> in the US.

#### POSITIVE PHASE 3 RESULTS FOR CAM2038 IN CHRONIC PAIN

The incidence of chronic pain in Europe and the US is about 20%. Depression, anxiety and opioid abuse are often linked to chronic pain, which makes it a major health issue with large negative consequences for both individuals and society. Treatment of patients with chronic pain and concomitant opioid misuse problems is particularly challenging. CAM2038 is designed for round-the-clock pain relief and an improved safety profile, as it minimizes the risks of developing opioid tolerance, addiction, misuse and overdose.

In September 2018, positive results from a pivotal phase 3 study of CAM2038 vs. placebo in patients with chronic low back pain were reported. The results show that CAM2038 provides clinically significant long-acting pain relief in patients who, prior to the study, were on daily medication with opioid painkillers.

The clinical development of CAM2038 in this indication continued during the year with a long-term safety study in a wider patient population. Topline results are expected in the second quarter of 2019. These will be followed by health authority discussions, before submitting applications for marketing authorization.

#### SIGNIFICANT OPPORTUNITIES WITH SUBCUTANEOUS OCTREOTIDE DEPOT

In July 2018, Camurus regained the exclusive development and commercialization rights to CAM2029 octreotide depot for the treatment of acromegaly and neuroendocrine tumors from Novartis. CAM2029 may be the first long-acting octreotide product for subcutaneous dosing and is designed for easy self-administration by patients. Clinical studies also show that CAM2029 provides more than 500% higher bioavailability of octreotide than the market leading product Sandostatin® LAR®.<sup>6</sup> This may contribute to improved efficacy in patients with acromegaly or neuroendocrine tumors.

During the second half of 2018, the phase 3 program design was finalized and preparations for the GMP manufacturing for upcoming phase 3 trials completed. A pivotal phase 3 study in acromegaly patients is planned to start mid-2019. New patents for CAM2029 in the US and Australia was granted, which strengthens the patent protection until 2032 or beyond.

#### PROMISING CLINICAL RESULTS FOR OUR TREPROSTINIL DEPOT

In the second quarter of 2018, positive results were reported from a Phase 1 study of single and repeated doses of CAM2043, treprostinil depot in development for the treatment of pulmonary arterial hypertension (PAH). Based on the pharmacokinetics and safety profile documented in the Phase 1 study, preparations for the continued clinical development of CAM2043. Started together with key opinion leaders and clinical experts. The goal is to start a phase 2 study in PAH patients in 2019.

## PROGRESS IN COLLABORATIONS AND PARTNERSHIPS

Partnership is an integral part of Camurus' business and has the potential for significant value generation from milestone payments and revenue from sales over the coming years. An example is the development of a weekly setmelanotide (CAM4072) for the treatment of genetic obesity disorders in collaboration with Rhythm Pharmaceuticals. CAM4072 has shown promising results in clinical studies, including positive pharmacokinetics and safety results in Phase 1. In 2018, the first development milestone was reached after completion of a successful Phase 1b. Thereafter, Rhythm has initiated a Phase 2 study of CAM4072 in patients with obesity. According to Rhythm, data for the weekly formulation are very promising and a decision to enter pivotal Phase 3 studies is expected in late 2019. Several other collaborations based on the proprietary FluidCrystal® technology have been started, including with biotech and large pharmaceutical companies. These may become public after signing of license agreements.

## CAMURUS WELL POSITIONED FOR GROWTH AND VALUE GENERATION

Apart from unforeseen events in Camurus' partner programs, 2018 was a strong year. The approvals of Buvidal® in the EU and Australia was a breakthrough for the company and a validation of the innovative FluidCrystal® technology. With a newly launched medicine, a dedicated marketing and sales organization, a broad and diversified development pipeline of innovative products in late-stage development, multiple partnerships, and a unique drug-delivery technology platform, Camurus is well positioned to become a leading player in opioid dependence – as well as in other disease areas where its products and technologies can make a real difference to patients.

Further information about ongoing development programs are found on pages 49-52.

#### **HIGHLIGHTS OF THE YEAR**

- Buvidal<sup>®</sup> approved by the European Commission as the first long-acting treatment for opioid dependence in the EU
- Buvidal<sup>®</sup> Weekly and Buvidal<sup>®</sup> Monthly approved in Australia as the first long-acting treatment of opioid dependence

- US FDA issues a tentative approval of Brixadi<sup>™</sup> for treatment of opioid use disorder
- Positive topline Phase 3 results for CAM2038 in opioid experienced patients with chronic low-back pain
- Camurus entered into license agreement with Medison for commercialization of CAM2038 in Israel
- Positive Phase 1 results announced for CAM2043
- Successful transfer of CAM2029 from Novartis to Camurus and finalized design of the pivotal Phase 3 program
- New patents issued for CAM2029 and CAM2038 in the US
- Clinical milestone achieved in collaboration with Rhythm Pharmaceuticals in the development of a weekly setmelanotide depot for the treatment of genetic obesity disorders
- episil oral liquid launched in Japan by Meiji Seika Pharma
- Directed share issue successfully completed with proceeds
  of MSEK 102
- Camurus Capital Markets and R&D Day held at IVA conference center in Stockholm
- Publications of positive CAM2029 Phase 2 results in acromegaly and neuroendocrine tumor patients in Cancer Chemotherapy and Pharmacology and episil<sup>®</sup> Phase 3 results in Onco Targets and Therapy
- Clinical results for CAM2038 presented at the American Society for Addiction Medicine (ASAM) Annual Conference, Congrès International d'Addictologie de l'Albatros, College on Problem Drugs and Dependence (CPDD), Annual Scientific Meeting International Society for Addiction Medicine (ISAM) in Busan Korea; Society for the Study of Addiction (SSA) in Newcastle UK; American Academy of Addiction Society (AAAP) in Bonita Springs, Florida; Australasian Professional Society on Alcohol and other Drugs (APSAD) in Auckland New Zealand.
- Company presentations at Biostock Live, Stockholm Corporate Finance Life Science Seminar, Cowen and Company Annual Health Care Conference, and Carnegie Nordic Healthcare Seminar, H.C. Wainwright & Co. Global Life Sciences Conference, and Jefferies Global Healthcare Conference

#### **RESEARCH AND DEVELOPMENT**

Research and development are key strategic priorities for Camurus. The company's longterm success is highly dependent on continuing innovation and the development of technologies as well as new and important pharmaceutical products.

#### DIRECTORS' REPORT

Camurus currently has, either itself or together with partners, several projects in clinical or pre-clinical development phase.

Camurus' research and development organization include pre-clinical, pharmaceutical and analytical, as well as clinical and regulatory functions. The company's research and development expenditure in 2018 amounted to MSEK 207.7 (MSEK 222.9 in 2017), corresponding to 63 percent (75 percent in 2017) of the operating expenses.

Alongside our clinical success and regulatory progress in the opioid dependence area, we have also been busy advancing other important clinical and early phase programs, both on our own and with our partners.

## Buvidal® – weekly and monthly buprenorphine depots for treatment of opioid dependence

Opioid dependence is a serious, chronic, relapsing disease and a growing global health problem. Medication assisted treatment (MAT) with daily buprenorphine and methadone is the current standard of care, effectively reducing withdrawal and cravings, misuse and spread of diseases. However, these treatments are also associated with limitations such as poor treatment adherence, misuse, medication diversion, and accidental pediatric exposure.

Buvidal® (CAM2038) weekly or monthly subcutaneous injectable formulation of buprenorphine is developed to promote compliance and eliminate the risk of abuse and diversion compared to current daily treatments. Buvidal® is the first long-acting injectable for treatment of opioid dependence that is approved in EU and Australia. It gives healthcare providers the possibility to individualize treatment according to the patient's needs and is designed to mirror the dosing regimen of daily buprenorphine, allowing for direct transition from daily buprenorphine therapy. Buvidal<sup>®</sup> relieves the patient from the daily reminder and burden of the disease and allows the healthcare provider to focus on treating the disease and counseling the patient rather than policing medical compliance. Buvidal® may promote greater patient adherence and compliance, thereby reducing costs for supervision and the risks of relapse, overdose and death.

On 22 November 2018, Camurus received EU approval for weekly and monthly Buvidal® for the treatment of opioid

dependence in adults and adolescents aged 16 years or over. Less than a week from the EU approval, Buvidal® Weekly and Buvidal® Monthly depots were also approved in Australia by the Australian Therapeutic Goods Administration (TGA) for maintenance treatment of opioid dependence within a framework of medical, social and psychosocial support.

In January 2018 Camurus' partner Braeburn in the US received a complete response letter (CRL) from the US Food and Drug Administration (FDA) for the CAM2038 New Drug Application (NDA) requesting additional information for completion of their review. In May, Braeburn had responded and resubmitted the NDA to the FDA. In December 2018, the FDA issued a tentative approval of Brixadi<sup>™</sup> (the US trade name for Buvidal<sup>®</sup>). With the tentative approval, Brixadi<sup>™</sup> has met all regulatory standards of clinical and non-clinical safety, efficacy and quality for US approval. However, final approval of a monthly depot is according to the FDA subject to the expiration of an exclusivity period granted to Sublocade<sup>™</sup> until 30 november 2020. In April 2019. Camurus' US partner Braeburn filed a lawsuit to the federal district court for the District of Columbia seeking to overturn the market exclusivity and pled for immediate approval of Brixadi™.

In Israel, Camurus' distribution partner Medison Pharma is currently compiling the application of marketing approval for Buvidal<sup>®</sup> in opioid dependence.

#### CAM2038 - Round-the-clock relief from chronic pain

Chronic pain is a global health problem, causing deterioration in general health, reduced quality of life, decreased work capacity and dependence and misuse of strong opioids. CAM2038 is being developed to provide round-the-clock pain relief, while decreasing the risk of respiratory depression and fatal overdoses associated with full µ-opioid agonists, such as morphine, oxycodone and fentanyl. With CAM2038 we aim to provide the combination of long-lasting efficacious analgesia with the reduced risk of misuse, abuse and illicit diversion.

In September 2018, Camurus announced positive results from a Phase 3 efficacy study of CAM2038, weekly and monthly buprenorphine depots, in opioid experienced patients with chronic low-back pain. The study successfully met its primary and first secondary endpoints by demonstrating that treatment with CAM2038 resulted in significantly improved relief of the average and worst pain intensity compared to placebo. The additional secondary endpoints were supportive of the main results. Following completion of the randomized efficacy part of the Phase 3 study, the long-term safety of CAM2038 is being evaluated in a 52- week open label extension study, in which patients either are continuing from the randomized efficacy part of the study or are included directly in the open label extension study phase. All patients have been enrolled and the study is continuing according to plan. The results are expected during the second quarter 2019.

## CAM2029 – improved treatment for patients with acromegaly and NET

CAM2029 is formulated with Camurus' patented FluidCrystal® Injection depot and contains the active ingredient octreotide, which is a synthetic peptide analogue of the natural peptide hormone somatostatin and used for treatment of acromegaly and neuroendocrine tumors (NET). The current market leading somatostatin analog product Sandostatin<sup>®</sup> LAR<sup>®</sup> needs to be reconstituted in several steps before intramuscular injection by healthcare professionals. CAM2029 is developed as a pre-filled syringe equipped with an automatic needle-stick prevention device and can easily be injected subcutaneously, also by patients themselves, without need for complex reconstitution before administration. Also, CAM2029 has higher bioavailability in comparison to Sandostatin<sup>®</sup> LAR<sup>®</sup>, which may improve treatment efficacy for patients not responding satisfactory to current therapies. CAM2029 has been evaluated in four clinical Phase 1/2 trials and has demonstrated positive results in a Phase 2 multicenter study in patients with acromegaly and NET, including well maintained or improved biochemical control in patients with acromegaly and symptom control in patients with functioning NET after switch from Sandostatin® LAR®

In July 2018, Camurus regained the global development and commercialization rights to CAM2029 and related assets from Novartis. Novartis had been responsible for the development of CAM2029 since October 2013. The company returned the rights to Camurus due to commercial reprioritization among its different programs. This decision did not reflect a change in the view of the development of CAM2029. Camurus is planning a Phase 3 trial for CAM2029 for the treatment of acromegaly in mid-2019, to assess its superiority compared to placebo in maintaining biochemical response. The long-term safety, pharmacokinetics and patient satisfaction for CAM2029 will also be evaluated. In addition, a Phase 3 trial for CAM2029 for the treatment of patients with NET is being planned.

## CAM2032 – flexible approach to advanced prostate cancer treatment

The well-established hormone therapies for prostate cancer, based on gonadotropin releasing hormone agonists such as leuprolide, aim to reduce testosterone levels and thereby impede the growth of cancer cells. CAM2032 is a long-acting subcutaneous leuprolide depot for the treatment of prostate cancer. Based on the FluidCrystal® injection depot technology, CAM2032 is being developed for self-administration with a prefilled syringe as a small dose volume which does not require any reconstitution or temperature conditioning. Additional potential indications for CAM2032 include precocious puberty and endometriosis. Discussions with potential development and commercialization partners are ongoing.

#### **Early pipeline projects**

#### Early project development

Several new product candidates, selected with support of market analyses, are being evaluated in pharmaceutical and pre-clinical studies. The projects comprise formulation optimization with regard to release of the active substance, stability, and as well as pharmacological and toxicological properties defined by the target product profiles.

#### Partner projects

The projects can be part of the life-cycle management for active substances already on the market or involving completely new substances in early development. At present, our partner projects include new treatments for diabetes, obesity, viral infections, endocrine disorders, and cancer.

#### In-house drug development

Camurus' R&D team is continuously evaluating new opportunities to broaden the company's development pipeline with new products based on the FlyidCrystal® technology. Every new product candidate is carefully evaluated with a focus on five key criteria: clear unmet medical needs, technology match, streamlined clinical development, market exclusivity and patent protection and market potential. If these criteria are met, the product candidate is evaluated in preclinical studies against the target product profile in terms of drug loading, manufacture, stability and drug release in vitro and in vivo.

## CAM2043 – an innovative sustained release treatment for pulmonary arterial hypertension

Pulmonary arterial hypertension (PAH) is a rare and severe progressive disease characterized by elevated blood pressure in the pulmonary arteries. Without therapeutic intervention, the disease progresses rapidly and the increased pulmonary vascular resistance and incremental strain on the right ventricle leads to heart failure and death, with a median survival of 3 years after diagnosis. Prostacyclin analogs, such as treprostinil, are known to be efficacious, and parenteral therapy with these is recommended for patients with severe or rapidly progressing disease. However, parenteral delivery is associated with risks of serious bloodstream infections or with infusion site pain and reactions which can be intolerable.

CAM2043 is a long-acting treprostinil formulation, based on our FluidCrystal<sup>®</sup> injection depot technology, being developed as a patient-friendly treatment option for PAH. CAM2043 is a ready-to-use subcutaneous injection which is self-administered via a prefilled syringe as a small dose volume (≤1 mL), allowing dose titration for efficacy and tolerability. In May 2018, positive results from an open-label Phase 1 study of single and repeated dosing of CAM2043, were announced. The study results demonstrated a doseproportional treprostinil plasma exposure and release profile suitable for weekly, or less frequent, dosing. The tolerability of CAM2043 was generally acceptable with no observations of unexpected or serious adverse events. Injection site reactions were acceptable and resolved over time. Further clinical development of CAM2043 is now being prepared and a Phase 2 proof-of-concept assessing efficacy, pharmacokinetics, safety and tolerability is planned to start during 2019.

## CAM2047, CAM2048 AND CAM2058 - for prevention and treatment of nausea and pain

Three new investigational products, based on our FluidCrystal® injection depot technology, are being developed for the treatment of chemotherapy induced nausea and vomiting (CAM2047), pain (CAM2048), and the combined treatment of postoperative pain, nausea and vomiting (CAM2058). Results from a Phase 1 trial of CAM2047, CAM2048 and CAM2058 demonstrated that all products were well tolerated locally and systemically, with pharmacokinetic profiles meeting the target specifications for these product candidates. Planning of the registration program and analysis of market potential of these product candidates are ongoing.

#### CAM4072 – a novel melanocortin-4 receptor agonist (MC4R) for treatment of genetic obesity

CAM4072 is a weekly formulation of the melanocortin 4 (MC4) agonist setmelanotide based on Camurus FluidCrystal® technology and is being developed by our partner Rhythm Pharmaceuticals for the treatment of rare genetic obesity disorders. The FDA has granted Rhythm's setmelanotide Breakthrough Therapy designation for the treatment of pro-opiomelanocortin (POMC) and leptin receptor (LepR) deficiency obesity and Orphan Drug Designation of treatment Prader-Willis Syndrome. Rhythm Pharmaceuticals has also received PRIority Medicines (PRIME) designation for setmelanotide in Rare Genetic Disorders of Obesity from the EMA. Results from Phase 2 clinical trials of setmelanotide demonstrated significant reductions in compulsive overeating and body weight for patients with POMC and LepR deficiency obesity. Phase 3 clinical trials are ongoing for the daily setmelanotide formulation and for each of these indications while the long-acting formulation of setmelanotide, CAM4072, is being developed in parallel. Rhythm has successfully completed Phase 1 studies of single and repeat doses of CAM4072 and the continued clinical development of weekly setmelanotide is a high priority and decisions on starting pivotal studies are expected late 2019.

#### MEDICAL DEVICE PRODUCT episil<sup>®</sup> - oral liquid for effective oral pain relief

episil® oral liquid is a medical device for the treatment of inflammatory and painful conditions in the oral cavity, currently being marketed in Europe, the US and other territories. The product provides fast pain relief and protection of sore and inflamed mucosal surfaces caused, for example, by oral mucositis, a common and serious side effect of cancer treatment. When in contact with the buccal membrane, episil® transforms into a thin protective layer of gel, offering effective pain relief for up to 8 hours. episil® oral liquid is based on Camurus' FluidCrystal® topical bioadhesive technology.

Sales and distribution of episil<sup>®</sup> are conducted via in-house marketing in Sweden, Denmark, Norway, and the UK, and by a number of distribution partners in various countries. In 2018, episil<sup>®</sup> was launched in Japan 2018 by Camurus' partner Solasia and is sold through Meiji Seika Pharma. Recently, episil® was also approved in China by the National Medical Products Administration (NMPA, formerly CFDA). Furthermore, a distribution agreement was signed with BTC Health Ltd for the exclusive rights to distribute episil® oral liquid in Australia and New Zealand, where the product was approved in February 2019 and launch is planned in mid-2019.

#### **REVENUE AND EARNINGS**

In 2018, the Group's net revenue amounted to MSEK 49.3 (54.3) and was generated from license agreements as well as project related activities and product sales. The difference compared with the preceding year is mainly attributable to that the company's revenue streams, from license and development milestones, varies from year to year.

PRODUCT	PHASE 1-2	PHASE 3	REGISTRATION	MARKET		
Buvidal <sup>®</sup> q1w OPIOID DEPENDENCE				APPROVED	*	$\langle \langle \rangle \rangle$
Buvidal <sup>®</sup> q4w OPIOID DEPENDENCE				APPROVED	*	
Brixadi <sup>™</sup> q1w OPIOID DEPENDENCE <sup>⊨</sup>			TENTATIVELY APPROVED			
Brixadi <sup>™</sup> q4w OPIOID DEPENDENCE <sup>:</sup>			TENTATIVELY APPROVED	1		
CAM2038 q1w CHRONIC PAIN		PHASE 3				
CAM2038 q4w CHRONIC PAIN <sup>1</sup>		PHASE 3				
CAM2029 ACROMEGALY	PHASE 1-2					
CAM2029 NEUROENDOCRINE TUMORS	PHASE 1-2		1) Braeburn holds	the		
CAM2032 PROSTATE CANCER	PHASE 1-2		rights to North Am 2) Developed by F	nerica.		
CAM4072 GENETIC OBESITY DISORDERS <sup>2</sup>	PHASE 1-2		Pharmaceuticals	under		
CAM2043 PULMONARY ARTERIAL HYPERTENSION	PHASE 1-2		a worldwide licens FluidCrystal®	se to		
CAM2047 CHEMOTHERAPY INDUCED NAUSEA & VOMIT	ING PHASE 1-2		3) PONV: Postope nausea and vomit.			
CAM2048/2058 POSTOPERATIVE PAIN & PONV <sup>1,3</sup>	PHASE 1-2			0		
MEDICAL DEVICE						

According to plan, the continued expansion of the commercial organization in, among other things, medical affairs, market access and marketing as well as the establishment of a subsidiary in Australia, preparations for the launch of Buvidal® in Europe and Australia including commercial manufacturing and distribution, and also clinical studies of Buvidal® in Australia, have entailed an increase of the Group's costs for the year.

The Group's marketing and sales costs during the year amounted to MSEK 100.9 (45.9).

Administrative expenses for the year was MSEK 22.0 (26.6) and research and development costs amounted to MSEK 207.7 (222.9).

Other income during the year amounted to MSEK 0.8 (0.1) and was mainly generated from exchange gains. Other expenses amounted to MSEK 0.0 (1.1).

The operating result for the year was MSEK -287.2 (-243.5). The Group's net financial items amounted to MSEK 0.2 (0.2). Following an assessment of the Parent Company's tax loss carryforward, a tax revenue of MSEK 52.4 (52.8) was recognized in the Group.

The Group's result for the year was negative MSEK -234.7 (-190.6).

#### **CASH FLOW AND INVESTMENTS**

Cash flow from operating activities before change in working capital was negative MSEK -282.9 (-239.3). Change in working capital affected the cash flow negatively by MSEK 8.8 (36.2). Cash flow from investment was MSEK -4.8 (-2.1), and from finance activities MSEK 99.9 (11.1) related to issuance of subscription warrants and a directed issue completed in June. Cash flow for the year amounted to MSEK -179.0 (-194.1).

#### **FINANCIAL POSITION**

As of 31 December 2018, the Group's cash position was MSEK 134.4 (314.5). The change compared to previous year relates mainly to the operating result and the change in working capital.

Consolidated equity as of 31 December 2018, was MSEK 252.3 (385.0).

There were no outstanding loans as of 31 December 2018, and no loans have been taken up since.

#### Development pipeline

episil® oral liquid ORAL MUCOSITIS

#### SEASONAL VARIATIONS

The company's sales patterns do not reflect any distinct seasonal variations.

#### **PARENT COMPANY**

The Parent Company's revenue amounted to MSEK 67.1 (64.6) in 2018. The operating result was a negative MSEK -292.4 (-243.6). The result for the year was negative MSEK -238.8 (-190.6).

On 31 December 2018, the Parent Company's equity was MSEK 230.9 (367.7).

