

## **INTERIM REPORT 2016**



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"Camurus continues to make good progress with positive results from several clinical trials and a Phase 3 registration program in opioid addiction nearing completion."

### Financial calendar

Q3 2016	8 November 2016
Full Year Report 2016	16 February 2017
Annual Report 2016	30 March 2017
Q1 2017	3 May 2017
Annual General Meeting 2017	3 May 2017

Camurus is a Swedish research-based pharmaceutical company committed to developing and commercializing innovative and differentiated medicines for the treatment of severe and chronic conditions. New drug products with best-in-class potential are conceived based on the proprietary FluidCrystal<sup>®</sup> drug delivery technologies and an extensive R&D expertise. The company's share is listed on Nasdaq Stockholm under the ticker "CAMX".

## Continued progress with our development pipeline

Camurus continues to make good progress with positive results from several clinical trials and a Phase 3 registration program in opioid addiction nearing completion. Top-line efficacy results are expected during the fourth quarter. To prepare for the planned marketing approval of CAM2038, we are building our European commercial organization under the leadership of Richard Jameson who recently joined as Chief Commercial Officer.

An important highlight during the period was the positive results from our pivotal Phase 2 study of our long-acting buprenorphine (CAM2038) in opioid dependent patients. The study showed that treatment with CAM2038 provided a rapid and sustained blockade of the patients' drug liking after challenges with intravenous hydromorphone injections. Together with the longacting duration of CAM2038, the study results indicate that CAM2038 can be effective in protecting opioid dependent patients against relapse and continued misuse and abuse of illicit opioids. Confirmatory efficacy results are expected in the fourth quarter, after completion of a 24-week, randomized, double blind, double dummy Phase 3 trial.

CAM2038 is also being developed as a treatment for pain. During the period, enrollment was completed in an ongoing Phase 2 study in opioid dependent patients suffering from chronic pain. Results are expected in the fourth quarter.

In our collaboration with Novartis, we recently completed a Phase 2 study of long-acting octreotide FluidCrystal® formulation (CAM2029), supporting its potential for treating patients with acromegaly or neuroendocrine tumors (NETs). In the study CAM2029 provided long-acting octreotide release with wellmaintained control of symptoms and disease biomarkers after switching from Sandostatin<sup>®</sup> LAR<sup>®</sup>. Furthermore, the safety and local tolerability of CAM2029 was good, and consistent between the two treatments. As a next step, we look forward to the start of planned Phase 3 trials of CAM2029 by Novartis in 2017.

In June we also announced the positive topline results from a Phase 2 study of CAM2032 for treatment of prostate cancer. Data on pharmacokinetics, pharmacodynamics and safety after repeated dosing of CAM2032 confirm earlier positive results with the product. The properties of CAM2032 with the option of selfadministration by patients make this a potentially interesting future treatment alternative for patients with advanced prostate cancer. The further development of CAM2032, including potential partnerships, is currently being evaluated.

In the early pipeline, we have successfully completed toxicology studies for two promising new product candidates. GMP-manufacturing is currently ongoing and start of clinical development of these candidates is planned for the fourth quarter 2016. In parallel, we are continuing several interesting early stage collaboration projects with international pharmaceutical and biotech companies.

Importantly, we are also making good progress with the establishment of our commercial organization, preparing for the European launch of CAM2038 in opioid dependence. Richard Jameson has now assumed the role as our Chief Commercial Officer and more recently Peter Hilgert has been recruited as General Manager for Central Europe. Peter comes from a position as General Manager for Grünenthal in France and has a wealth of commercial experience from the pain therapeutic area, including recent product launches. Like Richard, he has worked in a number of leading roles across marketing and sales of specialty pharmaceuticals. I am delighted to welcome them both into our team.



To ensure patients and physicians in Europe to access CAM2038 as soon as possible after the planned marketing approval in 2018, we have started to prepare for translating the results from our extensive development program into health-economic outcomes to support reimbursement. We will also work closely with stakeholders with medical communications, scientific exchange and educational programs to increase disease awareness and the benefits of our new and potentially transformative treatment options.

Fredrik Tiberg, President and CEO

## Q2 in brief

## **BUSINESS HIGHLIGHTS**

- Positive results from Phase 2 study of the opioid blocking effect of CAM2038.
- Positive results from Phase 2 study of CAM2032 for treatment of prostate cancer.
- Patient recruitment completed in Phase 2 study of CAM2038 in patients with chronic pain.
- Distribution and license agreement signed with R-Pharm US for episil® in the US.
- Richard Jameson assumed role as Camurus' Chief Commercial Officer and Peter Hilgert is recruited as General Manager, Central Europe.
- Two new product candidates have been selected for clinical development.

## SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

• Positive results from Phase 2 study of CAM2029 in patients with neuroendocrine tumors and acromegaly, in our collaboration with Novartis.

## **FINANCIAL SUMMARY**

- Revenues MSEK 25.8 (22.7).
- Operating result before and after items affecting comparability MSEK -25.9 (-31.6) and MSEK -25.9 (-147.6), respectively.
- Result after tax MSEK -20.6 (-115.2)
- Earnings per share SEK -0.55 (-4.57), before and after dilution.
- Cash position MSEK 549.0 (136.3).

## H1 in brief

## **BUSINESS HIGHLIGHTS**

- Patient recruitment completed in two Phase 3 trials of CAM2038 for treatment of opioid dependence.
- Positive results from Phase 2 study of the opioid blocking effect of CAM2038.
- Positive results from Phase 2 study of CAM2032 for treatment of prostate cancer.
- Completion of Phase 1 study of CAM4071 in our collaboration with Novartis.
- Two new product candidates have been selected for clinical development.
- License agreement signed with Rhythm Inc. for long-acting FluidCrystal® setmelanotide under development for rare genetic obesity disorders.

## **FINANCIAL SUMMARY**

- Revenues MSEK 46.1 (81.2).
- Operating result before and after items affecting comparability MSEK -50.7 (-18.5) and MSEK -50.7 (-134.5) respectively.
- Result after tax MSEK -40.0 (-105.0)
- Earnings per share SEK -1.07 (-4.16), before and after dilution.
- Cash position MSEK 549.0 (136.3)



## Our development pipeline

#### **Product development 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, for example, 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 treatment of cancer and the side effects of cancer treatment, endocrine diseases, pain and addiction, see figure. A summary and status update on the different projects is given below.



### CAM2038 – opioid dependence

CAM2038 includes subcutaneous weekly and monthly depots of buprenorphine, developed by Camurus and its partner Braeburn Pharmaceuticals for treatment of opioid dependence from painkillers or heroin. The CAM2038 products, granted FastTrack status by US FDA, address a number of shortcomings of currently available medications, including limited patient compliance with frequent relapses and problems associated with misuse, abuse and diversion of current daily medications. To date, the CAM2038 products have been evaluated in four Phase 1/2 clinical trials. Three more trials, including two Phase 3 studies, are currently ongoing. Good safety profiles as well as pharmacokinetic and pharmacodynamic properties suitable for weekly and monthly dosing have been shown in the completed clinical trials.

#### **STATUS Q2**

During the period positive results were announced from a Phase 2 study of the opioid blocking effect of CAM2038 in opioid dependent subjects. The results show that treatment with CAM2038 effectively blocks the liking of injected hydromorphone, which indicates that it can protect patients against relapse and continued illicit opioid use and abuse. Two Phase 3 studies of CAM2038 are currently ongoing to document efficacy and long-term safety of CAM2038 in opioid dependent patients: a Phase 3 randomized, double-blind, double-dummy, active-controlled, 24-week efficacy trial, and a Phase 3 openlabel, 48-week safety study. Phase 3 efficacy results are expected in fourth guarter, 2016. Furthermore, a Phase 2 study evaluating pharmacokinetics, pain and safety during repeated dosing of CAM2038 is ongoing (see chronic pain section). These studies are part of the registration program for CAM2038, which has been discussed and aligned with both European and US regulatory authorities.

### CAM2038 – chronic pain

CAM2038, weekly and monthly depots, are also being developed for treatment of chronic pain. CAM2038 is designed to provide round-the-clock pain relief, while decreasing the risks of respiratory depression and fatal overdoses associated with full  $\mu$ -opioid agonists, such as morphine, oxycodone and fentanyl. The properties of CAM2038 conform to the guidelines and recommendations for treatments of chronic pain, i.e. combining of stable efficacious plasma levels with a reduced risk of misuse, abuse and illicit diversion.

#### STATUS Q2

During the period, the last patients were enrolled in a Phase 2 study of CAM2038 in opioid dependent patients with chronic pain. The study evaluates pharmacokinetics, pain and safety after repeated dosing of the CAM2038 weekly and monthly products. Results are expected in the fourth quarter of 2016. In addition, the start of a Phase 3 study in patients with chronic pain is planned.

