

INTERIM REPORT 2018 Q2

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#### FINANCIAL CALENDAR

Q3 2018

25 October 2018

### **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**  "We made significant progress towards regulatory approvals for CAM2038 in the US, Europe and Australia"

# Launch preparations and positive pipeline development

During the second quarter, we continued to progress approval processes for our weekly and monthly buprenorphine depots, CAM2038, for the treatment of opioid dependence, and intensified our launch preparations in Europe and Australia. We regained the worldwide rights to CAM2029 octreotide depot, received positive clinical results for CAM2043, and completed a directed share issue.

#### Progress in approval processes and launch readiness

During the second quarter, we made significant progress towards regulatory approvals of CAM2038 in the US, Europe and Australia. The New Drug Application (NDA) was resubmitted to the FDA by our US partner Braeburn. After the period, we were delighted to receive notice of the FDA's acceptance of the complete response together with a PDUFA goal date of December 26, 2018. Market Authorization Application (MAA) review processes in the EU and Australia continued to advance, with expected approvals on all key markets in 2018.

Results from our randomized, double-blind, double-dummy, active-controlled Phase 3 study were published in JAMA Internal Medicine, demonstrating favorable clinical outcomes for CAM2038 versus current standard treatment with daily sublingual buprenorphine/naloxone in opioid dependent patients. This represents the first publication of Phase 3 study results for a longacting buprenorphine injectable treatment. Clinical study results, including subgroup analyses of Phase 3 results in heroin and injection drug users, have also been presented at leading international scientific addiction conferences, showing statistically improved outcomes for key measures for CAM2038 versus daily sublingual buprenorphine/naloxone.

Launch preparations for CAM2038 continued to progress. In the US, Braeburn made significant advances in establishing an effective marketing, reimbursement and distribution model for CAM2038. Responses from payors and prescribers have been encouraging. In Europe, we have further strengthened our organization within marketing, medical affairs and market access, and our commercial

teams have continued to execute on the regional go-to-market plans for CAM2038. In Australia, we recruited a business unit head with experience in the opioid dependence therapy area to build the organization and prepare for launch. Additionally, we initiated the expansion of our global distribution network to ensure access to treatment for patients outside EU and Australia and signed an agreement with Medison Pharma for commercialization of CAM2038 in Israel.

#### Conclusion of pivotal study in chronic pain

A randomized, placebo-controlled Phase 3 study of CAM2038 for the treatment of chronic low back pain was concluded in May 2018. Subsequently, our study teams have been preparing for database lock and unblinding of the study. Topline efficacy results are expected in the third quarter. Meanwhile, a long-term safety extension study of CAM2038 is ongoing, which is anticipated to be clinically completed towards the end 2018.

#### Preparing for CAM2029 Phase 3 studies

After regaining the exclusive worldwide rights to our CAM2029 octreotide depot and related products from Novartis, we have worked diligently to ensure a smooth transfer of the project and have also started to prepare for Phase 3 registration programs for CAM2029 in acromegaly and neuroendocrine tumors (NET). During the second half of 2018, we plan to complete ongoing manufacturing preparations for Phase 3 and engage with healthcare authorities in the EU and US to align clinical registration program updates. The market for long-acting somatostatin products, Sandostatin® LAR® and Somatuline® Autogel<sup>®</sup>, has shown steady growth for the past two decades with 2017 global sales exceeding USD 2.4 billion. Based on our product design advantages and positive clinical results from Phase 1 and 2 studies, we expect that CAM2029, if approved, could gain a significant market share and become an important catalyst for future growth and value creation for Camurus.

#### Promising Phase 1 results for CAM2043

In our early pipeline, we obtained topline results from the first clinical study of our weekly treprostinil depot, CAM2043, in development for treatment of pulmonary arterial hypertension (PAH). Based on the positive pharmacokinetic and tolerability results in healthy volunteers, we have started preparing the further clinical development of CAM2043 in collaboration with key opinion leaders and clinical experts.



#### Directed share issue completed

To support the commercialization of CAM2038 in Australia and the initiation of clinical development programs for CAM2029 and CAM2043, a directed share issue of approximately MSEK 102 was completed in June, securing these important activities up to the expected US approval and launch of CAM2038.

The second quarter has been intense and productive, during which our dedicated teams continued to deliver on key priorities. I am proud of the commitment of my coworkers and thankful for the many positive results that they have achieved. With the approvals of CAM2038, we will have the opportunity to positively impact the lives of hundreds of thousands of patients living with opioid dependence. In the longer term we aim to address important treatment needs in other patient groups with severe and chronic diseases.