At the end of the year, total assets amounted to MSEK 341.4 (460.1), of which cash and cash equivalents was MSEK 123.9 (309.8).

#### **Other information**

#### **ENVIRONMENTAL INFORMATION**

Camurus' operations are not subject to authorization in accordance with the Swedish Environmental Code, but are regularly controlled through environmental inspections. The company abides by the requirements of government authorities on the management and destruction of hazardous waste and works proactively to reduce energy consumption and the use of environmentally hazardous substances. Camurus is not involved in any environmental disputes.

#### SHARE CAPITAL AND OWNERSHIP STRUCTURE

Camurus' share capital amounted SEK 959,537 divided into 38,381,486 shares, with a quota value per share of SEK 0.025. The total the number of shares outstanding on 31 December 2018 was 38,381,486 common shares, each of which carries one vote. On 31 December 2018, Sandberg Development AB was the single largest shareholder of Camurus, with a total of 20,414,978 shares, corresponding to 53.2 percent of the votes and capital.

#### **EMPLOYEES**

In 2018, the average number of employees in the Group was 73 (63), of which 40 (35) were women. At year-end, the number of employees was 94 (71) of whom 58 (48) worked within research and development.

#### Five-year summary, Group<sup>1)</sup>

MSEK	2018	2017	2016	2015	2014
Net revenue	49.3	54.3	113.7	154.8	208.2
Operating result before items affecting comparability	-287.2	-243.5	-102.5	-30.5	62.3
Operating result	-287.2	-243.5	-102.5	-204.1	62.3
Net financial items	0.2	0.2	-0.9	-0.2	0.2
Result for the period	-234.7	-190.6	-81.0	-159.5	48.3
Earnings per share before dilution, SEK	-6.20	-5.11	-2.17	-6.02	2.06
Earnings per share after dilution, SEK <sup>1)</sup>	-6.20	-5.11	-2.17	-6.02	1.92
Equity ratio in Group, %	69%	81%	88%	78%	59%
Equity	252.3	385.0	564.4	640.6	123.5
Cash and cash equivalents	134.4	314.5	508.6	716.1	0.1
Number of employees at end of period	94	71	62	48	43
Number of employees in R&D at end of period	58	48	44	35	28

1) The dilution effect is calculated according to IAS 33

Of the total number of employees in 2018, 54 percent were women and 46 percent men. All employees receive the same treatment and are offered the same opportunities regardless of their age, gender, religion, sexual orientation, disabilities or ethnicity.

Salaries and other remuneration amounted to MSEK 119.7 (90.4).

## EVENTS AFTER THE CLOSE OF THE FINANCIAL YEAR, THROUGH 14 APRIL 2019

European launch of Buvidal® for treatment of opioid dependence initiated in January 2019.

Resolution by the Board of Directors in February 2019 on a fully underwritten rights issue subject to approval by the extraordinary general meeting.

On 27 March 2019, the rights issue was completed which provided the company with MSEK 403 before issue costs, which are judged to amount to approximately MSEK 35.

On 9 April 2019 Camurus' partner Braeburn initiated court proceedings to overturn the 3-year market exclusivity for Sublocade™ and seeks immediate market approval of Brixadi™ in the US.

#### GUIDLINES FOR REMUNERATION AND OTHER EMPLOYMENT TERMS FOR SENIOR EXECUTIVES, 2019

The guidelines for remuneration to senior executives which will be proposed at the AGM 2019, will be published on camurus.com during the month of April. In essence, it is proposed that the guidelines in their design remain unchanged against the decision by the Annual General Meeting of 3 May 2018. For current guidelines, which are valid until the AGM 2019, and remunerations in 2018, see Notes 9 and 24.

## PROPOSED APPROPRIATION OF PROFITS FOR THE FINANCIAL YEAR 2018

The following is at the disposal of the AGM:

The Board of Directors proposes that the retained earnings of KSEK 218,564 be carried forward.

The Board of Directors proposes that no dividend be paid for the 2018 financial year.

For further information on the Company's earnings and financial position, refer to the following income statement and balance sheet with accompanying notes to the accounts.

Camurus and its operations are associated with risks in relation to set targets. Camurus' integrated process for risk management is aimed at ensuring that risks and uncertainties are identified, assessed and managed at the earliest stage possible.

At Camurus, risk management is an integrated part of dayto-day operations and the management team continuously takes an inventory of the risks and performs risk assessments based on the company's set goals. Risk assessment evaluates the probability of a risk occurring and the consequences of such a risk materializing into an event. Identified risks and risk-minimization measures are documented. Feedback is provided to the Board of Directors on a continuous basis.

Tax and financial risks are subject to regular review for preventative purposes and any tax, legal or financial risk deemed substantial is reported in the consolidated financial statements.

#### The most substantial risks

#### RISKS RELATED TO THE INDUSTRY AND OPERATIONS Pharmaceutical development and projects in early stages of development

Camurus currently has, either itself or together with partners, about ten clinical programs and a number of projects undergoing pre-clinical trials. The projects require continued research and development and are therefore subject to typical risks related to pharmaceutical development, such as that product development becomes delayed and that costs become higher than expected or that the product candidates, at any stage of their development, may ultimately prove to be insufficiently effective or safe, and that Camurus will not obtain the necessary regulatory approvals.

#### Technology platform with limited regulatory validation

Buvidal® (CAM2038 for treatment of opioid dependence) is currently the only pharmaceutical product based on Camurus FluidCrystal® injection depot which has achieved market approval. There is a risk that other product candidates based on the Company's FluidCrystal® injection depot or its other technology platforms are delayed to market or never reach it, and that problems that make it more difficult to produce, or enter into partnerships for, additional products with future commercial value, are identified.

#### **Clinical trials**

Prior to launching a product candidate in the market, Camurus or its partner must carry out pre-clinical and clinical trials to document and prove that the product candidate gives rise to significant efficacy and has an acceptable safety profile. Camurus is unable to predict with any certainty when planned clinical trials can be started or when ongoing trials can be completed since these are circumstances that are affected by numerous different factors outside Camurus' direct control. for example regulatory approval, ethical review, access to patients and clinical trial units, performing the clinical trial at the trial unit and the considerations of Camurus' partners. It is also difficult to accurately predict the costs associated with clinical trials. Actual costs for carrying out a trial may significantly exceed estimated and budgeted costs. Clinical trials may also give rise to results that do not confirm the intended treatment efficacy or an acceptable safety profile due to undesirable side effects or an unfavourable risk-benefit assessment of the product. Positive results in previously completed pre-clinical and clinical trials do not guarantee positive results in later stages of development and subsequent clinical trials. This could lead to clinical trials being discontinued or cancelled, or the product candidate not being granted the necessary regulatory approval for further clinical trials or sale in the market.

#### Heavy dependence on the most advanced products

Camurus is dependent on the continued success of these products and on negative results not arising or negative decisions not being made on the continuation of product development. To date, Camurus has invested a significant portion of its human and financial resources in research and development of its product candidates that are the furthest advanced in their development to market, in particular Buvidal<sup>®</sup>/ Brixadi<sup>™</sup> (which has achieved market approval in Europe and Australia), CAM2038 for chronic pain and CAM2029. Camurus is thus highly dependent on the continued success of these products and product candidates and on negative results not arising or negative decisions by authorities not being made on the continuation of product development. Examples of events that could have serious adverse consequences for the Company are rejected applications for clinical trials or market approvals for Camurus' and its partners' products, or assessments that the product candidates cannot be successfully commercialized due to other reasons. The same applies if a market approval is delayed or combined with restrictive conditions, as in the case with the tentative approval of Brixadi<sup>™</sup> (monthly depot) from the US Food and Drug Administration ("FDA"), in which a final approval from the FDA is related to the expiration of an exclusivity period granted by the FDA to a competing product.

Camurus' ability to finance its operations by receiving milestone payments and generating revenue from product sales is also dependent to a significant extent on the continuation of successful clinical development, grant of market authorization approvals and successful commercialization of these furthest advanced products. Delays to or suspensions of these programmes can be expected to significantly reduce Camurus' future revenue opportunities and thus also have material adverse effects on Camurus' operations, financial position and earnings. Many of the risks associated with the continued development and commercialization of the Company's product candidates are also outside Camurus' control (including, in addition to the need for successful clinical trials, receipt of required regulatory approvals and successful commercialization, other factors such as the absence of the launch of competing products). Also to the extent that development measures, clinical trials and market approvals are financed by Camurus' partners, the above mentioned risks are relevant to Camurus.

## Product and technology collaborations with other pharmaceutical companies

Product and technology collaborations are key components of Camurus' strategy for increasing its development capacity and commercial penetration, and for achieving profitability. A licensing agreement typically provides that the partner takes over the main responsibility for the further development and commercialization of a product in a defined market. This means that Camurus may have limited ability to exercise influence over the licensee's or collaboration partner's future development and commercialization activities. There is a risk that one or more of the Company's existing collaboration agreements will be terminated or that Camurus will be unsuccessful in entering into other such agreements in the future. Camurus' ability to realize the value of its product candidates could be delayed or hindered by the absence of such partnership agreements. There is also a risk that differences of opinion will arise between Camurus and its partners or that such partners do not meet their contractual commitments. Furthermore, projects and collaborations can suffer delays for various reasons, something that is a common occurrence in pharmaceutical development since the schedules prepared when partnerships are entered into are indicative in nature. In addition, there is a risk that Camurus' collaboration partners and licensees may prioritize the development of alternative products and product candidates that might also compete with the products and product candidates featured in their collaborations with Camurus. If this were to occur, it could reduce the ability and/or willingness of the Company's collaboration partner or licensee to fulfil its obligations regarding the development and commercialization of the product candidates included in the collaboration with Camurus.

#### **Revenues from partners and licensees**

A significant portion of Camurus' revenues are expected to comprise revenues from collaboration partners and licensees. These revenues may comprise milestone payments, which for example are dependent on the further development of product candidates, market approvals and future product sales, and sales-based royalties. All such revenues are dependent on the successful development of the Company's product candidates and the achievement of agreed development and regulatory milestones, and the subsequent product launch and sales in the market. The level of future sales of Camurus' and its partners' products, if any, is uncertain and will ultimately depend on a wide variety of factors, such as clinical results and marketing success. If a collaboration partner or licensee were to decide to discontinue the development of a product or end sales of a product – a decision over which Camurus can be expected to have no control – Camurus' revenues and financial position could be materially adversely affected.

## Regulatory review and registration of new pharmaceuticals

A license or approval must be obtained from the relevant authorities in each country or region in order to commence and carry out clinical trials for or to market and sell a pharmaceutical product. Various licenses and approvals are also required for the manufacture and distribution of a drug. Obtaining licenses and approvals can be time consuming and can further delay, hinder or make the development and commercialization of a product more expensive, for example due to differing opinions on which clinical trials are required for registration, even between the authorities of different countries, or manufacturing not being deemed to meet the applicable requirements. Authorities may make different assessments compared with Camurus and Camurus' partners, for instance, regarding the interpretation of data from trials or the quality of data. Changes in authorities' practices or procedures, as well as new or changed rules, may require additional work or ultimately result in the necessary license not being obtained or withdrawn. Regulatory authorities, e.g. in the US and the EU, may award orphan drug exclusivity to competing products, which could delay market entrance in a corresponding indication for Camurus' products containing the same active pharmaceutical ingredient.

Camurus and its partners will be liable to meet certain regulatory requirements even after a product has been approved for marketing, including requirements for safety reporting and supervision of the marketing of the products. There is a risk of product side effects being manifested which have not been identified to the same extent in the earlier clinical trials. Furthermore, the Company's manufacturer will be responsible for continuing to follow the rules that apply to the various stages of manufacturing, testing, quality control and documentation of the product in guestion. Production facilities will be regularly inspected by regulatory bodies, which could lead to observations and new production requirements. If Camurus or its partners, including external manufacturers, do not meet the applicable regulatory requirements, Camurus may be subject to fines, withdrawal of regulatory approval, recalls or seizure of products, other operational restrictions and criminal sanctions that could have material adverse effects on Camurus' operations, financial position and earnings.

#### Handling narcotic substances

CAM2038 (including Buvidal® and Brixadi™) contains narcotics that are classified as "controlled substances" and therefore are subject to special regulatory rules, for example, regarding their production, handling, import and export. Failure on the part of Camurus, its collaboration partners, contract manufacturers or distributors to comply with these rules could result in administrative, civil or criminal sanctions that could have a material adverse effect on Camurus' operations, financial position and earnings. Furthermore, it may also be difficult to find alternative manufacturers since the number of potential manufacturers holding the necessary regulatory licenses for producing these controlled substances may be limited.

## Commercialisation, market acceptance and dependence on reimbursement systems

If a pharmaceutical product obtains market approval, the risk remains that sales, regionally or globally, may not meet expectations and that the product is not commercially successful. The degree of market acceptance and sales of a drug depend on a number of factors, including product properties, clinical documentation and results, competing products, distribution channels, availability, price, reimbursement, sales and marketing efforts, prescribing physician awareness and clinical benefit outweighing side effects and other impacts of treatment, among other factors.

Sales of prescription drugs are influenced by the price set and obtained from the responsible authorities (such as the Dental and Pharmaceutical Benefits Agency in Sweden), from reimbursement payers and by healthcare payors, including insurance companies, hospitals and regionally responsible authorities. The reimbursement rate that, from time to time. applies for a pharmaceutical product often depends on the value that the product is deemed to add for the patient, the healthcare system and the society as a whole. There is a risk that the products do not qualify for subsidies from privately and publicly financed healthcare programmes or that reimbursement is lower than expected, which among other things may affect the market acceptance of the product or the operating margin. Reimbursement systems may also change from time to time, making it more difficult to predict the benefit and reimbursement that a prescription product may obtain. Various initiatives are in place in many countries to curb rising pharmaceutical costs, which could affect future sales margins and product sales for Camurus and its partners. Such measures are expected to continue and could result in fewer reimbursement possibilities and lower reimbursement levels in certain markets.

#### Patents and other intellectual property rights

Camurus has an active intellectual property rights strategy, whereby the Company endeavors to protect its platform technologies and products in important global markets. There is a risk that existing and future patents, brands and other intellectual property rights held by Camurus will not comprise full commercial protection from infringement and competition.

#### MARKET RISKS

#### Competition

The pharmaceutical industry is highly competitive, and the product developments are characterized by significant innovation. Camurus' present and potential competitors range from multinational pharmaceutical companies, established biotech companies, specialist pharmaceutical companies and generic companies to universities and other research institutions. Several of Camurus' competitors may have significantly greater financial, technical and staffing resources, including research and development organizations, and more established manufacturing, distribution, sales and marketing organizations. There is also the risk of Camurus' products under development, becomes subject to competition from similar products or entirely new product concepts that provide greater added value to patients.

#### FINANCIAL RISKS Exchange-rate risks

Camurus is exposed to currency risks in the form of transaction exposure. Camurus' registered office is located in Sweden and reports on its financial position and earnings in SEK. Transaction exposure arises in the purchase and sale of goods and services in currencies other than SEK. A significant portion of Camurus' revenues and expenses are in foreign currencies, mostly in EUR, USD, GBP and AUD and will continue to be so in the future. Camurus' treasury policy allows for the use of hedging instruments. However, if Camurus' measures for managing the effects of exchange rate fluctuations do not prove to be sufficient, Camurus' financial position and profits may be adversely impacted.

#### **Credit risks**

Credit risk is the risk that a counterparty is unable to fulfil its payment obligations, thereby resulting in a loss for Camurus. If Camurus' measures to manage credit risks are inadequate, this could have a negative impact on Camurus' financial position and earnings.

#### **Financing risk**

There are existing risks that the cash flow from operations remains neutral or negative until Camurus can generate continuous annual revenue from products in the market. Going forward, Camurus will continue to require significant capital for continuing the research and development of potential products. Both the extent and timing of the Camurus' future capital requirements depend on a number of factors, such as costs for the operations, the potential success of research and development projects and opportunities for entering into partnership and licensing agreements, the timing for the receipt and amount of milestone payments and royalties, and the market reception of potential products. Access to and the terms and conditions for additional financing are influenced by several factors, such as market conditions, the general availability of credit and Camurus' credit rating and credit capacity. There is always the risk that Camurus cannot raise financing at acceptable terms.

#### Significant risks and uncertainties

When publishing the year-end report, the Board of Directors submitted the following outlook:

The company management makes estimates and assumptions about the future. Such estimates can deviate considerably from the actual outcome, since they are based on various assumptions and experiences. The estimates and assumptions that may lead to the risk of significant adjustments to reported amounts for assets and liabilities relate mainly to measurement and allocation of revenue and costs in connection with licensing agreements and deferred tax receivable.

Risks in ongoing development projects comprise technical and manufacturing-related risks (including products failing to meet set specifications post manufacturing), safety and effect-related risks that can arise in clinical trials, regulatory risks relating to applications for approval of clinical trials and market approval, commercial risks relating to the sale of proprietary and competing products and their development in the market, as well as IP risks relating to approval of patent applications and patent protection. In addition, there are risks relating to the development, strategy and management decisions of Camurus' partners.

Camurus pursues operations and its business in the international market and the company is therefore exposed to currency risks, since revenue and costs arise in different currencies, mainly SEK, EUR, USD, GBP and AUD.

The Group reports a deferred tax asset of MSEK 171 as of 31 December 2018. The deferred tax asset is calculated on the basis that Camurus AB's entire losses carried forward will be utilized against taxable surpluses in the future. The basic circumstance leading the company to make this assessment is that the company, for the development of new drug candidates, utilizes its own proprietary and regulatory validated long-acting FluidCrystal® injection depot. By combining this technology with already existing active drug substances whose efficacy and safety profile previously has been documented, new proprietary drugs with improved properties and treatment results can be developed in shorter time, at a lower cost and risk compared to the development of completely new drugs. Accounting for deferred tax assets according to IFRS requires that it is probable that taxable surpluses will be generated in the future which the losses carried forward can be used against. In addition, a company that has reported losses in recent periods must be able to demonstrate convincing factors that taxable profits will be generated. The progress made in the development of CAM2038 for the treatment of opioid dependence (Phase 3 studies and regulatory approvals) and success in previous projects using FluidCrystal® injection depot is what convincingly suggests that the company will be able to utilize its losses carried forward. The fact that the Company has reported losses is natural in an industry where it takes considerable time to develop and launch new products, even when these are based on a proven technology and substances that are well-proven. We see the European Commission approval of Buvidal® for treatment of opioid dependence on 22 November, 2018, Australian TGA's approval on 28 November 2018, and the FDA's tentative approval for Brixadi<sup>™</sup>, weekly and monthly depot on 21 December 2018 (meaning that Brixadi<sup>™</sup> has met all regulatory requirements regarding clinical and preclinical safety, treatment effect and quality, but that a final approval of Brixadi<sup>™</sup> (monthly depot) is dependent on the expiry of an exclusivity period granted by the FDA to Sublocade<sup>™</sup>; which may not last longer than until November 2020,), as further validation of our formulation technology FluidCrystal®, and are events that confirm the likelihood assessments made by the Company when calculating the amount of the deferred tax asset. Future revenues will be generated through entered partnerships for the markets where Camurus out licensed FluidCrystal® and/or product candidates or products such as Buvidal<sup>®</sup>, and from Camurus' own sales organization for the markets where Camurus have own commercialization capabilities to sell pharmaceutical products. Losses carried forward are only reported in Sweden and without any due dates based on current tax legislation in Sweden.

The Board of Directors has not changed its outlook on future developments in relation to their outlook published in the yearend report for 2018.

#### CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

		Financial	year
KSEK	Note	2018	2017
Net sales	5	49,321	54,308
Cost of goods sold	6	-6,822	-1,356
Gross profit		42,499	52,952
Operating expenses			
Marketing and distribution costs	6, 28	-100,884	-45,893
Administrative expenses	6, 8, 28	-21,999	-26,590
Research and development costs	6	-207,664	-222,939
Other operating income	7, 13	830	93
Other operating expenses	13	-	-1,147
Operating result		-287,218	-243,524
Finance income	10	175	174
Finance expenses	10	-25	-18
Net financial items		150	156
Result before tax		-287,068	-243,368
Income tax	11	52,392	52,794
Result for the period		-234,676	-190,574
Exchange-rate differences		46	16
Comprehensive income for the year		-234,630	-190,558

Comprehensive income for the year is attributable to Parent Company shareholders.

Earnings per share based on earnings attributable to Parent Company shareholders for the period (in SEK per share)

	Note	2018	2017
Earnings per share before dilution, SEK	12	-6.20	-5.11
Earnings per share after dilution, SEK	12	-6.20	-5.11

\*) As from the full year report for 2018, exchange-rate differences from conversion of subsidiaries outside of Sweden are reported under the item "Comprehensive income for the period". Adjustments has been made accordingly for 2017, which has entailed that the exchange-rate differences for 2017 amounting to KSEK 16 has been moved, within consolidated equity from the item "Retained earnings" to the item "Comprehensive income for the period". The items "Adjustment for non-cash items" and "Translation difference in cash flow and liquid assets" in the consolidated cash flow statement have been adjusted accordingly with KSEK 16.

		Financial	inancial year	
KSEK	Note	2018	2017	
Net sales	5, 28	67,111	64,640	
Cost of goods sold	6	-6,822	-1,356	
Gross profit		60, 289	63,284	
Operating expenses				
Marketing and distribution costs	6	-46,970	-30,234	
Administrative expenses	6, 8, 28	-99,890	-54,689	
Research and development costs	6	-206,709	-220,849	
Other operating income	7, 13	838	61	
Other operating expenses	13	-	-1,147	
Operating result		-292,442	-243,574	
Interest income and similar items	10	175	174	
Interest expense and similar items	10	-24	-18	
Result after financial items		-292 291	-243,418	
Tax on profit for the period	11	53,527	52,853	
Result for the period		-238,764	-190,565	

Total comprehensive income is the same as result for the period, as the Parent Company contains no items that are recognized under other comprehensive income.