## CAM2029 – acromegaly and neuroendocrine tumors (NET)

CAM2029 is a subcutaneous monthly depot of octreotide under development for the treatment of patients with acromegaly or neuroendocrine tumors (NET). CAM2029 is being developed by Novartis as a potential treatment alternative to the current market leading product Sandostatin® LAR®, with global sales of USD 1.63 billion in 2015. CAM2029 is administered as a ready-touse subcutaneous injection, whereas Sandostatin® LAR® has to be prepared from a powder in a process consisting of six steps before being injected intramuscularly by a healthcare professional. CAM2029 has in clinical trials demonstrated about a 500 percent higher bioavailability of octreotide compared with Sandostatin® LAR®, with potential for improved treatment effects in patients who do not respond satisfactorily to current treatments.

#### STATUS Q2

Camurus and Novartis have during the period completed a Phase 2 study of CAM2029 in patients with acromegaly and NET previously treated with Sandostatin<sup>®</sup> LAR<sup>®</sup>. After the end of the period, positive study results were reported regarding pharmacokinetics, safety and maintenance of disease control. The disease control was evaluated by the control of carcinoid symptoms in NET patients and plasma levels of insulin growth factor-1 (IGF-1) and growth hormone (GH) in acromegaly patients. Results will be presented in a future publication. In parallel, Novartis is completing the preparations of Phase 3 trials of CAM2029, planned to start 2017.

### CAM2032 – prostate cancer

CAM2032 is a new subcutaneous depot product that is being developed by Camurus for treatment of prostate cancer. Other possible indications include premature sexual maturation and endometriosis. The product is based on the active ingredient leuprolide, belonging to the class of gonadotropin releasing hormone analogs. CAM2032 is as the first product in its class developed for easy subcutaneous injection by patients themselves, in the form of a small volume injection with a duration of one month.

#### STATUS Q2

During the period, positive results were reported from a Phase 2 study of CAM2032 in patients with advanced metastatic prostate cancer. Data from the study demonstrated comparable pharmacokinetic profiles for CAM2032 and Eligard®. The bioavailability of the active substance leuprolide was 50% higher for CAM2032 relative to Eligard®, whilst maintaining a low initial release. Additionally, CAM2032 demonstrated dose and time independent pharmacokinetics. The treatment effect, assessed by the suppression of testosterone and prostate specific antigen (PSA) levels over time, was similar between the two CAM2032 dosages and the Eligard® treatment. Safety and local tolerability was good for all treatments, with few (less than 10%) incidences of mild and transient erythema or swelling observed for all treatments. Lower mean injection site pain scores were indicated for CAM2032 compared with Eligard®.

## New product candidates

Several new product candidates are being evaluated in pharmaceutical and preclinical studies, supported by initial market research. The development includes formulation optimization with respect to release performance, stability and pharmacological properties, according to predefined target product profiles.

#### STATUS Q2

During the period, we have completed supporting toxicology studies for two product candidates. Decisions have been taken to initiate clinical development of both candidates with start in fourth quarter 2016. Manufacturing of investigational drug product for clinical trials is ongoing.

## **Pre-clinical project collaborations**

Camurus is also in a number of collaboration projects with international pharmaceutical companies where new product candidates based on Camurus' formulation technology and the partner company's patented active ingredient are evaluated. These collaborations often involve formulation development and assessments with respects to pre-specified technical and market related objectives. The time frame of these feasibility studies is typically 6–12 months. After successful evaluations, product development can continue under a license agreement, with opportunities for future development and commercial milestone payments as well as royalty on future sales.

#### STATUS Q2

Several project collaborations are ongoing with international pharmaceutical companies, based on Camurus' FluidCrystal® technologies and the partners' proprietary drug substance. These projects target different indications such as cancer, obesity, diabetes and viral infection. During the first quarter, a license agreement was signed with the Boston-based biotech company Rhythm, regarding the use of Camurus FluidCrystal® injection depot for developing a once-weekly formulation of setmelanotide (RM-493), a novel melanocortin-4 receptoragonist (MC4R) for treatment of genetic obesity. According to the agreement, Rhythm obtains global rights to use, manufacture and commercialise a subcutaneous formulation of setmelanotide for once-weekly dosing. Rhythm is currently preparing GMP-manufacturing of the once-weekly setmelanotide FluidCrystal<sup>®</sup> formulation for the start of a clinical Phase 1 trial.

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

episil<sup>®</sup> is a medical device for treatment of inflammatory and painful conditions in the oral cavity. The product provides effective pain relief and works by spreading and adhering to the oral mucosa as a thin bioadhesive film, which acts as a longacting protective barrier that reduces pain and protection of sore and inflamed mucosal surfaces, such as caused by oral mucositis, a common and serious side effect of cancer treatment. episil<sup>®</sup> transforms into a protective layer of gel in contact with the buccal membrane, offering effective pain relief for up to 8 hours.

