

**FULL YEAR REPORT 2018** 

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## FINANCIAL CALENDAR

Presentation full year results 2018 6 February 2019, 2:00 pm CET

Annual Report 2018 5 April 2019

Annual General Meeting 2019 9 May 2019

Q1 report 2019 9 May 2019, 1.00 pm CET

Q2 report 2019 18 July 2019 Q3 report 2019 8 November 2019

# camurus

Camurus is committed to developing and commercializing innovative and long-acting medicines for the treatment of severe and chronic conditions, including opioid dependence, pain, cancer and endocrine disorders. New drug products are based on our proprietary FluidCrystal® technologies with the purpose to deliver improved quality of life, treatment outcomes and resource utilization. The company's share is listed on Nasdaq Stockholm under the ticker "CAMX". For more information, visit camurus.com



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

2018 was a breakthrough year for Camurus. Buvidal was approved as the first long-acting depot treatment of opioid dependence in the EU and Australia. With distribution, marketing and sales in place, the European launch was quickly initiated with the first patients receiving treatment already by mid-January 2019. Physician and patient feedback has been positive, which is encouraging as we continue the roll-out of Buvidal on new markets. Also gratifying during the year was the positive Phase 3 results for CAM2038 in chronic pain.

In November 2018, we announced that the European commission and Therapeutic Goods Administration had approved Buvidal as the first long-acting injection treatment for opioid dependence in the EU and Australia.

To bring an innovative drug candidate from idea to approved medicine is a challenging process and the approvals are monumental milestones in our company's history. We are proud to be able to give patients with opioid dependence access to a muchneeded new treatment paradigm with a demonstrated potential to improve treatment outcomes and quality of life of patients by reducing the significant burdens and risks associated with current daily medications.

The approval of Buvidal is a major milestone for Camurus and an important validation of our innovative FluidCrystal® technology.

Science-led commercial-stage pharmaceutical company During 2018, we have continued the transformation of Camurus from an R&D focused company to an integrated, science-led commercial company. We grew our organization and are now one hundred employees and twenty fulltime consultants working from our Lund headquarter and regional offices in Cambridge, Mannheim, Paris and Sydney. Half of our people are in the commercial organization working with market access, medical education, marketing and sales and receiving cross-functional support from our strong teams in R&D, manufacturing and

supplies, HR and finance. Together we are working passionately to make Buvidal available to patients around the world.

Of the estimated 1.5 million high-risk heroin and opioid users in Europe and Australia, less than half receive opioid dependence treatment today. Based on our current estimates. approximately 740,000 persons with opioid dependence could benefit from treatment of opioid dependence with long-acting medications and at least 100.000 patients could be in treatment with Buvidal in five

By providing weekly and monthly dosing options, Buvidal can improve adherence, without the requirement of frequent, often daily, visits to treatment clinics which can be burdensome and socially stigmatizing.

#### Buvidal launched in Finland, Sweden and the UK

In January 2019, Buvidal was launched in Finland, Sweden and the UK. The initial feedback from treating physicians and patients has been very positive, which is encouraging as we continue to roll-out Buvidal in Europe and Australia.

Alongside our commercial activities, we are expanding the comprehensive clinical evidence-base for Buvidal. During the period, recruitment of patients was started in a clinical study in the custodial setting. The study, sponsored by the Government of New South Wales, is conducted in seven prisons and evaluates the treatment with Buvidal versus methadone. We also have a study of Buyidal versus sublingual buprenorphine in the outpatient setting ongoing with focus on patient satisfaction and quality of life outcomes. Both studies are recruiting well and expected to deliver topline results late 2019.

After announcing positive Phase 3 efficacy results in chronic pain during the third guarter, the clinical development of Buvidal (CAM2038) in this indication continued with the long-term safety extension study. Results are expected in the second guarter 2019 and will be followed by discussions with health authorities before submission of market authorization applications.

## Tentative US approval of Brixadi™

In the US, our partner Braeburn received a tentative approval of Brixadi (the US trade name for Buvidal), signifying that all regulatory requirements for approval were fulfilled. However, final approval of the monthly product was blocked by a market exclusivity granted extending to November 2020. The unexpected broad scope of the market exclusivity was decided by the FDA at the time of the tentative approval of Brixadi. Given the magnitude



of the opioid crisis in the US, it is imperative that Brixadi is available as soon as possible to allow patients access to a new treatment which fulfils critical unmet medical needs. Several paths to address the current situation and being pursued by Braeburn.

### Fully underwritten rights issue

From a financial perspective, the tentative approval meant that the USD 35 million milestone payment expected from Braeburn after market approval of Brixadi in 2018 is delayed. In view of this, our Board of Directors has resolved to, subject to Extraordinary General Meeting approval, carry out a new share issue with preferential rights for the company's shareholders to raise gross proceeds of approximately SEK 400 million.

The proceeds from the rights issue will be used to finance the launch and marketing of Buvidal in Europe and Australia, progress the clinical development of key pipeline programs, including Phase 3 studies of CAM2029 in acromegaly and neuroendocrine tumors, and other prioritized programs, such as a Phase 2 study of CAM2043 for treatment of pulmonary

The rights issue is fully committed and underwritten by current shareholders and external guarantors. We are of course thankful to all our shareholders for their support and commitment.

We look forward to a productive 2019 as we continue to launch Buvidal in key markets and progress the development of our innovative therapies.