Fredrik Tiberg, President & CEO

# Q2

# **Business highlights**

- NDA for CAM2038 resubmitted to FDA
- JAMA Internal Medicine published positive Phase 3 study results for CAM2038 for treatment of opioid use disorder
- Camurus regained exclusive worldwide rights to CAM2029 and related
  product candidates from Novartis
- Topline results announced from Phase 1 study of CAM2043 for the treatment PAH
- Directed share issue completed with proceeds of 102 MSEK
- Camurus and Medison entered into agreement for CAM2038 in Israel
- episil<sup>®</sup> oral liquid launched in Japan by Meiji Seika Pharma
- Company presentation at the H.C. Wainwright & Co. Global Life Sciences Conference, and Jefferies Global Healthcare Conference
- Clinical results for CAM2038 presented at the American Society for Addiction Medicine (ASAM) Annual Conference, Congrès International d'Addictologie de l'Albatros, and the College on Problem Drugs and Dependence (CPDD) Annual Scientific Meeting
- New patents issued for CAM2029 and CAM2038 in the US

## Significant event after the period

 FDA accepts complete response and issues user fee (PDUFA) goal date of December 26, 2018

# **Financial summary**

MSEK	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun
	7.0	40.4	00.0	00.0
Net Sales	7.3	19.1	22.0	36.3
Operating result	-81.2	-58.7	-127.6	-110.3
Result after tax	-67.5	-45,8	-103.8	-86.1
Earnings per share SEK before and after dilution	-1.81	-1,23	-2.78	-2.31
Cash position	199.1	413.4	199.1	413.4

# **January - March**

# **Business highlights**

- Complete response letter issued by the FDA regarding the CAM2038 new drug application (NDA) for the treatment of OUD
- Type A Meeting Package submitted to the FDA regarding the Agency's request for additional information for the CAM2038 NDA
- All patients completed treatment in a randomized, placebocontrolled Phase 3 study of CAM2038 in chronic pain
- First clinical milestone achieved in collaboration with Rhythm Pharmaceuticals in the development of a weekly setmelanotide depot for the treatment of genetic obesity disorders
- Company presentations given at Biostock Live, Stockholm Corporate Finance Life Science Seminar, Cowen and Company Annual Health Care Conference, and Carnegie Nordic Healthcare Seminar

# Late-stage diversified product 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.

PARTNER	PRODUCT	PRE-CLINICAL	PHASE 1-2	PHASE 3	REGISTRATION	MARKET
braeburn camurus.	CAM2038 q1w OPIOID DEI	PENDENCE			REGISTRATION	
braeburn' camurus.	CAM2038 q4w OPIOID DE	PENDENCE			REGISTRATION	1
braeburn' camurus.	CAM2038 q1w CHRONIC F	AIN		PHASE 3		
braeburn' camurus.	CAM2038 q4w CHRONIC F	PAIN		PHASE 3	1	1
camurus.	CAM2029 NEUROENDOC	RINE TUMORS	PHASE 1-	2	1	1
camurus.	CAM2029 ACROMEGALY		PHASE 1-	2	1	1
camurus.	CAM2032 PROSTATE CAN	ICER	PHASE 1-	-2	1	1
camurus.	CAM2047 CINV3		PHASE 1-2		1	
braeburn <sup>1</sup> camurus.	CAM2048/58 POSTOPERA	TIVE PAIN & PONV⁴	PHASE 1-2	1	4	
rhythm <sup>2</sup>	CAM4072 GENETIC OBES	ITY	PHASE 1-2		1	
camurus.	<b>CAM2043</b> PAH <sup>5</sup>		PHASE1-2	1	1	.1
	1) Rights to North America 2) Worldwig	e rights 3) Chemotherapy induced nause	a and vomiting 4) Postonerative nausea a	nd vomiting 5) Pulmonary arterial hyper	tension	

1) Rights to North America, 2) Worldwide rights, 3) Chemotherapy induced nausea and vomiting, 4) Postoperative nausea and vomiting, 5) Pulmonary arterial hypertension

#### MEDICAL DEVICE

episil

nsil<sup>®</sup>oral liquid

MARKET

# CAM2038 – 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. CAM2038 is being developed as both weekly and monthly long-acting subcutaneous buprenorphine depots for the treatment of opioid dependence. The investigational products are based on our proprietary FluidCrystal<sup>®</sup> injection depot technology and are intended for subcutaneous administration by healthcare professionals using prefilled syringes, provided in multiple doses, to allow individualized treatment of patients with opioid dependence. Patients being treated with CAM2038 are freed from the burden and stigma associated with the daily, often supervised, distribution and administration of current buprenorphine medications. Treatment with CAM2038 also has the potential to generate substantial savings for the healthcare system and society by reducing the costs of frequent supervised treatment, improving treatment compliance, and lowering diversion, misuse and abuse.