#### STATUS Q2

Camurus partner Solasia Pharma has initiated the market registration process for episil<sup>®</sup> in China and Japan. After signing of a distribution and license agreement with R-Pharm US, preparations for launch of episil<sup>®</sup> on the US market is ongoing.

## Financial overview

#### REVENUES

Revenues during the second quarter came from project activities and product sales and amounted to MSEK 25.8 (22.6).

#### **OPERATING RESULT**

Marketing, business development and distribution costs during the second quarter, were MSEK 5.3 (4.2).

Administrative expenses amounted to MSEK 5.8 (12.1). The difference compared to the same period last year is mainly related to a retroactive reallocation between administrative expenses, marketing and distribution costs and research and development costs.

Research and development costs were MSEK 40.9 (36.3), including depreciation and amortization of tangible and intangible assets.

Other operating incomes/expenses mainly consist of currency exchange gains in operational activities of a total of MSEK 0.6 (loss -1.6), as a result of fluctuations in the Swedish krona against the euro and the US dollar.

Depreciation and amortization amounted to MSEK 0.8 (0.8). The operating result for the second quarter, before and after items affecting comparability was MSEK -25.9 (-31.6) and MSEK -25.9 (-147.6).

#### FINANCIAL ITEMS AND TAX

Financial items for the period was MSEK -0.5 (-0.0).

Tax for the quarter was MSEK 5.8 (32.4). The difference compared to the previous year is mainly attributable to deferred tax for losses during the quarter.

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

The result for the period was MSEK -20.6 (115.2), corresponding

to an earnings per share of SEK -0.55 (-4.57) before and after dilution.

#### CASH FLOW AND INVESTMENTS

Cash flow from operating activities, before change in working capital, was negative for the second quarter and amounted to MSEK -25.5 (-58.7).

Working capital affected the cash flow with MSEK -0.6 (78.7) reflecting that the company's cash flows coming from license and milestone payments vary between quarters.

Cash flow from investing activities was MSEK -0.1 (-0.1), and from finance activities to MSEK 3.2 (0.0) in relation to issuance of warrants.

#### CASH

The Company's cash position at the end of the quarter was MSEK 549.0 (136.3) and the increase is mainly attributable to the proceeds from the listing of Camurus' shares on Nasdaq, Stockholm.

There were no outstanding loans as of June 30, 2016, and no loans have been taken up since.

#### EQUITY

Consolidated equity as of June 30, 2016, was MSEK 603.8 (106.8) and the increase compared to the same date last year relates mainly to the issued proceeds in conjunction with the listing of the Company's shares on Nasdaq Stockholm on December 3, 2015.

#### ACQUISITIONS

No acquisitions or divestments have occurred during the quarter.

#### CAMURUS' SHARE

Camurus' share is listed on Nasdaq Stockholm since the December 3, 2015. At the end of the period, the total number of shares in the company was 37,281,486 (25,208,560).

In accordance with a decision by a Shareholder's General Meeting in May 2016, an incentive program (TO2016 / 2019) under which a maximum of 550 000 warrants can be issued, was introduced. The dilutive effect at full utilization of the program will be 1.5% of the share capital and voting rights. The number of warrants that have been issued are 550 000 and which give the right to subscribe for an equal number of shares during the period May 15, 2019 - December 15, 2019. As per June 30, 2016 318.250 warrants had been subscribed for.

#### PARENT COMPANY

Revenues for the first quarter amounted to MSEK 25.8 (22.6) and the result after tax was MSEK -20.1(-114.8).

On June 30, 2016, equity in the Parent Company amounted to MSEK 586.7 (76.2). The difference compared with the yearearlier period is mainly attributable to the issued proceeds in connection with the stock market listing of the company's share.

Total assets at the end of the period was MSEK 645.9 (197.4), of which cash and cash equivalents constituted MSEK 549.0 (136.3).

## Other disclosures

#### PERSONNEL

At the end of the period, Camurus had 52 (51) employees, of whom 38 (38) were within research and development. The average number of employees during the quarter was 49 (45).

#### SIGNIFICANT RISKS AND UNCERTAINTIES

The company management makes estimates and assumptions about the future. Such estimates can deviate considerably from the actual outcome, since they are based on various assumptions and experiences.

The estimates and assumptions that may lead to the risk of significant adjustments to reported amounts for assets and liabilities relate mainly to measurement and allocation of revenues and costs in connection with licensing agreements.