Fredrik Tiberg, President & CEO



# **Business highlights**

- Buvidal approved by the European Commission as the first long-acting treatment for opioid dependence in the EU
- Buvidal Weekly and Buvidal Monthly approved in Australia as the first long-acting treatment of opioid dependence
- US FDA issues a tentative approval of Brixadi for treatment of opioid
- Camurus Capital Markets and R&D Day held at IVA conference center
- Publications of positive: CAM2029 Phase 2 results in acromegaly and neuroendocrine tumor patients in Cancer Chemotherapy and Pharmacology; episil® Phase 3 results in Onco Targets and Therapy
- Clinical results for CAM2038 presented at 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

# Significant events after the period

- European launch of Buvidal initiated
- Resolution by the Board of Directors to carry out a fully underwritten rights issue of approximately MSEK 400, subject to approval by the extraordinary general meeting

# Q1 - Q3

# **Business highlights**

- 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
- episil oral liquid launched in Japan by Meiji Seika Pharma
- Clinical milestone achieved in collaboration with Rhythm Pharmaceuticals in the development of a weekly setmelanotide depot for the treatment of genetic obesity disorders
- 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
- Directed share issue successfully completed with proceeds of
- 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
- 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

# **Financial summary**

| MSEK                                             | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|--------------------------------------------------|-----------------|-----------------|-----------------|-----------------|
| Net Percente                                     | 7.8             | <i></i>         | 40.2            | E4.2            |
| Net Revenue                                      | 7.8             | 5.5             | 49.3            | 54.3            |
| Operating result                                 | -103.2          | -66.1           | -287.2          | -243.5          |
| Result for the period                            | -87.1           | -55.2           | -234.7          | -190.6          |
| Earnings per share SEK before and after dilution | -2.27           | -1.40           | -6.20           | -5.11           |
| Cash position                                    | 134.4           | 314.5           | 134.4           | 314.5           |

# A strong and diversified pipeline

Camurus is a research-based pharmaceutical company with a focus on the development and commercialization of new and innovative pharmaceuticals for 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 own proprietary formulation technology, such as the long-acting injection depot FluidCrystal®. 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. A summary and status update on the different projects is given below.

| PRODUCT                | PRECLINICAL                      | PHASE 1-2       | PHASE 3   |         | REGISTRATION | MARKET        |
|------------------------|----------------------------------|-----------------|-----------|---------|--------------|---------------|
| Buvidal® (CAM2038) q1w | OPIOID DEPENDENCE                |                 |           |         |              | APPROVED      |
| Buvidal® (CAM2038) q4w | OPIOID DEPENDENCE                |                 |           |         |              | APPROVED      |
| Brixadi® (CAM2038) q1w | OPIOID DEPENDENCE1               |                 |           |         | TENTAT       | VELY APPROVED |
| Brixadi® (CAM2038) q4w | OPIOID DEPENDENCE1               |                 |           |         | TENTAT       | VELY APPROVED |
| CAM2038 q1w CHRONIC    | PAIN <sup>1</sup>                |                 |           | PHASE 3 |              |               |
| CAM2038 q4w CHRONIC    | PAIN <sup>1</sup>                |                 |           | PHASE 3 |              |               |
| CAM2029 ACROMEGALY     |                                  |                 | PHASE 1-2 |         |              |               |
| CAM2029 NEUROENDOC     | RINETUMORS                       |                 | PHASE 1-2 |         |              |               |
| CAM2032 PROSTATE CAI   | NCER                             |                 | PHASE 1-2 |         |              |               |
| CAM4072 GENETIC OBES   | SITY DISORDERS <sup>3</sup>      | PHASE 1-        | 2         |         |              |               |
| CAM2043 PULMONARY A    | RTERIAL HYPERTENSION             | PHASE 1-        | 2         |         |              |               |
| CAM2047 CHEMOTHERA     | PY INDUCED NAUSEA & VO           | MITING PHASE 1- | 2         |         |              |               |
| CAM2048/58 POSTOPERA   | ATIVE PAIN & PONV <sup>1,2</sup> | PHASE 1-        | 2         |         |              |               |

<sup>1.</sup> Braeburn holds the rights to North America; 2. Postoperative nausea and vomiting; 3. Developed by Rhythm Pharmaceuticals under a worldwide license to FluidCrystal®

## MEDICAL DEVICE

MARKET

# Buvidal® – 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. Buyidal is the only 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 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.

Buvidal has been studied in a comprehensive clinical program comprising seven clinical studies, including two Phase 3 studies. A pivotal efficacy study met both the FDA and EMA primary efficacy endpoints (responder rate and mean percentage of urine samples negative for illicit opioids). In addition, superiority of Buvidal was demonstrated for the cumulative percentage of patients with no evidence of illicit opioid use during treatment

weeks 4 to 24. The safety profile of Buvidal was generally consistent with the known safety profile of buprenorphine except for mild-to-moderate injection-site adverse events. The results of clinical trials have been presented at several international scientific/clinical meetings as well as published in well-renowned international scientific/medical iournals.

#### STATUS Q4

On 22 November 2018, Camurus received EU approval for weekly and monthly Buvidal for opioid dependence for the treatment of opioid dependence in adults and adolescents from 16 years of age. 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.

During the guarter, commercial manufacturing and the distribution infrastructure for the first launch markets in the EU and Australia were completed. After the period, in January, Buvidal was launched in Finland, Sweden, the UK, and Germany, and launches in Denmark and Norway will follow. Alongside the initial roll-out in Europe, preparations for the Australian launch in the second guarter of 2019 are being completed.

In December 2018, the US FDA issued Camurus' partner Braeburn a tentative approval of Brixadi (the US trade name for Buvidal) for the treatment of moderate-to-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 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™. The restriction period will not last longer

than November 2020, but both the scope and duration could be reduced if successfully challenged.

