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#### FINANCIAL CALENDAR

Annual Report 2017 22 March 2018 Q1 2018 3 May 2018, 13.00 Annual General Meeting 2018 3 May 2018 Q2 2018 17 July 2018 Q3 2018 25 October 2018



"We are fully dedicated to achieving approvals for CAM2038 in Europe, Australia and the US during 2018, and the launch preparations for this much-needed treatment of opioid dependence are progressing according to plan."

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.

# Successful Q4 followed by delay of US approval

Highlights from the last quarter of 2017 include the FDA Advisory Committee recommendation for approval of CAM2038 for opioid dependence and the start of a new clinical program for treatment of pulmonary arterial hypertension.

Listening to the testimonies of patients that participated in our clinical studies of CAM2038 was a touching experience for me at the Advisory Committee meeting. Their stories of how CAM2038 had contributed to their recovery, and improved their self-esteem, without the stigma and disease reminders associated with daily sublingual medication, was a firm acknowledgement that we have developed a treatment with the potential to significantly improve lives. The positive response from so many patients and study investigators spurs us in our guest to make CAM2038 available on the market as quickly as possible.

During the final guarter of 2017 we were delighted to receive a positive FDA Advisory Committee recommendation for CAM2038. However, on the 19 January 2018, Braeburn Pharmaceuticals, our US partner for CAM2038, received a complete response letter from the FDA, requiring further information to the New Drug Application (NDA) for CAM2038. No additional clinical studies are required, and we are working with Braeburn to address the FDA's questions. While the complete response letter for CAM2038 was unexpected and disappointing, we do not believe this delay will significantly impact the future market potential for CAM2038.

Approval of CAM2038 in other markets progressed according to plan. The CAM2038 market approval application (MAA) submitted to the Australian Therapeutic Goods Administration (TGA) was accepted for review and is being processed alongside the European MAA. An opinion from the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use is expected in Q3 2018, and final approval decisions from both the EMA and TGA are anticipated in Q4 2018.

In preparation for the commercial launch of CAM2038, we are continuing to add experts to our regional teams in the UK, Germany, France, and the Nordics. In parallel, we are engaging with key opinion leaders and payors to demonstrate the value CAM2038 will bring to health economies and the wider society.

During Q4. Phase 3 results from our comprehensive clinical study program for CAM2038 for opioid dependence were presented by our study investigators at several leading international addiction conferences and regional meetings: ISAM Annual Meeting in Abu Dhabi, AAAP in San Diego, APSAD in Melbourne, ATHS in Biarritz, and SSA in Newcastle.

Aside from scientific and regulatory progress in the opioid dependence area, we also made progress with other important programs in Q4:

- CAM2038 for the treatment of chronic pain. The pivotal Phase 3 efficacy study is currently being completed and have been extended with a long-term safety study, which was fully enrolled during the quarter. Topline efficacy results are expected to be announced in Q2 2018, while long-term safety data are planned for Q4 2018.
- · CAM2029 for the treatment of acromegaly and neuroendocrine tumors. The collaboration with Novartis is in full force. We plan to present updated timelines on the start of the Phase 3 program mid-2018.
- Weekly setmelanotide, CAM4072, for the treatment of rare genetic disorders of obesity. Following the successful completion of a single-dose study, Rhythm recently completed a repeat dose study of CAM4072. The formulation, based on our FluidCrystal® technology, demonstrated tolerability and pharmacokinetics that support further clinical development.
- CAM2043 for the treatment of pulmonary arterial hypertension (PAH). An Investigational New Drug Application (IND) was submitted to the FDA and the first cohort was treated with our weekly treprostinil depot. Initial results from this study are expected during Q2 2018.



PAH is a rare and severe chronic disease of the heart and lungs. The current PAH market exceeds USD 5 billion globally, of which almost one quarter is treprostinil sales. A weekly subcutaneous depot could provide important patient benefits compared to current infusion products, which are associated with risks of serious infections, severe infusion site pain and which require a complex extracorporeal pump system.