Risks in ongoing development projects comprise technical and manufacturing related risks (including products failing to meet set specifications post manufacturing), safety and effectrelated risks that can arise in clinical trials, regulatory risks relating to applications for approval of clinical trials and market approval, commercial risks relating to the sale of proprietary and competing products and their development 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 currency risks, since revenues and costs arise in different currencies, mainly SEK, EUR and USD.

The Board of Directors has not changed its outlook on future developments in relation to their outlook published in the interim report for the first quarter 2016

#### AUDIT

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

#### **FURTHER 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, July 14, 2016 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 Group's operations, financial position and results and describes significant risks and uncertainties that the Company and the companies included in the Group face.

Lund, July 14 2016

Camurus AB

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

Martin Jonsson Board Member Svein Mathisen Board Member Per Sandberg Board Member

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

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

## Financial statement

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

KSEK	Note	2016 Apr - Jun	2015 Apr - Jun	2016 Jan – Jun	2015 Jan – Jun	2015 Jan - Dec
	Note	Api - Juli	Api - Juli	Jan – Jun	Jan – Jun	Jan - Dec
Net sales	3	25,834	22,659	46,080	81,227	154,799
Cost of goods sold		-303	27	-366	-1	-237
Gross profit		25,531	22,686	45,714	81,226	154,562
Marketing and distribution costs		-5,293	-4,240	-9,591	-7,170	-19,411
Administrative expenses		-5,812	-12,146	-9,526	-17,787	-11,934
Research and development costs		-40,963	-36,309	-76,357	-73,677	-153,080
Other operating income		655	13	32	28	57
Other operating expenses		0	-1,649	-1,011	-1,158	-658
Operating result before items affecting comparability	7	-25,881	-31,645	-50,739	-18,539	-30,464
Items affecting comparability attributable to public listing costs	7	0	0	0	0	-33,970
Items affecting comparability attributable to Share bonus program	7	0	-116,000	0	-116,000	-139,671
Operating result	6	-25,881	-147,645	-50,739	-134,539	-204,104
Finance income		6	0	8	0	2
Finance expenses		-471	-9	-508	-17	-166
Net financial items		-465	-9	-501	-17	-164
Result before tax		-26,347	-147,654	-51,240	-134,556	-204,268
Income tax	9	5,796	32,484	11,273	29,602	44,727
Result for the period		-20,551	-115,170	-39,967	-104,954	-159,542

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.

SEK	2016	2015	2016	2015	2015
	Apr - Jun	Apr - Jun	Jan – Jun	Jan – Jun	Jan - Dec
Earnings per share before dilution, SEK	-0.55	-4.57	-1.07	-4.16	-6.33
Earnings per share after dilution, SEK	-0.55	-4.57	-1.07	-4.16	-6.33

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

Since 2013, Camurus had a long-term share based incentive program in place, aimed at employees and Board members and in connection with the listing of the company's share on 3 December 2015 the programme was completed. The impact on previous year's results amounted MSEK 108.9 after tax, with a corresponding increase in equity of MSEK 108.8 and a social security fee liability of MSEK 30.8. For further information please see Note 7. Earnings per share 2015 was effected by -4.32 SEK per share before and after dilution.

## CONSOLIDATED BALANCE SHEET

KSEK No	e 30-06-2016	30-06-2015	31-12-2015	KSEK	Note	30-06-2016	30-06-2015	31-12-2015
ASSETS				FOUTY				
Fixed assets				EQUITY				
Intangible assets				Equity attributable to parent company				
Capitalized development expenditure	19,782	21,865	20,823	<b>shareholder</b> Share capital		932	630	932
				Other contributed capital		629,428	58,634	626,181
<b>Tangible assets</b> Equipment	6,229	6,568	6,634	Retained earnings, including result for the period		-26,523	47,539	13,444
Financial assets				Total equity	4, 10	603,837	106,803	640,557
Long-term receivables Group companies	0	406	0					
Deferred tax receivables	9 50,589	21,523	39,317	LIABILITIES				
Total fixed assets	76,600	50,362	66,775					
				Long-term liabilities				
Current assets				Deferred tax liability		0	458	0
				Total long-term liabilities		0	458	0
Inventories								
Finished goods and goods for resale	3,149	1,700	3,241	Short-term liabilities				
Current receivables				Liabilities to Group companies		0	215	0
Receivables from Group companies	0	0	207	Trade payables		7,571	12,356	31,832
Trade receivables	0 10,747	0 11,410	207 8,917	Income taxes		0	9,148	9,917
Other receivables	3,092	1,170	5,500	Other liabilities		3,549	2,095	88,088
Prepayments and accrued income	17,691	10,004	15,613	Accrued expenses and deferred income		45,305	79,847	45,954
		.,	- ,	Total short-term liabilities		56,425	103,660	175,791
Cash and cash equivalents	548,983	136,276	716,096	TOTAL EQUITY AND LIABILITIES		660,261	210,922	816,349
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Total current assets	583,661	160,560	749,574					
TOTAL ASSETS	660,261	210,922	816,349					