In Israel, Camurus' distribution partner Medison Pharma is currently compiling the application of marketing approval for Buvidal in opioid dependence for submission to the Israeli health authorities in the first quarter of 2019.

# CAM2038 - 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.

CAM2038 has been successfully evaluated in a randomized Phase 3 efficacy study in opioid experienced patients with chronic low-back pain. The study 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.

# STATUS Q4

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 results are expected in H1 2019.

# CAM2029 – 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® LAR® 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® LAR®, 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<sup>®</sup> LAR<sup>®</sup>. The results were published in Cancer Chemotherapy and Pharmacology in December 2019.1

#### STATUS Q4

Preparations for the Phase 3 programs for CAM2029 for the treatment of acromegaly and neuroendocrine tumors continued. The pivotal Phase 3 trial for CAM2029 for the treatment of acromegaly is planned to start in mid-2019, once approval of the study design has been received from the health authorities. In parallel, a Phase 3 trial for

CAM2029 for the treatment of patients with NET is being planned.

# **CAM2043 - PAH**

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 by guidelines 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 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 an open-label Phase 1 study of single and repeated dosing of CAM2043, 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.

#### STATUS Q4

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 in H2 2019.

# Other pipeline projects

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

# **STATUS Q4** 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 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.

#### CAM2047, CAM2048 and CAM2058

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

<sup>&</sup>lt;sup>1</sup> Pavel M et al. Cancer Chemother, and Pharmacol., 2018, available online

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.

#### 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 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.

# Medical device - episil®

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 by, for example, 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 our FluidCrystal topical bioadhesive technology.

#### STATUS Q4

During the period, the results from a randomized, activecontrolled Phase 3 study of episil in China in patients with oral mucositis performed by our partner Solasia Pharma were published in Onco Targets and Therapy. <sup>2</sup> The study results demonstrated pain reduction with episil versus Kangsu<sup>™</sup>. The oral pain measured as the average 6-hour AUC was 14.20±10.29 for the episil group and 24.46±14.15 for the Kangsu group (p=0.0022). Earlier in 2018, episil was launched in Japan by Solasia's partner, Meiji Seika Pharma. During the period, a license distribution agreement was signed for episil in Australia and Nya Zealand, granting BTC Health Ltd and its wholly

owned subsidiary BioImpact Pty Ltd the exclusive rights to distribute episil oral liquid in Australia and New Zealand.

<sup>&</sup>lt;sup>2</sup> Cheng Y, et al, OncoTargets and Therapy, Vol 2018:11 p 8555—8564, DOI https://doi.org/10.2147/OTT.S185915

### **REVENUES**

Revenues during the guarter amounted to MSEK 7.8 (5.5), generated from project activities and product sales. See also note 3.

#### **OPERATING RESULT**

Marketing, business development and distribution costs during the quarter, were MSEK -39.5 (-11.3). The increase compared to the same period last year is mainly attributable to the expansion of the commercial organization and the preparation for launch of Buvidal in Europe and Australia.

Administrative expenses was MSEK -6.2 (-11.1). The difference compared to the same period previous year is mainly related to costs for establishing the commercial infrastructure during Q4 2017.

R&D costs, including depreciation and amortization of tangible and intangible assets were MSEK -61.9 (-48.1). The difference compared with the same period last year is primarily related to costs for the ongoing clinical trials of Buvidal (CAM2038) in Australia and preparations for commercial manufacturing and distribution of Buvidal.

The operating result for the guarter was MSEK -103.2 (-66.1).

#### FINANCIAL ITEMS AND TAX

Tax was MSEK 16.0 (13.8) and is mainly attributable to deferred tax for the reported loss during the quarter.

## **RESULT FOR THE PERIOD**

The result for the period was MSEK -87.1 (-52.2), corresponding to earnings per share of SEK -2.27 (-1.40) before and after dilution.

## **CASH FLOW AND INVESTMENT**

Cash flow from operating activities, before change in working capital, was negative and amounted to MSEK -102.2 (-65.0).

Change in working capital affected the cash flow

positively by MSEK 21.8 (10.0) and the difference compared to the same period last year is mainly attributable to reduced trade receivables and increased accounts pavable which together exceeded the increase in inventory of Buvidal ahead of the launch in January 2019. Cash flow from investing activities was MSEK -1.7 (-0.6) and from financing activities MSEK 0.0 (0.3).

#### **CASH**

The company's cash position as of 31 December 2018, was MSEK 134.4 (314.5). The difference compared to the previous year is mainly attributable to the operating result.

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

#### **EQUITY**

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

#### **ACQUISITIONS**

No acquisitions or divestments have occurred during the quarter.

## **CAMURUS' SHARE**

Camurus' share is listed on Nasdag Stockholm.

At the end of the period, the total number of shares and votes was 38,381,486 (37,281,486).

Camurus has three subscription warrant programs active for the company's employees.

#### Warrant program TO2016/2019

In accordance with a decision by the Shareholder's General Meeting in May 2016, an incentive program, TO2016/2019, was introduced. 550 000 warrants were issued, 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 stay-on bonus the participants received as part of the program was paid in full by end of the third quarter 2018 and no additional costs have been incurred.

## Warrant program TO2017/2020

In accordance with a decision by the Shareholder's General Meeting in May 2017, an incentive program, TO2017/2020, was introduced. 750,000 warrants were issued, which give the right to subscribe for an equal number of shares during the period 15 May 2020 – 15 December 2020. 44 employees have joined the program and subscribed for 658.932 warrants. However, 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% of the share capital and the voting rights. During the guarter, earnings after tax were negatively impacted by MSEK 0.9 related to 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, an incentive program, TO2018/2021, was introduced. 1,000,000 warrants were issued, which give the right to subscribe for an equal number of shares during the period 15 May 2021 – 15 December 2021. So far 47 employees have joined the program and subscribed for 562,400 warrants. The dilution effect on a maximum utilization of subscribed warrants corresponds to 1.5% of the share capital and the voting rights. During the quarter, earnings after tax were negatively impacted by MSEK 0.7 related to the stay-on bonus the participants receive as part of the program.