CAM2038 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 CAM2038 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 CAM2038 was generally consistent with the known safety profile of buprenorphine except for mild-to-moderate injection-site adverse events.

#### STATUS Q2

Marketing Authorization Applications (MAAs) are currently being evaluated by the European Medicines Agency (EMA) and the Australian Therapeutic Goods Administration (TGA). Final approval decisions from both authorities are anticipated in Q4 2018.

In the US, our partner Braeburn resubmitted the New Drug Application (NDA) for CAM2038 weekly and monthly buprenorphine depot injections to the US Food and Drug Administration (FDA) in May, in response to the Complete Response Letter (CRL) received in January 2018. A notification by the FDA of a Prescription Drug User Fee Act (PDUFA) action date is expected shortly.

Also in May, we announced the publication of positive Phase 3 pivotal study results for CAM2038 in the Journal of the American Medical Association (JAMA). The results, supporting efficacy and potential clinical advantages of the investigational medical product for the treatment of opioid dependence, represent the first scientific publication of Phase 3 data of a long-acting buprenorphine injection.

In June, we announced a new partnership with Medison Pharma for distribution of CAM2038 in Israel. Medison will have the exclusive right to commercialize CAM2038 in all indications, including opioid dependence and chronic pain, and will also be responsible for obtaining regulatory approval in Israel.

# 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  $\mu$ -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.

#### **STATUS Q2**

In the Phase 3 efficacy study of CAM2038 in chronic lower-back pain, all patients have been fully treated in the efficacy phase. In the following long-term safety extension study, all patients have been included and the study is continuing according to plan. Topline results from the efficacy study are expected in Q3 2018, followed by longterm safety results in Q4 2018.

# CAM2029 – acromegaly and NET

CAM2029 is being developed for the treatment of acromegaly and neuroendocrine tumors (NET). CAM2029 is a ready-to-use, long-acting subcutaneous injection of the active substance octreotide formulated with our proprietary FluidCrystal<sup>®</sup> injection depot technology. It provides several potential advantages compared to the currently marketed product Sandostatin<sup>®</sup> LAR<sup>®</sup> including higher bioavailability, fast onset of effect, and the potential for improved patient convenience. CAM2029 has been evaluated in four clinical Phase 1/2 studies and demonstrated positive results in a Phase 2 multicenter study in patients with acromegaly and NET.

#### **STATUS Q2**

In May, it was announced that Camurus regained the global development and commercialization rights to CAM2029, and related assets, from Novartis. We subsequently worked closely with Novartis to secure a smooth project and knowhow transfer from Novartis to Camurus. We plan to start the pivotal clinical program for CAM2029 during the first half of 2019.

# **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 2.8 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<sup>®</sup> injection depot technology, being developed as a patient-friendly treatment option for PAH. CAM2043 is a ready-to-use subcutaneous injection which is self-administered via a prefilled syringe as a small dose volume (≤1 mL), allowing dose titration for efficacy and tolerability.

#### **STATUS Q2**

In May we announced the positive results from an openlabel Phase 1 study of single and repeated dosing of CAM2043. The topline results showed that CAM2043 provided a dose-proportional treprostinil plasma exposure and release profile suitable for weekly, or less frequent, dosing. The tolerability of CAM2043 was generally good with no observations of unexpected or serious adverse events. Injection site reactions were of mild to moderate intensity and resolved over time.

Further clinical development of CAM2043 is now being prepared and the next step will include a Phase 2 proof-ofconcept study with an expected start date in early 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 Q2 CAM2032

The well-established hormone therapies for prostate cancer, based on gonadotropin releasing hormone agonists such as leuprolide, aim to reduce testosterone levels and thereby impede the growth of cancer cells. CAM2032 is a long-acting subcutaneous leuprolide depot for the treatment of prostate cancer. Based on our FluidCrystal<sup>®</sup> 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<sup>®</sup> injection depot technology, are being developed for the treatment of chemotherapy induced nausea and vomiting (CAM2047), pain (CAM2048), and the combined treatment of postoperative pain, nausea and vomiting (CAM2058).