Looking ahead, we can expect an exciting year as we and our partners continue to move our clinical pipeline forward. We are fully dedicated to achieving approvals for CAM2038 in Europe, Australia and the US during 2018, and the launch preparations for this much-needed treatment for opioid dependence are progressing according to plan. We are also anticipating positive Phase 3 results for a second indication of chronic pain, which, like opioid dependence, is an area with high unmet medical needs and significant market potential. In addition, results from several of our other clinical programs and collaborations are expected during the year, with the potential for further value creation and company

Fredrik Tiberg, President & CEO

**Q4** 

# **Business highlights**

- Recommendation of approval of CAM2038 NDA by the FDA Advisory Committees.
- Acceptance of CAM2038 MAA for review by the Australian TGA.
- All patients enrolled in Phase 3 efficacy and long-term safety extension study of CAM2038 in chronic pain
- Positive Phase 1 results after repeat dosing of weekly setmelanotide formulation, CAM4072, for treatment of genetic obesity disorders in collaboration with Rhythm.
- IND approval and first cohort treated in Phase 1 study of CAM2043 for treatment of pulmonary arterial hypertension.
- Presentations of Phase 3 results for CAM2038 at ISAM Annual Meeting in Abu Dhabi, UAE, AAAP Annual Meeting in San Diego, US, APSAD in Melbourne; ATHS meeting in Biarritz; and SSA meeting in Newcastle.
- Company presentations at Jefferies London Healthcare Conference 2017, London.

# Significant event after the period

 Braeburn Pharmaceuticals received a complete response letter from the FDA, requiring additional information to the new drug application (NDA) for CAM2038

# **Financial summary**

- Revenues MSEK 5.5 (37.1).
- Operating result MSEK -66.1 (-35.1).
- Result after tax MSEK -52.2 (-27.8).
- Earnings per share SEK -1.40 (-0.75), before and after dilution.
- Cash position MSEK 314.5 (508.6).

# **Full Year**

# **Business highlights**

- Recommendation of approval of CAM2038 NDA approval by FDA Advisory Committees.
- Acceptance of CAM2038 MAA for review by the Australian TGA.
- Validation of CAM2038 MAA by the European EMA.
- Acceptance CAM2038 NDA with Priority Review by the U.S. FDA.
- Completion of clinical program for CAM2038 in opioid dependence.
- Positive Phase 3 long-term safety results for CAM2038 in opioid dependence.
- Positive Phase 1 results for CAM2047 and CAM2048/58
- Positive Phase 1 results for weekly setmelanotide FluidCrystal® (CAM4072) under development for treatment of genetic obesity disorders.
- First cohort treated in Phase 1 study of CAM2043 under for treatment of pulmonary arterial hypertension.
- Publication of CAM2038 clinical study results in JAMA Psychiatry, Journal of Substance Abuse Therapy, and Advances in Therapy.
- Presentations of CAM2038 efficacy and safety results at leading scientific addiction conferences, including CPDD, ISAM, and AAAP Annual Meetings.

# **Financial summary**

- Revenues MSEK 54.3 (113.7).
- Operating result MSEK -243.5 (-102.5).
- Result after tax MSEK -190.6 (-81.0).
- Earnings per share SEK -5.11 (-2.17), before and after dilution.
- Cash position MSEK 314.5 (508.6).



# 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 project is given below.

PARTNER	PRODUCT	PRE-CLINICAL	PHASE 1-2	PHASE 3	REGISTRATION
camurus. 6 braeburn	CAM2038 q1w OPIOID DEF	PENDENCE			REGISTRATION
camurus. 6 braeburn	CAM2038 q4w OPIOID DE	PENDENCE			REGISTRATION
camurus. 6 braeburn	CAM2038 q1w CHRONIC F	PAIN		PHASE 3	
camurus. 6 braeburn	CAM2038 q4w CHRONIC F	PAIN		PHASE 3	
NOVARTIS	CAM2029 NEUROENDOCE	RINE TUMORS	PHASE 1-	2	
NOVARTIS	CAM2029 ACROMEGALY		PHASE 1-	2	
camurus.	CAM2032 PROSTATE CAN	CER	PHASE 1-	2	
camurus.	CAM2047 CINV <sup>1</sup>		PHASE 1-2		
camurus. 6 braeburn	CAM2048/58 POSTOPERA	ATIVE PAIN & PONV <sup>2</sup>	PHASE 1-2		
rhythm	CAM4072 GENETIC OBES	ITY	PHASE 1-2		
NOVARTIS	CAM4071 UNDISCLOSED	INDICATION	PHASE 1-2		
camurus.	CAM2043 PAH <sup>3</sup>		PHASE 1-2		

<sup>1)</sup> Chemotherapy induced nausea and vomiting, 2) Postoperative nausea and vomiting. 3) Pulmonary arterial hypertension.