#### SIGNIFICANT EVENTS AFTER THE PERIOD

European launch of Buvidal for treatment opioid dependence initiated.

Resolution by the Board of Directors on a fully underwritten rights issue of approximately MSEK 400 subject to approval by the extraordinary general meeting.

#### PARENT COMPANY

Revenues for the guarter amounted to MSEK 13.6 (10.6) and the result after tax was MSEK -87.5 (-62.6).

On 31 December 2018, equity in the Parent Company amounted to MSEK 230.9 (367.7).

Total assets at the end of the period was MSEK 341.4 (460.1) of which MSEK 123.9 (309.8) were cash and cash equivalents.

#### **PERSONNEL**

At the end of the period, Camurus had 94 (71) employees, of whom 58 (48) were within research and development, 29 (15) within business development and marketing and sales, while 6 (7) were within administration. The full-time equivalent employees during the guarter amounted to 83 (64).

#### SIGNIFICANT RISKS AND UNCERTAINITIES

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 revenues and costs in connection with licensing agreements and deferred tax receivables.

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 non-approval or

delays of clinical trial applications and market approvals, and commercial risks relating to the sale of proprietary and competing products and their development on 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 on the international market and the company is therefore exposed to current risks, since revenues and costs arise in different currencies, mainly SEK, EUR, GBP and USD.

The Group reports a deferred tax asset of MSEK 171 as of December 31, 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 convincinally 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 November 22, 2018, Australian TGA's approval on November 28, 2018, and the FDA's tentative approval for Brixadi, weekly and monthly depot on December 21, 2018 (meaning that Brixadi has met all regulatory requirements regarding clinical and preclinical safety, treatment effect and quality, but that a final approval of Brixadi (monthly depot) is dependent on the expiry of an exclusivity period granted by the FDA to Sublocade™; 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 outlicensed FluidCrystal and / or product candidates or products such as Buvidal, 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 relations to their outlook published in the interim report for the second quarter 2018.

#### AUDIT

This report has not been reviewed by the company's auditors.

#### **EXTRAORDINARY GENERAL MEETING**

An extraordinary general meeting will be held on Tuesday 5 March 2019 at 11.00 CET, at Elite Hotel Ideon, Scheelevägen 27, Ideon Science Park, 223 63 Lund, Sweden.

# **ANNUAL GENERAL MEETING 2019**

Camurus Annual General Meeting will be held on Thursday 9 May at 17.00 CET, at Elite Hotel Ideon, Scheelevägen 27, Ideon Science Park, 223 63 Lund, Sweden.

# **FURHER INFORMATION**

For further information, please contact: Fredrik Tiberg, President & CEO Tel.: +46 46 286 46 92, e-mail: ir@camurus.com

Lund, Sweden, 5 February 2019 Camurus AB Board of Directors



# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

| KSEK                                | Note | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|-------------------------------------|------|-----------------|-----------------|-----------------|-----------------|
|                                     |      |                 |                 |                 |                 |
| Net revenues                        | 3    | 7,805           | 5,458           | 49,321          | 54,308          |
| Cost of goods sold                  |      | -3,937          | -754            | -6,822          | -1,356          |
| Gross profit                        |      | 3,868           | 4,704           | 42,499          | 52,952          |
| Marketing and distribution costs    |      | -39,547         | -11,347         | -100,884        | -45,893         |
| Administrative expenses             |      | -6,212          | -11,055         | -21,999         | -26,590         |
| Research and development costs      |      | -61,863         | -48,142         | -207,664        | -222,939        |
| Other operating income              |      | 565             | 34              | 830             | 93              |
| Other operating expenses            |      | -               | -269            | -               | -1,147          |
| Operating result                    |      | -103,189        | -66,075         | -287,218        | -243,524        |
| Finance income                      |      | 59              | 51              | 175             | 174             |
| Finance expenses                    |      | -3              | -3              | -25             | -18             |
| Net financial items                 |      | 56              | 48              | 150             | 156             |
| Result before tax                   |      | -103,133        | -66,026         | -287,068        | -243,368        |
| Income tax                          | 8    | 15,986          | 13,836          | 52,392          | 52,794          |
| Result for the period               | 4    | -87,147         | -52,190         | -234,676        | -190,574        |
| Exchange-rate differences           |      | -86             | 8               | 46              | 16              |
| Comprehensive income for the period |      | -87,233         | -52,182         | -234,630        | -190,558        |

Total comprehensive income is attributable to parent company shareholders.

# **FINANCIAL STATEMENTS**

# EARNINGS PER SHARE, based on earnings attributable to parent company shareholders for the period (in SEK per share)

| SEK                                     | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|-----------------------------------------|-----------------|-----------------|-----------------|-----------------|
|                                         |                 |                 |                 |                 |
| Earnings per share before dilution, SEK | -2.27           | -1.40           | -6.20           | -5.11           |
| Earnings per share after dilution, SEK  | -2.27           | -1.40           | -6.20           | -5.11           |

Presently, the company has three subscription warrant programs active. For further information see page 9 Camurus' share, and page 22.