Results from a Phase 1 trial of CAM2047, CAM2048 and CAM2058 demonstrated that all products were well tolerated locally and systemically, with pharmacokinetic profiles meeting the target specifications for these product candidates. Planning of the registration program and analysis of market potential of these product candidates are ongoing.

#### CAM4071

CAM4071 is a long-acting formulation of pasireotide based on our FluidCrystal<sup>®</sup> 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, based on our FluidCrystal® technology, is a weekly formulation of the MC4 agonist setmelanotide, 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 Designation for treatment Prader-Willis Syndrome. Results from Phase 2 clinical trials of setmelanotide demonstrated significant weight loss and substantial reductions in hunger for patients with POMC and LepR deficiency obesity. Phase 3 clinical trials are ongoing for each of these indications, and in parallel the long-acting formulation of setmelanotide, CAM4072, is being developed. Rhythm has successfully completed Phase 1 studies of single and repeat doses of CAM4072 and continued clinical studies of CAM4072 in patients with rare genetic obesity disorders are currently being prepared.

# Medical device - episil<sup>®</sup>

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

#### **STATUS Q2**

In May, episil<sup>®</sup> was launched in Japan by our partner Solasia Pharma's commercialization and promotion partner, Meiji Seika Pharma, after receiving reimbursement and being added to the NHI drug reimbursement price list the previous month. Solasia also progressed with a market approval application for episil<sup>®</sup> in China, where a randomized, active-controlled Phase 3 study of episil<sup>®</sup> in patients with oral mucositis was recently completed. Study results are expected to be announced during the second half of 2018.

#### REVENUES

Revenues during the quarter amounted to MSEK 7.3 (19.1), generated from license agreements, project activities and product sales.

The difference compared to the same period last year is mainly attributable to the variation in revenue streams between quarters. See also note 3.

#### **OPERATING RESULT**

Marketing, business development and distribution costs during the quarter, were MSEK -24.1 (-14.6) and Administrative expenses amounted to MSEK -5.5 (-2.6). The increase compared to the same period last year is mainly attributable to the expansion of the commercial organization in preparation of the planned launch of CAM2038 in Europe.

R&D costs, including depreciation and amortization of tangible and intangible assets were MSEK -57.3 (-59.0). The decrease compared with the same period last year is primarily attributable to costs related to completing the pivotal clinical program for CAM2038 in opioid dependence.

Other operating expenses, which mainly consist of currency exchange losses in operational activities, were MSEK -0.3 (-0.6).

The operating result for the quarter was MSEK -81.2 (-58.7).

#### FINANCIAL ITEMS AND TAX

Financial items for the period was MSEK 0.0 (-0.0). Tax was MSEK 13.6 (12.9) and is mainly attributable to deferred tax for the reported loss during the guarter.

Deferred tax assets have been updated following the decision by the Swedish Parliament in June 2018 on new corporate taxation., and the effect was not significant.

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

The result for the period was MSEK -67.5 (-45.8), corresponding to earnings per share of SEK -1.81 (-1.23) before and after dilution.

#### CASH FLOW AND INVESTMENT

Cash flow from operating activities, before change in working capital, was negative and amounted to MSEK -80.0 (-57.7).

Change in working capital affected the cash flow positively by MSEK 7.9 (-2.9).

Cash flow from investing activities was MSEK -1.8 (-0.3) and from financing activities MSEK 6.7 (10.5) related to issuance of warrants.

#### CASH

The company's cash position as of June 30, 2018, was MSEK 199.1 (413.4). The difference compared to the previous year is mainly attributable to the operating result.

In addition, the company will receive MSEK 102.3, before issue costs, from the directed new issue that was completed in June. At end of the period, the share issue was registered but not paid. Proceeds from the issue has been paid after period.

There were no outstanding loans as of June 30, 2018, and no loans have been taken up since.

#### EQUITY

Consolidated equity as of June 30, 2018, including proceeds from the directed new issue completed in June, was MSEK 383.0 (488.9).

#### ACQUISITIONS

Establishment of the European commercial organization progressed and a wholly owned subsidiary has been set up in France.

#### CAMURUS' SHARE

Camurus' share is listed on Nasdaq Stockholm.

