

FULL YEAR REPORT 2019

"This was a pivotal year for Camurus and we are looking forward to a 2020 with continued strong growth and a positive news flow"

#### 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

## **camurus**<sub>®</sub>

## **SUMMARY FOURTH QUARTER 2019**

- Total revenues of SEK 35.0 M (7.8) in Q4 and SEK 105.6 M (49.3) for the full year
- Product sales were SEK 30.3 M (4.8) in Q4 and SEK 72.1 M (11.3) for the full year
- Product sales increased by 55 percent compared to the previous quarter
- Net cash position 31 December SEK 358.7 M (134.4)
- FDA granted Citizen Petition revoking the Orphan Designation for Sublocade<sup>™</sup>, allowing Brixadi<sup>™</sup> to be available on the US market from 1 December 2020
- Distribution agreement signed with NewBridge Pharmaceuticals for Buvidal® in 12 countries in the MENA region
- Announcement of topline DEBUT study results showing superior patient global satisfaction with Buvidal<sup>®</sup> compared to standard of care with sublingual buprenorphine
- Market authorization application submitted to health authority in New Zealand
- Completion of directed share issue with SEK 300 M in proceeds for market preparations for CAM2038 in chronic pain and performance of Phase 3 study of CAM2029 in NET
- Clinical data for Buvidal presented at Lisbon Addiction, Oct 23-25, Lisbon, Portugal and AAAP (American Academy of Addiction Psychiatry) Dec 5-8, San Diego, California

## **FINANCIAL OUTLOOK 2020**

- Net revenues are expected to be in the range of SEK 290 330 M (excl milestone payments relating to Brixadi<sup>™</sup>) whereof product sales of SEK 240 – 280 M
- Full year OPEX is expected to be in the range of SEK 570 610 M

## **FINANCIAL SUMMARY**

MSEK	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Net Revenue	35.0	7.8	105.6	49.3
– Whereof product sales	30.3	5.1	72.1	11.3
Operating result	-88.4	-103.2	-360.0	-287.2
Result for the period	-71.9	-87.1	-289.9	-234.7
Earnings per share SEK before and after dilution	-1.47	-2.11	-6.23	-5.77
Cash position	358.7	134.4	358.7	134.4



## **FINANCIAL CALENDAR 2020**

Presentation	
Full Year Report 2019	12 February 2020, 2 pm CET
Q1 Interim Report 2020	7 May 2020, 1 pm CET
AGM 2020	7 May 2020, 5 pm CET
Q2 Interim Report 2020	16 July 2020
Q3 Interim Report 2020	5 November 2020

#### INVESTOR CONFERENCE CALL, ANALYSTS AND MEDIA

Full Year Report 2019 and an operational update will be presented by CEO Fredrik Tiberg and members of the Camurus management team on Wednesday 12 February 2020, at 2 pm (CET). The conference call can also be followed by a link on the website, **camurus.com** 

#### External link:

https://financialhearings.com/event/12255

# Strong finish to launch year for Buvidal®

The successful launch of Buvidal<sup>®</sup> in first wave markets in the EU and Australia continued during the fourth quarter, delivering strong double-digit sales growth. The very positive feedback received from patients was reflected in topline results from the DEBUT clinical study, which demonstrated superior patient reported outcomes with Buvidal compared to buprenorphine standard of care. In the US, the FDA approved a Citizen Petition which enables Brixadi<sup>™</sup> to enter the market from 1 December 2020. Finally, we took important steps to advance our pipeline of innovative therapies and raised SEK 300 million for Phase 3 development in neuroendocrine tumors and premarketing activities in chronic pain.

#### **GROWING BUVIDAL SALES**

During the quarter, we saw a continued robust growth of Buvidal sales in the first wave launch markets in the EU and Australia. Product sales grew by 55 percent compared to the previous quarter to SEK 30.3 million. Full year product sales were SEK 72.1 million, meeting our 2019 guidance, although at the lower end due to unforeseen external delays in legislation changes and market access processes. Total revenues were SEK 35.0 million for the quarter and SEK 105.6 million for the year.

# "Product sales grew by 55% compared to the previous quarter"

We are pleased with our first year as a commercial stage pharmaceutical company with an own marketing and sales organization. Buvidal was launched in seven countries and the feedback from patients and healthcare professionals have throughout been very positive, which is an important source of inspiration for all of us working at Camurus. In Finland, our first launch market. Buvidal is already the market leader with a 45 percent vear-end share of buprenorphine patients, and 30 percent of all medication assisted treatment (MAT) patients. After receiving pricing and reimbursement, similar rapid growth was seen in Norway and Australia, while sales in other markets developed at more modest rates but are gaining momentum as access limitations and other momentary hurdles are being addressed. At the end of the year around 4,000 patients were in treatment with Buvidal - a 60 percent increase compared to the end of the third guarter. In 2020, we anticipate Buvidal sales in the range of SEK 240-280 million.

During the fourth quarter we entered a strategic partnership with NewBridge Pharmaceuticals for the commercialization of Buvidal across 12 countries in the Middle East and North Africa (MENA). NewBridge has a strong presence in the region, with



local and regional regulatory and medical expertise, an established marketing and sales organization, and a broad pharmaceuticals portfolio in neurology, immunology, and oncology. We look forward to a rewarding collaboration to make Buvidal available to the many patients living with opioid dependence in MENA.