#### CONSOLIDATED BALANCE SHEET

KSEK	Note	31-12-2018	31-12-2017
ASSETS	2		
Fixed assets			
Intangible assets			
Capitalized development expenditure	14	15,975	16,653
Tangible assets			
Equipment	15	10,899	9,902
Financial assets			
Deferred tax receivables	16	170,955	114,997
Total fixed assets		197,829	141,552
Current assets			
Inventories			
Finished goods and goods for resale	18	4,700	2,829
Rawmaterial		5,130	724
Current receivables			
Trade receivables	19, 20	2,280	5,781
Other receivables		9,604	3,285
Prepayments and accrued income	21	10,804	7,239
Total current receivables		22,688	16,305
Cash and cash equivalents	19, 22	134,377	314,524
Total current assets		166,895	334,382
TOTAL ASSETS		364,724	475,934

KSEK	Note	31-12-2018	31-12-2017
EQUITY AND LIABILITIES			
EQUITY			
Equity attributable to	2, 23		
Parent Company shareholders			
Share capital		960	932
Other contributed capital		744,140	642,175
Retained earnings, including result for the period		-492,776	-258,107
Total equity		252,324	385,000
LIABILITIES	2		
Short-term liabilities			
Trade payables	19	35,781	15,086
Income taxes		1,708	517
Other liabilities	19	3,549	2,672
Accrued expenses and deferred income	25	71,362	72,659
Total short-term liabilities		112,400	90,934
TOTAL EQUITY AND LIABILITIES		364,724	475,934

#### **BALANCE SHEET – PARENT COMPANY**

KSEK	Note	31-12-2018	31-12-2017
ASSETS	2		
Fixed assets			
Tangible assets			
Equipment	15	10,689	9,725
Financial assets			
Interests in Group companies	17	1,800	1,545
Deferred tax assets	16	175,056	119,426
Total fixed assets		187,545	130,696
Current assets			
Inventories			
Finished goods and goods for resale	18	4,700	2,829
Raw material		5,130	724
Current receivables			
Trade receivables	20	2,280	5,781
Other receivables		7,219	3,040
Prepayments and accrued income	21	10,679	7,202
Total current receivables		20,178	16,022
Cash and bank deposits	22	123,858	309,821
Total current assets		153,866	329,397
TOTAL ASSETS		341,411	460,093

KSEK	Note	31-12-2018	31-12-2017
EQUITY AND LIABILITIES			
EQUITY	2, 23		
Restricted equity			
Share capital		960	932
Statutory reserve		11,327	11,327
Total restricted equity		12,287	12,259
Unrestricted equity			
Retained earnings		-253,159	-62,594
Share premium reserve		710,487	608,560
Result for the period		-238,764	-190,565
Total unrestricted equity		218,564	355,401
Total equity		230,851	367,660
LIABILITIES			
Untaxed reserves			
Depreciation/amortization in excess of plan		3,486	3,486
Total untaxed reserves		3,486	3,486
Long-term liabilities			
Liability to subsidiaries		572	571
Total long-term liabilities		572	571
Short-term liabilities			
Liabilities to Group companies	28	9,065	3,769
Trade payables		32,650	14,431
Other liabilities		2,355	2,053
Accrued expenses and deferred income	25	62,432	68,123
Total short-term liabilities		106,502	88,376
TOTAL EQUITY AND LIABILITIES		341,411	460,093

#### CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

#### PARENT COMPANY STATEMENT OF CHANGES IN EQUITY

KSEK	Note	Share capital	Other contributed capital	Retained earnings, including result for the period	Total
NSEN	Note	capital	capital	the period	equity
Opening balance at 1 January, 2017		932	631,034	-67,549	564,418
Comprehensive income for the year	12			-190,558	-190,558
Transactions with shareholders					
Warrants issued			11,141 <sup>1)</sup>		11,141
Closing balance at 31 December 2017		932	642,175	-258,107	385,000
Opening balance at 1 January, 2018		932	641,175	-258,107	385,000
Comprehensive income for the year	12			-234,630	-234,630
Transactions with shareholders					
Directed share issue		28	102,272		102,300
Issuance costs, net after deferred tax			-7,456		-7,456
Warrants issued			7,110 <sup>1)</sup>		7,110
Closing balance at 31 December 2018		960	744,101	-492,737	252,324

1) Warrant issues according to resolution by the annual general meeting 3 May 2017 and 3 May 2018. For further information see Notes 9 and 24.

		Restricted	dequity	Unrestricted equity		
KSEK Not	Note	Share capital	Statutory reserve	Share premium reserve	Retained earnings, including result for the period	Total equity
Opening balance at 1 January	, 2017	932	11,327	597,418	-62,594	547,083
Result and comprehensive income for the year	12				-190,565	-190,565
Transactions with sharehold Warrants issued	lers			11,141 <sup>1)</sup>		11,141
Closing balance at 31 Decemb	per, 2017	932	11,327	608,560	-253,159	367,660
<b>Opening balance at 1 January</b> Result and comprehensive income for the year	<b>, 2018</b> 12	932	11,327	608,560	<b>-253,159</b> -238,764	<b>367,660</b> -238,764
Transactions with sharehold Directed share issue	lers	28		102.272		102,300
Issuance costs, net after defe Warrants issued	erred tax	20		-7,456 7,110 <sup>1)</sup>		-7,456 7,110
Closing balance at 31 Decem	ber, 2018	960	11,327	710,487	-491,923	230,851

1) Warrant issues according to resolution by the annual general meeting 3 May 2017 and 3 May 2018. For further information see Notes 9 and 24.

#### CONSOLIDATED STATEMENT OF CASH FLOW

		<b>Financial year</b>		
KSEK	Note	2018	2017	
Operating activities				
Operating profit/loss before financial items		-287,218	-243,524	
Adjustments for non-cash items	27	4,450	4,088*)	
Interest received		175	174	
Interest paid		-25	-18	
Income taxes paid		-272	0	
		-282,890	-239,280	
Increase/decrease in inventories	18	-6,277	8,827	
Increase/decrease in trade receivables		3,501	2,523	
Increase/decrease in other current receivables		-9,884	9,787	
Increase/decrease in trade payables		20,695	-2,474	
Increase/decrease in other current operating liabilities		771	17,532	
Cash flow from changes in working capital		8,806	36,196	
Cash flow from operating activities		-274,084	-203,084	
Investing activities				
Acquisition of intangible assets	14	-1,404	-	
Acquisition of tangible assets	15	-3,357	-2,143	
Cash flow from investing activities		-4,761	-2,143	
Financing activities				
Directed share issue		92,741	_	
Warrants issued		7,110	11,141	
Cash flow from financing activities	23	99,851	11,141	
Net cash flow for the year		-178,994	-194,070	
Cash and cash equivalents at beginning of the year	22	314,524	508,594	
Translation difference in cash flow and liquid assets		-1,153	-16 *)	
Cash and cash equivalents at end of period	22	134,377	314,524	

\*) As from the full year report for 2018, exchange-rate differences from conversion of subsidiaries outside of Sweden are reported under the item "Comprehensive income for the period". Adjustments has been made accordingly for 2017, which has entailed that the exchange-rate differences for 2017 amounting to KSEK 16 has been moved, within consolidated equity from the item "Retained earnings" to the item "Comprehensive income for the period". The items "Adjustment for non-cash items" and "Translation difference in cash flow and liquid assets" in the consolidated cash flow statement have been adjusted accordingly with KSEK 16.

#### PARENT COMPANY STATEMENT OF CASH FLOW

		Financial year		
KSEK	Note	2018	2017	
Operating activities				
Operating profit/loss before financial items		-292,442	-243,574	
Adjustments for non-cash items	27	2,335	1,997	
Interest received		175	174	
Interest paid		-24	-18	
Income taxes paid		0	0	
		-289,956	-241,421	
Increase/decrease in inventories	18	-6,277	8,827	
Increase/decrease in trade receivables		3,501	2,523	
Increase/decrease in other current receivables		-7,655	7,030	
Increase/decrease in trade payables		18,219	-3,129	
Increase/decrease in other current operating liabilities		-93	19,192	
Cash flow from changes in working capital		7,695	34,443	
Cash flow from operating activities		-282,261	-206,978	
Investing activities				
Acquisition of tangible assets	15	-3,299	-1,963	
Investment in Group companies	17	-255	-730	
Cash flow from investing activities		-3,554	-2,693	
Financing activities				
Directed share issue		92,741	-	
Warrants issued		7,110	11,141	
Cash flow from financing activities	23	99,851	11,141	
Net cash flow for the period		-185,964	-198,530	
Cash and cash equivalents at beginning of period	22	309,821	508,351	
Cash and cash equivalents at end of period	22	123,858	309,821	

#### Note 1 General information

Camurus AB (publ), reg. No 556667-9105, is an R&D-focused pharmaceutical company. Camurus AB is the Parent Company of the Camurus Group. The company is now based in Lund, Sweden, at Ideon Science Park, 223 70 Lund.

The largest owner of Camurus AB is Sandberg Development AB, reg. Nr. 556091-0712, who accounts for 53.2 percent of the shares. PGS Group AB, reg. Nr. 556301-8745, is the top company in the Group, which Camurus AB is consolidated to.

The company's share is listed on Nasdaq Stockholm since 3 December 2015.

This annual report was subject to approval by the Board on 15 April 2019.

## Note 2 Summary of key accounting policies

The most important accounting policies that are applied in the preparation of these consolidated financial statements are detailed below. These policies have been applied consequently for all presented periods unless otherwise is stated.

#### 2.1 BASIS OF PREPARATION OF REPORTS

The consolidated financial statements for the Camurus AB Group ("Camurus") have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU, as well as the Swedish Financial Reporting Board's Recommendation RFR 1 Supplementary Accounting Rules for Groups, and the Swedish Annual Accounting Act. Camurus adopted IFRS on 1 January 2012. The Parent Company statements have been prepared in accordance with RFR 2 Accounting for legal entities and the Annual Accounts Act. The Parent Company's accounting policies are the same as for the Group, unless otherwise stated in Note 2.22.

Preparing financial statements to conform to IFRS requires use of certain critical accounting estimates. It also requires management to make certain judgments when applying the Group's accounting policies, see Note 4.

#### 2.1.1 CHANGES TO ACCOUNTING POLICIES AND DISCLOSURES

## New and revised standards applied by the Group from 1 January 2018

None of the new standards, changes and interpretations from 1 January 2018 have had any significant impact on the Group's financial reports.

## New and revised standards that have not come into force or been proactively applied by the Group

A number of new standards and interpretations enter into force for the financial year starting 1 January 2018, and have not been applied when preparing this financial report. Below are the standards that are deemed to be of relevance to the Group:

#### IFRS 9 Financial Instruments and associated amendments to various other standards

IFRS 9 replaces the multiple classification and measurement models in IAS 39 Financial instruments. Recognition and measurement with a single model that has three classification categories: amortized cost and fair value and a third measurement category (FVOCI) for certain financial assets that are debt instruments. Classification of debt assets will be driven by the entity's business model for managing the financial assets and the contractual cash flow characteristics of the financial assets. A debt instrument is measured at amortized cost if: a) the objective of the business model is to hold the financial asset for the collection of the contractual cash flows, and b) the contractual cash flows under the instrument solely represent payments of principal and interest. All other debt and equity instruments, including investments in complex debt instruments and equity investments, must be recognized at fair value.

All fair value movements on financial assets are taken through the statement of profit or loss, except for equity investments that are not held for trading, which may be recorded in the statement of profit or loss or in reserves (without subsequent recycling to profit or loss). For financial liabilities that are measured under the fair value option entities will need to recognize the part of the fair value change that is due to changes in the their own credit risk in other comprehensive income rather than profit or loss.

The new hedge accounting rules align hedge accounting more closely with common risk management practices. As a general rule, it will be easier to apply hedge accounting going forward. The new standard also introduces expanded disclosure requirements and changes in presentation.

IFRS 9 also introduced a new expected credit loss (ECL) model which involves a three-stage approach whereby financial assets move through the three stages as their credit quality changes. The stage dictates how an entity measures impairment losses and applies the effective interest rate method. A simplified approach is permitted for financial assets that do not have a significant financing component (eg trade receivables). On initial recognition, entities will record a day-1 loss equal to the 12 month ECL (or lifetime ECL for trade receivables), unless the assets are considered credit impaired.

The first application of IFRS 9 has had no effect on the consolidated accounts as of 1 January 2018. Nor has the transition to IFRS 9 caused any changes in the classification and valuation of financial instruments other than the designation of the classification categories: Loan receivables and accounts receivable and other financial liabilities under IAS 39, are under IFRS 9 classified and valued at amortized cost. The Group has not identified any financial assets that are valued at fair value through profit or loss or fair value through other comprehensive income.

The effect of the first application of expected loan losses has been immaterial to the Group. For this reason, no additional provision has been made at the transition, so the carrying amounts of assets reported at amortized cost have not been affected.

#### IFRS 15 Revenue from contracts with customers

From 1 January 2018 the Group applies IFRS 15 which is the new standard for revenue recognition. It replaces IAS 18 which covers contracts for goods and services and IAS 11 which covers construction contracts. The new standard is based on the principle that revenue is recognized when control of a goods or services transfers to a customer – so the notion of control replaces the existing notion of risks and rewards. A new five-step process must be applied before revenue can be recognized:

- Step 1. identify contracts with customers
- Step 2. identify the separate performance obligation
- Step 3. determine the transaction price of the contract
- Step 4. allocate the transaction price to each of the separate performance obligations, and
- Step 5. recognize the revenue as each performance obligation is satisfied.

Key changes to current practice are:

- Any bundled goods or services that are distinct must be separately recognized, and any discounts or rebates on the contract price must generally be allocated to the separate elements.
- Revenue may be recognized earlier than under current standards if the consideration varies for any reasons (such as for incentives, rebates, performance fees, royalties, success of an outcome etc) minimum amounts must be recognized if they are not at significant risk of reversal.
- The point at which revenue is able to be recognized may shift: some revenue which is currently recognized at a point in time at the end of a contract may have to be recognized over the contract term and vice versa.
- There are new specific rules on licenses, warranties, nonrefundable upfront fees and, consignment arrangements, to name a few.
- As with any new standard, there are also increased disclosures.

The Company have chosen full retrospective application and based on the Company's analysis, the assessment is that the transition has not had any impact on the Group's accounts.

#### IFRS 16 Leases

IFRS 16 is the new standard for lease and is effective for annual periods beginning on or after 1 January 2019. In January 2016, IASB issued a new lease standard that will replace IAS 17 Leases and the related interpretations IFRIC 4, SIC-15 and SIC-27. The standard requires assets and liabilities arising from all leases, with some exceptions, to be recognized on the balance sheet. This model reflects that, at the start of a lease, the lessee obtains the right to use an asset for a period of time and has an obligation to pay for that right. The accounting for lessors will in all material aspects be unchanged. Early application is possible if IFRS 15 Revenue from Contracts with Customers is also applied.

According to the new standard, lessees must report the obligation to pay the leasing fees as a leasing debt in the balance sheet. The right to utilize the underlying asset during the lease term is reported as a right- of-use asset. Depreciation of the asset is recognized in profit or loss as well as an interest on the lease debt. Leasing fees paid are reported partly as interest payment and partly as amortization of the lease debt.

#### Impacts of the transition to IFRS 16

Camurus have chosen to perform the transition in line with the Cumulative catch-up approach and have applied the practical approach to not restate any comparative information.

Camurus have assessed the impact of the transition to the new standard IFRS 16 Leases effective 1 January 2019. Camurus' initial estimate is that IFRS 16 will have a small positive impact on operating profit and a smaller negative impact on profit after financial items. As of 1 January 2019, the Group is expected to report rights of use, related to the remaining lease commitments according to the table below.

MSEK	assets	interest bearing
Estimated adjustments due to transition to IFRS 16 Leases	;;	
opening balance 1 January 201	9 29.8	28.7

Distant of the s

No effect arises in equity at the transition. The difference between the rights-of-use assets and leasing liabilities is due to the fact that prepayments are included in the right-of-use assets, but as this amount is paid, it is not part of the lease liabilities.

The leasing portfolio contains few leasing agreements and mainly comprises operational leases for offices, laboratories and company cars. For contracts concerning premises, Camurus has determined a contract period, taken into account how notice and extension clauses have been applied previously, the premise's importance to the Company's operations and R&D, any planned or already implemented investments to the leased facility as well as market situation for premises.

Right-of-use assets have been determined as an amount equal to the lease liabilities as identified at initial application. A discount rate has been applied per asset classes Buildings and vehicles.

Lease contracts shorter than 12 months or ending within 12 months at the date of application are considered short-term and hence not recognized as lease liability or right-of-use asset.

Furthermore, low value contracts (with a value as new below USD 5,000) are also excluded from being recognized as lease liability or right-of-use asset.

According to the main rule in IFRS 16, non-leasing components shall be reported separately from the leasing component in a leasing agreement. However, a lessee may choose not to separate non-leasing components from the leasing component and this choice is made based on asset classes. The Group has chosen not to apply this relief rule. Below is a reconciliation between commitments regarding operational leasing as of 31 December 2018 and the lease liability at the beginning of 2019:

MSEK
17,9
-6,4
30,1
-0,9
0,0
-11,3
-0,8

None of the other IFRS or IFRIC interpretations that have yet to enter into force are expected to be of relevance to or have any material impact on the Group. The Parent Company does not intend to introduce IFRS 16, but will apply the exception in RFR 2, which means that the lease recognition will not be changed in the future.

## 2.2 CONSOLIDATED FINANCIAL STATEMENTS Subsidiaries

Subsidiaries are all companies (including structured entities) over which the Group has a controlling interest. The Group controls a company when it is exposed or entitled to variable returns from its holding in the company and has the opportunity to influence the return through its interest in the company. Subsidiaries are consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

The Group uses the acquisition method to recognize the Group's business combinations. The purchase price for the acquisition of a subsidiary comprises the fair value of transferred assets, liabilities incurred by the Group to former owners of the acquired company and the shares issued by the Group. The purchase price also includes the fair value of all liabilities resulting from a contingent consideration arrangement. Identifiable acquired assets and liabilities assumed in a business combination are measured initially at their fair values on the acquisition date.

Acquisition-related costs are expensed as they arise. Inter-company transactions, balance sheet items, income and expenditure on transactions between Group companies are eliminated. Profit and losses resulting from inter-company transactions and that are recognized in assets are also eliminated. The accounting policies for subsidiaries have been amended, where applicable, to ensure consistent application of the Group's policies.

#### 2.3 FUNCTIONAL CURRENCY AND PRESENTATION CURRENCY

The functional currency of the Parent Company is the Swedish

krona (SEK), which is also the presentation currency of the Group. This means that the financial statements are presented in SEK. Unless otherwise stated, all amounts are given and rounded to the nearest thousand (KSEK).

#### 2.4 FOREIGN CURRENCY TRANSLATION Transactions and balance sheet items

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing on the transaction date. Exchange gains and losses arising on payment of such transactions and on translation of monetary assets and liabilities denominated in foreign currencies at the exchange rate on the balance sheet date are recognized in operating profit in the income statement.

#### Translation of foreign Group companies

The earnings and financial position of all Group companies with a functional currency that differs from the presentation currency are translated into the Group's presentation currency. Assets and liabilities for each balance sheet are translated from the foreign operation's functional currency into the Group's presentation currency, SEK, at the exchange rate on the balance sheet date. Income and expenditure for each income statement are translated into SEK at the average exchange rate prevailing at the point of each transaction. Translation differences arising when translating the data of foreign operations are recognized in other comprehensive income.

#### 2.5 SEGMENT REPORTING

Operating segments are reported in the same way as internal reporting, which is submitted to the highest executive decision maker. The highest executive decision maker is the function responsible for allocating resources and assessing the operating segments' results. In the Group this function is identified as the CEO. For further information see Note 5.

#### 2.6 INTANGIBLE ASSETS Capitalized development costs

The Group conducts research and development relating to new products. The overall level of risk associated with current development projects is high. The risk comprises technical and manufacturing-related risks, safety and effect-related risks that can arise in clinical studies, regulatory risks relating to applications for approval of clinical studies and market approval, as well as IP risks relating to approval of patent applications and patent protection. All development work is therefore treated as research (since the work does not meet the criteria listed below), until the point at which the product has been granted market approval. Research expenditure is expensed as it occurs.

Expenses directly attributable to development and testing of identifiable and unique products controlled by the Group are recognized as intangible assets once the following criteria have been satisfied:

- it is technically possible to complete the product so that it can be used,
- the company intends to complete the product and use or sell it,
- the conditions are in place to use or sell the product,
- it can be shown that the product will generate probable future economic benefits,
- adequate technical, financial and other resources to complete the
- development and to use or sell the product are available, and
- expenses attributable to the product during its development can be reliably calculated.

Capitalized assets that have satisfied the capitalization criteria above have a limited useful life and are carried at cost less accumulated amortization. Amortization is initiated once the asset is ready for use. Amortization is conducted on a straightline basis to distribute the cost of the proprietary intangible assets over their estimated useful life, which coincides with the product's remaining patent period and amounts to between 10-15 years.

Directly attributable costs that are capitalized include development expenditure, as well as personnel costs and a reasonable proportion of indirect costs. Other development expenditure that does not satisfy the above criteria is expensed as it arises. Development expenses that have been previously expensed are not recognized as assets in the subsequent period.

#### 2.7 PROPERTY, PLANT, AND EQUIPMENT

Property, plant and equipment are recognized at cost less depreciation. The cost of acquisition includes expenditures that can be related directly to the acquisition of the asset.

Additional expenses are added to the asset's carrying amount or recognized as a separate asset, depending on which is appropriate, only when it is likely that the future economic benefits associated with the asset will be of use to the Group, and the cost of the asset can be reliably measured. The carrying amount of a replaced part is derecognized from the balance sheet. All other forms of repair and maintenance are recognized as costs in the income statement in the period in which they arise.

Depreciation is carried out on a straight-line basis as follows: Equipment 4–8 years.

The assets' residual values and useful lives are reviewed at the end of each reporting period and adjusted if required. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount. Gains and losses on disposal of property, plant or equipment are determined by comparing sales proceeds with the carrying amount and are recognized in other operating income or other operating expenses in the income statement.

#### 2.8 IMPAIRMENT OF NON-FINANCIAL NON-CURRENT ASSETS

Intangible assets that have an indeterminable useful life or intangible assets that are not ready for use are not subject to amortization but are tested annually for impairment. Assets subject to amortization are reviewed for impairment in value whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized at the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of the asset's fair value less distribution costs and its value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). For assets, previously impaired, a review is conducted every balance sheet date as to whether a reversal should be carried out.

#### **2.9 INVENTORIES**

Inventories are carried at the lower of cost and net realizable value. Cost is established via the First In First Out method, (FIFO) and with regard to the products' remaining shelf life. The net realizable value is the estimated selling price in the ordinary course of business less applicable variable distribution costs.

#### 2.10 FINANCIAL INSTRUMENTS 2.10.1 IFRS 9

Financial instruments are any form of agreement that gives rise to a financial asset in a company and a financial liability or equity instrument in another company. The report depends on how the financial instruments have been classified.