In June, Camurus completed a directed share and 1,100,000 new shares were issued. 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 May 15, 2019 – December 15, 2019. However, transfer of subscription warrants to future employees was not allowed after the Annual General Meeting 2017. In all 47 employees have joined the program and subscribed for 404,300 warrants. The dilution effect on a maximum utilization of subscribed warrants corresponds to 1.8% of the share capital and the voting rights. During the quarter, earnings after tax were negatively impacted by MSEK 0.4 related to the stay-on bonus the participants receive as part of the program. *Warrant program TO2017/2020* 

In accordance with a decision by the Shareholder's General Meeting in May 2017, an 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 May 15, 2020 – December 15, 2020. However, transfer of subscription warrants to future employees was not allowed after the Annual General Meeting 2018. 44 employees have joined the program and subscribed for 658,932 warrants. The dilution effect on a maximum utilization of subscribed warrants corresponds to 1.8% of the share capital and the voting rights. During the quarter, earnings after tax were negatively impacted by MSEK 0.8 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 May 15, 2021 – December 15, 2021. The dilution effect on a maximum utilization of the programs corresponds to 2.7% of the

share capital and the voting rights. As of 30 June, 2018, 42 employees had joined the program and subscribed for 523,900 warrants. During the quarter, earnings after tax were negatively impacted by MSEK 2.3 related to the stay-on bonus the participants receive as part of the program.

#### SIGNIFICANT EVENT AFTER THE PERIOD

FDA accepts complete response and issues user fee (PDUFA) goal date of December 26, 2018.

#### PARENT COMPANY

Revenues for the quarter amounted to MSEK 11.0 (19.4) and the result after tax was MSEK -68.2 (-45,3).

On June 30, 2018, equity in the Parent Company amounted to MSEK 364.6 (472.3) including proceeds from the directed new share issue that was completed in June. At end of period the issue was registered but not paid.

Total assets at the end of the period was MSEK 469.5 (557,7) of which MSEK 189.3 (413.2) were cash and cash equivalents.

#### PERSONNEL

At the end of the period, Camurus had 76 (66) employees, of whom 52 (47) were within research and development, 15 (11) within business development and marketing and sales, while 8 (7) were within administration. The full time equivalent employees (FTEs) during the quarter amounted to 67 (62).

#### 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 nonapproval 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 Board of Directors has not changed its outlook on future developments in relations to their outlook published in the interim report for the first quarter 2018.

#### AUDIT

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

#### FURHER INFORMATION

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

Lund, Sweden, July 16, 2018 Camurus AB Board of Directors

# **Board assurance**

The Board of Directors and the CEO certify that this interim report gives a true and fair view of the company's and Groups' operations, financial position and results and describes significant risks and uncertainties that the Company and the companies included in the Group face.

Lund, July 16, 2018

Camurus AB

Per-Olof Wallström Chairman of the Board

Martin Jonsson Board Member

Kerstin Valinder Strinnholm Board Member Per-Anders Abrahamsson Board Member

Behshad Sheldon Board Member Marianne Dicander Alexandersson Board Member

Fredrik Tiberg President and CEO, Board Member

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

# **Financial statements**

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#### CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

KSEK	Note	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Net sales	3	7,315	19,138	21,954	36,330	54,308
Cost of goods sold		-1,217	-1,101	-2,764	-1,132	-1,356
Gross profit		6,098	18,037	19,190	35,198	52,952
Marketing and distribution costs		-24,146	-14,577	-41,648	-21,557	-45,893
Administrative expenses		-5,516	-2,558	-10,515	-9,997	-26,590
Research and development costs		-57,337	-59,026	-94,839	-113,255	-222,939
Other operating income		46	40	227	40	93
Other operating expenses		-301	-638	-	-739	-1,147
Operating result		-81,156	-58,722	-127,585	-110,310	-243,524
Finance income		37	0	77	1	174
Finance expenses		-11	-8	-18	-11	-18
Net financial items		26	-8	59	-10	156
Result before tax		-81,130	-58,730	-127,526	-110,320	-243,368
Income tax	8	13,622	12,927	23,749	24,270	52,794
Result for the period	4	-67,508	-45,803	-103,777	-86,050	-190,574

Total comprehensive income is the same as the result for the period, as the consolidated group contains no items that are recognized under other comprehensive income. 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	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Earnings per share before dilution, SEK	-1.81	-1.23	-2.78	-2.31	-5.11
Earnings per share after dilution, SEK	-1.81	-1.23	-2.78	-2.31	-5.11

Presently, the company has three subscription warrant programs active. For further information see page 9 Camurus' share, and page 21.