#### SUPERIOR TREATMENT OUTCOMES IN DEBUT STUDY

Positive results from the DEBUT clinical study, assessing treatment with Buvidal versus daily sublingual buprenorphine in 120 Australian patients with opioid dependence, were announced during the fourth quarter. This is to our knowledge the first randomized, controlled trial comparing patient reported outcomes

## "At the end of the year around 4,000 patients were in treatment with Buvidal"

(PROs) between a long-acting buprenorphine injection and standard of care in a head-to-head study. Buvidal met the primary endpoint and demonstrated superior patient satisfaction and significant improvements in treatment burden, quality of life and other secondary endpoints compared to standard of care. This is in agreement with earlier published results from our Phase 3 long-term safety study and the positive anecdotal feedback from patients and physicians using Buvidal in real life

#### clinical settings.

In parallel, the core part of the UNLOCT study, comparing weekly and monthly Buvidal to oral methadone in seven prisons in New South Wales, Australia, was completed. Positive preliminary results were presented at the Lisbon Addiction Conference in October 2019 alongside oral and plenary presentations and workshops about Buvidal in the outpatient setting. During 2020 we will continue our high activity at international conferences and publication of new study data for Buvidal in leading scientific journals.

#### FINAL APPROVAL AND LAUNCH OF BRIXADI IN THE US

The FDA's decision on 6 November 2019 to grant Braeburn's Citizen Petition and revoke the orphan designation for Sublocade<sup>™</sup> removed the risk of any further exclusivity barriers and Brixadi is now on track for final NDA approval and launch in December 2020, with the possibility of an early launch of the weekly product. The market potential for Brixadi is very significant: with more than 2 million people diagnosed with opioid use disorder and about 1 million patients in MAT in the US, we estimate the US market potential for Brixadi to be approximately USD 600–1,200 million based on a 5–10 percent market share of buprenorphine patients.

## MARKET AUTHORIZATION APPLICATION AND PHASE 3 STUDIES

During the quarter preparations continued for the planned submission of an EU market authorization application in the second or third quarter of 2020 for CAM2038 for the treatment of chronic pain, with an anticipated approval in 2021. CAM2038 has a strong and competitive product profile and meets an important medical need for patients with chronic pain whose current treatment options are often limited to daily medication with strong opioids. We are currently conducting detailed market analysis to optimize product positioning and market access in our key markets. We estimate significant potential for CAM2038 in segments of the pain market, at the same magnitude as Buvidal for the treatment of opioid dependence.

During 2019 we started two global Phase 3 studies of our

long-acting octreotide depot, CAM2029, for the treatment of acromegaly. The studies will in total include approximately 140 patients across 60 specialist clinics in the US and Europe and are expected to be fully recruited in 2020 with results in 2021. In parallel to these studies, where the investigational drug is administered as a prefilled syringe, we are developing an autoinjector to further simplify and enhance patient self-admini-

## "Brixadi is on track for final NDA approval and launch in December 2020"

stration. A pharmacokinetic bridging study is planned to start during the year. Following the successful directed share issue in December 2019, we are also preparing for the start of the pivotal study program for CAM2029 in neuroendocrine tumors as well as in an additional indication where third-party assessments have confirmed the attractiveness and market potential of the CAM2029 product profile, which addresses significant unmet medical needs.

#### EARLY STAGE PIPELINE AND PARTNERSHIPS

During the fourth quarter we submitted a clinical trial application for a Phase 2a study of our treprostinil weekly depot, CAM2043, in patients with Reynaud's phenomenon; a rare and serious condition characterized by episodes of pallor followed by cyanosis of fingers or toes, which can be very painful and cause digital ulcers and dry necrosis. The clinical trial application was granted in January 2020 and the study is expected to start during the second quarter of 2020. In parallel, a Phase 2 study of CAM2043 for treatment of pulmonary arterial hypertension is being planned.

In the collaboration with Rhythm Pharmaceuticals, a weekly setmelanotide depot, CAM4072, for the treatment of genetic obesity disorders is being developed. A Phase 2 study

is currently ongoing with more than 70 patients with obesity recruited to date.<sup>1</sup> Results from the study, which is designed to evaluate the pharmacokinetics, pharmacodynamics, and safety of CAM4072 after 3 months treatment, are expected in 2020. In parallel, manufacturing preparations for the start of the pivotal study program are ongoing.

In our new collaboration with Ra Pharmaceuticals on the development of a long-acting zilucoplan, preparations are ongoing for the start of clinical development during 2020. During the quarter, it was announced that the Belgian pharmaceutical company UCB has bid to acquire Ra. The acquisition is expected to be approved during the first quarter of 2020.

## STRONG FOURTH QUARTER LAYS THE FOUNDATION FOR A SUCCESSFUL 2020

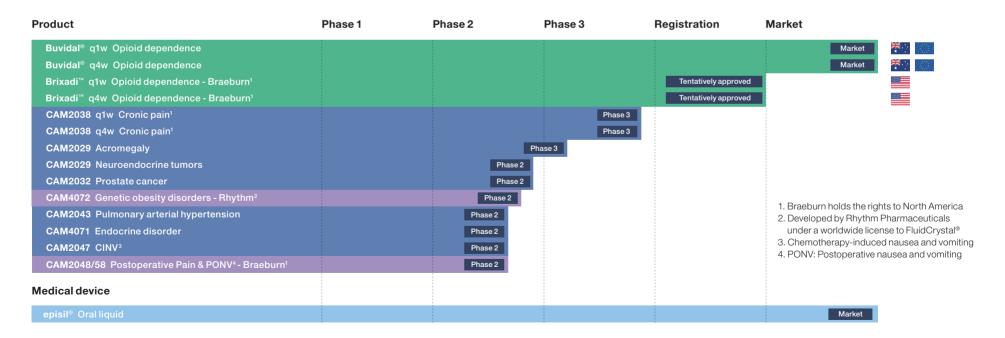
Our achievements during the fourth quarter, including strong sales growth for Buvidal, improved access for patients, and preparations for launch in new markets, lay the foundation for a successful 2020. Our strategy for Buvidal focuses on increasing our market share, expanding sales to second and third wave markets, and establishing Buvidal as the evidence-based standard of care for the treatment of opioid dependence. In addition to developments on our own markets, we are looking forward to Brixadi becoming available to US patients as well as Buvidal approvals and launches on new markets in e.g. the MENA region. This guarter we also completed a directed share issue, raising SEK 300 million to secure further investments in our late-stage pipeline projects, including chronic pain and neuroendocrine tumors, as well as prioritized early stage projects. I would like to thank existing and new shareholders for your support during 2019 and our growing number of dedicated co-workers at Camurus. This was a pivotal year for Camurus and we are looking forward to 2020 with continued strong growth and a positive news flow.