A financial asset or financial liability is recognized in the balance sheet when Camurus becomes a party to an agreement. Accounts receivable are recognized in the balance sheet when an invoice has been sent and the company's right to compensation is unconditional. Debt is recognized when the counterparty has performed and there is a contractual obligation to pay, even if the invoice has not yet been received. Accounts payable are recognized when the invoice is received.

A financial asset, or part of a financial asset, is removed from the balance sheet when the rights are realized, expire or the company loses control of them. A financial liability, or part of a financial liability, is removed from the balance sheet when the obligation is fulfilled or otherwise extinguished. A financial asset and a financial liability are offset and reported with a net amount in the balance sheet only when there is a legal right to offset the amounts and that there is an intention to settle the items with a net amount or to simultaneously realize the asset and settle the debt.

Gains and losses from removal from the balance sheet and modification are reported in the result.

#### **Financial assets**

Debt instruments: the classification of financial assets that are debt instruments is based on the Group's business model for managing the asset and the nature of the asset's contractual cash flows.

The instruments are classified into:

- amortized cost
- fair value through comprehensive income, or
- fair value through the result.

The Group's assets in the form of debt instruments are classified at amortized cost, ie, net of gross value and loss reserve. Changes in the loss reserve are reported in the result.

Financial assets classified at amortized cost are initially measured at fair value with the addition of transaction costs. Accounts receivable are initially recognized at the invoiced value. After the first accounting opportunity, the assets are valued according to the effective interest method. Assets classified at amortized cost are held according to the business model to collect contractual cash flows that are only payments of principal amounts and interest on the outstanding capital amount. The assets are covered by a loss reserve for expected credit losses.

#### **Financial liabilities**

Financial liabilities are classified at amortized cost. Financial liabilities recognized at amortized cost are initially measured at fair value including transaction costs. After the first accounting date, they are valued at accrued acquisition value according to the effective interest method.

#### Impairment of financial assets

The Group's financial assets are subject to write-downs for expected credit losses. Write-downs for credit losses according to IFRS 9 are forward-looking and a loss reserve is made when there is an exposure to credit risk, usually at the first accounting date. Expected credit losses reflect the present value of all cash flow deficits attributable to default either for the next 12 months or for the expected remaining term of the financial instrument, depending on the asset class and on the credit deterioration since the first accounting date. Expected credit losses reflect an objective, probability-weighted outcome that takes into account most scenarios based on reasonable and verifiable forecasts.

The simplified model is applied to accounts receivable. A loss reserve is reported, in the simplified model, for the expected residual maturity of the asset or asset.

For other items covered by expected credit losses, an impairment model with three stages is applied. Initially, as well as on each balance sheet date, a loss reserve for the next 12 months is reported, or for a shorter period of time

depending on the remaining maturity (stage 1). The Group's assets have been deemed to be in stage 1, that is, no significant increase in credit risk has occurred.

If there has been a significant increase in credit risk since the first accounting date, resulting in a rating below investment grade, a loss reserve for the asset's remaining maturity (stage 2) is reported. For assets that are deemed to be credit impaired, provisions for continued loan losses for the remaining maturity (stage 3) are still reserved. For credit-impaired assets and receivables, the calculation of interest income is based on the asset's carrying amount, net of loss reserves, as opposed to the gross amount as in the previous stages.

The valuation of expected loan losses is based on various methods. Other receivables and assets that are not covered by the simplified method are written down according to a rating-based method through external credit rating. The financial assets covered by provisions for expected credit losses according to the general method consist of cash and cash equivalents and other receivables. Expected credit losses are valued at the product of probability of default, loss given default and the exposure in the event of default.

The financial assets are recognized in the balance sheet at amortized cost, ie net of gross value and loss reserve. Changes in the loss reserve are reported in the income statement.

#### Cash and cash equivalents

Cash and cash equivalents consist of cash and immediately available balances with banks and corresponding institutions, and short-term liquid investments with a maturity of less than three months from the acquisition date. Cash and cash equivalents are subject to the requirement for loss reserves for expected loan losses.

#### 2.10.2 Comparative year according to IAS 39

Financial instruments are reported in accordance with IAS 39 in the comparative year 2017. IAS 39 had other classification categories than IFRS 9. The classification categories according to IAS 39 yet entailed corresponding accounting at amortized cost.

Furthermore, IAS 39 had another method for provisions for credit losses, which meant that a provision was made at a recognized credit event, unlike the method in IFRS 9, where provision is made for expected credit losses. Otherwise, there are no differences between the standards for the Group.

#### 2.11 TRADE RECEIVABLES

Trade receivables are financial instruments comprising amounts that are due to be paid by customers for goods and services sold in the ordinary course of business. Payments expected within one year or less are classified as current assets. Otherwise they are recognized as fixed assets. Trade receivables are initially recognized at fair value and thereafter at amortized cost using the effective interest method, less any provision for decrease in value.

#### 2.12 CASH AND CASH EQUIVALENTS

Cash and cash equivalents are financial instruments and comprise cash and bank balances.

#### 2.13 EQUITY

Ordinary shares are classified as equity. Transaction costs directly attributable to the issue of new ordinary shares or warrants are recognized, net after tax, in equity as deductions from the issue proceeds.

When the warrants are exercised, the company issues new shares. Payments received are credited to the share capital (quota value) and other contributed capital.

#### 2.14 TRADE PAYABLES

Trade payables are financial instruments and relate to obligations to pay for goods and services that have been acquired in the ordinary course of business. Trade payables are classified as current liabilities if they are payable within one year. Otherwise they are recognized as long-term liabilities. Trade payables are initially recognized at fair value, and thereafter at amortized cost using the effective interest method.

#### 2.15 CURRENT AND DEFERRED TAX

Tax expense for the period includes current income tax and deferred tax. The current income tax expense is calculated on the basis of the tax regulations that are enacted or substantively enacted on the balance sheet date in countries where the Parent Company and its subsidiaries operate and generate taxable revenue. Deferred tax is recognized using the balance sheet method, on all temporary differences arising between the tax base of assets and liabilities and their carrying amounts in the consolidated accounts. Deferred income tax is determined using the tax rates enacted or announced by the balance sheet date and that are expected to apply when the related deferred tax asset is realized or the deferred tax liability is settled.

Deferred tax assets on loss carryforwards are recognized to the extent that it is likely future taxable surpluses will be available, against which the losses can be utilized.

Deferred tax assets and tax liabilities are offset when a legally enforceable right to offset exists for current tax assets and liabilities, the deferred tax assets and liabilities refer to taxes charged by one and the same tax authority and relate either to the same taxable entity or different taxable entities and there is an intention to settle the balances using net payments.

#### 2.16 EMPLOYEE BENEFITS Pension obligations

The Group has defined contribution pension schemes, as well as defined benefit Alecta plans. All plans are recognized as defined contribution plans. The plan extends to all employees, including the Group CEO and senior executives.

A defined contribution plan is a pension plan under which the Group pays fixed contributions into a separate legal entity. The Group does not have any legal or informal obligation to pay additional contributions if this legal entity does not have sufficient assets to pay all benefits to employees attached to the employees' service during the current or previous periods.

For defined contribution plans, the Group pays contributions to public or privately administered pension insurance plans on a mandatory, contractual or voluntary basis. The Group has no additional payment obligations once the contributions have been paid. The contributions are recognized as personnel costs when they fall due for payment. Prepaid contributions are recognized as an asset to the extent that cash repayment or reduction of future payments may benefit the Group.

For salaried employees in Sweden, the ITP 2 plan's defined benefit pension obligations for retirement pension and family pension are secured through insurance held at Alecta. A defined benefit plan is a pension plan that is not a defined contribution plan. Defined benefit plans differ in that they define an amount of pension benefit that an employee will receive on retirement, usually dependent on one or more factors such as age, years of service and salary.

As per UFR 10 Classification of ITP plans financed by insurance in Alecta (a statement issued by the Swedish Financial Reporting Board), this is a multi-employer defined benefit plan. The Company has not had access to information for the period in order to report its proportional share of the plan's commitments, plan assets and costs, which has meant that it has not been possible to recognize the plan as a defined benefit plan.

The ITP 2 pension plan, secured through insurance held at Alecta, is thus recognized as a defined contribution plan. The premium for the defined benefit retirement and family pension is calculated individually and depends on such factors as salary, previously earned pension and expected remaining period of service. Anticipated contributions the next reporting period for ITP 2 insurance with Alecta amount to MSEK 2.6 (2017: MSEK 2.5, 2016: MSEK 2.3). The Group's share of the total contributions to the plan is not significant.

The collective consolidation level comprises the market value of Alecta's assets as a percentage of the insurance obligations, calculated in accordance with Alecta's actuarial methods and assumptions, which does not correspond with IAS 19. The collective consolidation level is normally allowed to vary between 125 and 155 percent. If Alecta's collective consolidation level falls short of 125 percent or exceeds 155 percent, measures will be taken to create conditions to restore the consolidation level to the normal interval. In the event of low consolidation, a possible measure might be to raise the

agreed price of new subscription and extension of existing benefits. In the event of high consolidation, a possible measure might be to introduce premium reductions. At the end of 2018 Alecta's surplus (in the form of the collective consolidation level) was 142 percent (2017: 154 percent).

Pension commitments in the form of direct pension are secured by a company-owned capital insurance. The commitment is entirely dependent on the value of the capital insurance. These commitments are reported at the same amount as the fair value of the endowment insurance as of the balance sheet date.

#### 2.17 REVENUE RECOGNITION

Revenues include the fair value of goods and services sold excluding value added tax, discounts, returns and other price reductions. The Group's revenue is reported as follows:

The transaction price is measured at the value Camurus deems to accrue to the company at the entrance of the agreement, less deductions for discounts and value added tax.

The transaction price is updated continuously if the conditions underlying the measurement have changed.

#### License and collaboration agreements

Revenue from agreements that are made with customers in research projects is recognized based on the financial implications of the agreement. Revenue from license and collaboration agreements may consist of one-off payments, license, royalty and milestone payments for the use of Camurus intellectual property rights and remuneration for research services. In addition, under the agreements Camurus may also be entitled to compensation for costs incurred. Revenue recognition reflects earning of revenues based on the commitments made in accordance with the specific contractual terms.

Camurus applies the criteria for revenue recognition on each separately identified commitment, so that the financial implications of the transaction can be reflected in the financial statements. This means, that the various transactions in the agreements are divided into distinct performance obligations and are recognized separately. The agreements often include compensation for the use of Camurus intellectual property rights licensed to the counterparty and compensation for research work carried out by Camurus. These commitments are analyzed to determine whether they constitute distinct performance commitments that must be reported individually or if they are to be regarded as one commitment. The license is deemed to constitute a separate performance commitment in cases where the license can be used without associated consulting services from Camurus. If the total value of the agreement falls short of the fair value of all performance obligations, the difference ('discount') is allocated among the separate performance obligations based on their relative standalone selling price.

The principles for revenue recognition of the performance obligations (and for corresponding separate transactions) in license and collaboration agreements are described below.

#### Licensing rights to Camurus' intangible assets

An assessment is made as to whether the license acquired by the counterparty in the agreement gives a right to use the intangible asset as it is when the license was granted, or a right to access the intangible asset throughout the license period.

The assessment is made based on the financial implications of the agreement. An assignment of licensing rights for a fixed fee under a non-cancellable agreement allowing the licensee to freely utilize Camurus' rights, and where Camurus does not have any remaining obligations to perform, is essentially regarded a right to use, which is recognized at a given time. If, instead, the agreement means that the recipient has a right to access during the entire license period, the compensation is allocated linearly over the term of the agreement. Usually, distinct licenses of the kind are "the right to use" as research services that could affect the value and benefit of the license are reported separately as a separate distinct performance commitment.

The transaction price that is to be received as compensation for the undertaken commitment to transfer a license to a customer may, depending on the terms of the agreement, be fixed or variable. Fixed income for a license to be reported at a given time is reported when the customer receives control of the license and can benefit from it. For variable income revenue recognition, see below under Royalty and milestone payments.

#### Milestone and one-time payments

In cases where Camurus receives a one-time payment in relation to signing an agreement, it is allocated as described above to the license commitment and the research services. The part that has been allocated to the license is recognized as revenue when the counterparty has obtained control of the license. Additional potential remuneration, i.e. variable remuneration, which is due to the occurrence of certain milestones in future pharmaceutical development, is first recognized as revenue when it is judged that it is very likely that a substantial reversal of accumulated income that has been reported does not arise. This time point is not expected to occur until it has been confirmed by the counterparty that the milestone has been achieved.

#### Royalty

A counterparty can also remunerate Camurus for the use of an IP right by paying royalties on future sales of a pharmaceutical product based on the IP right. Revenues for sales-based royalties agreed as exchange for a license for intellectual property is only reported when the subsequent sale takes place.

#### **Research services**

Regular remuneration is received for research services, both in advance as a fixed amount as well as on an ongoing basis. Research remuneration is recognized in the period in which the services are carried out. Revenue is calculated by an output method establishing the degree of completion for the performance obligation based on the proportion the services rendered represent in relation to the total services to be performed. Research services performed on an open account basis are recognized as income as the services are carried out.

#### Sale of goods

Revenue from the sale of goods is recognized when the control of the goods has been transferred to the customer and when Camurus no longer has any commitment in the ongoing management of business operations normally associated with ownership, and neither exercises any real control over the sold goods. This is usually when the goods are delivered to the retailers who are the Group's customer. In some cases, the transaction price is not known at the time of delivery, as the final price depends on the discount that will be paid to the public or private insurers who pay for the patients' drug. Because the final transaction price is not known, the Group estimates and recognises this discount deduction on a current basis. Retailers have the right to return unsold goods, and therefore the Group estimates a deduction for expected eventual future returns. Revenues from the sale of goods is only reported to the extent it is highly likely that a substantial reversal of accumulated recognised revenue is not expected.

#### **Compensation for costs incurred**

Compensation for costs incurred, i.e. costs that are forwarded onto the customer, is recognized in accordance with the guidance under IFRS 15 for determining whether an entity is acting as a principal or as an agent. This means that Camurus analyses whether the Company is acting as a principal in the transaction, i.e. that Camurus controls the goods or service before it is transferred to the customer. If Camurus is a principal in the transaction, the amount received from the counterparty is recognized as revenue. If Camurus is acting as an agent, the revenue instead comprises commission received.

#### 2.18 INTEREST INCOME

Interest income is recognized as revenue using the effective interest method. When the value of a receivable which is reported at amortized cost has fallen, the Group reduces the carrying amount to the recoverable value, which comprises estimated future cash flow, discounted with the original effective interest rate for the instrument, and continues to dilute the discounting effect as interest income. Interest income on impaired loans and receivables is recognized at the original effective interest rate.

#### 2.19 SHARE-BASED PAYMENT

#### Warrant programs

Presently Camurus has three long-term incentive programs active. In accordance with a decision by the Annual General Meeting in May 2016, May 2017, and May 2018, subscription warrant programs for the company's employees, have been introduced. The warrants are valued by an independent institute in accordance with the Black&Scholes model and were acquired by the participants at market value.

As part of the program, the participants receive a threepiece stay-on bonus in the form of gross salary addition from the company, equivalent to the amount paid by the participant for its subscription warrants. As the stay-on bonus is conditional on continued employment, costs including social security fee, are expensed over the vesting period and a liability is calculated at each balance sheet date based on how much has been earned.

Expenses are recognized as personnel expense in the income statements.

For a more detailed description of the warrant program, see Note 24.

#### 2.20 LEASES

The Group recognizes only operating leases for premises, vehicles, machinery and equipment. Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases are expensed in the income statement over the lease period.

#### 2.21 CASH FLOW STATEMENT

The cash flow statement has been prepared in accordance with the indirect method. This means that the operating profit is adjusted for transactions that have not involved incoming payments or disbursements during the period, and for any revenue and expenses relating to the cash flows of investing or financing activities.

#### 2.22 ACCOUNTING POLICIES, PARENT COMPANY

In connection with the transition to reporting according to IFRS in the consolidated accounts, the Parent Company adopted, RFR 2 Accounting principles for legal entities. The Parent Company's principles are consequently consistent with those of the Group, unless otherwise stated below.

#### Formats

The income statement and balance sheet follow the Swedish Annual Accounting Act statement. Statement of changes in equity follows the Group format but contains the columns listed in the Swedish Annual Accounts Act. The formats for the Parent Company gives a difference in designation, compared with the consolidated financial statements, primarily related to financial income and expenses and items within equity.

#### Interests in subsidiaries

Interests in subsidiaries are reported at cost, less any impairment losses. The cost includes acquisition related expenses and any additional considerations. When there is an indication that interests in subsidiaries have decreased in value, a calculation is made of the recoverable amount. If this amount is lower than the reported amount, an impairment is carried out.

#### **Group contributions**

The company applies the alternative rule in accordance with RFR 2 Accounting principles for legal entities, and, consequently, recognizes Group contributions received/paid as appropriations.

#### **Financial instruments**

Due to the connection between accounting and taxation, the rules on financial instruments in accordance with IFRS 9 are not applied in legal entity, but the company applies the acquisition value method in accordance with the Annual Accounts Act. In the company, therefore, financial fixed assets are valued at acquisition value and financial current assets according to the lowest value principle, with the application of write-downs for expected loan losses according to IFRS 9 for assets that are debt instruments. For other financial assets, write-downs are based on market values.

Impairment of financial assets that are debt instruments

Financial assets that are debt instruments are subject to write-downs for expected credit losses. Write-downs for loan losses according to IFRS 9 are forward-looking and a loss reserve is made when there is an exposure to credit risk, usually at the first accounting date. The simplified model is applied to accounts receivable. A loss reserve is reported, in the simplified model, for the expected residual maturity of the asset or asset.

For other items covered by expected loan losses, an impairment model with three stages is applied. Initially, as well as on each balance sheet date, a loss reserve for the next 12 months is reported, or for a shorter period of time depending on the remaining maturity (stage 1). If there has been a significant increase in credit risk since the first accounting date, a loss reserve for the asset's remaining maturity (stage 2) is reported. For assets that are deemed to be impaired, reserves are still reserved for expected credit losses for the remaining maturity (stage 3), and the calculation of interest income on the asset's carrying amount, net of loss reserves, as opposed to the gross amount as in the previous stages. The company's assets have been deemed to be in stage 1, since there has been no significant increase in credit risk which entails a rating below the corresponding investment grade.

The valuation of expected loan losses is based on various methods. The method for accounts receivable is based on historical customer losses combined with forward-looking factors. Other receivables and assets are written down according to a rating-based method with reference to external credit rating. Expected credit losses are valued at the product of probability of default, loss given default and the exposure in the event of default. For credit-impaired assets and receivables, an individual assessment is made, taking into account historical, current and forward-looking information. The valuation of expected loan losses takes into account any collateral and other credit enhancements in the form of guarantees.

Claims on Group companies are also subject to writedowns for expected loan losses. The company is of the opinion that the group companies currently have similar risk
profiles and the assessment is done on a collective basis for similar transactions. Based on the company's assessments according to the above method, taking into account other known information and forward-looking factors, expected loan losses are not deemed to be significant and no provision

# Note 3 Financial risk management

# **3.1 FINANCIAL RISK FACTORS**

has therefore been reported.

As a result of its business, the Group is exposed to a number of different risks: market risk (including foreign exchange risk), credit risk and liquidity risk. The Group has decided not to actively manage its risks through the use of derivatives, for example.

# a) Market risk

The most significant market risk for the Group is the foreign exchange risk, which is described in a separate section below. The interest rate risk is limited within the Group, as there is no long-term borrowing or long-term interest-bearing investment.

# Foreign exchange risk

The Group operates internationally and is exposed to foreign exchange risks arising from various currency exposures, primarily relating to the US dollar (USD), Euro (EUR) and Pound Sterling (GBP). The foreign exchange risk arises through future finance transactions, recognized assets and liabilities. Foreign exchange risks arise when future finance transactions or recognized assets or liabilities are expressed in a currency that is not the functional currency of the entity.

If the Swedish krona had weakened/strengthened by 5 percent in relation to the EUR and GBP, with all other variables remaining constant, the recalculated profit/loss for the year and equity at 31 December 2018, would have been MSEK 0.1 (0.1) respectively 0.2 (0.0) higher/ lower. Changes to SEK in relation to other currencies are not deemed to have any material impact on profit/loss for the year.

The Group has the following balance sheet exposure for assets, which include trade receivables and cash		
and cash equivalents (KSEK)	31-12-2018	31-12-2017
USD	1 100	4 770
	1,188	4,779
EUR	3,423	4,069
GBP	1,521	2,945
NOK	982	250
Other currencies	31	283
Total	7,145	12,078
The balance sheet exposure for trade payables is as follows (KSEK)	31-12-2018	31-12-2017
	31-12-2018	31-12-2017
	<b>31-12-2018</b> -963	<b>31-12-2017</b> -4,781
trade payables is as follows (KSEK)		
trade payables is as follows (KSEK)	-963	-4,781
trade payables is as follows (KSEK) USD EUR	-963 -20,578	-4,781 -2,758
trade payables is as follows (KSEK) USD EUR DKK	-963 -20,578 -2,352	-4,781 -2,758 -880
trade payables is as follows (KSEK) USD EUR DKK GBP	-963 -20,578 -2,352 -5,351	-4,781 -2,758 -880

# (b) Credit risk

Credit risk exists through cash and cash equivalents and cash balances with banks and financial institutions, and credit exposures to customers, wholesalers and retailers, including outstanding receivables and committed transactions. Only banks and financial institutions that are among the four largest Swedish banks according to Standard & Poor's rating list are accepted.

Before an agreement is entered into, the Group's customers are subjected to a credit assessment, whereupon information about the customer's financial position is accessed from various credit assessment companies. The overall assessment also considers other factors. The customer's financial position is also followed up and continually monitored. Trade receivables are continually followed up with checks on overdue invoices. Management does not expect any losses resulting from non-payment as the Group's counterparties mainly comprise major companies, which is why the credit risk is currently deemed to be low.

# (c) Liquidity risk

The Group closely monitors rolling forecasts for its liquidity reserve to ensure that the Group has sufficient cash funds to meet requirements in the ordinary course of business.

The table below analyses the Group's non-derivative financial liabilities classified by the time that, on the balance sheet date, remained until the contractually agreed maturity date. The amounts given in the table are the contractually agreed undiscounted cash flows.