# 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 represents current standard of care and has been shown effective in reducing withdrawal and cravings. misuse and spreading of diseases. However, these treatments are also associated with limitations such as poor treatment adherence, misuse, medication diversion, and accidental pediatric exposure. CAM2038 includes two long-acting subcutaneous buprenorphine depots for the treatment of opioid dependence. The investigational products are based on Camurus' proprietary FluidCrystal® injection depot technology and are intended for either weekly or monthly subcutaneous administration by healthcare personnel using prefilled syringes, provided in multiple doses, to allow individualized treatment of patients with opioid dependence. In addition, 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.

#### STATUS Q4

A New Drug Application (NDA) for CAM2038 in opioid use disorder was submitted by our partner Braeburn Pharmaceuticals to the US Food and Drug Administration (FDA) during Q3 2017. Later in Q3, the FDA informed that they accepted the NDA and granted a Priority Review with a PDUFA date set for 19 January 2018. In parallel, during Q3 2017, a Marketing Authorization Application (MAA) was submitted and validated by the European Medicines Agency (EMA). In Q4 2017, an MAA to the Australian authority, Therapeutic Goods Administration (TGA), was

accepted for evaluation. These submissions were supported by a comprehensive clinical program comprising seven clinical studies, including two Phase 3 studies. A core component of the submissions was the positive results from a randomized, double-blind, doubledummy study of weekly and monthly CAM2038 depot injections versus daily treatment with sublingual buprenorphine/naloxone in 428 adult patients with opioid use disorder. The study met both the FDA and EMA primary endpoints for responder rate and mean percent of urines samples negative for illicit opioids. Superiority 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.

On November 1, the FDA Advisory Committee for Psychopharmacologic Drugs and Drug Safety and Risk Management voted 17-3 recommending approval of CAM2038. After the period, in January 2018 the FDA issued a complete response letter (CRL) for the CAM2038 NDA requesting additional information to complete the review. The request, issued to Camurus' partner Braeburn Pharmaceuticals, did not request new clinical studies and the Agency's requests will be addressed in a timely manner.

# CAM2038 – chronic pain

Chronic pain is a global health problem, and is causing deterioration in general health, reduced quality of life, decreased work capacity and dependence and misuse of strong opioids. CAM2038 is therefore 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. The properties of CAM2038 are considered to conform the targeted properties for

treatments of chronic pain, i.e. the combination of longlasting efficacious analgesia with a reduced risk of misuse, abuse and illicit diversion.

#### STATUS Q4

The Phase 3 efficacy study of CAM2038 in chronic lowerback pain is being completed and we have initiated a longterm safety extension study. Recruitment was completed during the quarter. Topline results from the efficacy study are expected in Q2 2018, followed by long-term safety results in Q4 2018.

# CAM2029 – acromegaly and NET

CAM2029 is being developed for the treatment of acromegaly and neuroendocrine tumours (NET). CAM2029 is a ready-to-use, long-acting subcutaneous injection depot of the active substance octreotide formulated with Camurus' proprietary FluidCrystal® Injection depot technology. It provides several potential advantages compared to presently marketed product Sandostatine® LAR® by means of higher bioavailability, fast onset of effect, and improved dosing; a prefilled syringe with a thin needle. 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 neuroendocrine tumours. CAM2029 is being developed by Novartis under licence from Camurus.

#### STATUS Q4

Our collaboration with Novartis is continuing with full force and we plan in mid-2018 to communicate updated project time-lines for the start of the Phase 3 program.