Fredrik Tiberg, President & Chief Executive Officer

# **Broad 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<sup>®</sup>. 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.



## Buvidal<sup>®</sup>- 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 stigma and burdens of daily, often supervised, dosing, limited treatment adherence, misuse, medication diversion, and accidental pediatric exposure.

Buvidal<sup>®</sup> 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 sublingual buprenorphine, allowing for direct transition from previous 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 treatment adherence, thereby reducing costs for supervision and the risks of relapse, overdose and death.

Buvidal has been studied in a comprehensive pivotal 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 several well-renowned international scientific/medical journals.

In 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. Later in the month, Buvidal Weekly and Buvidal Monthly depots were also approved in Australia by the Australian Therapeutic Goods Administration. Shortly thereafter, in January 2019, Buvidal was launched as the first long-acting opioid dependence treatment in the EU.

In December 2018, the FDA issued a tentative approval of Brixadi<sup>™</sup> (the US trade name for Buvidal). 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<sup>™</sup> until 30 November 2020.

In April 2019, Braburn filed an action in federal district court for the District of Columbia, seeking to overturn the 3-year market exclusivity for Sublocade. In parallel they submitted a Citizen Petition to the FDA, requesting that it revokes the orphan drug designation for Sublocade and refuses to accept any claim for orphan drug exclusivity.

In July 2019 the court granted Braeburn's motion for summary judgement, vacating FDA's decision to block final market approval of Brixadi monthly product. The court remanded the FDA to reconsider, with deliberate speed, Braeburn's application for final approval of Brixadi monthly product fro treatment of opioid dependence in the US.

#### STATUS Q4

Sales of Buvidal progressed during the quarter in seven countries in the EU and Australia. During the period, topline results were reported from the 24-week, randomized, controlled, open-label, DEBUT study of weekly and monthly Buvidal (prolonged-release buprenorphine) versus standard of care with daily sublingual buprenorphine (e.g. Suboxone<sup>®</sup> Film) in 120 randomized outpatients at six clinical sites in Australia. The study, performed in real-world treatment setting with validated patient reported outcomes, met the primary end-point, demonstrating superiority for the Treatment Satisfaction Questionnaire for Medication (TSQM) global satisfaction score for Buvidal versus standard of care at week 24, p=0.0143, as well as significantly higher TSQM effectiveness and convenience domain scores, p<0.0001. Furthermore, patients treated with Buvidal reported statistically significant improvements in quality of life, reduced burden of treatment, and other secondary outcomes versus daily standard of care. Retention in treatment with Buvidal was high; with an 88% retention rate at week 24.

In addition, the custodial settings study, UNLOC-T, was completed. UNLOC-T compared non-randomized treatment of Buvidal versus methadone a total of 129 patients in eight minimum to maximum security prisons in New South Wales (NSW) and was sponsored by the NSW Ministry of Health.

Results from the DEBUT and UNLOC-T studies will be presented at leading conferences during 2020 and in scientific publications.

In November 2019, the FDA announced that they granted Braeburn's Citizen Petition to revoke orphan drug designation of Sublocade. At the same time they upheld their previous tentative approval decision, with the three-year exclusivity for Sublocade blocking Brixadi monthly product from the US market until 30 November 2020.

## 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 longlasting 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 several 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.

A 52-week Phase 3 long-term safety extension study of CAM2038 in chronic pain has also been completed with positive safety and long-term efficacy results.

#### **STATUS Q4**

The compilation of a marketing authorization application in the EU continued was started during the quarter. In parallel, we initiated detailed market access studies to analyze questions related to product profile, price and reimbursement. Sub-mission of the MAA to EMA is planned for the second or third quarter of 2020 with a possible approval in 2021.

## CAM2029 – acromegaly and neuroendocrine tumors

CAM2029 is a ready-to-use long-acting subcutaneous depot of the active substance octreotide, a synthetic peptide analogue of the natural peptide hormone somatostatin and used for the 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 designed for easy self-administration by patients themselves using a prefilled syringe or an autoinjector offering the potential for improved patient convenience. In addition, CAM2029 provides higher bioavailability of octreotide 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 and 2 trials and demonstrated positive results in a multicenter study in patients with acromegaly and NET, with well maintained or improved biochemical control in patients with acromegaly and symptom control in patients with functioning NET after switch from Sandostatin LAR.

In mid-2019 the pivotal Phase 3 program for CAM2029 was initiatied with a randomized, double blind, placebo-controlled, multinational, multi-center study in patients with acromegaly and previously treated with long-acting somatostatin analogues. The patients are randomized to receive either CAM2029 or placebo for 24 weeks, and the primary efficacy measure is bio-chemical response, as measured by insulin-like growth factor 1 (IGF-1) levels. The pivotal study program was during the third quarter expanded with a 52 week Phase 3 long-term safety study including both newly recruited patients as well as rollover patients from the ongoing pivotal efficacy study.