## 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 2015		630	58,634	64,193	123,457
Result for the period and comprehensive income				-104,954	-104,954
Transaction with shareholders				88,300	88,300
Closing balance 30 June 2015		630	58,634	47,539	106,803
Opening balance 1 January 2015		630	58,634	64,193	123,457
Result for the period and comprehensive income				-159,542	-159,542
Transactions with shareholders					
Share bonus program for personnel and Board members		47		108,793	108,840
Direct share issue to principal owner		11	23,879		23,890
Direct share issue, public listing		244	554,756		555,000
Issuance cost, net after deferred tax			-11,088		-11,088
Closing balance 31 December 2015		932	626,181	13,444	640,557
Opening balance 1 January 2016		932	626,181	13,444	640,557
Result for the period and comprehensive income			,	-39,967	-39,967
Transactions with shareholders					
Warrants issued			3,247		3,247
Closing balance 30 June 2016	4,10	932	629,428	-26,523	603,837

## CONSOLIDATED STATEMENT OF CASH FLOW

KSEK	Note	2016 Apr - Jun	2015 Apr - Jun	2016 Jan - Jun	2015 Jan - Jun	2015 Jan - Dec
Operating activities						
Operating activities Operating profit/loss before financial items		-25,882	-147,646	-50,739	-134,539	-204,104
Adjustments for non-cash items	8	- <b>23,002</b> 846	-147,040 89,154	1,686	90,002	112,345
Interest received	0	6	09,154	1,000	0	2
Interest paid		-472	-9	-509	-17	-166
Income taxes paid		0	-212	-9,917	-452	317
		-25,502	-58,713	-59,471	-45,006	-91,606
Increase/decrease in inventories		8	-902	92	-998	-2,539
Increase/decrease in trade receivables		3,423	43,596	-1,830	-5,292	-2,800
Increase/decrease in other current receivables		-5,387	-615	536	1,634	-8,511
Increase/decrease in trade payables		5	5,299	-24,261	2,418	21,893
Increase/decrease in other current operating liabilities		1,378	31,284	-85,187	26,021	77,906
Cash flow from changes in working capital		-573	78,662	-110,650	23,783	85,949
Cash flow from operating activities		-26,075	19,949	-170,121	-21,223	-5,657
Investing activities						
Acquisition of intangible assets		0	0	0	-355	-355
Acquisition of tangible assets		-104	-85	-239	-110	-984
Divestment/amortization of other financial assets		0	0	0	0	406
Increase/decrease in current financial investments		0	0	0	157,908	157,908
Cash flow from investing activities		-104	-85	-239	157,443	156,975
Financing activities						
Increase/decrease in current financial liabilities		0	0	0	0	0
New share issue		0	0	0	0	564,722
Warrants issued		3,247	0	3,247	0	0
Cash flow from financing activities		3,247	0	3,247	0	564,722
Net cash flow for the period		-22,933	19,864	-167,113	136,220	716,040
Cash and cash equivalents at beginning of period		571,916	116,412	716,096	56	56
Exchange rate differences in cash equivalents		0	0	0	-1	0
Cash and cash equivalents at the end of period		548,983	136,276	548,983	136,276	716,096

## **INCOME STATEMENT – PARENT COMPANY**

KSEK	Note	2016 Apr - Jun	2015 Apr - Jun	2016 Jan – Jun	2015 Jan - Jun	2015 Jan - Dec
	Note	Apresun	Apresan	Jan – Jan	Jan-Jan	Jan Dec
Net sales		25,834	22,659	46,080	81,227	154,799
Cost of goods sold		-303	27	-366	-1	-237
Gross profit		25,531	22,686	45,714	81,226	154,562
Marketing and distribution costs		-5,293	-4,240	-9,591	-7,170	-19,411
Administrative expenses		-5,812	-12,146	-9,526	-17,787	-11,934
Research and development costs		-40,443	-35,787	-75,316	-72,990	-151,354
Other operating income		655	13	32	28	57
Other operating expenses		0	-1,649	-1,011	-1,158	-658
Operating result before items affecting comparability	7	-25,361	-31,123	-49,698	-17,851	-28,738
Items affecting comparability attributable to public listing costs	7	0	0	0	0	-33,970
Items affecting comparability attributable to Share bonus program	7	0	-116,000	0	-116,000	-139,671
Operating result		-25,361	-147,123	-49,698	-133,851	-202,379
Result from interests in Group companies		0	0	0	0	0
Interest income and similar items		6	0	8	0	2
Interest expense and similar items		-471	-9	-508	-17	-166
Result after financial items		-25,826	-147,132	-50,198	-133,868	-202,543
Appropriations		0	0	0	0	15,096
Result before tax		-25,826	-147,132	-50,198	-133,868	-187,447
Tax on profit for the period	9	5,682	32,369	11,044	29,451	41,026
Result for the period		-20,145	-114,763	-39,155	-104,417	-146,421