# CAM2032 - prostate cancer

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. Additional potential indications for CAM2032 include precocious puberty, and endometriosis. CAM2032 is based on Camurus' FluidCrystal<sup>®</sup> Injection depot technology for administration as a small dose volume with a prefilled syringe and is not requiring any reconstitution or temperature conditioning. Based on simplicity of its administration, CAM2032 is being developed for easy subcutaneous injections by patients themselves.

#### STATUS Q4

Discussions with potential regional development and commercialization partners are currently ongoing.

# Early 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 with regard to release of the active substance, stability, and as well as pharmacological and toxicological properties defined by the target product profiles.

#### STATUS Q4 CAM4071

CAM4071 is a product candidate in clinical development under an option, collaboration and licensing agreement with Novartis. The product candidate is a long-acting formulation of an undisclosed peptide and based on the FluidCrystal® Injection depot. A Phase 1 trial of pharmacokinetics and pharmacodynamics, performed together with Novartis, has been completed and reported.

#### CAM2047, CAM2048 and CAM2058

Three new investigational products based on Camurus'

FluidCrystal® Injection depot, CAM2047, CAM2048 and CAM2058, are being developed for the treatment of chemotherapy induced nausea and vomiting (CAM2047), pain (CAM2048), and combined treatment of postoperative pain, nausea and vomiting (CAM2058).

A Phase 1 trial of CAM2047, CAM2048 and CAM2058 was completed in Q3 2017. Results from the study demonstrated that all products were well tolerated locally and systemically, with pharmacokinetic profiles meeting the target specifications for these product candidates. Next steps comprise in depth analysis of clinical registration programs and market potentials of the different product candidates.

#### CAM2043

CAM2043 is a new long-acting subcutaneous treprostinil depot, based on Camurus' FluidCrystal® technology, and is being developed for treatment of pulmonary arterial hypertension (PAH). Recently completed preclinical data indicate that CAM2043 is well tolerated, without any significant or unexpected injection site observations, and provides dose proportional plasma exposure of treprostinil suitable for weekly dosing. During Q4 2017, an IND was approved by the FDA and the first cohort of healthy volunteers was treated in a dose escalating Phase 1 study with CAM2043. Interim results from the study are expected in Q2 2018, and final results are anticipated in Q3 2018.

#### CAM4072

Setmelanotide is a novel melanocortin-4 receptor agonist (MC4R) for treatment of genetic obesity. The FDA granted Rhythm's setmelanotide Breakthrough Therapy designation for the treatment of pro-opiomelanocortin (POMC) and leptin receptor (LepR) deficiency obesity. 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. Rhythm recently initiated Phase 3 clinical trials for each of these indications.

In parallel, a long-acting formulation of setmelanotide (CAM4072) is being developed, based on Camurus' FluidCrystal® technology, which has demonstrated positive pharmacokinetic and pharmacodynamic results in preclinical studies. Statistically significant decreases in body weight as well as food intake have also been demonstrated.

Following the completion of a single-dose study. Rhythm recently completed a multi-dose clinical Phase 1 study evaluating the long-acting, once-weekly formulation of setmelanotide, CAM4072. The study demonstrated tolerability and pharmacokinetics that support further clinical development. According to Rhythm, a NDA could be ready for submission at earliest in 2019.

# Medical device - episil®

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

#### STATUS Q4

Preparations for launch of episil® in Japan are on-going in close collaboration between our partner Solasia Pharma and their distribution partner Meiji Seika. episil® received marketing approval in Japan by the Japanese Ministry of Health, Labour and Welfare in June 2018, Reimbursement and pricing was recently announced by Solasia.

#### **REVENUES**

Revenues during the quarter amounted to MSEK 5.5 (37.1), 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.

#### **OPERATING RESULT**

According to plan, the main cost drivers are the completion of the comprehensive pivotal clinical program of CAM2038 in opioid dependence, the continuous development of the early project pipeline and the expansion of the commercial organization in preparation of the planned launch of CAM2038 in Europe.

Marketing, business development and distribution costs during the quarter, were MSEK 11.3 (9.4).

Administrative expenses amounted to MSEK 11.1 (4.1).