#### **STATUS Q4**

Recruitment of patients to both Phase 3 studies continued during the quarter- The studies are expected to be fully recruited during 2020 and report during first half of 2021. In total they will include about 150 patients and about 60 clinical sites in the US and in Europe. In parellel, the development of an autoinjector as a complement to the existing prefilled syringe configuration continued. A pharmacokinetic bridging clinical study comparing CAM2029 in autoinjector with prefilled syringe is planned to start during 2020.

## CAM2043 – Pulmonary arterial hypertension and Raynaud's phenomenon

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.

Reynaud's phenomenon (RP) is a condition characterized by episodes of pallor followed by cyanosis of fingers or toes when exposed to cold or stress. Often this is followed by a phase of redness, swelling and pain. Secondary Raynaud's phenomenon is caused by an underlying disease, e.g. scleroderma or SLE, and can cause skin thickening, digital ulcers and necrosis.

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 and RP. 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 reports of unexpected or serious adverse events. Injection site reactions were acceptable and resolved over time.

#### STATUS Q4

During the quarter, a clinical trial application (CTA) for a Phase 2a study of our treprostinil weekly depot, CAM2043, in secondary Reynaud's phenomenon was submitted. Following approval of the CTA study is expected to start in the second quarter of 2020. In parallel, a Phase 2 study of CAM2043 for treatment of PAH is being prepared

## **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. 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 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.

#### CAM4071

CAM4071 is a long-acting formulation of pasireotide based on our FluidCrystal technology, which has been successfully investigated in a completed Phase 1 trial. The results from the study were presented at the European Congress of Endocrinology 2018, demonstrating a rapid onset and long-acting release of pasireotide and pharmacodynamic response after dosing of CAM4071.

#### 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.

In August 2019, Rhytyhm released positive results from their pivotal Phase 3 study of daily dosed setmelanotide in patients with obesity caused by pro-opiomelanocortin (POMC) or leptin receptor (LEPR) deficiency. The results strengthen the prospects of positive treatment results and approval of our weekly setmelanotide depot.

A 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. Rhythm is currently conducting a Phase 2 study with more than 70 patients with obesity recruited to date. The study is designed to evaluate pharmacokinetics, pharmacodynamics, safety after three months on CAM4072 and includes daily cohort receiving doses higher than those used in Rhythm's Phase 3 pivotal trials for the daily formulation.<sup>1</sup> Results from the study is expected in 2020. In parallel, manufacturing preparations for start of the pivotal study program are ongoing.

#### CAM4083

CAM4083 is a weekly formulation of zilucoplan, a complement component 5 (C5) inhibitor in development by Camurus' partner Ra Pharmaceuticals for the treatment of generalized myasthenia gravis, immune-mediated necrotizing myopathy, and other tissue-based, complement-mediated disorders with high unmet medical need. The FDA has granted zilucoplan Orphan Drug designation for treatment of myasthenia gravis.

In pre-clinical testing, a single dose of the zilucoplan FluidCrystal formulation in non-human primates rapidly achieved and maintained target levels of complement inhibition for at least seven days without the need for an intravenous loading regimen. Ra Pharmaceuticals is currently preparing for start of clinical development of the zilucoplan FluidCrystal formulation during 2020.

### Medical device – episil<sup>®</sup>

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. episil has been launched by Camurus on selected markets in Europe and by partners; in the US by R-Pharm US, in Japan and China by Solasia Pharma, and in Australia by BioImpact Pty.

#### **STATUS Q4**

During the quarter, Camurus' partner Solasia Pharma received market approval for episil in South Korea. Launch in Korea is targeted in the beginning of 2020.

#### REVENUES

During the fourth quarter product sales grew by 55 percent to MSEK 30.3 (5.1), compared to MSEK 19.5 in the previous quarter. Full year product sales amounted to MSEK 72.1 (11.3) in line with our guidance.

Total net revenues for the quarter were MSEK 35.0 (7.8), an increase of 349 percent compared to the fourth quarter 2018. Full year net revenues amounted to MSEK 105.6 (49.3), an increase of 114 percent. The revenues did not meet guidance of MSEK 130 – 160 due to moving forward revenue recognition of a prepaid income.

For further information, see note 4.

#### **OPERATING RESULT**

Marketing and distribution costs during the quarter were MSEK 41.9 (39.5) and MSEK 170.5 (100.9) for the full year. The increase compared to last year is mainly related to the expansion of the commercial organization and the Buvidal<sup>®</sup> launch in Europe and Australia.

Administrative expenses for the quarter were MSEK 5.6 (6.2) and MSEK 23.5 (22.0) for the full year.

R&D costs, including depreciation and amortization of tangible and intangible assets were MSEK 63.2 (61.9) for the quarter and MSEK 249.2 (207.7) for the full year. The increase compared to the previous year is primarily related to the start of the Phase 3 program for CAM2029, octreotide depot, for the treatment of acromegaly.

The operating result for the quarter was MSEK -88.4 (-103.2) and MSEK -360.0 (-287.2) for the full year.

#### FINANCIAL ITEMS AND TAX

Financial items in the period were MSEK -0.3 (0.1) and MSEK -1.5 (0.2) for the full year. The difference is mainly related to the implementation of IFRS 16 Leases in January 2019. Tax in the quarter was MSEK 16.9 (16.0) and for the full year MSEK 71.7 (52.4), representing mainly deferred tax for the reported loss during the period.