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	30-06-2016	30-06-2015	31-12-2015
ASSETS				
Fixed assets				
Tangible fixed assets				
Equipment		6,229	6,568	6,634
Financial fixed assets				
Interest in Group companies		573	573	573
Deferred tax assets	9	55,434	29,689	44,391
Total fixed assets		62,236	36,830	51,598
Current assets				
Inventories				
Finished goods and goods for resale		3,149	1,700	3,242
Current receivables				
Receivables from parent company		0	0	207
Trade receivables		10,747	11,410	8,917
Other receivables		3,092	1,171	5,500
Prepayments and accrued income		17,692	10,004	15,613
Total current receivables		31,530	22,585	30,237
Cash and bank deposits		548,983	136,276	716,096
Total current assets		583,662	160,561	749,575
TOTAL ASSETS		645,898	197,391	801,173

KSEK Note	30-06-2016	30-06-2015	31-12-2015
EQUITY AND LIABILITIES			
Restricted equity			
Restricted equity (37 281 486 shares)	932	630	932
Statutory reserve	11,327	11,327	11,327
Total restricted equity	12,259	11,957	12,259
Unrestricted equity			
Retained earnings	17,746	143,643	164,167
Share premium reserve	595,811	25,017	592,565
Result for the period	-39,155	-104,417	-146,421
Total unrestricted equity	574,402	64,273	610,311
TOTAL EQUITY	586,661	76,230	622,570
LIABILITIES			
Untaxed reserves			
Depreciation/amortization in excess of plan	2,239	1,825	2,239
Tax allocation reserve	0	15,510	0
Total untaxed reserves	2,239	17,335	2,239
Long-term liabilities			
Liability to subsidiaries	573	166	573
Total long-term liabilities	573	166	573
Short-term liabilities			
Liabilities to Group companies	0	215	0
Trade payables	7,571	12,355	31,832
Current tax liability	0	9,148	9,917
Other liabilities	3,549	2,095	88,088
Accrued expenses and deferred income	45,305	79,847	45,954
Total short-term liabilities	56,425	103,660	175,791
TOTAL EQUITY AND LIABILITIES	645,898	197,391	801 173

## Key figures

MSEK	2016 Apr - Jun	2015 Apr - Jun	2016 Jan – Jun	2015 Jan – Jun	2015 Jan - Dec
Net revenue	25.8	22.7	46.1	81.2	154.8
Operating result before items affecting comparability	-25.9	-31.6	-50.7	-18.5	-30.5
Operating result	-25.9	-147.6	-50.7	-134.5	-204.1
Result for the period	-20.6	-115.2	-40.0	-105.0	-159.5
Cash flow from operating activities	-26.1	19.9	-170.1	-21.2	-5.7
Cash and cash equivalents	549.0	136.3	549.0	136.3	716.1
Equity	603.8	106.8	603.8	106.8	640.6
Equity ratio in Group, percent	91%	51%	91%	51%	78%
Total assets	660.3	210.9	660.3	210.9	816.3
Average number of shares, before dilution	37,281,486	25,208,560	37,281,486	25,208,560	25,208,560
Average number of shares, after dilution	37,358,426	25,208,560	37,319,956	25,208,560	26,497,361
Earnings per share before dilution, SEK	-0.55	-4.57	-1.07	-4.16	-6.33
Earnings per share after dilution, SEK	-0.55	-4.57	-1.07	-4.16	-6.33
Equity per share before dilution, SEK	16.20	4.24	16.20	4.24	25.41
Equity per share after dilution, SEK	16.16	4.16	16.18	4.16	17.18
Number of employees at end of period	52	51	52	51	48
Number of employees in R&D at end of period	38	38	38	38	35
R&D costs as a percentage of operating expenses	79%	69%	80%	75%	83%

## DEFINITIONS

Equity ratio, %	Equity divided by total capita
Average number of shares, before dilution	Average number of shares before adjustment for dilution effect of net shares
Average number of shares, after dilution	Average number of shares adjustment for the dilution effect of new shares
Earnings per share before dilution, SEK	Result divided by the average number of shares outstanding before dilution shares
Earnings per share after dilution, SEK	Result divided by the average number of shares outstanding after dilution
Equity per share before dilution	Equity divided by the number of shares at the period before dilution
Equity per share after dilution	Equity divided by the number of shares at the end of the period after dilution
R&D cost as a percentage of operating expenses	Research and development costs divided by operating expenses, excluding items affecting comparability (marketing and distribution costs, administrative expenses and research and development costs).