Group, 31 december 2018	Up to one month	1–3 months	3 months– 1 year	1–5 years
Trade payables Other short-term	35,177	604	-	-
liabilities	190	-	-	_
Total	35,367	604	-	-

Group, 31 december 2017	Up to one month	1–3 months	3 months– 1 year	1–5 years
Trade payables Other short-term	15,080	6	-	-
liabilities	191	-	-	_
Total	15,271	6	-	_

## **3.2 MANAGEMENT OF CAPITAL**

The aim of the Group regarding capital structure is to ensure the Group's ability to continue its operations so that it can continue to generate a return for shareholders and benefit for other stakeholders, as well as maintaining an optimal capital structure to keep costs of capital down.

To maintain or adjust the capital structure, the Group can issue new shares or sell assets to reduce debt.

During 2018 the Group has mainly been engaged in research and development activities and in establishing the commercial infrastructure preparing for the launch of Buvidal<sup>®</sup> in the EU and Australia. Operations have been financed through earnings generated from successful research and development collaborations and through the issue conducted in connection with the listing of the company's share on Nasdaq Stockholm, December 3, 2015. Equity is therefore viewed as the Group's capital.

## **3.3 FAIR VALUE ESTIMATION**

The Group does not hold any instruments that are measured at fair value. The fair value of current receivables and liabilities corresponds to their carrying amounts, since discounting effects are minimal.

# Note 4 Important estimates and assessments

Estimates and assessments are evaluated continually and are based on historic experience and other factors, including expectations of future events that are judged reasonable under prevailing conditions

# IMPORTANT ESTIMATES AND ASSESSMENTS FOR ACCOUNTING PURPOSES

Group management makes estimates and assumptions concerning the future. There is a risk that the estimates made for accounting purposes do not corresponding to the actual result. The estimates and assumptions that involve a significant risk of material adjustments to carrying value of assets and liabilities within the next coming financial year, are outlined in brief below.

## **REVENUE RECOGNITION**

Camurus has complex customer agreements and the management must make assessments and estimates when applying revenue recognition principles. The section 'Accounting policies' regarding revenue details the areas for which assessments and estimates need to be carried out. Key areas in the assessment include the division and identification of the performance obligations in the agreements, how the price of these obligations should be allocated, the point in time and in which way the obligations should be recognized (on a single occasion or over a period of time). Camurus also needs to decide whether an agreement that includes a license to utilize Camurus' intellectual property constitutes a right to use, which is recognized at a given time, or if, instead, the agreement means that the recipient has a right to access during the entire license period, the compensation is allocated linearly over the term of the agreement. The assessments made by management affect the period in which, and amount at which the revenue is recognized.

# CAPITALIZED PRODUCT DEVELOPMENT EXPENDITURE

The Group capitalizes costs attributable to product development projects to the extent that they are deemed to satisfy the criteria in accordance with IAS 38 p. 57 (see Note 2.6 Intangible assets).

Intangible assets that are not ready for use are not subject to amortization but are tested annually for impairment. Intangible assets that are not ready for use are not subject to amortization but are tested annually for impairment. Impairment testing for capitalized development costs has therefore been carried out to ensure that the carrying amount does not exceed the recoverable amount. The material assumptions used for calculations of value in use include:

- Market size
- Anticipated market share
- Anticipated economic benefits
- Discount rate
- Anticipated growth rate

# DEFERRED TAX RECEIVABLES

Company management also makes judgments and estimates regarding the possibility of utilizing incurred losses and temporary differences as the basis for the reported tax receivable. For more information see section Significant risks and uncertainties page 56-57.

# Note 5 | Segment information

The highest executive decision maker is the function responsible for allocating resources and assessing the operating segments results. In the Group this function is identified as the CEO based on the information he handles. As the business, i.e. the development of pharmaceutical products based on Camurus' technology platform, the Group is organized as an integrated unit, with similar risks and opportunities for the products and services produced, the entire Group's business constitutes one operating segment. The operating segment are monitored in a manner consistent with the internal reporting provided to the chief operating decision maker. In the internal reporting to the CEO, only one segment is used.

To follow is a breakdown of revenues from all	Gre	Group		Parent Company	
products and services	2018	2017	2018	2017	
Sales of development-related					
goods and services	11,378	41,394	11,378	41,394	
Licensing revenues and					
milestone payments	26,626	10,607	26,626	10,607	
Product sale*)	11,316	2,096	11,316	2,096	
Intercompany sales	-	-	17,790	10,332	
Other	1	211	1	211	
Total	49,321	54,308	67,111	64,640	

\*) Related to episil®

Revenues from external customers is allocated by country, based on	Gre	oup	Parent C	Parent Company	
where the customers are located	2018	2017	2018	2017	
Europe	3,687	7,229	20,348	17,561	
(of which Sweden)	(327)	(239)	(327)	(239)	
USA	35,562	41,350	35,562	41,350	
Japan	9,661	5,522	9,661	5,522	
Other geographical areas	411	207	1,540	207	
Total	49,321	54,308	67,111	64,640	

Revenues during 2018 of approximately MSEK 24.8 (39.0) relates to a single external customer.

# **Note 6** | Expenses by nature

Operating expenses are presented in the statement of comprehensive income with a classification based on the functions 'Cost of sales', 'Marketing and distribution costs', 'Administrative expenses' and 'Research and development costs'. The sum of the function-dived costs were divided into the following cost items.

	Gro	oup	Parent C	ompany
Allocation by cost item	2018	2017	2018	2017
Raw materials and				
consumable supplies	6,822	1,356	6,822	1,356
Other expenses <sup>1) 2)</sup>	135,372	157,269	203,327	189,002
Costs of premises, including				
laboratory costs	72,688	44,826	61,516	41,857
Costs relating to employee				
benefits (Note 9)	119,693	90,386	87,833	74,063
Depreciation, amortization and				
impairment losses (Note 14 and 15)	4,450	4,088	2,335	1,997
Total cost of sales, research				
and development, sales and				
administration	339,025	297,925	361,833	308,275

1) This item includes costs that form the basis for research and development projects and for the Parent Company cost related to sales agent and service fee from subsidiaries of KSEK 78,275 (33,265).

2) Costs incurred for partner financed activities within research and development during the period have most essentially matched the size of the revenue. See also Note 5 Segment information and the item 'Sales of development-related goods and services.

# Note 9 Personnel, personnel costs and remuneration to Board members and senior executives

	Group		Parent C	Parent Company	
Other operating income	2018	2017	2018	2017	
Exchange gains (Note 13)	561	-	775	-	
Other items	269	93	63	61	
Total other operating income	830	93	838	61	

# Note 8 Audit fees

	Gre	Group		Parent Company	
Audit and other assignments	2018	2017	2018	2017	
PwC					
Auditing assignment	594	588	427	519	
Auditing beyond the					
auditing assignment	219	63	219	63	
Tax assignments	165	85	165	85	
Other assignments	182	301	182	301	
Total	1,160	1,037	993	968	

Audit fees for PwC Sweden during 2018 amounts to MSEK 0.4, and fees for other services performed amounted to MSEK 0.6.

Average no. of employees	Gro	oup	Parent C	Parent Company	
	2018 (of which women)	2017 (of which women)	2018 (of which women)	2017 (of which women)	
Sweden	58 (33)	58 (33)	58 (33)	56 (33)	
United Kingdom	5 (1)	2 (0)	-	-	
Germany	6 (4)	2 (1)	_	-	
Norway	1 (0)	1 (0)	_	-	
Finland	1 (0)	1 (0)	-	-	
France	1 (1)	1 (1)	0 (0)	1 (1)	
Australia	1 (0)	_	_	_	
Total	73 (40)	63 (35)	58 (33)	57 (34)	

Gender distribution in the Group, for Board members and other senior management Number on balance sheet date	Gro	oup	Parent C	Company
(of which women)	2018	2017	2018	2017
Board members <sup>1)</sup>	9 (4)	9 (3)	7 (3)	7 (2)
CEO and other senior management	8 (3)	11 (4)	7 (3)	10 (4)

1) The CEO, Chief Commercial Officer and the CFO, who are board members, are also reported as CEO and senior management.

Salaries, other remuneration	Group		Parent Company	
and social security costs	2018	2017	2018	2017
Salaries and other compensation <sup>1)</sup>	85,410	62,756	58,198	48,317
Social security cost	22,556	17,495	19,166	15,611
Pension expenses defined				
contribution plans	11,727	10,135	10,469	10,135
Total	119,693	90,386	87,833	74,063

Salaries and other remuneration by Board members and CEO, and other	Gro	pup	Parent Company		
employees (of which bonus)	2018	2017	2018	2017	
Board members, CEO and other	22,576	19,846	18,346	15,896	
senior management <sup>1)</sup>	(6,556)	(2,702)	(5,220)	(2,186)	
Other employees	62,834	42,910	39,852	32,421	
Total	85,410	62,756	58,198	48,317	

1) In the fixed salary 2018 and 2017, paid and earned stay-on bonus according to the terms of the warrant program TO2016/2019; TO2017/2020 and TO2018/2021 are included. See Note 24 and 28.

	Group		Parent Company	
Pension expenses	2018	2017	2018	2017
Board members, CEO and other				
senior management	4,060	4,580	4,060	4,580
Other employees	7,667	5,555	6,409	5,555
Total	11,727	10,135	10,469	10,135

The above salaries and remuneration do not include invoiced services from the Board and senior management. For remuneration and other benefits to the Board and senior management, see Note 28 Related party transactions. See also Note 24 Long-term incentive programs.

#### **Guidelines and remuneration 2018**

The AGM 2018 adopted the following gudelines for remuneration to senior executives 2018.

#### Guidelines for remuneration and other employment terms for senior executives, 2018

The Annual General Meeting of 2018 resolved to approve the Board of Directors' proposal on the principles of remuneration to the Company's senior executives as follows, until the time of the 2019 Annual General Meeting. In this context, the term senior executives refer to Camurus' CEO and the managers reporting to the CEO at any time, who are part of the Company's management team.

## **Reason for the motion**

The Company is to offer market aligned terms that facilitate the recruitment and retention of qualified senior executives. Remuneration comprises a balanced composition of fixed salary, variable remuneration, pension benefits, other benefits as well as conditions for termination. Cash remuneration comprises fixed salary and, when applicable, variable remuneration. The fixed salary and variable remuneration should be proportionate to the executive's responsibilities and authorities.

Long-term incentive programs may be offered as a complement to the above but must be referred to the general meeting for adoption. Remuneration is primarily based on the individual's position and performance, and the Company's and the individual's fulfilment of pre-defined targets.

#### **Fixed salary**

The fixed salary of the CEO and other senior executives should be monthly, at market rates, and reflect the requirements and responsibilities that their positions entail.

## Variable salaries

Variable remuneration is based on outcomes in relation to pre-determined, well-defined targets. These targets are set with the aim of advancing the Company's/Group's development, and to generate value and financial growth in the long term. Variable remuneration payments are to be maximized and may not exceed fifty (50) percent of the fixed annual salary for the CEO and other senior executives. Variable remuneration may also be paid in terms of long-term incentive programs.

#### Share-based program

Long-term incentive programs are to be available as a complement to fixed salaries and variable remuneration. Decisions on sharebased programs are made by the general meeting. Programs for variable remuneration should be designed to allow the Board of Directors, if exceptional financial conditions prevail, to restrict or omit payment of the variable remuneration if such action is deemed reasonable and consistent with the Company's responsibility towards shareholders, employees and other stakeholders.

## Other remuneration and terms of employment

Pension benefits are payable in accordance with applicable ITP plans or otherwise be premiumbased and amount to a maximum of 35 percent of the salary. Benefits other than fixed salary, variable remuneration and pension benefits are to be applied with restriction. Cont. Note 9

# Note 10 Other interest income and interest expenses and similar income items

A termination notice of 12 months from the Company and 6 months from the CEO applies between the Company and its CEO. No severance payment will be made. In the event that the CEO's employment in the Company is terminated due to, or in connection with, the transfer of the Company to new owners, a 24-month notice of termination from the Company applies. During the period of notice, fixed monthly salaries and other forms of remuneration are to be paid in accordance with the applicable employment contracts. In such an event, remuneration from the Company is not to be reduced by other forms of compensation that the CEO may receive during the period of notice.

A mutual notice period of 3 to 12 months applies to termination of contract between the Company and other senior executives. No severance payment will be made.

To the extent that Board members perform work for the Company, in addition to work on the Board of Directors, a market aligned consultancy fee may be payable for such work. Remuneration is to be in line with market terms and the amount, as with other terms, is decided by the Board of Directors.

# **Deviation from the guidelines**

The Board is entitled to deviate from these guidelines if the Board warrants that there are particular grounds for doing so in individual cases. During the year, the guidelines were followed without deviations.

# Guidelines for remuneration and other employment terms for senior executives, 2019

In essence it is proposed that the guidelines in its design is unchanged against the decision by the AGM of 3 May 2018.

	Gr	Group		Parent Company	
Finance income	2018	2017	2018	2017	
Interest income, cash pool	175	173	175	173	
Interest income, other	0	1	0	1	
Finance income	175	174	175	174	

	Group		Parent Company	
Finance expenses	2018	2017	2018	2017
Interest expenses, cash pool	0	-7	0	-7
Interest expenses, other	-25	-11	-24	-11
Finance expenses	-25	-18	-24	-18
Total financial items – net	150	156	151	156

# Note 11 Income tax

	Group		Parent C	Parent Company	
	2018	2017	2018	2017	
Income tax:					
Income tax on profit for the year	-1,463	-518	-	-	
Total current tax	-1,463	-518	-	_	
Deferred tax (see Note 16)	53,855	53,312	53,527	52,853	
Total deferred tax	53,855	53,312	53,527	52,853	
Income tax	52,392	52,794	53,527	52,853	

The income tax on profit differs from the theoretical amount that would have resulted from the use of a weighted average tax rate for earnings in the consolidated companies in accordance with the following:

	Group		Parent C	Company
	2018	2017	2018	2017
Profit/loss before tax Income tax is calculated in accordance with the national	-287,068	-243,368	-292,291	-243,418
tax rates in force prior to the results in each country	63,169	53,493	64,304	53,552
Tax effects of:				
- Non-taxable revenue	457	429	457	429
<ul> <li>Non-deductible expenses</li> <li>Adjustment for reduced</li> </ul>	-570	-1,128	-570	-1,128
income tax rate	-10,664	-	-10,664	-
Recognised effective tax	52,392	52,794	53,527	52,853

Weighted average tax rate for the Group is 18.3 percent (21.7 percent) and for the Parent Company 18.3 percent (21.7 percent).

# Note 12 Earnings per share based on earnings attributable to Parent Company shareholders for the year

## (a) Before dilution

Earnings per share before dilution is calculated by dividing the result attributable to shareholders of the Parent Company by a weighted average number of ordinary shares outstanding during the period. During the period, no shares held as treasury shares by the Parent Company have been repurchased.

	2018	2017
Result attributable to Parent Company shareholders Weighted average number of ordinary shares outstanding (thousands)	-234,676 37,842	-190,574 37,281

## b) After dilution

In order to calculate earnings per share, the number of existing ordinary shares is adjusted for the dilutive effect of the weighted average number of outstanding ordinary shares. The Parent Company has one category of ordinary shares with anticipated dilution effect in the form of warrants. For warrants, a calculation is made of the number of shares that could have been purchased at fair value (calculated as the average market price for the year for the Parent Company's shares), at an amount corresponding to the monetary value of the subscription rights linked to outstanding warrants. The number of shares calculated as above is compared to the number of shares that would have been issued assuming the warrants are exercised. For further information related to warrant programs, see Note 24. For further information see also Note 28 Related party transactions.

	2018	2017
Result attributable to Parent Company shareholders Weighted average number of ordinary shares outstanding (thousands)	-234,676 37,842	-190,574 37,281
Adjustments: - warrants (thousands) - share issues (thousands)	1,389 –	777
Weighted average no. of ordinary shares used in calculation of earnings per share after dilution (thousands)	39,231	38,058

# Note 13 | Exchange rate differences

Exchange rate differences have been recognized in the income statement as follows:

Group		Parent C	Company
2018	2017	2018	2017
2,217	-	2,217	-
-1,656	-1,147	-1,442	-1,147
561	-1,147	775	-1,147
	<b>2018</b> 2,217 -1,656	2018 2017 2,217 – -1,656 -1,147	2018         2017         2018           2,217         -         2,217           -1,656         -1,147         -1,442

# Note 15 Property, plant, and equipment

	Gre	oup	Parent C	ompany
Tangible assets	31-12-2018	31-12-2017	31-12-2018	31-12-2017
Ingoing accumulated acquisition value	20,436	18,293	20,256	18,293
Investments	3,357	2,143	3,298	1,963
Exchange-rate differences	7	-	_	· _
Outgoing accumulated acquisition value	23,800	20,436	23,555	20,256
Ingoing accumulated depreciaton	-10,534	-8,534	-10,531	-8,534
Exchange-rate differences	1	-	_	-
Depreciation	-2,368	-2,000	-2,335	-1,997
Outgoing accumulated depreciation	-12,901	-10,534	-12,866	-10,531
Closing balance	10,899	9,902	10,689	9,725

Note 14 | Intangible assets

	Group		
Capitalized development expenditure	31-12-2018	31-12-2017	
Ingoing accumulated acquisition value	22,906	22,906	
Capitalized expenses	1,404	-	
Outgoing accumulated acquisition value	24,310	22,906	
Ingoing accumulated depreciaton	-6,253	-4,165	
Depreciation	-2,082	-2,088	
Outgoing accumulated depreciation	-8,335	-6,253	
Closing balance	15,975 <sup>1)</sup>	16,653 <sup>2)</sup>	

1) The amount relate to episil^ and the ongoing clinical trial of  $\mathsf{Buvidal}^{\circledast}$  in Australia.

During 2018 episil® generated revenues of MSEK 12,3 from product sales, license revenues and milestone payments, see also Note 5.

2)The amount relates to episil®, which in 2017 generated revenues of MSEK 9.2 from product sales, license revenues and milestone payments, see also Note 5

In impairement tests, the recoverable amount consists of the cashgenerating unit's estimated value in use. Depreciation expenses of KSEK 2,082 (2,088) are included in their entirety among research and development expenses.

Depreciation expenses of KSEK 2,368 (2,000) are included in their entirety among research and development expenses.

# Note 16 Deferred tax

## Deferred tax assets and liabilities are distributed as follows:

	Gro	oup	Parent C	ompany
Deferred tax assets	31-12-2018	31-12-2017	31-12-2018	31-12-2017
Deferred tax assets to be used after 12 months	175.056	119.426	175,056	119,426
Deferred tax assets to be used within 12 months	-	-	-	
Total deferred tax assets	175,056	119,426	175,056	119,426
<b>Deferred tax liabilities</b> Deferred tax liabilities to be used after 12 months	-3,655	-3,972	_	_
Deferred tax liabilities to be used within 12 months	-446	-458	_	-
Total deferred tax liabilities	-4,101	-4,430	_	_
Deferred tax assets (net)	170,955	114,997	175,056	119,426

	Group		Parent Company	
Gross change regarding deferred taxes	2018	2017	2018	2017
Opening balance	114,997	61,685	119,426	66,574
Recognition in equity	2,103	-	2,103	-
Recognition in income				
statement (Note 11)	53,855	53,312	53,527	52,853
Closing balance	170,955	114,997	175,056	119,426

Details of changes in deferred tax assets and tax liabilities during the year that have been recognized in the income statement, excluding offsetting that has been carried out within the same tax jurisdiction, are given below:

	G	Group		
Deferred tax liabilities	Untaxed reserves	Intangible assets	Total	
On 1 January, 2017	-766	-4,123	-4,889	
Recognized in income statement	0	458	458	
On 31 December, 2017	-766	-3,665	-4,430	
On 1 January, 2018	-766	-3,665	-4,430	
Recognized in income statement	0	329	329	
On 31 December, 2018	-766	-3,336	-4,101	

		Parent C	ompany	
Deferred tax assets	Loss carry- forward	Temporary differences	Accrued revenue	Total
On 1 January, 2017	66,146	428	-	66,574
Recognized in income statement	52,823	29	-	52,852
On 31 December, 2017	118,969	457	-	119,426
On 1 January, 2018	118,969	457	-	119,426
Recognized in income statement	55,250	380	-	55,630
On 31 December, 2018	174,219	837	-	175,056

Depending on the Group's activities with considerable research and development costs, the company is not liable for tax. The Parent Company's accumulated loss carryforwards at the end of 2018 is provisionally MSEK 842.2, of which MSEK 540.9 are taxed.

# Note 17 | Interests in Group companies

#### **Parent Company**

On 1 January, 2017	816	On 1 January, 2018	1,545
Transactions	729	Transactions	255
On 31 December, 2017	1,545	On 31 December, 2018	1,800

During 2018 subsidiaries have been established in France and Australia.

### The Parent Company holds shares in the following subsidiaries:

	Corporate	Country of registration	Share of	Number	Booke	d value
Name	identity number	and operation	equity	of shares	31-12-2018	31-12-2017
Camurus Inc	43-1648843	USA	100%	1,000	83	83
Cubosome Inc	43-1648841	USA	100%	1,000	83	83
Camurus						
Development AB	556421-1208	Sweden	100%	3,591,143	407	407
Camurus GmbH	HRB727015	Germany	100%	25,000	243	243
Camurus Ltd	10571011	Great Britain	100%	1	0	0
Camurus Oy	2864875-7	Finland	100%	25,000	238	238
Camurus AS	920137253	Norway	100%	250,000	253	253
Camurus SAS	67838703114	France	100%	25,000	238	238
Camurus Pty Ltd	627784605	Australia	100%	40,000	255	-
Total					1,800	1,545

# Note 18 Inventories

	Group		Parent Company	
	31-12-2018	31-12-2017	31-12-2018	31-12-2017
Finished goods	2,206	230	2,206	230
Work in progress	2,494	2,599	2,494	2,599
Raw materials	5,130	724	5,130	724
Total	9,830	3,553	9,830	3,553

The cost of inventories recognized as an expense is included in cost of goods sold and amounted to MSEK 6.3 (1.3)

# Note 19 | Financial instruments per category

Below the Group's financial assets and liabilities, classified in the categories according to IFRS 9. The Group's financial assets and liabilities for the comparative year 2017 are presented in accordance with IAS 39 classification categories.