The Swedish corporate tax rate for 2019 has been reduced to 21.4 percent.

#### **RESULT FOR THE PERIOD**

The result for the period was positively affected by net sales growth of Buvidal, and amounted to MSEK -71.9 (-87.1), a reduced loss compared to the fourth quarter 2018. The result for the full year was MSEK -289.9 (-234.7) mainly due to investments in the Phase 3 program for CAM2029 and expansion of the commercial organisation associated with the launch of Buvidal in the EU and Australia.

Earnings per share during the quarter amounted to SEK -1.47 (-2.11) before and after dilution, and for the full year SEK -6.23 (-5.77).

1 January 2019 IFRS 16 Leases was implemented. This affected the result negatively by MSEK -0.9 during th quarter and MSEK -0.6 for the full year.

#### **CASH FLOW AND INVESTMENT**

Cash flow from operating activities, before change in working capital, was MSEK -87.9 (-102.2) during the period and MSEK -355.5 (-282.9) for the full year.

Change in working capital affected the cash flow negatively by MSEK -15.4 (21.8) and the difference compared to previous year is mainly attributable to an increase in inventory of Buvidal and trade receivables. During the full year change in working capital affected cash flow negatively by MSEK -47.9 (8.8).

Cash flow from investing activities was MSEK -13.5 (-1.7) in the quarter, and MSEK -28.1 (-4.8) for the full year, and relates to investments in the DEBUT study in Australia and observation studies in Germany.

From financing activities cash flow in the period was MSEK 281.9 (0.0). The difference compared to the same quarter last year relates mainly to proceeds from the directed share issue in December 2019. Cash flow from financing activities for the full year was MSEK 655.5 (99.9) and the difference is mainly related to the two share issue completed during the year; rights issue in March and directed share in December.

#### CASH

The company's cash position as of 31 December, 2019 was MSEK 358.7 (134.4). The difference compared to the previous year is mainly attributable to the operating result and to the two rights issues completed during 2019.

The company had no loans as of 31 December, 2019, and no loans have been taken up since.

#### EQUITY

Consolidated equity as of 31 December, 2019 was MSEK 631.6 (252.3). The difference compared to the previous year is related to the company's result and the two rights issues during the year when MSEK 662.3 in net proceeds were raised.

#### **PARENT COMPANY**

Revenues for the quarter amounted to MSEK 34.9 (13.6) and to MSEK 123.0 (67.1) for the full year. The result after tax was MSEK -79.5 (-87.5) and MSEK -314.5 (-238.8) for the full year.

On 31 December, 2019, equity in the Parent Company amounted to MSEK 585.3 (230.9).

Total assets at the end of the period was MSEK 685.7 (341.4) of which MSEK 332.6 (123.9) were cash and cash equivalents. The difference compared to the previous year relates to the net result for the period and the two rights issues completed during 2019.

#### ACQUISITIONS

No acquisitions or divestments have been made during the quarter.

#### CAMURUS' SHARE

Camurus' share is listed on Nasdaq Stockholm.

At the end of the period, the total number of shares and votes was 51,636,858 (38,381,486) and the difference compared to the previous year relates to the two rights issues completed during the year.

Currently Camurus has three subscription warrant programs active for the company's employees. During the quarter, earnings after tax were negatively impacted by MSEK 1.1 related to the stay-on bonus the participants receive as part of the programs. The program TO2016/2019 expired 15 December 2019 without subscription being possible with regards to the shareprice during the subscription period.

For information about number of warrants, potential dilution, subscription periods, strike prices and number of employees participating in the programs, see Note 2.3.

#### PERSONNEL

At the end of the period, Camurus had 120 (94) employees, of whom 67 (58) were within research and development, 42 (29) within business development and marketing and sales, while 10 (6) were within administration. The number of employees, in terms of full-time equivalents, amounted to 113 (83) during the quarter.

#### **FINANCIAL OUTLOOK FOR 2020**

Total net revenues are expected to grow to MSEK 290-330 (excl. milestone payments relating to Brixadi approvals in the US) primarily due to increasing Buvidal sales.

Product sales are expected to grow to between MSEK 240-280, due to increasing Buvidal market shares and treatment expansion in our first wave markets in Europe and Australia, and geographic expansion to second and third wave markets.

OPEX is expected to increase to between MSEK 570-610 primarily due to increasing investments in the Phase 3 programs in acromegaly and NET, market preparations for CAM2038 in chronic pain, and expansion of our commercial organization and activities. This outlook is based on exchange rates in December 2019.

#### **ANNUAL GENERAL MEETING 2020**

Camurus Annual General Meeting will be held on Thursday 7 May 2020, at 17.00 CET, at Elite Hotel Ideon, Scheelevägen 27, Ideon Science Park, 223 63 Lund, Sweden.

In accordance with the dividend policy adopted by the Board, no dividend is proposed for the financial year 2019.

The Annual Report for 2019 will be published on www.camurus.com on 8 April 2020. It will also be available from Camurus AB's headquarters in Lund.

#### AUDIT

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

#### FORWARD-LOOKING STATEMENTS

This report includes forward-looking statements about expected and assumed future events, such as start of new development programs and regulatory approvals, and financial performance. These events are subject to risks, uncertainties and assumptions. This may cause actual results to differ materially from previous judgements.