#### CONSOLIDATED BALANCE SHEET

KSEK	Note	2018-06-30	2017-06-30	2017-12-31	KSEK	Note	2018-06-30	2017-06-30	2017-12-31
ASSETS					EQUITY				
Fixed assets									
					Equity attributable to parent company				
Intangible assets					shareholder				
Capitalized development expenditure		15,609	17,697	16,653	Share capital		960	932	932
					Other contributed capital		741,682	641,524	642,175
Tangible assets					Retained earnings, including results for the period		-359,651	-153,597	-258,107
Equipment		11,256	10,259	9,902	Total equity	9	382,991	488,860	385,000
Financial assets					LIABILITIES				
Deferred tax receivables	8	141,431	85,954	114,997	LIABILITIES				
Total fixed assets	0	141,431 168,296	113,910	141,552	Short-term liabilities				
I Utal likeu assets		100,290	115,910	141,552	Trade payables		29,186	17,133	15,086
Current assets					Income taxes		1,138	-	517
ourient assets					Other liabilities		6,078	4,668	2,672
Inventories					Accrued expenses and deferred income		70,740	59,742	72,659
Finished goods		2,317	1,425	2,829	Total short-term liabilities		107,142	81,543	90,934
Raw materials		4,004	12,623	724	TOTAL EQUITY AND LIABILITIES		490,133	570,403	475,934
Total inventories		6,321	14,048	3,553			,	,	-,
Current receivables									
Registered but unsettled issue payment	9	94,357	-	-					
Trade receivables		2,430	12,010	5,781					
Other receivables			6,230	3,285					
Prepayments and accrued income		13,156	10,845	7,239					
Total current receivables	5	116,423	43,133	16,305					
Cash and cash equivalents									
Total current assets		199,093	413,360	314,524					
TOTAL ASSETS		321,837	456,493	334,382					
ASSETS		490,133	570,403	475,934					

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#### CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

KSEK	Note	Share capital	Other contributed capital	Retained earnings, including result for the period	Total equity
Opening balance 1 January 2017		932	631,034	-67,549	564,418
Result for the period and comprehensive income				-86,050	-86,050
Exchange-rate differences		-	-	2	2
Transactions with shareholders					
Warrants issued		-	10,490	-	10,490
Closing balance 30 June 2017		932	641,524	153,597	488,860
Opening balance 1 January 2017		932	631,034	-67,549	564,418
Result for the period and comprehensive income				-190,574	-190,574
Exchange-rate differences		-	-	16	16
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
Result for the period and comprehensive income				-103,777	-103,777
Exchange-rate differences		-	-	197	197
Transactions with shareholders					
Directed share issue		28	102,272	-	102,300
Issuance costs, net after deferred tax		-	-7,456	-	-7,456
Warrants issued		-	6,726	-	6,726
Closing balance 30 June 2018	9	960	743,717	-361,687	382,991

#### CONSOLIDATED STATEMENT OF CASH FLOW

KSEK	Note	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
		•	ł			
Operating activities						
Operating result before financial items		-81,156	-58,722	-127,585	-110,310	-243,524
Adjustment for non-cash items	7	1,126	1,025	2,322	2,038	4,104
Interest received		37	-	77	1	174
Interest paid		-11	-8	-18	-11	-18
Income taxes paid		-	-	-	-	0
		-80,004	-57,705	-125,204	-108,282	-239,264
Increase/decrease in inventories		-3,957	-5,796	-2,768	-1,667	8,827
Increase/decrease in trade receivables		-1,098	-5,322	3,413	-3,706	2,523
Increase/decrease in other current receivables		-7,186	65	-10,790	3,239	9,788
Increase/decrease in trade payables		16,607	4,081	14,100	-426	-2,474
Increase/decrease in other current operating liabilities		3,542	4,043	2,108	6,612	17,532
Cash flow from changes in working capital		7,908	-2,929	6,063	4,052	36,196
Cash flow from operating activities		-72,096	-60,634	-119,141	-104,230	-203,068
Investing activities						
Acquisition of tangible assets		-1,758	-299	-2,424	-1,494	-2,143
Cash flow from investing activities		-1,758	-299	-2,424	-1,494	-2,143
Financing activities						
Warrants issued		6,726	10,490	6,726	10,490	11,141
Cash flow from financing activities		6,726	10,490	6,726	10,490	11,141
Net cash flow for the period		-67,128	-50,443	-114,839	-95,234	-194,070
Cash and cash equivalents at beginning of period		266,633	463,804	314,524	508,594	508,594
Translation difference in cash flow and liquid assets		-412	-	-592	-	-
Cash and cash equivalents at the end of period		199,093	413,360	199,093	413,360	314,524