R&D costs, including depreciation and amortization of tangible and intangible assets were MSEK 48.1 (59.0).

Other operating expenses, which mainly consist of currency exchange losses in operational activities, were MSEK -0.2 (1.4).

The operating result for the guarter was MSEK -66.1 (-35.1).

#### FINANCIAL ITEMS AND TAX

Financial items for the period was MSEK 0.0 (-0.0).

Tax was MSEK 13.8 (7.4) and is mainly attributable to deferred tax losses during the quarter.

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

The result for the period was MSEK -52.2 (-27.8), corresponding to earnings per share of SEK -1.40 (-0.75) before and after dilution.

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

Cash flow from operating activities, before change in working capital, was negative and amounted to MSEK -65.0 (-34.3).

Change in working capital affected the cash flow by MSEK 10.0 (26.7).

Cash flow from investing activities was MSEK -0.6 (-2.7) and from the financing activities MSEK 0.3 (0.7) related to issuance of warrants.

#### CASH

The company's cash position as of December 31, 2017, was MSEK 314.5 (508.6). The difference compared to the previous year is mainly attributable to the operating result.

There were no outstanding loans as of December 31, 2017, and no loans have been taken up since.

#### **EQUITY**

Consolidated equity as of December 31, 2017, was MSEK 385.0 (564.4)

#### **ACQUISITIONS**

No acquisitions or divestments have occurred during the quarter.

#### **CAMURUS' SHARE**

Camurus' share is listed on Nasdag Stockholm. At the end of the period, the total number of shares was 37,281,486 (37.281.486).

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

#### Warrant program TP2016/2016

In accordance with a decision by the Shareholder's General Meeting in May 2016, an incentive program, TO2017/2020, 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. The dilution of a full utilization of the

program corresponds to 1.5 % of the share capital and voting rights. Transfer of subscription warrants to future employees may not occur after the Annual General Meeting 2017. As per December 31, 2016, 47 employees had chosen to participate in TO2016/2019 and subscribed for 404,300 warrants. No further warrants have been subscribed for thereafter. During the year, earnings after tax were negatively impacted by MSEK 1.7 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. The dilution of a full utilization of the program corresponds to 2.0% of the share capital and voting rights. By end of December 2017, 658,932 warrants had been subscribed for and equity increased with MSEK 11.1. Earnings after tax were negatively impacted by MSEK 5.4 related to the stay-on bonus the participants receive as part of the program.

#### **EVENTS AFTER THE REPORTING PERIOD**

On the 19th of January, our partner Braeburn Pharmaceuticals received a complete response letter from the US Food and Drug Administration (FDA), requiring additional information to the new drug application (NDA) for CAM2038. No additional clinical studies are required.

#### PARENT COMPANY

Revenues for the guarter amounted to MSEK 10.6 (37.1) and the result after tax was MSEK -62.6 (-28.4).

On December 31, 2017, equity in the Parent Company amounted to MSEK 367.7 (547.1).

Total assets at the end of the period was MSEK 460.1 (626.5) of which MSEK 309.8 (508.6) were cash and cash equivalents.

#### **PERSONNEL**

At the end of the period, Camurus had 71 (62) employees, of whom 48 (44) were within research and development. The full time equivalent employees (FTEs) during the quarter amounted to 64 (56).

#### **CHANGE OF MANAGEMENT GROUP**

As we entered 2018, a minor structural change of the company's executive management group was implemented.

#### 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 third quarter 2017.

#### AUDIT

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

#### **ANNUAL GENERAL MEETING 2018**

Camurus Annual General Meeting 2018 will be held on Thursday May 3, 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 2017.

The Annual Report for 2017 will be published on the company's website, camurus.com on March 22, 2018. It will also be available from Camurus AB's headquarters in Lund.