#### **FURTHER INFORMATION**

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

> Lund, Sweden, 11 February 2020 Camurus AB Board of Directors

## Consolidated statement of comprehensive income

KSEK Note	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Net revenues 4	35,023	7,805	105,605	49,321
Cost of goods sold	-13,540	-3,937	-23,287	-6,822
Gross profit	21,483	3,868	82,318	42,499
Marketing and distribution costs	-41,905	-39,547	-170,540	-100,884
Administrative expenses	-5,601	-6,212	-23,468	-21,999
Research and development costs	-63,205	-61,863	-249,226	-207,664
Other operating income	817	565	894	830
Other operating expenses	-	-	-	-
Operating result	-88,411	-103,189	-360,022	-287,218
Finance income	21	59	43	175
Finance expenses	-346	-3	-1,585	-25
Net financial items	-325	56	-1,542	150
Result before tax	-88,736	-103,133	-361,564	-287,068
Income tax 9	16,880	15,986	71,699	52,392
Result for the period 5	-71,856	-87,147	-289,865	-234,676
Exchange-rate differences	-209	-86	258	46
Comprehensive income for the period	-72,065	-87,233	-289,607	-234,630

Total comprehensive income is attributable to Parent Company shareholders.

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

SEK	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Earnings per share before dilution, SEK	-1.47	-2.11	-6.23	-5.77
Earnings per share after dilution, SEK	-1.47	-2.11	-6.23	-5.77

For more information about calculation of earnings per share, see Note 5. Presently, the company has four subscription warrant programs active. For further information see page 9 Camurus' share, and Note 2.3.

## **Consolidated balance sheet**

KSEK Not	te	2019-12-31	2018-12-31
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development expenditure		37,335	15,975
Tangible assets			
Lease asset		27,722	_
Equipment		10,662	10,899
Financial assets			
Deferred tax receivables	9	256,637	170,955
Total fixed assets		332,356	197,829
Current assets			
Inventories			
Finished goods		14,243	4,700
Raw materials		18,849	5,130
Total inventories		33,092	9,830
Current receivables			
Trade receivables		34,791	2,280
Other receivables		5,197	9,604
Prepayments and accrued income		7,866	10,804
Total current receivables	6	47,854	22,688
Cash and cash equivalents		358,744	134,377
Total current assets		439,690	166,895
TOTAL ASSETS		772,046	364,724

KSEK	Note	2019-12-31	2018-12-31
EQUITY			
Equity attributable to parent company shareholder			
Share capital		1,291	960
Other contributed capital		1,412,687	744,101
Retained earnings, including comprehensive result for the period		-782,344	-492,737
Total equity	10	631,634	252,324
LIABILITIES			
Long-term liabilities			
Lease liabilities		22,938	-
Total long-term liabilities		22,938	-
Short-term liabilities			
Trade payables		17,387	35,781
Lease liabilities		4,394	-
Income taxes		1,687	1,708
Other liabilities		5,806	3,549
Accrued expenses and deferred income		88,200	71,362
Total short-term liabilities		117,474	112,400
TOTAL EQUITY AND LIABILITIES		772,046	364,724

## Consolidated statement of changes in equity

		Share	Other contributed		Total
KSEK	Note	capital	capital	for the period	equity
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		960	744,101	-492,737	252,324
Opening balance 1 January 2019		960	744,101	-492,737	252,324
Comprehensive income for the period		_	-	-289,607	-289,607
Transactions with shareholders					
Share issues*		331	702,794	_	703,125
Issuance costs, net after deferred tax		-	-40,815	_	-40,815
Warrants issued		-	6,607	_	6,607
Closing balance 31 December 2019	10	1,291	1,412,687	-782,344	631,634

\*) Rights issue in March and directed share issue in December

## Consolidated statement of cash flow

KSEK No	te	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Operating activities					
Operating result before financial items		-88,411	-103,189	-360,022	-287,218
Adjustment for non-cash items	8	2,461	1,164	9,014	4,450
Interest received		21	59	43	175
Interest paid		-346	-3	-1,585	-25
Income taxes paid	_	-1,577	-261	-2,962	-272
		-87,852	-102,230	-355,512	-282,890
Increase/decrease in inventories		2,199	-2,608	-23,262	-6,277
Increase/decrease in trade receivables		-12,238	16,921	-32,511	3,501
Increase/decrease in other current receivables		1,799	-2,973	6,241	-9,884
Increase/decrease in trade payables		354	16,479	-18,394	20,695
Increase/decrease in other current operating liabilities		-7,542	-5,979	20,069	771
Cash flow from changes in working capital		-15,428	21,840	-47,857	8,806
Cash flow from operating activities		-103,280	-80,390	-403,369	-274,084
Investing activities					
Acquisition of intangible assets		-10,549	-1,404	-23,442	-1,404
Acquisition of tangible assets		-2,996	-318	-4,631	-3,357
Cash flow from investing activities		-13,545	-1,722	-28,073	-4,761
Financing activitie					
Increase/decrease in long-term liabilities		124	-	-2,339	_
Share issue		281,819 <sup>1)</sup>	-	651,197 <sup>1,2)</sup>	92,741 <sup>3)</sup>
Warrants issued		-	-	6,607	7,110
Cash flow from financing activities		281,943	-	655,465	99,851
Net cash flow for the period		165,118	-82,112	224,023	-178,994
Cash and cash equivalents at beginning of period		192,331	216,347	134,377	314,524
Translation difference in cash flow and liquid assets		1,295	142	344	-1,153
Cash and cash equivalents at the end of period		358,744	134,377	358,744	134,377

<sup>1)</sup>Directed share issue in December 2019. <sup>2)</sup> Rights issue in March 2019. <sup>3)</sup> Directed share issue in June 2018.