# **CONSOLIDATED BALANCE SHEET**

| KSEK Note                           | 2018-12-31 | 2017-12-31 |
|-------------------------------------|------------|------------|
| ASSETS                              |            |            |
| Fixed assets                        |            |            |
| Fixed assets                        |            |            |
| Intangible assets                   |            |            |
| Capitalized development expenditure | 15,975     | 16,653     |
|                                     | ,          | ,          |
| Tangible assets                     |            |            |
| Equipment                           | 10,899     | 9,902      |
| • •                                 | ,          | ,          |
| Financial assets                    |            |            |
| Deferred tax receivables 8          | 170,955    | 114,997    |
| Total fixed assets                  | 197,829    | 141,552    |
|                                     |            |            |
| Current assets                      |            |            |
| Inventoria                          |            |            |
| Inventories                         | 4.700      | 0.000      |
| Finished goods                      | 4,700      | 2,829      |
| Raw materials                       | 5,130      | 724        |
| Total inventories                   | 9,830      | 3,553      |
| Current receivables                 |            |            |
| Trade receivables                   | 2,280      | 5,781      |
| Other receivables                   | 9,604      | 3,285      |
| Prepayments and accrued income      | 10,804     | 7,239      |
| Total current receivables 5         | 22,688     | 16,305     |
|                                     |            |            |
| Cash and cash equivalents           | 134,377    | 314,524    |
| Total current assets                | 166,895    | 334,382    |
| TOTAL ASSETS                        | 364,724    | 475,934    |

| KSEK                                                             | Note | 2018-12-31 | 2017-12-31 |
|------------------------------------------------------------------|------|------------|------------|
| FOURTY                                                           |      |            |            |
| EQUITY                                                           |      |            |            |
| Equity attributable to parent company                            |      |            |            |
| shareholder                                                      |      |            |            |
| Share capital                                                    |      | 960        | 932        |
| Other contributed capital                                        |      | 744,140    | 642,175    |
| Retained earnings, including comprehensive result for the period |      | -492,776   | -258,107   |
| Total equity                                                     | 9    | 252,324    | 385,000    |
| LIABILITIES                                                      |      |            |            |
| Short-term liabilities                                           |      |            |            |
| Trade payables                                                   |      | 35,781     | 15,086     |
| Income taxes                                                     |      | 1,708      | 517        |
| Other liabilities                                                |      | 3,549      | 2,672      |
| Accrued expenses and deferred income                             |      | 71,362     | 72,659     |
| Total short-term liabilities                                     |      | 112,400    | 90,934     |
| TOTAL EQUITY AND LIABILITIES                                     |      | 364,724    | 475,934    |

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

|                                        |      |               | Other                  | Retained earnings,                 |              |
|----------------------------------------|------|---------------|------------------------|------------------------------------|--------------|
| KSEK                                   | Note | Share capital | contributed<br>capital | including result<br>for the period | Total equity |
|                                        |      |               |                        |                                    |              |
| Opening balance 1 January 2017         |      | 932           | 631,034                | -67,549                            | 564,418      |
| Comprehensive income for the period    |      |               |                        | -190,558                           | -190,558     |
| Transactions with shareholders         |      |               |                        |                                    |              |
| Warrants issued                        |      | -             | 11,141                 | -                                  | 11,141       |
| Closing balance 31 December 2017       |      | 932           | 642,175                | -258,107                           | 385,000      |
| Opening balance 1 January 2018         |      | 932           | 642,175                | -258,107                           | 385,000      |
| Comprehensive income for the period    |      |               |                        | -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                  | -                                  | 7,110        |
| Closing balance 31 December 2018       | 9    | 960           | 744,101                | -492,737                           | 252,324      |

# CONSOLIDATED STATEMENT OF CASH FLOW

| KSEK Note                                                | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|----------------------------------------------------------|-----------------|-----------------|-----------------|-----------------|
|                                                          |                 |                 |                 |                 |
| Operating activities                                     |                 |                 |                 |                 |
| Operating result before financial items                  | -103,189        | -66,083         | -287,218        | -243,524        |
| Adjustment for non-cash items 7                          | 1,164           | 1,037           | 4,450           | 4,088           |
| Interest received                                        | 59              | 51              | 175             | 174             |
| Interest paid                                            | -3              | -3              | -25             | -18             |
| Income taxes paid                                        | -261            | -               | -272            | -               |
|                                                          | -102,230        | -64,998         | -282,890        | -239,280        |
|                                                          |                 |                 |                 |                 |
| Increase/decrease in inventories                         | -2,608          | -439            | -6,277          | 8,827           |
| Increase/decrease in trade receivables                   | 16,921          | 1,981           | 3,501           | 2,523           |
| Increase/decrease in other current receivables           | -2,973          | 1,268           | -9,884          | 9,788           |
| Increase/decrease in trade payables                      | 16,479          | -2,697          | 20,695          | -2,474          |
| Increase/decrease in other current operating liabilities | -5,979          | 9,928           | 771             | 17,532          |
| Cash flow from changes in working capital                | 21,840          | 10,041          | 8,806           | 36,196          |
| Cash flow from operating activities                      | -80,390         | -54,957         | -274,084        | -203,084        |
|                                                          |                 |                 |                 |                 |
| Investing activities                                     |                 |                 |                 |                 |
| Acquisition of intangible assets                         | -1,404          | -               | -1,404          | -               |
| Acquisition of tangible assets                           | -318            | -607            | -3,357          | -2,143          |
| Cash flow from investing activities                      | -1,722          | -607            | -4,761          | -2,143          |
|                                                          |                 |                 |                 |                 |
| Financing activities                                     |                 |                 |                 |                 |
| Directed share issue                                     | -               | -               | 92,741          | -               |
| Warrants issued                                          | -               | 335             | 7,110           | 11,141          |
| Cash flow from financing activities                      | -               | 335             | 99,851          | 11,141          |
| Net cash flow for the period                             | -82,112         | -55,229         | -178,994        | -194,086        |
| Cash and cash equivalents at beginning of period         | 216,347         | 369,748         | 314,524         | 508,594         |
| Translation difference in cash flow and liquid assets    | 142             | 5               | -1,153          | 16              |
| Cash and cash equivalents at the end of period           | 134,377         | 314,524         | 134,377         | 314,524         |
| ·                                                        |                 |                 | ,               | •               |