#### **FURHER INFORMATION**

For further information, please contact: Fredrik Tiberg, Chief Executive Officer Rein Piir, VP Investor Relations Tel.: +46 46 286 46 92, e-mail: ir@camurus.com

Lund, Sweden, February 14, 2018 Camurus AB Board of Directors



#### CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

KSEK	Note	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
NOEN	11010	001 200	001 200	our Dec	oun Dec
Net sales	3	5,458	37,126	54,308	113,737
Cost of goods sold		-754	-1,229	-1,356	-2,140
Gross profit		4,704	35,897	52,952	111,597
Marketing and distribution costs		-11,347	-9,385	-45,893	-24,738
Administrative expenses		-11,055	-4,067	-26,590	-17,985
Research and development costs		-48,142	-59,017	-222,939	-172,077
Other operating income		34	1,436	93	751
Other operating expenses		-269	-	-1,147	-
Operating result		-66,075	-35,136	-243,524	-102,452
			07		
Finance income		51	87	174	95
Finance expenses		-3	-128	-18	-1,002
Net financial items		48	-41	156	-907
Result before tax		-66,026	-35,178	-243,368	-103,359
Income tax	8	13,836	7,367	52,794	22,367
Result for the period	4	-52,190	-27,811	-190,574	-80,993

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.

## **FINANCIAL STATEMENTS**

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

SEK	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Earnings per share before dilution, SEK	-1.40	-0.75	-5.11	-2.17
Earnings per share after dilution, SEK	-1.40	-0.75	-5.11	-2.17

Presently, the company has two subscription warrant programs active. For further information see page 8, Camurus' share and page 20.

#### **CONSOLIDATED BALANCE SHEET**

KSEK Note	31-12	-2017	31-12-2016
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development expenditure	16	5,653	18,741
Tangible assets			
		000	0.750
Equipment	٤	9,902	9,759
Financial assets			
Deferred tax receivables	3 114	4,997	61,685
Total fixed assets		1,552	90,185
		,	,
Current assetts			
Inventories			
Finished goods		724	300
Raw materials	2	2,829	12,080
Current receivables			
Trade receivables	5	5,781	8,304
Other receivables	3	3,285	3,855
Prepayments and accrued income	7	7,239	16,459
Total current receivables	16	6,305	28,618
Cash and cash equivalents	314	4,524	508,594
Total current assets	334	4,382	549,592
TOTAL ASSETS	475	5,934	639,776

KSEK	Note	31-12-2017	31-12-2016
FOURTY			
EQUITY			
Equity attributable to parent company			
shareholder			
Share capital		932	932
Other contributed capital		642,175	631,034
Retained earnings, including results for the period		-258,107	-67,549
Total equity	9	385,000	564,418
LIABILITIES			
Short-term liabilities			
Trade payables		15,086	17,560
Income taxes		517	-
Other liabilities		2,672	2,571
Accrued expenses and deferred income		72,659	55,228
Total short-term liabilities		90,934	73,358
TOTAL EQUITY AND LIABILITIES		475,934	639,776

#### **CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**

			Other	Retained earnings,	
KSEK	Note	Share capital	contributed capital	including result for the period	Total equity
Opening balance 1 January 2016		932	626,181	13,444	640,557
Result for the period and comprehensive income				-80,993	-80,993
Transactions with shareholders					
Warrants issued			4,853		4,853
Closing balance 31 December 2016		932	631,034	-67,549	564,418
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	9	932	642,175	-258,107	385,000

#### CONSOLIDATED STATEMENT OF CASH FLOW

KSEK Note	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Operating activities				
Operating result before financial items	-66,083	-35,136	-243,524	-102,452
Adjustment for non-cash items 7	1,042	845	4,104	3,524
Interest received	51	87	174	95
Interest paid	-3	-128	-18	-1,002
Income taxes paid	0	0	0	-9,917
	-64,993	-34,332	-239,264	-109,752
Increase/decrease in inventories	-439	-8,423	8,827	-9,139
Increase/decrease in trade receivables	1,981	9,104	2,523	613
Increase/decrease in other current receivables	1,268	8,095	9,788	1,005
Increase/decrease in trade payables	-2,697	9,728	-2,474	-14,272
Increase/decrease in other current operating liabilities	9,928	8,167	17,532	-76,243
Cash flow from changes in working capital	10,041	26,672	36,196	-98,036
Cash flow from operating activities	-54,952	-7,660	-203,068	-207,788
Investing activities				
Acquisition of tangible assets	-607	-2,712	-2,143	-4,567
Cash flow from investing activities	-607	-2,712	-2,143	-4,567
Financing activities				
Warrants issued	335	718	11,141	4,853
Cash flow from financing activities	335	718	11,141	4,853
Net cash flow for the period	-55,224	-9,654	-194,070	-207,502
Cash and cash equivalents at beginning of period	369,748	518,248	508,594	716,096
Cash and cash equivalents at the end of period	314,524	508,594	314,524	508,594