	Grou	ıp
Balance sheet assets	31-12-2018	31-12-2017
	Financial assets measured at amortized cost	Loans and receivables
Trade receivables	2,280	5,781
Other receivables	-	-
Cash and cash equivalents	134,377	314,524
Total	136,657	320,305
Balance sheet liabilities		
	Financial liabilities measured at amortized cost	Other liabilities
Trade payables	35,781	15,086
Other liabilities	190	191
Total	35,971	15,277

When determining whether the credit risk of a financial asset has increased significantly since initial recognition and when estimating ECL (expected credit loss), the Group considers reasonable and supportable information that is relevant and available without undue cost and effort. This includes both quantitative and qualitative information and analysis, based on the Group's historical experience and informed credit assessment and including forward looking information.

# Note 20 | Trade receivables

	Group		Parent Company	
	31-12-2018	31-12-2017	31-12-2018	31-12-2017
Trade receivables	2,506	5,792	2,506	5,792
Deduction: Provision for bad debts	-226	-11	-226	-11
Trade receivables – net	2,280	5,781	2,280	5,781

On 31 December 2018, overdue trade receivables totaled KSEK 1,643 (KSEK 2,058), and no impairment requirement deemed to exist for the Group. The overdue receivables relate to a number of customers who have not previously had any payment difficulties.

	Group		Parent Company		
Their aging analysis is as follows	31-12-2018	31-12-2017	31-12-2018	31-12-2017	
1-30 days	1,555	1,723	1,555	1,723	
31-60 days	78	65	78	65	
> 61 days	10	270	10	270	
Total receivables due	1,643	2,058	1,643	2,058	

Reported amount, by currency,	Gro	bup	Parent Company	
for trade receivables are as follows	31-12-2018	31-12-2017	31-12-2018	31-12-2017
SEK	34	482	34	482
EUR	65	259	65	259
USD	1,969	4,942	1,969	4,942
Other currencies	212	98	212	98
Total trade receivables	2,280	5,781	2,280	5,781

# Note 21 | Prepayments and accrued income

	Group		Parent Company	
	31-12-2018	31-12-2017	31-12-2018	31-12-2017
Prepayments	9,738	4,741	9,613	4,704
Accrued income	1,067	2,498	1,067	2,498
Total	10,804	7,239	10,679	7,202

# Note 22 Cash and cash equivalents

The following is included in cash and cash equivalents in the balance	Gro	oup	Parent C	Parent Company	
sheet and cash flow statement	31-12-2018 31-12-2017		31-12-2018	31-12-2017	
Cash and bank deposits	134,375	314,522	123,856	309,819	
Petty cash	2	2	2	2	
Total	134,377	314,524	123,858	309,821	

# Note 23 | Share capital and other contributed capital

	Note (i	Number of shares thousands)	Share capital	Other contributed capital	Total
On 1 January, 2017		37,281	932	631,034	631,966
Warrants issued	24	-	-	11 141	11,141
On 31 December, 2017	24	37,281	932	642,175	643,107
On 1 January, 2018		37,281	932	642,175	643,107
Directed share issue		1,100	28	102,272	102,300
Issuance costs, net after defe	rred tax	-	-	-7,456	-7,456
Warrants issued	24	-	-	7,110	7,110
On 31 December, 2018	24	38,381	960	744,101	745,061

Share capital consists of 38,381,486 shares with a quota value of SEK 0.025. The shares carry a voting right of one (1) vote per share. All shares issued by the Parent Company are fully paid up.

# Note 24 | Long-term incentive programs

## WARRANT PROGRAM TO2016/2019

In accordance with a decision by the Shareholder's General Meeting in May 2016, an incentive program was introduced (TO2016/2019) for the Company's employees, under which 550,000 warrants have been issued and which give the right to subscribe for an equal number of shares during the period 15 May 2019 - 15 December 2019. In all, 47 employees have joined the program and subscribed for 404,300 warrants. Transfer of subscription warrants to future employees was not allowed after the Annual General Meeting 2017. The dilution effect on a maximum utilization of subscribed warrants corresponds to 1.1% of the share capital and the voting rights.

The strike price for subscription of shares upon exercise of the transferred warrants was set at SEK 99.50. The warrants were valued by an independent institute in accordance with the Black&Scholes model and were acquired by the participants at market value.

As part of the program, participants receive a three-piece stay-on bonus in the form of gross salary additions from the Company, equivalent to the amount paid by the participant for its subscription warrants. The first bonus payout, in total equivalent to one-third (1/3) of the amount paid by the participant for its subscription warrants, occurs in connection with the participants payment for the subscription warrants. The second bonus payment, equivalent to one-third (1/3) of the amount (1/3) of the amount paid by the participant for its subscription warrants, occured on 1 July 2017, provided that the participant at such time remained in its position (or equivalent) within the Group. The third and last bonus payment, equivalent to one-third (1/3) of the amount paid by the participant at such time the third quarter, provided that the participant at such time the third quarter, provided that the participant at such time held his/her position (or equivalent) within the Group. No additional costs have been incurred.

## Costs, dilution etc.

The Company's cost, including statutory social security contributions, for the "stay-on bonus" to the participants at full initial participation and at an assumed market value for the subscription warrants of SEK 9.45, is estimated to be maximum approximately MSEK 6.9 before income tax. In addition, the Company may be charged minor costs for social security contributions for subscription warrants to participants in other jurisdictions. Other than that, the program is not expected to entail any significant costs for the Company. For that reason, no measures to secure the program has been taken. Assuming that all 404,300 subscribed warrants are exercised for subscription of new shares, the Company's share capital will increase by a maximum of SEK 10,108, resulting in a maximum dilution effect equivalent to approximately 1.1 percent calculated as the number of new shares in proportion to the number of existing and new shares. The key figure earnings per share for the full year 2018 had in such case been affected such that the loss per share had been reduced by approximately SEK 0.07 from SEK -6.20 to SEK -6.14. The above is subject to re-calculations of the subscription warrants in accordance with the

customary terms stated in the complete terms and conditions. The proposal from the Board has been prepared by the Board. The members of the Board, other than the CEO, will not be allotted subscription warrants. Fredrik Tiberg, CEO and member of the Board, who may be allotted subscription warrants in the program, has not taken part in the preparation of this matter.

In 2018 MSEK 0.9, after income tax, have been expensed for the "stay-on bonus" the participants receive as part of the program.

#### WARRANT PROGRAM TO2017/2020

In accordance with a decision by the Shareholder's General Meeting in May 2017, an additional incentive program; TO2017/2020, was introduced for the Company's employees, under which 750,000 warrants have been issued and which give the right to subscribe for an equal number of shares during the period 15 May 2020 - 15 December 2020. In all, 44 employees have joined the program and subscribed for 658,932 warrants. Transfer of subscription warrants to future employees was not allowed after the Annual General Meeting 2018. The dilution effect on a maximum utilization of subscribed warrants corresponds to 1.7 percent of the share capital and voting rights.

The strike price for subscription of shares upon exercise of the transferred warrants was set at SEK 167.20. The warrants were valued by an independent institute in accordance with the Black&Scholes model and were acquired by the participants at market value.

As part of the program, participants receive a three-piece stay-on bonus in the form of gross salary additions from the Company, equivalent to the amount paid by the participant for its subscription warrants. The first bonus payout, in total equivalent to one-third (1/3) of the amount paid by the participant for its subscription warrants, occurs in connection with the participant's payment for the subscription warrants. The second bonus payment, equivalent to one-third (1/3) of the amount paid by the participant at such time remains in its position (or equivalent) within the Group. The third bonus payment, equivalent to one-third (1/3) of the amount paid by the participant at such time remains in its position (or equivalent) within the Group. The third bonus payment, equivalent to one-third (1/3) of the amount paid by the participant for its subscription warrants, occurs on 1 July 2019, provided that the participant at such time remains in its position from the above stated principles for bonus payment, the Board may, if necessary in individual cases, resolve on alternative payment schedules.

## Costs, dilution etc.

The Company's cost, including statutory social security contributions, for the "stay-on bonus" to the participants at full initial participation and at an assumed market value for the subscription warrants of SEK 15.00, is estimated to be maximum approximately MSEK 14.0 before income tax. In addition, the Company may be charged minor costs for social security contributions for subscription warrants to participants in other jurisdictions. Other than that, the program is not expected to entail any significant costs for the Company. For that reason, no measures to secure the program has been taken. Assuming that all 658,932 subscripscribed warrants are exercised for subscription of new shares, the Company's share capital will increase by a maximum of SEK

16,473, resulting in a maximum dilution effect equivalent to approximately 1.7 percent calculated as the number of new shares in proportion to the number of existing and new shares. The key figure earnings per share for the full year 2017 had in such case been affected such that the loss per share had been reduced by approximately SEK 0.11 from SEK -6.20 to SEK -6.10. The above the program has a constrained and the cubercritic percent calculated to expected to end the cubercritic percent calculated to expected to end the cubercritic percent calculated to end to end the cubercritic percent calculated to end to e

is subject to re-calculations of the subscription warrants in accordance with the customary terms stated in the complete terms and conditions. The proposal from the Board has been prepared by the Board. The members of the Board, other than the CEO, will not be allotted subscription warrants. Fredrik Tiberg, CEO and member of the Board, who may be allotted subscription warrants in the program, has not taken part in the preparation of this matter.

In 2018 MSEK 4.0, after income tax, have been expensed for the "stay-on bonus" the participants receive as part of the program.

## WARRANT PROGRAM TO2018/2021

In accordance with a decision by the Shareholder's General Meeting in May 2018, a third incentive program; TO2018/2021, was introduced for the Company's employees, under which 1,000,000 warrants have been issued and which give the right to subscribe for an equal number of shares during the period 15 May 2021 - 15 December 2021. In all, 47 employees have joined the program and subscribed for 562,400 warrants. Transfer of subscription warrants to future employees was not allowed after the Annual General Meeting 2019. The dilution effect on a maximum utilization of subscribed warrants corresponds to 1.5 percent of the share capital and voting rights.

The strike price for subscription of shares upon exercise of the transferred warrants was set at SEK 144.90. The warrants were valued by an independent institute in accordance with the Black&Scholes model and were acquired by the participants at market value.

As part of the program, participants receive a three-piece stay-on bonus in the form of gross salary additions from the Company, equivalent to the amount paid by the participant for its subscription warrants. The first bonus payout, in total equivalent to one-third (1/3) of the amount paid by the participant for its subscription warrants, occurs in connection with the participant's payment for the subscription warrants. The second bonus payment, equivalent to one-third (1/3) of the amount paid by the participant at subscription warrants, occurs on 1 July 2019, provided that the participant at such time remains in its position (or equivalent) within the Group. The third bonus payment, equivalent to one-third (1/3) of the amount paid by the participant to one-third (1/3) of the amount paid by the subscription warrants, occurs on 1 July 2020, provided that the participant at such time remains in its position from the above stated principles for bonus payment, the Board may, if necessary in individual cases, resolve on alternative payment schedules.

#### Costs, dilution etc.

The Company's cost, including statutory social security contributions, for the "stay-on bonus" to the participants at full initial participation and at an assumed market value for the subscription warrants of SEK 12, is estimated to be maximum approximately MSEK 16.9 before income

tax. In addition, the Company may be charged minor costs for social security contributions for subscription warrants to participants in other jurisdictions. Other than that, the program is not expected to entail any significant costs for the Company. For that reason, no measures to secure the program has been taken. Assuming that all 562,400 subscribed warrants are exercised for subscription of new shares, the Company's share capital will increase by a maximum of SEK 14,060, resulting in a maximum dilution effect equivalent to approximately 1.5 percent calculated as the number of new shares in proportion to the number of existing and new shares. The key figure earnings per share for the full year 2018 had in such case been affected such that the loss per share had been reduced by approximately SEK 0.09 from SEK -6.20 to SEK -6.11. The above is subject to re-calculations of the subscription warrants in accordance with the customary terms stated in the complete terms and conditions. The proposal from the Board has been prepared by the Board. The members of the Board, other than the CEO, will not be allotted subscription warrants in the program, has not taken part in the preparation of this matter.

In 2018 MSEK 3.5, after income tax, have been expensed for the "stay-on bonus" the participants receive as part of the program.

Program	Maximum number of subscription warrants	Dilution of a full utilization of the program	Number of subscribed warrants	Potential dilution of the subscribed warrants	Subscription period	Strike price for subscription of shares upon exercise	Number of employees participating in the program
TO2016/2019	550,000	1.4%	404,3001)	1.1%	15 May 2019 15 Dec 2019	- 99.50	47
TO2017/2020	750,000	2.0%	658,932 <sup>2)</sup>	1.7%	15 May 2020 15 Dec 2020	- 167.20	44
TO2018/2021	1,000,000	2.6%	562,400 <sup>3)</sup>	1.5%	15 May 2021 15 Dec 2021	- 144.90	47

No further allocation can be made as the AGM 3 May 2017 has been passed.
 No further allocation can be made as the AGM 3 May 2018 has been passed.
 No further allocation can be made once the AGM 9 May 2019 has been passed

In March 2019, the Company completed a rights issue, and according to the terms of the warrant programs, the number of warrants shall be re-calculated. Maximum utilization of the above subscribed warrants corresponds to a maximum of 1,764,941 (before re-calculation 1,625,632) new shares in Camurus, with a dilution effect of approximately 3.7% (4.2%).

# Note 25 Accruals and deferred income

# Note 27 Other non-cash items

	Gro	bup	Parent C	Company
	31-12-2018	31-12-2017	31-12-2018	31-12-2017
Accrued holiday pay and other items	20,238	13,679	15,339	11,055
Accrued social security contributions	12,585	9,792	11,209	8,965
Accrued R&D costs	4,551	13,928	4,551	13,928
Accrued expenses, other	8,761	6,943	6,106	5,858
Accrued licensing fees	25,228	28,317	25,228	28,317
Total	71,362	72,659	62,432	68,123

	Group		Parent Co	ompany
	31-12-2018	31-12-2017	31-12-2018	31-12-2017
Depreciation	4,447	4,088	2,335	1,997
Other	3	16	-	-
Total	4,450	4,104	2,335	1,997

# Note 26 Leases

# **OPERATING LEASES**

The Group only has operating leases relating to premises, cars and machinery. Future minimum lease payments in accordance with non-cancellable operating leases valid at the end of the reporting period are due for payment as follows:

	Group		Parent C	ompany
	31-12-2018	31-12-2017	31-12-2018	31-12-2017
0-1 year	7,396	5,706	6,634	5,036
1–5 years	10,535	11,102	10,535	10,497
> 5 years	-	-	-	-
Total	17,931	16,808	17,169	15,533

Costs for operating leases in the Group during the financial year have amounted to KSEK 8,666 (KSEK 7,800).

# Note 28 Related party transactions

On 31 December 2018, Sandberg Development AB owns 53.2 percent of the shares in Camurus AB and therefore has a controlling interest in the Group. Other related parties are all subsidiaries in the Group, along with key management personnel in the Group, i.e. the Board and company management, as well as their family members (and Piir & Partner AB during 2017).

(a) Purchase and sales of services	2018	2017
Purchase of services:		
– Piir & Partner AB	-	359
<ul> <li>Subsidiaries (sales agency fee, service fee)</li> </ul>	78,274	33,266
Total	78,274	33,625
Sales of services:		
– Subsidiaries (management fee)	17,789	10,332
Total	17,789	10,332

Goods and services are purchased and sold on normal commercial terms. Transactions with the subsidiaries of Camurus AB occur regarding management fee, sales agency fee and service fee. Pricing is done in accordance with allocation of costs in relation to utilization rate and on commercial terms.

With Piir and Partner AB, transactions related to their representative's work in the management team have taken place. Billing is done in relation to the utilization, and pricing are subject to market conditions.

(b) Remuneration for executive management	2018	2017
Salaries and other short-term benefits	20,031	18,478
Other long-term benefits	3,645	4,563
Total	23,676	23,042

# GUIDELINES

Remunerations are paid to the Chairman of the Board, Board members and for committee work in accordance with decisions made by the Annual General meeting 3 May 2018.

Remuneration to the CEO and other senior executives comprises basic salary, variable remuneration, pension benefits, other benefits and terms of notice. Other senior executives include those individuals who together with the CEO from the Group management. For the current composition of the Group management, see pages 102-103.

The division between basic salary and variable remuneration is to be linked to the executive's level of responsibility and authority. The variable remuneration is to be based on the outcome of predetermined well-defined objectives. The variable cash remuneration is to be limited to fifty (50) percent of the fixed annual salary for the CEO and for other senior executives. Variable remuneration may also be paid in the form of long-term incentive programs. For further information, see Note 9.

#### Decided remuneration and other benefits 2018

	Board fee <sup>1)</sup>	Audit committee <sup>1)</sup>	Remuneration committee <sup>1)</sup>	Total
Board of Directors				
Per-Olof Wallström, Chairman	550	50	50	650
Martin Jonsson	200	100	25	325
Fredrik Tiberg	-	-	-	-
Per-Anders Abrahamsson	200	-	-	200
Marianne Dicander Alexandersson	200	50	-	250
Kerstin Valinder Strinnholm	200	-	25	225
Beshad Sheldon <sup>2)</sup>	200	-	-	200
Total	1,550	200	100	1,850

	Basic salary	Variable remuneration	Other benefits	Pension expenses	Total
Group management					
Fredrik Tiberg, CEO	4,899	1,617	87	1,488	8,090
Other executive management	10,370	2,751	308	2,157	15,586
(7 individuals)					
Total	15,269	4,368	395	3,645	<b>23,676</b> <sup>3)</sup>

#### Decided remuneration and other benefits 2017

	Board fee <sup>1)</sup>	Audit l committee <sup>1)</sup>	Remuneration committee <sup>1)</sup>	Total
Board of Directors				
Per-Olof Wallström, Chairman4)	500	50	50	600
Svein Mathisen <sup>4)</sup>	175	50	25	250
Martin Jonsson	175	100	25	300
Fredrik Tiberg	-	-	-	-
Per-Anders Abrahamsson	175	_	_	175
Marianne Dicander Alexandersson <sup>4)</sup>	175	50	-	225
Kerstin Valinder Strinnholm	175	-	25	200
Total	1,375	250	125	1,750

	Basic salary	Variable remuneration	Other benefits	Pension expenses	Total
Group management					
Fredrik Tiberg, CEO	3,904	826	79	1,651	6,460
Other executive management (10 individuals)	11,201	2,040	429	2,913	16,528
Total	15,105	2,866	507	4,563	<b>23,042</b> <sup>3)</sup>

1)AGM resolved fees, for the period May 2018 – May 2019 (May 2017-May 2018) for payment twice a year. No board remuneration for CEO is paid.

2)Elected at the Annual General Meeting 3 May 2018.

3) In addition to the above agreed remuneration, earned and paid stay-on bonuses, in accordance with the terms in the subscription warrant programs TO2016/2019, TO2017/2020 and TO2018/2021, to CEO of KSEK 1,012 (KSEK 782) and other senior executives of KSEK 2,170 (KSEK 2,010), has been accounted for. See also Note 24. 4) Remuneration invoiced via company.

### PENSIONS

The pensionable age for the Chief Executive Officer and key management personnel is 65 years.

#### **TERMINATION BENEFITS**

The notice period between the Company and CEO is 12 months from the Company, and 6 months from the CEO. No severance payment will be made. If the CEO's employment at the Company ceases as a result of, or in connection with the Company being transferred to a new owner, a notice period of 24 months from the Company applies. During the notice period a fixed monthly salary is paid, along with other remuneration in accordance with the applicable employment agreement. Remuneration from the Company will not in this case be reduced by any other possible remuneration that the CEO may receive during the notice period. No severance pay is payable in the event of notice being given by the CEO. A mutual notice period of 3 to 12 months applies to termination of contract between the company and other senior executives. No severance payment will be made.

# (c) Receivables and liabilities at year-end resulting from purchase of services

Receivables from related parties	31-12-2018	31-12-2017
Camurus Development	1	_
Total	1	_

Liabilities to related parties	31-12-2018	31-12-2017
Piir & Partner AB	-	63
Subsidiaries	9,065	3,769
Total	9,065	3,832

Liabilities to related parties are essentially derived from sales agency fee and service fee.

# Note 29 | Pledged assets

Pledged assets	31-12-2018	31-12-2017
Asset liability as collateral for pension commitments	1,607	999
Total	1,607	999

# Note 30 Proposed appropriation of profits

For the financial year 2018, the Board of Directors propose that the retained earnings of KSEK 218,564 is carried forward.

The Board of Directors proposes that no dividend be paid for the 2018 financial year.

# Note 31 Events after the balance sheet date (until 14 April 2019)

European launch of Buvidal<sup>®</sup> for treatment of opioid dependence initiated in January 2019. Resolution by the Board of Directors in February 2019 on a fully underwritten rights issue subject to approval by the extraordinary general meeting.

On 27 March 2019 the rights issue was finalized, which provided the Company with MSEK 403 before issue costs, which are judged to amount to approximately MSEK 35.

On 9 April 2019 Camurus' partner Braeburn initiated court proceedings versus the FDA to overturn the 3-year market exclusivity for Sublocade<sup>™</sup> and seeks immediate market approval of Brixadi<sup>™</sup> in the US.

# ASSURANCE OF THE BOARD OF DIRECTORS AND PRESIDENT

The Board of Directors and CEO affirm that the consolidated financial statements have been prepared in accordance with international financial reporting standards IFRS, as adopted by the EU, and provide a true and fair view of the Group's financial position and earnings.

This Annual Report was prepared in accordance with generally accepted accounting policies and provides a true and fair view of the Parent Company's financial position and earnings. The Board of Directors' Report for the Group and Parent Company provides a true and fair overview of the performance of the Parent Company and the Group's operations, financial position and earnings and describes the material risks and uncertainties faced by the Parent Company and the companies belonging to the Group.

The income statements and balance sheets will be presented for approval to the Annual General Meeting on 9 May 2019.

Lund, 15 April 2019

Per-Olof Wallström Chairman of the Board Per-Anders Abrahamsson Board member Marianne Dicander Alexandersson Board member

Martin Jonsson Board member Behshad Sheldon Board member

Fredrik Tiberg President, CEO and Board member Kerstin Valinder Strinnholm Board member

Our Audit Report was submitted on 15 April 2019

PricewaterhouseCoopers AB Ola Bjärehäll Auditor in Charge Authorised Public Accountant

# AUDITOR'S REPORT

To the general meeting of the shareholders of Camurus AB (publ), corporate identity number 556667-9105

# REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

## Opinions

We have audited the annual accounts and consolidated accounts of Camurus AB (publ), for the year 2018. The annual accounts and consolidated accounts of the Company are included on pages 48-88 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of Parent Company as of 31 December 2018 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the Group as of 31 December 2018 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and consolidated statement of comprehensive income respectively and balance sheet for the Parent Company and the Group.