#### **INCOME STATEMENT – PARENT COMPANY**

KSEK Note	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Net sales	11,011	19,423	28,276	36,760	64,640
Cost of goods sold	-1,217	-1,100	-2,764	-1,132	-1,356
Gross profit	9,794	18,323	25,512	35,628	63,284
Marketing and distribution costs	-11,854	-7,670	-22,127	-14,789	-30,234
Administrative expenses <sup>1)</sup>	-22,995	-9,601	-38,690	-17,183	-54,689
Research and development costs	-56,828	-58,504	-93,795	-112,211	-220,849
Other operating income	15	30	270	30	61
Other operating expenses	-324	-637	-	-739	-1,147
Operating result	-82,192	-58,061	-128,830	-109,265	-243,574
Interest income and similar items	37	-	77	1	174
Interest expense and similar items	-11	-7	-18	-11	-18
Result after financial items	-82,166	-58,068	-128,771	-109,274	-243,418
Appropriations	-	-	-	-	-
Result before tax	-82,166	-58,068	-128,771	-109,274	-243,418
Tax on profit for the period 8	13,919	12,775	24,102	24,040	52,853
Result for the period	-68,247	-45,293	-104,669	-85,234	-190,565

1) 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.

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#### BALANCE SHEET – PARENT COMPANY

KSEK	ote 2018-06-3	0 2017-06-30	2017-12-31	KSEK	Note	2018-06-30	2017-06-30	2017-12-31
ASSETS				EQUITY AND LIABILITES				
Fixed assets				Restricted equity				
				Restricted equity (38 381 486 shares)		960	932	932
Tangible fixed assets				Statutory reserve		11,327	11,327	11,327
Equipment	11,07	8 10.259	9,725	Total restricted equity	_	12,287	12,259	12,259
			·				·	-
Financial fixed assets				Unrestricted equity				
Interest in Group companies	1,54	5 816	1,545	Retained earnings		-253,159	-62,595	-62,594
Deferred tax assets	8 145,63	1 90,614	119,426	Share premium reserve		708,000	607,908	608,560
Total fixed assets	158,25	4 101,689	130,696	Result for the period		-102,566	-85,234	-190,565
				Total unrestricted equity		352,275	460,080	355,401
Current assets				TOTAL EQUITY		364,562	472,339	367,660
Inventories				LIABILITIES				
Finished goods	2,31	7 1,425	2,829	Untaxed reserves				
Raw materials	4,00	4 12,623	724	Depreciation/amortization in excess of plan		3,486	3,486	3,486
Total inventories	6,32	1 14,048	3,553	Total untaxed reserves		3,486	3,486	3,486
Current receivables				Long-term liabilities				
Registered but unsettled issue payment	9 94,35	7 -	-	Liability to subsidiaries		571	571	571
Trade receivables	2,36	8 12,010	5,781	Total long-term liabilities		571	571	571
Other receivables	5,89	4 6,000	3,040	-				
Prepayments and accrued income	12,96	1 10,807	7,202	Short-term liabilities				
Total current receivables	115,58	0 28,817	16,022	Liabilities to Group companies		2,905	309	3,769
				Trade payables		28,845	16,721	14,431
Cash and bank deposits	189,30	2 413,170	309,821	Other liabilities		4,728	4,668	2,053
Total current assets	311,20	3 456,035	329,397	Accrued expenses and deferred income		64,359	59,630	68,123
TOTAL ASSETS	469,45	7 557,724	460,093	Total short-term liabilities		100,837	81,328	88,376
				TOTAL EQUITY AND LIABILITY		469,457	557,724	460,093