#### **INCOME STATEMENT - PARENT COMPANY**

KSEK Note	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
	00.200	03.230	Jul. 200	
Net sales <sup>1)</sup>	10,552	37,126	64,640	113,737
Cost of goods sold	-754	-1,229	-1,356	-2,140
Gross profit	9,798	35,897	63,284	111,597
Marketing and distribution costs	-9,602	-9,385	-30,234	-24,738
Administrative expenses <sup>2)</sup>	-18,164	-4,067	-54,689	-17,985
Research and development costs	-47,618	-58,497	-220,849	-169,994
Other operating income	-343	1,436	61	751
Other operating expenses	-276	-	-1,147	-
Operating result	-66,205	-34,615	-243,574	-100,370
Interest income and similar items	51	87	174	95
Interest expense and similar items	-3	-128	-18	-1,002
Result after financial items	-66,157	-34,657	-243,418	-101,277
Appropriations	0	-1,246	0	-1,246
Result before tax	-66,157	-35,903	-243,418	-102,523
Tax on profit for the period 8	13,855	7,526	52,853	22,183
Result for the period	-52,302	-28,377	-190,565	-80,340

<sup>1)</sup> In the fourth quarter the group internal sales have been reclassified from Other operating income to Net sales.
2) The increase in cost compared to previous year, is mainly related to group internal recharges.

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

#### BALANCE SHEET - PARENT COMPANY

KSEK	Note	31-12-2017	31-12-2016	KSEK Note	31-12-2017	31-12-2016
ACCETO				FOURTY AND LIABILITIES		
ASSETS Fixed assets				EQUITY AND LIABILITES		
rixed assets				Restricted equity	932	932
Tangible fixed access				Restricted equity (37 281 486 shares)	11,327	11,327
Tangible fixed assets		0.705	0.750	Statutory reserve		
Equipment		9,725	9,759	Total restricted equity	12,259	12,259
Financial fixed assets				Unrestricted equity		
Interest in Group companies		1,545	816	Retained earnings	-62,594	17,746
Deferred tax assets	8	119,426	66,574	Share premium reserve	608,560	597,418
Total fixed assets		130,696	77,149	Result for the period	-190,565	-80,340
				Total unrestricted equity	355,401	534,823
Current assets				TOTAL EQUITY	367,660	547,083
Inventories				LIABILITIES		
Finished goods		724	300	Untaxed reserves		
Raw materials		2,829	12,080	Depreciation/amortization in excess of plan	3,486	3,486
				Total untaxed reserves	3 486	3,486
Current receivables						
Trade receivables		5,781	8,304	Long-term liabilities		
Other receivables		3,040	3,855	Liability to subsidiaries	571	573
Prepayments and accrued income		7,202	16,459	Total long-term liabilities	571	573
Total current receivables		16,022	28,618			
				Short-term liabilities		
Cash and bank deposits		309,821	508,351	Liabilities to Group companies	3,769	-
Total current assets		329,397	549,351	Trade payables	14,431	17,560
TOTAL ASSETS		460,093	626,499	Other liabilities	2,053	2,571
				Accrued expenses and deferred income	68,123	55,227
				Total short-term liabilities	88,376	75,358