Our opinions in this report on the the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the Parent Company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

#### **Basis for Opinions**

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the Parent Company and the Group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited Company or, where applicable, its Parent Company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

#### Our audit approach

#### Audit scope

We designed our audit by determining materiality and assessing the risks of material misstatement in the consolidated financial statements. In particular, we considered where management made subjective judgements; for example, in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits, we also addressed the risk of management override of internal controls, including among other matters consideration of whether there was evidence of bias that represented a risk of material misstatement due to fraud.

We tailored the scope of our audit in order to perform sufficient work to enable us to provide an opinion on the consolidated financial statements as a whole, taking into account the structure of the Group, the accounting processes and controls, and the industry in which the Group operates. Based on this we have assessed what audit procedures to be performed on these entities. The Camurus Group consist of 10 entities, whereof two Swedish and eight foreign.

#### Materiality

The scope of our audit was influenced by our application of materiality. An audit is designed to obtain reasonable assurance whether the financial statements are free from material misstatement. Misstatements may arise due to fraud or error. They are considered material if individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

Based on our professional judgement, we determined certain quantitative thresholds for materiality, including the overall materiality for the financial statements as a whole. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures and to evaluate the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

## **Key audit matters**

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

### Key audit matter

#### Accounting of revenue

For the period January – December 2018 Camurus has reported approximately MSEK 49 in revenue, primarily consisting of sales of development related goods and services, milestone payments, licensing revenues and revenues from product sales. The sales have in all material extent been made to customers in Europe, Japan and USA.

As a basis for this it is the assessment by Camurus that there are adequate processes and controls in place in order to ensure a correct revenue recognition in the correct reporting period.

We refer to section 2.17 in the Accounting principles in the Annual report of Camurus for 2018 for a description of the applied accounting principles.

# How our audit addressed the Key audit matter

We have obtained an understanding of the controls in place related to accounting of revenue and, in particular, the accuracy and cut-off of sales of development related goods and services, milestone payments, licensing revenues and product sales. We have, by sample, performed test of details of customer agreements in order to verify the transfer of control associated with the sale, amounts and basis for calculation and allocation of the revenue. We have also performed audit procedures to verify the cut-off of the revenue, including, for product sales, examination of delivery terms. We have also performed procedures related to payments received from customers.

For sales of development related goods and services we have also performed procedures related to the expenses which form the base for this type of revenue and that the subsequent invoicing has been made and accounted for in the correct period.

For uninvoiced, accrued revenue, we have received supporting documentation from management of Camurus in order to assess whether the revenue is attributable to the financial year 2018.

## Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-47 and 100-105. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

# Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or mistake.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the Company's and the Group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis

#### Accounting of deferred tax asset

Camurus accounts for a deferred tax asset of approximately MSEK 171 on Group level. The deferred tax asset is based on tax losses carried forward and is recognized to the extent that Camurus assesses it to be likely that future taxable surpluses will be available, against which the losses can be utilized.

As a basis for this balance sheet item Camurus uses forecasts for future taxable income. As part of our audit we have evaluated the forecasts regarding future taxable surpluses that the board of directors and management have used for their assessment. We have obtained an understanding of the assumptions in the forecasts. We have also performed audit procedures of the other supporting documents that Camurus has presented to us related to this deferred tax asset, as well as tested the mathematical accuracy in the calculation of the deferred tax asset made by Camurus. of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the Company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the Company's financial reporting process.

## Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

A further description of our responsibility for the audit of the annual accounts and consolidated accounts is available on Revisorsinspektionen's website www.revisorsinspek tionen.se/revisornsansvar. This description is part of the auditor's report.

# REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS

#### Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Camurus AB (publ), for the year 2018 and the proposed appropriations of the Company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

#### **Basis for Opinions**

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the Parent Company and the Group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the Company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the Company's and the Group's type of operations, size and risks place on the size of the Parent Company's and the Group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the Company's organization and the administration of the Company's affairs. This includes among other things continuous assessment of the Company's and the Group's financial situation and ensuring that the Company's organization is designed so that the accounting, management of assets and the Company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfil the Company's accounting in accordance with law and handle the management of assets in a reassuring manner.

#### Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the Company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the Company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the Company, or that the proposed appropriations of the Company's profit or loss are not in accordance with the Companies Act.

A further description of our responsibility for the audit of the administration is available on Revisorsinspektionen's website: www.revisorsinspektionen.se/revisornsansvar. This description is part of the auditor's report.

PricewaterhouseCoopers AB, 113 97 Stockholm, was appointed auditor of Camurus AB (publ) by the general meeting of shareholders on May 3, 2018 and has been the Company's auditors since May 11, 2015.

> Stockholm, April 15, 2019 PricewaterhouseCoopers AB

> > Ola Bjärehäll Authorized public accountant Auditor in charge

# **CORPORATE GOVERNANCE REPORT**

#### Corporate governance structure



Camurus' corporate governance is based on the laws, regulations and recommendations applicable to listed companies, such as the Swedish Corporate Governance Code (the "Code"), the Nasdaq Stockholm Rule Book for Issuers, Camurus' Articles of Association and other rules and guidelines specific to the Company. During 2018, Camurus applied to the Code without deviations. This report pertains to the 2018 financial year and has been reviewed by the Company's auditors.

## **CORPORATE GOVERNANCE AT CAMURUS**

The aim of Camurus' corporate governance is to create a distinct allocation of roles and responsibilities between shareholders, the Board of Directors and the Company's management.

The governance, management and control of Camurus is distributed between the general meeting of shareholders, Board of Directors and its elected Committees, and the CEO.

# EXTERNAL REGULATORY FRAMEWORKS THAT INFLUENCE CORPORATE GOVERNANCE

- The Swedish Companies Act
- Regulatory frameworks for external reporting
- Nasdaq Stockholm's Rule Book for Issuers, nasdaqomxnordic.com
- The Swedish Corporate Governance code, corporategovernanceboard.se
- Other applicable rules and recommendations



# INTERNAL REGULATORY FRAMEWORKS OF SIGNIFICANCE TO CORPORATE GOVERNANCE

- Articles of Association
- Board of Directors' rules of procedure including instructions to the Board's Committees
- Instructions relating to the allocation of work between the board and the CEO as well as the financial reporting
- · Guidelines for remuneration to senior executives
- IT Policy
- Financial Manual
- Personnel Manual
- · Code of Conduct
- Communication/information Policy
- Insider Policy

# Corporate governance structure

#### SHAREHOLDERS AND THE SHARE

Camurus AB's share capital comprises one class of shares that entitles the holders to equal voting rights and equal rights to the Company's assets. For information about shareholders and the Camurus share, see pages 44-45 of the annual report 2018 and camurus.com.

## **GENERAL MEETINGS OF SHAREHOLDERS**

Shareholders' exercise their influence at the general meeting, which is Camurus' highest decision-making body. The general meeting decides on the Articles of Association and at the Annual General Meeting (AGM), which is the scheduled annual general meeting of shareholders, shareholders elect the Board members, the Chairman of the Board and auditors, and resolve on their fees.

In addition, the AGM makes decisions on the adoption of the income statement and balance sheet, on the appropriation of the Company's profits and on the discharge of Board members and the CEO from liability to the Company. The AGM also makes decisions on the composition and work of the Nomination Committee, and on remuneration guidlines and terms of employment for the CEO and other senior executives. Shareholders have the right to participate and vote for all of their shares. Shareholders are also entitled to be represented by proxy at the meeting. The AGM is to be held in Lund each year before the end of June. Extraordinary general meetings (EGMs) are convened as needed. Notice convening the annual general meetings and extraordinary general meetings where amendments to the articles of association are to be addressed, must be done no earlier than six weeks and no later than four weeks prior to the meeting. Notice convening other extraordinary general meetings must be done no earlier than six weeks and no later than three weeks prior to the meeting. Official notice must be given through an announcement in the Swedish Official Gazette (Sw. Post- och Inrikes Tidningar) and on the Company's website. Simultaneously therewith, the fact that notice has been given must be published in Svenska Dagbladet.

# 2018 ANNUAL GENERAL MEETING (AGM)

The AGM for 2018 was held on May 3. At the meeting, approximately 64 percent of the total votes were represented. Attorney Jakob Wijkander was elected Chairman of the meeting.

The AGM resolutions concerned:

- Number of board members and auditors.
- Remuneration to the Chairman of the Board and Board members elected by the AGM, and the auditor.
- Re-election of the Board members Per Olof Wallström, Per-Anders Abrahamsson, Marianne Dicander Alexandersson, Martin Jonsson, Fredrik Tiberg and Kerstin Valinder Strinnholm and new-election of Behshad Sheldon. Svein Mathisen had declined re-election. As chairman of the Board, Per Olof Wallström was re-elected.
- Re-election of PricewaterhouseCoopers AB, with Ola Bjärehäll as authorised public accountant.
- Guidelines for remuneration to senior executives.
- Implementation of incentive program in accordance with the Board's proposal for the Company's employees by way of directed issue of subscription warrants.
- Authorization for the Board to decide on a new issue of shares with or without deviation from shareholders'

preferential rights. The authorization may be exercised on one or more occasions until the Annual General Meeting 2019 and a total of maximum 3 728 148 shares may be issued, corresponding to 10 per cent of the Company's share capital.

- Adoption of the income statement and the balance sheet as well as the consolidated income statement and the consolidated balance sheet.
- Appropriation of the Company's earnings in accordance with the adopted balance sheet
- Discharge from liability in relation to the Company for the Board members and the CEO for the financial year 2018.

The minutes and information from the 2018 AGM are available on camurus.com.

## 2019 AGM

Camurus' 2019 AGM will be held on Thursday 9 May 2019 at 5:00 p.m. CET at Elite Hotel Ideon, on Scheelevägen 27, Ideon Science Park, 223 63 Lund, Sweden. For further information and the right to participate, see page 105 of Camurus' Annual Report 2018 or camurus.com. The minutes of the AGM will be available at camurus.com.

# NOMINATION COMMITTEE

The Nomination Committee represents Camurus' shareholders and has the task of preparing resolutions on election and reimbursement issues at the AGM. According to the instructions and statutes adopted by the AGM on 3 May 2016, the Nomination Committee is to consist of four members, three of whom are to represent the Company's three largest shareholders based on the ownership according to Euroclear Sweden AB as per 31 August of the year before the AGM. As stipulated in the same resolution, the fourth person is to be the Chairman of the Board. The Nomination Committee observes the rules that apply to Board members' independence under the Swedish Corporate Governance Code. Furthermore, the composition of the Nomination Committee is to be announced no later than six months before the annual general meeting. The Nomination Committee of Camurus is tasked with assignments including the preparation and drafting of proposals for

the election of Board members, the Chairman of the Board, the auditors and the Chairman of the Meeting. In addition, the nomination committee's mission includes proposing fees to the members of the Board, members of the Board's committees and the auditors. The Nomination Committee's duties also include proposing fees to Board members, committee members and auditors.

The Nomination Committee for the AGM 2019 has held three (3) meetings and also maintained contact by telephone. As a basis for its work, the Nomination Committee has taken note of the Chairman's presentation of the Board's work, including an anonymous survey-based evaluation of the Board's work through of an external independent party, as well as individual interviews with all Board members. Furthermore, the Chairman of the Board and the CEO has reported the development of the Company's operations, goals and strategy.

The Nomination Committee has prepared proposals to the Annual General Meeting regarding election of the chairman and other members of the Board, remuneration to board members and committee members, election of auditors and remuneration to them.

As in previous years, the Nomination Committee has devoted special attention to issues of diversity. From the Nomination Committee's proposal to the 2019 Annual General Meeting it shows that the Nomination Committee, when preparing its proposal of Board of Directors, has applied paragraph 4.1 of the Code as Diversity Policy. The aim of the policy is that, with regards to the Company's operations, development stages and circumstances, the Board should have a purposeful composition, characterized by versatility and breadth regarding the members' skills, experience and background as well as the need for an even gender distribution. With regards to gender distribution in the Board, the Nomination Committee's ambition is to work towards the goals set by the College of Swedish Corporate Governance. The Annual General Meeting 2018 decided to appoint members of the Board in accordance with the nomination committee's proposal, which meant that seven members were elected, of which three women and four men (corresponding to 43 and 57 per cent respectively).

# The Nomination Committee for the AGM 2019 consists of the following<sup>1</sup>

#### Representatives Shareholders

Per Sandberg, appointed by Sandberg Development AB Max Mitteregger, appointed by Gladiator Arne Lööw, appointed by Fjärde AP-fonden Per Olof Wallström, Chairman of the Board

1) The shareholder statistics used must be sorted according to voting power (shareholder groups) and comprise the 25 largest shareholders. In the event that these shareholder statistics comprises nominee-registered holdings, such holdings will only be taken into consideration if the administrator has declared the underlying shareholder's identity to Euroclear Sweden, or if the Company – without implementing any own measures – obtains other information to indicate the underlying shareholder's identity.

The Nomination Committee in respect of the Annual General Meeting 2019 consists of the Chairman of the Board and the three largest shareholders in terms of voting rights as of 31 August 2018, who together represents approximately 60 percent of the number of shares and votes in the Company.

# **Board of Directors**

## COMPOSITION AND INDEPENDENCE

In accordance with the Articles of Association, Camurus' Board of Directors is to comprise a minimum of three and maximum of ten Board members elected by the AGM, for the period until the end of the next AGM. At the 2018 AGM, seven (7) Board members were elected. Camurus' CEO is included among the Board of Directors and the Company's CFO functions as the Secretary to the Board. Other executives of Camurus participate at Board meetings to report on specific topics. According to the Code, a majority of the AGM-elected Board members must be independent in relation to the Company and the Company's management. With the exception of CEO Fredrik Tiberg, all Board members are deemed to be independent in relation to the Company and the Company's management. Five of these Board members are also deemed to be independent in relation to the Company's major shareholders. Camurus' thus meets the requirements of the Code on independence.

At the close of the financial year, Camurus' Board of Directors comprised seven (7) Board members: Chairman of the Board Per Olof Wallström and the Board members Per-Anders Abrahamsson, Marianne Dicander Alexandersson, Martin Jonsson, Behshad Sheldon, Fredrik Tiberg and Kerstin Valinder Strinnholm. Information about the Board members, with data about birth years, year of election to the Board of Directors, education, experience, ongoing and previous assignments, holdings of shares in the Company at 31 March, 2019 are presented on pages 100-101 in the annual report 2018. Holdings in the Company include the individual's personal holdings and/or the holdings of closely related parties. Other Group assignments are not presented.

# RESPONSIBILITY AND DUTIES OF THE BOARD OF DIRECTORS

The duties of the Board of Directors are regulated under the Swedish Companies Act, the Articles of Association, and the Swedish Corporate Governance Code. The work of the Board of Directors is further regulated by the written Rules of Procedure, which is adopted each year by the Board. The Rules of Procedure regulate the division of duties and responsibilities between the Board, the Chairman of the Board and the CEO. In addition, the Rules of Procedure govern the resolutions procedure within the Board, the Board's meeting schedule and the Board's work on accounting and audit matters, as well as the financial reporting. The Board has also established instructions for the CEO and adopted other specific policy documents. The Board is responsible for the Group's organization and the management of its affairs, the establishment of the Group's overall objectives, development and follow-up the overall strategies, resolutions regarding major acquisitions, divestments and capital expenditures, resolutions regarding possible investments and loans in accordance with financial policy, continuous monitoring of operations, the adoption of guarterly and year-end accounts, and the continuous assessment of the CEO and other members of Group management. The Board is also responsible for ensuring quality in financial reporting, including monitoring system and internal control regarding Camurus' financial statements and financial position (see also "Internal controls" below). Furthermore, the Board shall ensure that Camurus' external communication is characterized by transparency and is correct, relevant and reliable. The Board is also responsible for establishment of required guidelines and other policy documents, such as a Code of Conduct and Communication and Insider Policy. At the Board's meetings, there are, among other things, the following recurring items on the agenda: state of business, project status, market issues, adoption of interim and annual reports, strategic review, future prospects and economic and financial reporting.

The Chairman of the Board follows Camurus' operations through continuous contact with the CEO. The Chairman organizes and leads the Board's work and is responsible for ensuring that the Board members receive satisfactory information and decision data. The Chairman is also responsible for ensuring that both current and new Board members continuously update and deepen their knowledge about Camurus and that they receive further training required for the work of the board to operate effectively. It is also the Chairman who is responsible for managing contacts with shareholders on ownership matters and for the annual evaluation of work of the Board of Directors. In 2018, an anonymous survey-based evaluation was completed, through which the Board members got the opportunity to express themselves about the Board's work. This information has been collected, compiled and presented by the Company's lawyers. The Nomination Committee has through the Chairman of the Board, reviewed the evaluation of the Board's work and received information

about the Company's development. The main requirements that should be imposed on Camurus' Board of Directors and the importance of independent Board members have been discussed.

In addition to the inaugural Board meeting, a minimum of five ordinary Board meetings are to be held. The Board meets with auditors at the Board meeting when the audit is reviewed.

#### **BOARD OF DIRECTORS' WORK DURING 2019**

During the year, the Board held ten (10) ordinary Board meetings, including inaugural meeting, two (2) extraordinary meetings in relation the directed share issue in June and another two (2) when decisions regarding allocation of warrants in the TO2018/2021 program were taken per capsulam. During 2019, the Board's work has mainly been dominated by handling and make strategic decisions on matters concerning the Company's organizational development including resolutions to establish subsidiaries in Australia and Spain for the Company's commercialization of Buvidal<sup>®</sup>, product and business development and partnerships. The Board has taken resolutions regarding Camurus financial targets and dividend policy, financial interim reports and developed a new long-term incentive program for the Company's management and staff for proposal to the AGM 2019.

The Board has planned a total of ten (10) meetings for 2019.

#### **BOARD COMMITTEES**

Within itself, the Board of Directors has established two committees, an Audit Committee and a Remuneration Committee, which operates according to rules of procedure adopted by the Board of Directors.

#### Audit Committee

The main duties of the Audit Committee are to supervise the Company's financial reporting, monitor efficiency in its internal controls, and apprise itself of information regarding the audit of the annual report and consolidated financial statements, review and monitor the auditor's impartiality and independence and, in so doing take particularly into account whether the auditor provides Camurus with services other than audit services. The Audit Committee shall also assist the Nomination Committee with proposal to the general meeting for election of auditors. The Audit Committee has regular contacts with the auditors of Camurus. The members of the Audit Committee are Martin Jonsson (Chairman), Marianne Dicander Alexandersson, and Per Olof Wallström. The committee complies with the Companies Act's requirements for independence and accounting and auditing expertise. The Committee has convened six (6) times during the year. Camurus' auditors were present at three (3) of these meetings. The meetings addressed items such as the audit plan, the auditors' observations and the review of the Company and the Company's financial reports.

#### **Remuneration Committee**

The main duties of the Remuneration Committee are to prepare decisions by the Board of Directors on issues concerning remuneration principles, remuneration and other employment terms for the CEO and other members of the Group management, and to monitor and assess ongoing programs for variable remuneration to the Group management, as well as such programs as have been completed during the year. Furthermore, the Committee shall monitor and assess the application of the guidelines for remuneration to the executive management resolved by the annual general meeting, as well as applicable remuneration structures and remuneration levels in the Company.

The members of the Remuneration Committee are Per Olof Wallström (Chairman), Martin Jonsson, and Kerstin Valinder Strinnholm. The Committee is assessed to comply with the Code's requirements for independence and appropriate knowledge and experience in questions related to remuneration of executive management.

The Committee convened two (2) times during the year. At these meetings, the Committee discussed the Company's existing remuneration systems, proposed guidelines for the remuneration of the CEO and senior executives, and the future share-based incentive programs aimed at attracting and retaining competent and motivated employees. The incentive program will be presented at the AGM in May 2019, for resolution by the shareholders. Information regarding salaries and fees to the CEO and senior executives is provided in Note 9 in the annual report 2018.

### **CEO AND GROUP MANAGEMENT**

The CEO is responsible for the ongoing administration and development of Camurus in accordance with applicable legislation and rules, including the Nasdaq Stockholm Rule Book for Issuers and the Code, as well as the guidelines, instructions and strategies established by the Board of Directors. The CEO is to ensure that the Board of Directors receives the requisite factual and relevant information to enable taking well-founded decisions. Furthermore, the CEO is to ensure adherence to Camurus' goals, policies and strategic plans as established by the Board of Directors, and for keeping the Board updated on Camurus' development in-between Board meetings.

The CEO leads the work of the Group management, which is responsible for overall business development. In addition to the CEO, Camurus' Group management during the year has comprised the CFO, the Vice President for Technical Operations, the Vice President for Clinical and Regulatory Development, Chief Business Development, Chief Commercial Officer, Vice President Human Resources, and Vice President Corporate Development & General Counsel (a total of eight persons). During the year the Group management convened twenty one (21) times. For information about current senior executives at Camurus, when they assumed their positions and their year of birth, education, experience, holdings in the Company as of 31 March, 2019, and current and previous assignments, see pages 102-103 of the annual report. Holdings in the Company include the individual's personal holdings and/or the holdings of closely related parties. Other Group assignments are not presented. CEO has no significant shareholdings and coownership in companies that have significant business relationships with Camurus.

# The table below shows the fees paid to the elected Board members in 2018

				Remuneration, KSEK <sup>1)</sup>		Attendance <sup>2)</sup>			
Board member	Function Indep	pendence	Directors' fee	Audit Committee	Remuneration Committee	Total	Board of Directors	Audit Committee	Remuneration Committee
Per-Anders Abrahamsson	Board member	•	200	-	_	200	9/9	-	-
Marianne Dicander Alexandersson <sup>6)</sup>	Board member	•	200	50	_	250	9/9	6/6	-
Martin Jonsson	Board member	3)	200	100	25	325	9/9	6/6	2/2
Svein Mathisen <sup>5)</sup>	Board member	•	-	-	-	-	3/9	3/6	1/2
Kerstin Valinder Strinnholm	Board member	•	200	-	25	225	9/9	-	2/2
Behshad Sheldon <sup>6)</sup>	Board member	•	200	-	_	200	5/9	-	-
Fredrik Tiberg <sup>7)</sup>	Board member, President and CEC	D 4)	_	-	_	_	9/9	-	-
Per Olof Wallström <sup>6)</sup>	Chairman of the Board	•	550	50	50	650	9/9	6/6	2/2
Total			1,550	200	100	1,850			

6) Board member from AGM 3 May 2018.

7) For remuneration to the CEO, refer to Note 9 and 28 in the annual report 2018.

1) AGM resolved fees for the period May 2018 - May 2019.