# **INCOME STATEMENT - PARENT COMPANY**

| KSEK Note                             | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|---------------------------------------|-----------------|-----------------|-----------------|-----------------|
|                                       | 00,200          | 33, 233         | 04.1.200        | 00 200          |
| Net sales                             | 13,565          | 10,552          | 67,111          | 64,640          |
| Cost of goods sold                    | -3,937          | -754            | -6,822          | -1,356          |
| Gross profit                          | 9,628           | 9,798           | 60,289          | 63,284          |
| Marketing and distribution costs      | -17,562         | -9,602          | -46,970         | -30,234         |
| Administrative expenses <sup>1)</sup> | -33,004         | -18,164         | -99,890         | -54,689         |
| Research and development costs        | -63,171         | -47,618         | -206,709        | -220,849        |
| Other operating income                | 562             | -343            | 838             | 61              |
| Other operating expenses              | -               | -276            | -               | -1,147          |
| Operating result                      | -103,547        | -66,205         | -292,442        | -243,574        |
| Interest income and similar items     | 59              | 51              | 175             | 174             |
| Interest expense and similar items    | -2              | -3              | -24             | -18             |
| Result after financial items          | -103,490        | -66,157         | -292,291        | -243,418        |
| Result before tax                     | -103,490        | -66,157         | -292,291        | -243,418        |
| Tax on profit for the period 8        | 16,033          | 13,855          | 53,527          | 52,853          |
| Result for the period                 | -87,457         | -52,302         | -238,764        | -190,565        |

<sup>1)</sup> The increase in cost compared to previous year, is mainly related to group internal recharges.

Total comprehensive income is the same as profit/loss for the period, as the parent company contains no items that are recognized under other comprehensive income.

# **BALANCE SHEET - PARENT** COMPANY

| KSEK N                         | lote | 2018-12-31 | 2017-12-31 | KSEK No                                     | e 2018-12-31 | 2017-12-31 |
|--------------------------------|------|------------|------------|---------------------------------------------|--------------|------------|
| ASSETS                         |      |            |            | EQUITY AND LIABILITES                       |              |            |
| Fixed assets                   |      |            |            | Restricted equity                           |              |            |
| Fixed assets                   |      |            |            | Restricted equity (38 381 486 shares)       | 960          | 932        |
| Tangible fixed assets          |      |            |            | Statutory reserve                           | 11,327       | 11,327     |
| Equipment                      |      | 10,689     | 9,725      | Total restricted equity                     | 12,287       | 12,259     |
| Equipment                      |      | 10,009     | 9,723      | Total restricted equity                     | 12,207       | 12,239     |
| Financial fixed assets         |      |            |            | Unrestricted equity                         |              |            |
| Interest in Group companies    |      | 1,800      | 1,545      | Retained earnings                           | -253,159     | -62,594    |
| Deferred tax assets            | 8    | 175,056    | 119,426    | Share premium reserve                       | 710,487      | 608,560    |
| Total fixed assets             |      | 187,545    | 130,696    | Result for the period                       | -238,764     | -190,565   |
|                                |      |            |            | Total unrestricted equity                   | 218,564      | 355,401    |
| Current assets                 |      |            |            | TOTAL EQUITY                                | 230,851      | 367,660    |
| Inventories                    |      |            |            | LIABILITIES                                 |              |            |
| Finished goods                 |      | 4,700      | 2,829      | Untaxed reserves                            |              |            |
| Raw materials                  |      | 5,130      | 724        | Depreciation/amortization in excess of plan | 3,486        | 3,486      |
| Total inventories              |      | 9,830      | 3,553      | Total untaxed reserves                      | 3,486        | 3,486      |
| Current receivables            |      |            |            | Long-term liabilities                       |              |            |
| Trade receivables              |      | 2,280      | 5,781      | Liability to subsidiaries                   | 572          | 571        |
| Other receivables              |      | 7,219      | 3,040      | Total long-term liabilities                 | 572          | 571        |
| Prepayments and accrued income |      | 10,679     | 7,202      |                                             |              |            |
| Total current receivables      |      | 20,178     | 16,022     | Short-term liabilities                      |              |            |
|                                |      |            |            | Liabilities to Group companies              | 9,065        | 3,769      |
| Cash and bank deposits         |      | 123,858    | 309,821    | Trade payables                              | 32,650       | 14,431     |
| Total current assets           |      | 153,866    | 329,397    | Other liabilities                           | 2,355        | 2,053      |
| TOTAL ASSETS                   |      | 341,411    | 460,093    | Accrued expenses and deferred income        | 62,432       | 68,123     |
|                                |      |            |            | Total short-term liabilities                | 106,502      | 88,376     |
|                                |      |            |            | TOTAL EQUITY AND LIABILITY                  | 341,411      | 460,093    |