TOTAL EQUITY AND LIABILITY

460,093

626,499

MSEK	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Net revenues	5.5	37.1	54.3	113.7
Operating result	-66.1	-35.1	-243.5	-102.5
Result for the period	-52.2	-27.8	-190.6	-81.0
Cash flow from operating activities	-55.0	-7.7	-203.1	-207.8
Cash and cash equivalents	314.5	508.6	314.5	508.6
Equity	385.0	564.4	385.0	564.4
Equity ratio in Group, percent	81%	88%	81%	88%
Total assets	475.9	639.8	475.9	639.8
Average number of shares, before dilution	37,281,486	37,281,486	37,281,486	37,281,486
Average number of shares, after dilution*)	38,344,718	37,667,121	38,058,298	37,487,937
Earnings per share before dilution, SEK	-1.40	-0.75	-5.11	-2.17
Earnings per share after dilution, SEK*)	-1.40	-0.75	-5.11	-2.17
Equity per share before dilution, SEK	10.33	15.14	10.33	15.14
Equity per share after dilution, SEK*)	10.04	14.98	10.12	15.06
Number of employees at the end of period	71	62	71	62
Number of employees in R&D at the end of period	48	44	48	44
R&D costs as a percentage of operating expenses	68%	81%	75%	80%

<sup>\*)</sup> The dilution effect is calculated according to IAS 33

# Cash and cash equivalent

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)

#### **General information** Note 1

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 2017 was approved for publication in accordance with a decision by the Board of Directors on February 14, 2018.

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

#### Summary of key accounting Note 2 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 are consistent with those used in the preparation of Annual Report 2016, see

camurus.com/Investors/Financial Reports. No revised assessment regarding the impact from the coming IFRS standards, IFRS 15 and IFRS 9, has been made, i.e. the assessment that the standards will not have significant impact remains.

#### 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 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 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.

# 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	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Sales of development related goods and services	4,728	21,366	41,394	68,112
Milestone payments	0	14,699	7,025	34,217
Licensing revenues	387	60	3,582	8,485
Other	343	1,001	2,307	2,923
Total	5,458	37,126	54,308	113,737

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

KSEK	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Europe	256	2,127	7,229	22,921
(of which Sweden)	(55)	(67)	(239)	(3,727)
North America	5,202	34,362	41,350	87,359
Other geographical areas	0	637	5,729	3,457
Total	5,458	37,126	54,308	113,737

Revenues during the quarter of approximately MSEK 5,0 (50,9) relate to one single external customer. All fixed assets are located in Sweden.

# 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	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Result attributable to parent company shareholders	-52,190	-27,811	-190,574	-80,993
Total	-52,190	-27,811	-190,574	-80,993
Weighted average number of ordinary shares outstanding (thousands)	37,281	37,281	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	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Result attributable to parent company shareholders	-52,190	-27,811	-190,574	-80,993
Total	-52,190	-27,811	-190,574	-80,993
Weighted average number of ordinary shares outstanding (thousands) Adjustments:	37,281	37,281	37,281	37,281
- Warrants (thousands)	1,064	386	777	207
- Share issues (thousands)	-	-	-	-
Weighted average number of ordinary shares in calculation of earnings per share after dilution (thousands)	38,345	37,667	38,058	37,488

## 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

Investor relations services have been acquired from Piir & Partners AB, whose representative was a member of the management team. Pricing is done in accordance with market terms and costs are expensed in relation to utilization rate. During the period the company has purchased services from Piir & Partner AB to a value of MSEK 0,1 (0,3). At the end of the period the company had a debt to Piir & Partner AB regarding these services that amounted to MSEK 0,0 (0,3). No other receivables or liabilities existed.

Carrying amount, KSEK	31-12-2017	31-12-2016
Loans and receivables		
Trade receivables	5,781	8,304
Receivables from Group companies	-	-
Other receivables	-	-
Cash and cash equivalents	314,524	508,594
Total	320,305	516,898
Other liabilities		
Other financial liabilities	-	-
Liabilities to Group companies	-	-
Trade payables	15,086	17,560
Other current liabilities	191	191
Total	15,277	17,751

# Note 7 Other non-cash items

Adjustment for non-cash items:

# Note 8 Deferred tax

Tax for the quarter amounted to MSEK 13.8 (7.4), primary attributable to the negative result.

# Note 9 Equity

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

KSEK	2017 Oct-Dec	2016 Oct-Dec	2017 Jan-Dec	2016 Jan-Dec
Depreciation	1,037	845	4,088	3,524
Exchange-rate differences	5	-	16	-
Total	1,042	845	4,104	3,524