## **Income statement – Parent Company**

KSEK Note	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Net sales	34,887	13,565	123,042	67,111
Cost of goods sold	-12,409	-3,937	-22,965	-6,822
Gross profit	22,478	9,628	100,077	60,289
Marketing and distribution costs <sup>1)</sup>	-44,237	-17,562	-201,261	-46,970
Administrative expenses <sup>1)</sup>	-5,342	-33,004	-23,560	-99,890
Research and development costs	-72,784	-63,171	-269,325	-206,709
Other operating income	623	562	567	838
Other operating expenses	-	-	-	_
Operating result	-99,262	-103,547	-393,502	-292,442
Interest income and similar items	21	59	43	175
Interest expense and similar items	-1	-2	-33	-24
Result after financial items	-99,242	-103,490	-393,492	-292,291
Result before tax	-99,242	-103,490	-393,492	-292,291
Tax on profit for the period 9	19,779	16,033	78,983	53,527
Result for the period	-79,463	-87,457	-314,509	-238,764

<sup>1)</sup>During 2018 group internal recharges were included in the function administrative expenses.

As of 2019 these costs have been reclassified as marketing and distribution costs.

With the same classification in 2018, administrative expenses during the fourth quarter previous year would have amounted to KSEK 5,862, and full year to KSEK 21,615. Marketing and distribution costs during the fourth quarter previous year would have amounted to KSEK 44,704, and full year to KSEK 125,245. The increase in costs compared to previous year, is mainly related to group internal recharges regarding the commercial organization.

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 Note	2019-12-31	2018-12-31
ASSETS		
Fixed assets		
Tangible fixed assets		
Equipment	10,479	10,689
Financial fixed assets		
Interest in Group companies	2,317	1,800
Deferred tax assets 9	265,152	175,056
Total fixed assets	277,948	187,545
Current assets		
Inventories		
Finished goods	13,579	4,700
Raw materials	18,849	5,130
Total inventories	32,428	9,830
Current receivables		
Trade receivebles	31,777	2,280
Other receivables	2,356	7,219
Prepayments and accrued income	8,619	10,679
Total current receivables	42,752	20,178
Cash and bank deposits	332,607	123,858
Total current assets	407,787	153,866
TOTAL ASSETS	685,735	341,411

KSEK Note	2019-12-31	2018-12-31
EQUITY AND LIABILITES		
Restricted equity		
Restricted equity (47,976,858 shares)	1,291	960
Statutory reserve	11,327	11,327
Total restricted equity	12,618	12,287
Unrestricted equity		
Retained earnings	-491,923	-253,159
Share premium reserve	1,379,073	710,487
Result for the period	-314,509	-238,764
Total unrestricted equity	572,641	218,564
TOTAL EQUITY	585,259	230,851
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	572
Total long-term liabilities	572	572
Short-term liabilities		
Liabilities to Group companies	639	9,065
Trade payables	13,906	32,650
Other liabilities	3,576	2,355
Accrued expenses and deferred income	78,297	62,432
Total short-term liabilities	96,418	106,502
TOTAL EQUITY AND LIABILITY	685,735	341,411

KSEK	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Net sales	35.0	7.8	105.6	49.3
Operating result	-88.4	-103.2	-360.0	-287.2
Result for the period	-71.9	-87.1	-289.9	-234.7
Cash flow from operating activities	-103.3	-80.4	-403.4	-274.1
Cash and cash equivalents	358.7	134.4	358.7	134.4
Equity	631.6	252.3	631.6	252.3
Equity ratio, percent	82%	69%	82%	69%
Total assets	772.0	364.7	772.0	364.7
Average number of shares, before dilution	49,011,206	41,251,130	46,496,256	40,671,345
Average number of shares, after dilution	51,294,470	42,876,762	48,601,481	42,060,667
Earnings per share before dilution, SEK	-1.47	-2.11	-6.23	-5.77
Earnings per share after dilution, SEK	-1.47	-2.11	-6.23	-5.77
Equity per share before dilution, SEK	12.89	6.12	13.58	6.20
Equity per share after dilution, SEK	12.31	5.88	13.00	6.00
Number of employees at the end of period	120	94	120	94
Number of employees in R&D at the end of period	67	58	67	58
R&D costs as a percentage of operating expenses	57%	57%	56%	63%

#### **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 (calculated acc. to IAS 33)

#### Average number of shares, after dilution

Weighted average number of shares after adjustment for the dilution effect of new shares (calculated acc. to IAS 33)

#### 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 (calculated acc. to IAS 33)

#### Equity per share after dilution, SEK

Equity divided by the weighted number of shares at the end of the period after dilution (calculated acc. to IAS 33)

#### 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 2019 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 for 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 Group's accounting principles in full will be presented in the annual report for 2019.

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 2018, see camurus. com/Investors/Financial Reports. In addition, the new standard IFRS 16 Leases came into force 1 January 2019 replacing IAS 17 Leases.

At 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. Right-of-use assets have been determined as an amount equal to the lease liabilities as identified at initial application. 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. A discount rate has been applied for the 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 below USD 5,000) are also excluded from being recognized as lease liability or right-of-use asset.

As an effect of the transition, the Groups' total assets at the transition date 1 January 2019 have increased with MSEK 29,8, representing 8.2 percent of the balance sheet. The Group's financial liabilities have increased by MSEK 28,7, representing 7.9 percent of the balance sheet. For information about change in opening balance 1 January 2019, see table on next side.

During the quarter, IFRS 16 impact on the operating profit was MSEK 1.2 in increased depreciations and MSEK 1.4 in decreased other operating expenses. Thus, no material impact on operating profit and EPS.