| MSEK                                            | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|-------------------------------------------------|-----------------|-----------------|-----------------|-----------------|
|                                                 |                 |                 |                 |                 |
| Net sales                                       | 7.8             | 5.5             | 49.3            | 54.3            |
| Operating result                                | -103.2          | -66.1           | -287.2          | -243.5          |
| Result for the period                           | -87.1           | -52.2           | -234.7          | -190.6          |
| Cash flow from operating activities             | -80.4           | -55.0           | -274.1          | -203.1          |
| Cash and cash equivalents                       | 134.4           | 314.5           | 134.4           | 314.5           |
| Equity                                          | 252.3           | 385.0           | 252.3           | 385.0           |
| Equity ratio, percent                           | 69%             | 81%             | 69%             | 81%             |
| Total assets                                    | 364.7           | 475.9           | 364.7           | 475.9           |
| Average number of shares, before dilution       | 38,381,486      | 37,281,486      | 37,842,034      | 37,281,486      |
| Average number of shares, after dilution*)      | 40,007,118      | 38,344,718      | 39,231,356      | 38,058,289      |
| Earnings per share before dilution, SEK         | -2.27           | -1.40           | -6.20           | -5.11           |
| Earnings per share after dilution, SEK*)        | -2.27           | -1.40           | -6.20           | -5.11           |
| Equity per share before dilution, SEK           | 6.57            | 10.33           | 6.67            | 10.33           |
| Equity per share after dilution, SEK*)          | 6.31            | 10.04           | 6.43            | 10.12           |
| Number of employees at the end of period        | 94              | 71              | 94              | 71              |
| Number of employees in R&D at the end of period | 58              | 48              | 58              | 48              |
| R&D costs as a percentage of operating expenses | 57%             | 68%             | 63%             | 75%             |

<sup>\*)</sup> 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 adjustment 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 end of 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 percentage of operating expenses

Research and development costs divided by operating expenses (marketing and distribution costs, administrative expenses and research and development costs)

# Note 1 General information

Camurus AB. Corp. ID no. 556667-9105 is the parent company of the Camurus Group. Camurus AB's registered office is based in Lund, Sweden, at Ideon Science Park, 223 70 Lund. Camurus AB Group's interim report for the fourth quarter 2018 was approved for publication by the Board of Directors and the chief executive officer.

All amounts are stated in SEK thousand (KSEK), unless otherwise indicated. Figures in brackets refer to the year-earlier period.

# Note 2 | Summary of key accounting policies

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 Account Act.

This interim report has been drawn up in accordance with IAS 34, Interim Financial Reporting, the Swedish Annual Accounts Act and RFR 1 Supplementary Accounting Rules the Groups.

The parent company statements have been prepared in accordance with the Annual Accounts Act and recommendation RFR 2 Accounting for legal entities from the Swedish Financial Reporting Board. The application of RFR 2 means that the parent company in the interim report for the legal entity shall apply all EU-approved IFRS standards and statements as far as possible within the framework of the Annual Accounts Act, the Pension Obligations Vesting Act (Tryggandelagen) and taking into consideration the relationship between accounting and taxation. The parent company's accounting policies are the same for the Group, unless otherwise stated in Note

2.2.

The most important accounting policies that are applied in the preparation of these consolidated financial statements are detailed below and are the same and consistent with those used in the preparation of Annual Report 2017, see camurus.com/Investors/Financial Reports. In addition, as of January 1, 2018 the new standards IFRS 9 and IFRS 15 entered into force. As previously mentioned, the transition has not had any effect. Neither this report or the interim period 2018 have been affected. Presentation of the Group's full accounting principles will be made in the Annual Report 2018.

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. The estimated effects on the balance sheet are presented in the table below. The lease portfolio includes only a few lease contracts and covers mainly 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.

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. 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.

| MSEK                                                            | Right-of-use assets | Lease<br>liabilities,<br>interest bearing |
|-----------------------------------------------------------------|---------------------|-------------------------------------------|
| Closing balance 31 Dec 2018 before transition to IFRS 16 Leases | -                   | -                                         |
| Estimated reclassifications due to transition to IFRS 16 Leases | -                   | -                                         |
| Estimated adjustments due to transition to IFRS 16 Leases       | 29.8                | 28.7                                      |
| Estimated adjusted opening balance 1 Jan 2019                   | 29.8                | 28.7                                      |

#### 2.1 BASIS OF PREPARATION OF REPORTS

#### 2.1.1 Changes to accounting policies and disclosures

New or revised IFRS standards that have come into force have not had any material impact on the Group.

#### 2.2 PARENT COMPANY'S ACCOUNTING POLICIES

The parent company applies accounting policies that differ from those of the Group in the cases stated below.

## Internally generated intangible assets

All expenses that relate to the development of internally generated intangible assets are recognized as expenses as they arise.

## Interest in subsidiary

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. Impairment losses are recognized under the item "Result from interest in Group companies".

## **Group contributions**

Group contributions paid by the parent company to subsidiaries and Group contributions received from subsidiaries by the parent company are recognized as appropriations.

### Financial instruments

IFRS 9 "Financial instruments" addresses the classification, measurement and recognition of financial assets and liabilities and is applied with the exceptions that RFR2 allows, ie at amortized cost.

# Share-based payment

Camurus has two long-term incentive programs active for the company's employees. The warrants are valued by an independent institute in accordance with Black&Scholes model and are acquired by the participants at market value. As part of the program, the participants receive a threepiece stay-on bonus from the company in form of gross salary additions equivalent to the amount paid by the participant for the subscription warrants. As the stayon bonus is conditional on continued employment, costs including social security fee, are based on how much has been earned, and are expensed over the vesting period. Expenses are recognized as personnel cost in the income statement.

## Warrant program TO2016/2019

The program was introduced in accordance with a decision by the Annual General Meeting in May 2016. 404.300 warrants have been subscribed for. corresponding to 1.1% dilution. Warrant program TO2017/2020

The program was introduced in accordance with a decision by the Annual General Meeting in May 2017. 658,932 warrants have been subscribed for,

corresponding to 1.7% dilution.