2) The figures in the table show total attendance/meetings. In 2018, the Board held a total of 9 ordinary meetings.

3) The Board member is to be regarded as dependent in relation to major shareholders.

4) The Board member is to be regarded as dependent in relation to the Company and its Management.

5) Board member until AGM 3 May 2018.

# Remuneration for Board of Directors and senior executives

# **REMUNERATION FOR BOARD MEMBERS**

The AGM of 3 May 2018 resolved that for the period up to the closing of the 2019 AGM, fees to the Board members are as follows: SEK 550,000 to the Chairman of the Board and SEK 200,000 to each of the other Board members. The AGM further resolved that for committee work, a fee of SEK 100,000 to be paid to the Chairman of the Audit Committee and SEK 50,000 to each other member of the Committee, and a fee of SEK 50,000 to be paid to the Chairman of the Remuneration Committee and SEK 25,000 to each other member of the Committee.

## **REMUNERATION TO GROUP MANAGEMENT**

The remuneration committee of the Board of Directors handles questions of remuneration to the senior executives. Remuneration to the CEO is resolved by the Board.

Remuneration and terms for senior executives should be based on market conditions and consist of a balanced mix of fixed salary, variable remuneration, pension benefits, other benefits and terms of termination.

# GUIDELINES FOR REMUNERATION TO SENIOR EXECUTIVES

The AGM of 3 May 2018 resolved to approve the Board of Directors' proposal on the principles of remuneration to the Company's senior executives until the time of the 2019 AGM.

#### **Deviation from the guidelines**

The Board of Directors may deviate from these guidelines in certain cases if there are special reasons for doing so. Reasons for derogation must be reported at the next annual general meeting. During 2018 the guidelines have been followed without any deviations.

For more information on guidelines for remuneration to the Board and senior executives, see Note 9 and 28 in the Annual Report 2018.

Guidelines for remuneration to senior executives 2019

The Board proposes that the guidelines in its design is unchanged against the decision by the AGM of 3 May 2018.

## **EXTERNAL AUDITORS**

Camurus' auditor is since the AGM 11 May 2015 the auditing firm PricewaterhouseCoopers AB (PwC), with Authorised Public Accountant Ola Bjärehäll as auditor in charge. PwC was elected as Camurus' auditor at the AGM 2018, until the end of the AGM 2019.

The auditor performs a review of the interim report for the third guarter and audit the annual accounts and consolidated financial statements. The auditor also expresses an opinion on whether this Corporate Governance Report has been prepared in accordance with, and whether certain disclosures herein are consistent with, the annual accounts and consolidated financial statements. The auditor reports the results of his audit of the annual accounts and consolidated financial statements, his review of the Corporate Governance Report in the auditor's report, and the separate opinions on the Corporate Governance Report and guidelines for remuneration to senior executives, in a presentation to the AGM. In addition, the auditor presents detailed findings from his reviews to the Audit Committee three times per year, and to the Board in its entirety once per year. The fees invoiced by the auditors over the past two financial years are reported in Note 8 of the annual report for 2018.

#### Internal control and risk management

The Board of Directors' responsibility for internal controls are regulated by the Companies Act, the Annual Accounts Act – which includes requirements that the Corporate Governance Report must contain disclosures concerning the principal features of Camurus' internal control and risk management systems in connection with the annual financial reporting and the preparation of the consolidated financial statements – and the Code. The Board of Directors is to ensure that Camurus has appropriate internal controls and formalized procedures to ensure its compliance with established policies for financial reporting and internal controls, and the existence of appropriate systems for the monitoring and control of the Company's activities and the risks associated with the Company and its operations.

Camurus applies COSO's framework for the internal control of financial reporting. The procedures for internal controls on financial reporting were designed with the aim of ensuring reliable overall financial reporting and external reporting in accordance with IFRS, applicable laws and regulations, and other requirements applicable to companies listed on Nasdaq Stockholm. This work involves the Board of Directors, Group management and other employees.

#### **Control environment**

The Board of Directors has established instructions and governing documents with the aim of regulating the CEO's and the Board of Directors' roles and responsibilities. The manner in which the Board of Directors monitors and assures the quality of internal controls is documented in the Board of Directors' rules of procedure and Camurus' financial policy, as well as the policy for internal control, where the Board of Directors has established a number of fundamental guidelines of significance to the work with internal control. These guidelines include the regular control and follow-up of outcomes in comparison with expectations and preceding years, as well as supervision of the accounting policies applied by Camurus. The responsibility for maintaining an effective control environment and the ongoing work on risk assessment and internal control over the financial reporting is delegated to the CEO. However, the Board of Directors has ultimate responsibility. In turn, managers at various levels at Camurus have corresponding responsibilities within their respective spheres of responsibility.

Group management reports regularly to the Board of Directors in accordance with established procedures. The financial reporting control environment collectively comprises various responsibilities and authorities, instructions, guidelines, manuals and policies, in combination with laws and regulations.

Based on an efficient control environment and external reviews by auditors, the Board of Directors has deemed that there are no special circumstances in Camurus' operations or other circumstances to warrant the establishment of an internal-audit function.

#### **Risk assessment**

Camurus performs continuous risk assessments to identify risks pertaining to financial reporting, as well as risks associated with the Company's operations. These risks include inaccurate reporting as well as impropriety and fraud. Risk management is incorporated in each process and various methods are used to evaluate, identify and curtail risks, and to ensure that the risks to which Camurus is exposed are managed in line with the set policies, instructions and monitoring procedures.

For a description of Camurus' operational risks, see the Director's Report, pages 54-57 and for the financial risks, Note 3 Financial Risk Management, page 71 in Camurus Annual Report 2018.

#### **Control activities**

The formulation of control activities is of particular importance to Camurus' work to prevent and identify risks and shortcomings in the financial reporting. The control structure comprises distinct roles in the organization that facilitate an efficient division of responsibilities for specific control activities, including authorization control, IT systems, ERP system and authorization control. The continuous analyses carried out of the financial reporting are crucial to ensuring that the financial reports do not include any material errors.

#### Information and communication

Camurus has information and communication procedures aimed at promoting completeness and accuracy in financial reporting. Policies, guidelines and internal instructions with regard to financial reporting are available in digital and printed form. Regular updates on amendments to accounting policies, reporting requirements or other forms of information disclosure are accessible and known to the employees concerned. For external disclosure of information, guidelines have been designed with the aim of ensuring that Camurus meets the requirements covering the disclosure of accurate information to the market.

#### Monitoring, evaluation and reporting

The Board of Directors continuously evaluates the information submitted by Group management. The Board of Directors obtains regularly updated financial information about Camurus' development between Board meetings. The Group's financial position, strategies and capital expenditures are discussed at each Board meeting. The Board is also responsible for monitoring the internal control and monitoring that reporting to the Board works satisfactorily. This work entails ensuring that measures are taken to manage any shortcomings, as well as following-up on any proposed measures highlighted in connection with external reviews. The Company performs an annual self-assessment of its work with risk management and internal controls. This process includes a review of the manner in which established procedures and guidelines are applied. The Board of Directors receives information about important conclusions from this annual assessment process, and about proposed actions, if any, with regard to the Company's internal control environment. In addition, the external auditors report on a regular basis to the Board of Directors, partly through the Audit Committee, partly to the Board of Directors in its entirety.

#### **External audit**

The AGM appoints external auditors for a period of one vear at a time. The auditor reviews the annual accounts and bookkeeping, as well as the Board of Directors' and CEO's administration in accordance with an audit plan established in consultation with the Board's Audit Committee. In connection with the review, the auditor reports his findings to Group Management for discussion and subsequently to the Board of Directors through the Audit Committee. Reporting to the Audit Committee is carried out in conjunction with the completion of the examination of the administration and the review of the hard close of the annual accounts. The Board of Directors meets with the auditors not less than once a year, when the auditors report their observations directly to the Board of Directors without the presence of Camurus' CEO and CFO. The auditor also participates at the AGM, where he presents a summary of his auditing work and his recommendations in the audit report.

Lund, April 2019

Board of Directors

More information on Camurus's corporate governance and the Board of Directors can be found in the section of "Corporate governance" at camurus.com.

# THE AUDITORS' EXAMINATION OF THE CORPORATE GOVERNANCE REPORT

To the general meeting of the shareholders of Camurus AB (publ), corporate identity number 556667-9105

#### **Engagement and responsibility**

The Board of Directors is responsible for the Corporate Governance Report for the year 2018 on pages 92-98 of the printed version of this document having been prepared in accordance with the Annual Accounts Act.

## The scope of the audit

Our examination of the corporate governance report is conducted in accordance with FAR's auditing standard RevU 16 The auditor's examination of the corporate governance report. This means that our examination of the corporate governance report is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

#### Opinions

A corporate governance report has been prepared. Disclosures in accordance with Chapter 6, Section 6, the second paragraph, points 2-6 of the Annual Accounts Act and Chapter 7, Section 31, the second paragraph of the same law are consistent with the other parts of the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Act.

Stockholm, April 15, 2019

PricewaterhouseCoopers AB Ola Bjärehäll Authorized public accountant Auditor in charge

# **BOARD OF DIRECTORS**



#### PER OLOF WALLSTRÖM

Chairman of the Board since 2015 and Board member since 2010. Chairman of the Remuneration Committee and member of the Audit Committee.

Born: 1949. Education: M.Sc. in Pharmacy from Uppsala University. Other current appointments: Board member of Arosia Communication AB and Qlinea AB. Work experience: CEO of Q-Med AB, Melacure AB and Karo Bio AB. Senior management at Merck Sharpe & Dohme, Astra, Pharmacia and Bristol Myers Squibb. Holdings: 97,185 shares.



#### PER-ANDERS ABRAHAMSSON

Board member since 2006.

Born: 1949. Education: B.Sc., MD, Ph.D., Professor of Urology, Lund University. Adjunct Professor, University of Rochester, New York. Other current appointments: Chief Physician at Skåne University Hospital, Malmö. Board member of Cernelle AB, Medisport AB, Medisport Holding AB, IDL Biotech AB. Consultant Prostalund AB, Cernelle AB och IDL Biotech AB. Work experience: Senior Registrar in Urology – 40 years. Chairman, Department of Urology, Lund University – 20 years. Laboratory Director, Department of Urology, University of Rochester Medical Centre – 2 years and Adjunct Professor, University of Rochester, Rochester, New York 1993. Immediate Past Secretary General, European Association of Urology. Holdings: 41,951 shares.



#### MARIANNE DICANDER ALEXANDERSSON

Board member since 2015. Member of the Audit Committee.

Born: 1959. Education: M.Sc. in Chemical Engineering from Chalmers University of Technology. Other current appointments: Board member of Recipharm AB (publ), Enzymatica AB (publ), and Addera Care AB (publ), Praktikertjänst and Promore AB (publ). Chairman and founder of MDA Management AB, Chairman of Sahlgrenska Science Park, Member of the council at Skandia and member of the Advisory Council of the Dental and Pharmaceutical Benefits Agency. Work Experience: CEO of Kronans Droghandel, Global Health Partner and Sjätte AP-fonden, deputy CEO of Apoteket AB. Leading positions in quality and market development at Pharmacia, Imperial Chemical Industries and Volvo. Holdings: 16,062 shares.



## MARTIN JONSSON

Board member since 2013. Chairman of the Audit Committee and member of the Remuneration Committee.

Born: 1961. Education: M.Sc. in Business Administration from Lund University. Other current appointments: CEO and Board member of Sandberg Development AB. Chairman of Aimpoint AB, GRANULDISK AB, SWATAB AB and Rescue Intellitech AB. Board member of ISEC AB and Orbital Systems AB. Work Experience: Over 25 years of combined experience in corporate management and working in senior positions in various industries such as medical devices, biotechnology and industrial kitchens etc. Holdings: 28,352 shares.



#### **BEHSHAD SHELDON**

Board Member since 2018.

Born: 1963. Education: B.Sc. in Neuroscience from University of Rochester. Other current appointments: Chairman of the Board of FORCE (Female Opioid Research and Clinical Experts) in Princeton, New Jersey. Work Experience: President & CEO of Braeburn Pharmaceuticals until 2017. Extensive experience in various senior positions in international pharmaceutical companies, including Smithkline Beecham, Bristol-Myers Squibb and Otsuka Pharmaceuticals. Holdings: –



#### KERSTIN VALINDER STRINNHOLM

Board member since 2015. Member of the Remuneration Committee.

Born: 1960. Education: Degree from the School of Journalism at the University of Gothenburg. Other current appointments: Board member of Klifo A/S, Corline Biomedical AB, KVS Invest AB, Immunicum AB, Gedea Biotech AB and Cavastor AB. Work Experience: EVP Business Development for the Nycomed Group. Many years of experience in sales, marketing and business development from senior positions at Astra/AstraZeneca and Nycomed/Takeda. Holdings: 24,910 shares.



#### FREDRIK TIBERG

President & Chief Executive Officer since 2003. Board Member since 2002.

Born: 1963. Education: M.Sc. in Chemical Engineering from Lund Institute of Technology and Ph.D. and Assoc. Prof. in Physical Chemistry from Lund University. Other current appointments: Member of the Board Camurus Lipid Research Foundation. Member of the Royal Swedish Academy of Engineering Sciences (IVA).
Work Experience: CEO of Heptahelix AB, Head of R&D Camurus AB, Visiting Professor of Physical and Theoretical Chemistry, University of Oxford. Holdings: 1,703,188 shares and 205,000 subscription warrants.

## AUDITORS

#### OLA BJÄREHÄLL

Authorised Public Accountant PricewaterhouseCoopers AB

# **GROUP MANAGEMENT**



#### FREDRIK TIBERG

President & Chief Executive Officer since 2003. Board Member since 2002.

Born: 1963. Education: M.Sc. in Chemical Engineering from Lund Institute of Technology and Ph.D. and Assoc. Prof. in Physical Chemistry from Lund University. Other current appointments: Member of the Board Camurus Lipid Research Foundation. Member of the Royal Swedish Academy of Engineering Sciences (IVA). Work Experience: CEO of Heptahelix AB, Head of R&D Camurus AB, Visiting Professor of Physical and Theoretical Chemistry, University of Oxford. Holdings: 1,703,188 shares and 205,000 subscription warrants.



#### EVA PINOTTI-LINDQVIST

Chief Financial Officer since 2014.

Born: 1963. Education: BSC in Business Administration and Economics from Lund University. Work Experience: More than 25 years experience of Finance and 15 years experience of the pharmaceutical industry, including as CFO and Vice President Business Development at EQL Pharma AB and Market analyst at Nordic Drugs AB. Controller at Svedala Svenska AB and Finance Manager at Poseidon Yacht Charter AB. Holdings: 45,363 shares and 33,882 subscription warrants.



#### **RICHARD JAMESON**

Chief Commercial Officer since June 2016.

**Born:** 1964. **Education:** BSC (Hons) in Applied Biological Sciences from University West of England. **Work Experience:** More than 20 years in the speciality pharmaceutical industry including executive/ senior positions in sales leadership, marketing, market access and general management for companies which include Serono, Schering Plough, Ferring and Indivior PLC. **Holdings:** 20,490 shares and 120,000 subscription warrants.



#### AGNETA SVEDBERG

Vice President, Clinical and Regulatory Development since 2015.

**Born:** 1963. **Education:** M.Sc. in Radiophysics and Executive MBA, Executive Foundation Lund (EFL), B.Sc. in Medicine from Lund University. **Work Experience:** More than 25 years experience in drug development, including as COO of Zealand Pharma A/S, CEO of Cantargia AB and Senior Vice President, Clinical Development at Genmab A/S. **Holdings:** 11,342 shares and 70,000 subscription warrants.



#### FREDRIK JOABSSON

Chief Business Development Officer since 2019. Employed at Camurus since 2001.

**Born:** 1972. **Education:** Ph.D. in Physical Chemistry and M.Sc. in Chemistry from Lund University. **Work Experience:** More than 15 years experience in pharmaceutical R&D, business development and alliance management. **Holdings:** 45,463 shares and 40,000 subscription warrants.



## **CECILIA CALLMER**

Vice President, Human Resources since 2017.

Born: 1974. Education: Bachelor studies in Psychology at Lund University and Copenhagen University, and Master studies in Psychology at Copenhagen University and Bond University.
Work Experience: More than seventeen years experience of Human Resources in international companies and almost ten years within the pharmaceutical industry, including as HR Directo at Novo NordiskSweden, HR Director Nordic at Diesel Aps, and Senior HR Manager and HR Manager at Ferring Pharmaceuticals A/S.
Holdings: 26,000 subscription warrants.



#### TORSTEN MALMSTRÖM

Vice President, Technical Operations since 2013.

**Born:** 1968. **Education:** Ph.D. in Inorganic Chemistry and M.Sc in Chemistry from Lund University. **Work Experience:** Almost twenty years experience from the pharmaceutical industry including as Director Pharmaceutical Development for Zealand Pharma and Director of Development for Polypeptide. Team Manager at AstraZeneca. **Holdings:** 45,363 shares and 28,000 subscription warrants.



## URBAN PAULSSON

Vice President Corporate Development & General Counsel since 2017.

Born: 1963. Education: Master of Law from Lund University. Work Experience: More than 20 years experience from the life science industry including as Legal Counsel at Pharmacia Corporation and General Counsel for Vitrolife AB. Partner at law firms Bird & Bird and Nordia Law. Holdings: 8,125 shares and 115,000 subscription warrants.

# FINANCIAL DEFINITIONS

Key figures, MSEK	2018	2017	2016	2015	2014
Net revenues	49.3	54.3	113.7	154.8	208.2
Operating result before items affecting comparability	-287.2	-243.5	-102.5	-30.5	62.3
Operating result	-287.2	-243.5	-102.5	-204.1	62.3
Result for the period	-234.7	-190.6	-81.0	-159.5	48.3
Cash flow from operating activities	-274.1	-203.1	-207.8	-5.7	69.4
Cash and cash equivalents	134.4	314.5	508.6	716.1	0.1
Equity	252.3	385.0	564.4	640.6	123.5
Equity ratio in Group, percent	69%	81%	88%	78%	59%
Total assets	364.7	475.9	639.8	816.3	207.7
Average number of shares, before dilution	37,842,034	37,281,486	37,281,486	26,497,361	23,458,908
Average number of shares, after dilution*)	39,231,356	38,058,298	37,487,937	37,281,486	25,208,560
Earnings per share before dilution, SEK	-6.20	-5.11	-2.17	-6.02	2.06
Earnings per share after dilution, SEK*)	-6.20	-5.11	-2.17	-6.02	1.92
Equity per share before dilution, SEK	6.67	10.33	15.14	24.17	5.26
Equity per share after dilution, SEK*)	6.43	10.12	15.06	17.18	4.90
Number of employees at end of period	94	71	62	48	43
Number of employees in R&D at end of period	58	48	44	35	28
R&D costs as a percentage of operating expenses	63%	75%	80%	83%	77%

\*) The dilution effect is calculated according to IAS 33

# Cash and cash equivalents

Cash and cash bank balances

Equity ratio, % Equity divided by total capital

#### Average number of shares, before dilution

Weighted average number of shares before adjustment for dilution effect of net shares

### Average number of shares, after dilution

Weighted average number of shares adjusted for the dilution effect of new shares

## Earnings per share before dilution, SEK

Result divided by the weighted average number of shares outstanding before dilution

#### Earnings per share after dilution, SEK

Result divided by the weighted average number of shares outstanding after dilution

#### Equity per share before dilution, SEK

Equity divided by the weighted number of shares at the period before dilution

#### Equity per share after dilution, SEK

Equity divided by the weighted number of shares at the end of the period after dilution

## R&D costs as a percentage of operating expenses

Research and development costs divided by operating expenses, excluding items affecting comparability (marketing and distribution costs, administrative expenses and research and development costs)

# Welcome to the Annual General Meeting 2019

Camurus' Annual General Meeting 2019 will be held on Thursday 9 May at 5 pm CET, at Elite Hotel Ideon, Scheelevägen 27, Ideon Science Park, 223 63 Lund.

Registration begins at 4 pm CET, when there will also by light refreshments served. Shareholders who wish to attend the meeting must be recorded in the share register maintained by Euroclear Sweden AB (the Swedish Central Securities Depository) on Friday 3 May 2019.

## REGISTRATION

Notification of intention to attend the Annual General Meeting must be made no later than Friday 3 May 2019 in one of the following ways:

- via Camurus' website: camurus.com
- by phone:
- by mail:
- Camurus AB, c/o Euroclear Sweden AB, "Årsstämma" Box 191, 101 23 Stockholm

+46 46-286 38 90

## Upon giving notice, shareholders shall specify:

- Name
- Personal identity number / corporate registration number
- Address and telephone number
- Number of shares held
- Where applicable, information about any representatives/advisors

# NOMINEE REGISTERED SHARES

Shareholders who have registered their shares with a bank or another nominee must, to be entitled to participate in the General Meeting, register their shares in their own name so that the person concerned is recorded in the share register maintained by Euroclear Sweden AB share register on Friday 3 May 2019. Such registration may be temporary. Shareholders wishing to register their shares in their own name should inform the bank or nominee well before this date.

## PROXIES

Shareholders who intend to be represented by proxy must issue a written and dated power of attorney for the proxy. If the power of attorney is issued by a legal entity, a certified copy of a registration certificate or equivalent for the legal entity should be attached. The power of attorney is valid for one year from the issuance, or the longer period of validity as shown by the proxy, but not more than five years.

Registration certificates shall evidence the circumstances prevailing at the date of the General Meeting and should not be older than one year on the date of the AGM. The original power of attorney and any registration certificate should be sent to the Company by mail at the address indicated above well in advance of the meeting. A proxy form is available on the Company's website camurus.com and can also be sent to shareholders upon request.

## SHAREHOLDER INFORMATION

Interim reports, annual reports and Camurus' press releases are available on camurus.com and can be ordered from Camurus AB, Ideon Science Park, SE-223 70 Lund, Sweden.

The Annual Report for 2018 in printed form will be sent to all who so requests, and it is always available for down load from: camurus.com



# CALENDAR

9 May 2019, 1 pm CET	Interim Report January-March 2019
9 May 2019, 5 pm CET	Annual General Meeting
18 July 2019	Interim Report, January-June 2019
8 November 2019	Interim Report, January-September 2019

# CONTACT DETAILS

Camurus AB Ideon Science Park 223 70 Lund Visiting Address: Sölvegatan 41 A, 223 62 Lund Telephone: +46 46-86 57 30 Fax: +46 46-286 57 39 Website: camurus.com Investor relation Contact: ir@camurus.com

# camurus.

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