MSEK	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Net sales	7.3	19.1	22.0	36.3	54.3
Operating result	-81,2	-58.7	-127.6	-110.3	-243.5
Result for the period	-67.5	-45.8	-103.8	-86.0	-190.6
Cash flow from operating activities	-72.1	-60.6	-119.1	-104.2	-203.1
Cash and cash equivalents	199.1	413.4	199.1	413.4	314.5
Equity	383.0	488.9	383.0	488.9	385.0
Equity ratio in Group, percent	78%	86%	78%	86%	81%
Total assets	490.1	570.4	490.1	570.4	475.9
Average number of shares, before dilution	37,305,930	37,281,486	37,293,641	37,281,486	37,281,486
Average number of shares, after dilution*)	38,567,080	37,882,454	38,455,285	37,784,664	38,058,298
Earnings per share before dilution, SEK	-1.81	-1.23	-2.78	-2.31	-5.11
Earnings per share after dilution, SEK*)	-1.81	-1.23	-2.78	-2.31	-5.11
Equity per share before dilution, SEK	10.26	13.11	10.26	13.11	10.33
Equity per share after dilution, SEK*)	9.93	12.90	9.93	12.94	10.12
Number of employees at the end of period	76	66	76	66	71
Number of employees in R&D at the end of period	52	47	52	47	48
R&D costs as a percentage of operating expenses	66%	78%	65%	78%	75%

\*) 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 second quarter 2018 was approved for publication in accordance with a decision by the Board of Directors on July 16, 2018.

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.

The Group has begun its analysis of possible transition effects of IFRS 16, but this is still in the early stages. More information will be presented in future interim reports and annual reports for 2018.

#### 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**

IAS 39 is not applied in the parent company and financial instruments are measured at 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

Maximum 550,000 warrants could be issued and the program was introduced in accordance with a decision by the Annual General Meeting in May 2016. *Warrant program TO2017/2020* 

Maximum 750,000 warrants can be issued and the program was introduced in accordance with a decision by the Annual General Meeting in May 2017.

#### Warrant program TO2018/2021

Maximum 1,000,000 warrants can be issued and was introduced in accordance with a decision by the Annual General Meeting in May 2018.

### 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 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Sales of development related goods and services	4,072	14,747	7,903	28,675	41,394
Milestone payments	-	-	7,840	2,205	7,025
Licensing revenues	-	3,079	-	3,914	3,582
Other	3,243	1,312	6,211	1,536	2,307
Total	7,315	19,138	21,954	36,330	54,308

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

KSEK	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Europe	719	5,702	1,251	7,076	7,229
(of which Sweden)	(100)	(9)	(221)	(68)	(239)
North America	4,261	12,989	15,571	28,659	41,350
Other geographical areas	2,335	447	5,132	595	5,729
Total	7,315	19,138	21,954	36,330	54,308

Revenues during the quarter of approximately MSEK 4.1 (13.4) 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.

KSEK	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Result attributable to parent company shareholders	-67,508	-45,803	-103,777	-86,050	-190,574
Total	-67,508	-45,803	-103,777	-86,050	-190,574
Weighted average number of ordinary shares outstanding (thousands)	37,306	37,281	37,294	37,281	37,281

#### 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.

KSEK	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Result attributable to parent company shareholders	-67,508	-45,803	-103,777	-86,050	-190,574
Total	-67,508	-45,803	-103,777	-86,050	-190,574
Weighted average number of ordinary shares outstanding (thousands) Adjustments:	37,306	37,281	37,294	37,281	37,281
- Warrants (thousands)	1,261	601	1,161	504	777
- Share issues (thousands)	-	-	-	-	-
Weighted average number of ordinary shares in calculation of earnings per share after dilution (thousands)	38,567	37,882	38,455	37,785	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 during the period.

No receivables or liabilities existed as of June 30, 2018.

Carrying amount, KSEK	2018-06-30	2017-06-30	2017-12-31
Loans and receivables			
Trade receivables	2,368	12,010	5,781
Receivables from Group companies	-	-	-
Other receivables	-	-	-
Cash and cash equivalents	199,093	413,360	314,524
Total	201,461	425,370	320,305
Other liabilities			
Other financial liabilities	-	-	-
Liabilities to Group companies	-	-	-
Trade payables	29,186	17,133	15,086
Other current liabilities	191	191	191
Total	29,377	17,324	15,277

## Note 7 Other non-cash items

Adjustment for non-cash items:

### Note 8 Deferred tax

Tax for the quarter amounted to MSEK 13.6 (24.3), primary attributable to the negative result.

# Note 9 | Equity

The change in equity for the quarter is mainly attributable to the loss and the directed share issue completed in June.

KSEK	2018 Apr-Jun	2017 Apr-Jun	2018 Jan-Jun	2017 Jan-Jun	2017 Jan-Dec
Depreciation	1,077	1,025	2,125	2,038	4,088
Exchange-rate differences	49	-	197	-	16
Total	1,126	1,025	2,322	2,038	4,104



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