Warrant program TO2018/2021

The program was introduced in accordance with a decision by the Annual General Meeting in May 2018. 562.400 warrants have been subscribed for. corresponding to 1.5% dilution.

# Note 3 | 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 manages. As the operations in the Group, i.e. the development of pharmaceutical products based on Camurus' technology platform, 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 is 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.

# **Group-wide information**

To follow is a breakdown of revenues from all products and services.

| KSEK                                            | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|-------------------------------------------------|-----------------|-----------------|-----------------|-----------------|
|                                                 |                 |                 |                 |                 |
| Sales of development related goods and services | 1,757           | 4,728           | 11,378          | 41,394          |
| Milestone payments                              | -               | -               | 25,380          | 7,025           |
| Licensing revenues                              | 1,246           | 387             | 1,246           | 3,582           |
| Other*)                                         | 4,802           | 343             | 11,317          | 2,307           |
| Total                                           | 7,805           | 5,458           | 49,321          | 54,308          |

<sup>\*)</sup> Including product sales of episil

Revenues from external customers are allocated by country, based on where the customers are located.

| KSEK                     | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|--------------------------|-----------------|-----------------|-----------------|-----------------|
|                          |                 |                 |                 |                 |
| Europe                   | 1,691           | 256             | 3,687           | 7,229           |
| (of which Sweden)        | (82)            | (55)            | (327)           | (239)           |
| North America            | 1,236           | 5,202           | 35,562          | 41,350          |
| Other geographical areas | 4,878           | -               | 10,072          | 5,729           |
| Total                    | 7,805           | 5,458           | 49,321          | 54,308          |

Revenues during the quarter of approximately MSEK 4.8 (5.0) relate to one single external customer.

# Note 4 Earnings per share

# 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.

## b) After dilution

In order to calculate earnings per share after dilution, 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 are compared to the number of shares that would have been issued assuming the warrants are exercised.

| 2018<br>Oct-Dec | 2017<br>Oct-Dec               | 2018<br>Jan-Dec                                   | 2017<br>Jan-Dec                                                                                                                               |
|-----------------|-------------------------------|---------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
|                 |                               |                                                   |                                                                                                                                               |
| -87,147         | -52,190                       | -234,676                                          | -190,574                                                                                                                                      |
| -87,147         | -52,190                       | -234,676                                          | -190,574                                                                                                                                      |
|                 |                               |                                                   |                                                                                                                                               |
| 38,381          | 37,281                        | 37,842                                            | 37,281                                                                                                                                        |
|                 | Oct-Dec<br>-87,147<br>-87,147 | Oct-Dec Oct-Dec  -87,147 -52,190  -87,147 -52,190 | Oct-Dec         Oct-Dec         Jan-Dec           -87,147         -52,190         -234,676           -87,147         -52,190         -234,676 |

| KSEK                                                                                                       | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|------------------------------------------------------------------------------------------------------------|-----------------|-----------------|-----------------|-----------------|
|                                                                                                            |                 |                 |                 |                 |
| Result attributable to parent company shareholders                                                         | -87,147         | -52,190         | -234,676        | -190,574        |
| Total                                                                                                      | -87,147         | -52,190         | -234,676        | -190,574        |
| Weighted average number of ordinary shares outstanding (thousands)                                         | 38,381          | 37,281          | 37,842          | 37,281          |
| Adjustments:                                                                                               |                 |                 |                 |                 |
| - Warrants (thousands)                                                                                     | 1,626           | 1,064           | 1,389           | 777             |
| - Share issues (thousands)                                                                                 | -               | -               | -               | -               |
| Weighted average number of ordinary shares in calculation of earnings per share after dilution (thousands) | 40,007          | 38,345          | 39,231          | 38,058          |

# Note 5 | Financial instruments – Fair value of financial assets and liability measured at amortized cost

All of the Group's financial instruments that are measured at amortized cost are short-term and expire within one year. The fair value of these instruments is deemed to correspond to their reported amounts, since discounting effects are minimal.

# Note 6 Related party transaction

There were no related party transactions outside of the Camurus group during the period.

No receivables or liabilities existed as of 31 December 2018.

| Carrying amount, KSEK            | 2018-12-31 | 2017-12-31 |
|----------------------------------|------------|------------|
|                                  |            |            |
| Loans and receivables            |            |            |
| Trade receivables                | 2,280      | 5,781      |
| Receivables from Group companies | -          | -          |
| Other receivables                | -          | -          |
| Cash and cash equivalents        | 134,377    | 314,524    |
| Total                            | 136,657    | 320,305    |
|                                  |            |            |
| Other liabilities                |            |            |
| Other financial liabilities      | -          | -          |
| Liabilities to Group companies   | -          | -          |
| Trade payables                   | 35,781     | 15,086     |
| Other current liabilities        | 190        | 191        |
| Total                            | 35,971     | 15,277     |

# Note 7 Other non-cash items

Adjustment for non-cash items:

# Note 8 | Deferred tax

Tax for the quarter amounted to MSEK 16.0 (13.8), primary attributable to the negative result.

# Note 9 | Equity

The change in equity for the quarter is mainly attributable to the loss during the period.

| KSEK         | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|--------------|-----------------|-----------------|-----------------|-----------------|
| Depreciation | 1,164           | 1,037           | 4,450           | 4,088           |
| Total        | 1,164           | 1,037           | 4,450           | 4,088           |

This information is information that Camurus AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Swedish Securities Markets Act. The information was submitted for publication, through the agency of the chief executive officer, 07.00 AM (CET) on 6 February 2019.



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