## Change in opening balance 1 January 2019 due to transition to IFRS 16 Leases

KSEK	2018-12-31	IFRS 16 adjustment	2019-01-01
ASSETS			
Fixed assets			
Intangible assets	15,975	-	15,975
Tangible assets	10,899	29,780	40,679
Financial assets	170,955	-	170,955
Total fixed assets	197,829	29,780	227,609
Current assets			
Current assets	166,895	-1,104	165,791
Total current assets	166,895	-1,104	165,791
Total assets	364,724	28,676	393,400
EQUITY AND LIABILITIES			
Equity	252,324	-	252,324
Long-term liabilities			
Lease liabilities	-	25,277	25,277
Other liabilities, non-interest bearing	-	-	-
Totalt long-term liabilities	-	25,277	25,277
Short-term liabilities			
Lease liabilities	-	3,399	3,399
Other liabilities, non-interest bearing	112,400	-	112,400
Total short-term liabilities	112,400	3,399	115,799
TOTAL EQUITY AND LIABILITIES	364,724	28,676	393,400

#### 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, i.e. at amortized cost.

#### 2.3 SHARE-BASED PAYMENT

Camurus has three 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 stay-on 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. The programs were adopted by the Annual General Meeting in 2017, 2018 and 2019. Below a summary of the programs:

Program	Number of subscribed warrants	Potential dilution of the subscribed warrants	Subscription period	Strike price SEK, for subscription of shares upon exercise	Number of participats in the program
TO2017/2020	715,816 <sup>1,2)</sup>	1.39% <sup>1,2)</sup>	15 Maj 2020-15 Dec 2020	153.91 <sup>1)</sup>	44
TO2018/2021	605,519 <sup>1,2)</sup>	1.17% <sup>1,2)</sup>	15 Maj 2021-15 Dec 2021	133.391)	47
TO2019/2022	599,959 <sup>2)</sup>	1.16%2)	15 Maj 2022-15 Dec 2022	98.90	64
Total	1,921,294	3.72%			

<sup>1)</sup> After recalculation of TO2017/2020 and TO2018/2021, which according to the terms of the programs was called for in connection with the rights issue in March 2019. <sup>2)</sup> No further allocation can be made.

# Note 3 Significant risks and uncertainties

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 256.6 as of 31 December 2019. 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 November 22, 2018, Australian TGA's approval on November 28, 2018, the launch of Buvidal in EU and Australia, and the FDA's tentative approval for Brixadi<sup>™</sup>, weekly and monthly depot on December 21, 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™; 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 partnerships for markets where Camurus has out-licensed 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.

A more detailed description of the Group's risk exposure is included in Camurus Annual Report 2018 (The Director's Report).

The Board of Directors has not changed its outlook on future developments in relations to their outlook published in the interim report for the third quarter 2019.

## Note 4 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	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Sales of development related goods and services	3,308	1,757	7,001	11,379
License and milestone revenues	1,445	937	26,520	26,626
Product sales")	30,270	5,111	72,084	11,316
Total	35,023	7,805	105,605	49,321

\*) Relating to Buvidal and episil®.

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

KSEK	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Europe	23,750	1,691	61,426	3,687
(of which Sweden)	(2,294)	(82)	(4,028)	(327)
North America	3,122	1,236	24,803	35,562
Asia including Oceania	8,151	4,878	19,376	9,763
Other geographical territories	-	-	-	309
Total	35,023	7,805	105,605	49,321

Revenues during the quarter of approximately MSEK 23.3 (4.8) relate to one single external customer.

## Note 5 | 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 that would have been issued assuming the warrants are exercised.

KSEK	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Result attributable to parent company shareholders	-71,856	-87,147	-289,865	-234,676
Total	-71,856	-87,147	-289,865	-234,676
Weighted average number of ordinary shares outstanding (thousands)	49,011	38,381	45,950	37,842

KSEK	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Result attributable to parent company shareholders	-71,856	-87,147	-289,865	-234,676
Total	-71,856	-87,147	-289,865	-234,676
Weighted average number of ordinary shares outstanding (thousands)	49,011	38,381	45,950	37,842
Adjustment for fund issue element <sup>*)</sup> (thousands)	-	2,870	546	2,829
Weighted average number of ordinary shares outstanding	49,011	41,251	46,496	40,671
adjusted for fund issue element (thousands)				
Adjustment for warrants (thousands)	2,283	1,626	2,105	1,389
Weighted average number of ordinary shares in calculation of earnings per share after dilution (thousands)	51,294	42,877	48,601	42,061

<sup>1</sup>) The number of shares has been recalculated according to the so-called fund issue element in accordance with IAS 33, p. 26 and 64

## Note 6 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 7** | **Related party transaction**

Transactions with related party outside of the Camurus group to a total value of MSEK 0.2, in accordance with market terms, have occurred during the period.

No receivables or liabilities existed as of 31 December, 2019.

Carrying amount, KSEK	2019-12-31	2018-12-31
Loans and receivables		
Trade receivables	34,791	2,280
Receivables from Group companies	-	-
Other receivables	395	-
Cash and cash equivalents	358,744	134,377
Total	393,930	136,657
Other liabilities		
Other financial liabilities	-	-
Liabilities to Group companies	-	-
Trade payables	17,387	35,781
Other current liabilities	190	190
Total	17,577	35,971

## Note 8 Other non-cash items

Adjustment for non-cash items:

KSEK	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Depreciation	2,461	1,164	9,014	4,450
Total	2,461	1,164	9,014	4,450

## Note 9 | Tax

Tax income for the quarter amounted to MSEK 16.9 (16.0), primary attributable to the negative result.

## Note 10 | Equity

The change in equity for the quarter is mainly attributable to the loss during the period and the directed share issue completed in December 2019.

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, 7.00 AM (CET) on 12 February 2020.



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