## Notes

### Note 1 General information

Camurus AB, Corp. ID no. 556667-9105 is the parent company of the Camurus Group. Up until 7 October 2015, Camurus AB's registered offices were in Malmö, Sweden. The company is now based in Lund, Sweden, at Ideon Science Park, 223 70 Lund.

Camurus AB Group's interim report for the second quarter 2016 was approved for publication in accordance with a decision from the Board on 13 July 2016.

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 Accounts Act.

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

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

#### 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.

#### Interests in subsidiaries

Interests in subsidiaries are reported at cost, less any impairment losses. The cost includes acquisition-related expenses and any additional considerations.

When there is an indication that interests in subsidiaries have decreased in value, a calculation is made of the recoverable amount. If this amount is lower than the reported amount, an impairment is carried out. Impairment losses are recognized under the item "Result from interests 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

Until 3 December 2015, the group had a share-based compensation plan where the regulation should be made in shares and where the company received services from employees as consideration for the Group's own equity instruments (shares). The fair value of the service, which eligible employees to the allocation of shares, was expensed and the total amount to be expensed was based on the fair value of the shares granted.

At each reporting period Camurus assessed its estimates of the number of shares expected to vest based on the non-market vesting conditions and service conditions. Any deviation from the original estimates as the review gave rise to, were recognized in the income statement and corresponding adjustments made to equity

When bonus shares were exercised, the Company issued new shares. The proceeds received net of any directly attributable transaction costs are credited to share capital (quota value) and other capital contributions. The social security contributions which arose on the allocation of the shares was regarded as an integral part of the award, and the cost was treated as a cash-settled share-based payment.

## Note 3 Segment information

Company management have established that the Group as a whole constitutes one segment based on the information managed by the CEO, in consultation with the Board, and which is used as a basis for allocating resources and evaluating results.

#### Group-wide information

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

KSEK	2016 Apr - Jun	2015 Apr - Jun	2016 Jan - Mar	2015 Jan - Mar	2015 Jan - Dec
Sales of development related goods and services	19,452	22,419	35,423	52,161	93,845
Milestone payments	2,298	0	2,298	21,650	52,850
Licensing revenues	4,070	0	8,345	7,013	7,238
Other	14	240	14	403	866
Total	25,834	22,659	46,080	81,227	154,799

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

KSEK	2016 Apr - Jun	2015 Apr – Jun	2016 Jan – Mar	2015 Jan - Mar	2015 Jan - Dec
Europe	7,546	17,729	15,095	69,216	108,067
(of which Sweden)	(1,218)	(1,443)	(2,891)	(1,710)	(2,275)
North America	15,935	4,924	28,507	4,973	39,635
Other geographical areas	2,353	6	2,478	7,038	7,097
Totalt	25,834	22,659	46,080	81,227	154,799

Revenue during first quarter of approximately MSEK 19.4 (41.3) relates 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.

КЅЕК	2016 Apr - Jun	2015 Apr - Jun	2016 Jan - Mar	2015 Jan - Mar	2015 Jan - Dec
Result attributable to parent company shareholders	-20,551	-115,170	-39,967	-104,954	-159,542
Total	-20,551	-115,170	-39,967	-104,954	-159,542
Weighted average number of ordinary shares outstanding (thousands)	37,281	25,209	37,281	25,209	26,497

## b) After dilution

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

KSEK	2016 Apr – Jun	2015 Apr – Jun	2016 Jan - Mar	2015 Jan - Mar	2015 Jan - Dec
Result attributable to parent company shareholders	-20,551	-115,170	-39,967	-104,954	-159,542
Total	-20,551	-115,170	-39,967	-104,954	-159,542
Weighted average number of ordinary shares outstanding (thousands)	37,281	25,209	37,281	25,209	26,497
Adjustments:					
- warrants (thousands)	77	-	38	-	1,047
- Share issues (thousands)	-	1,877	-	626	9,037
Weighted average number of ordinary shares in calculation of earnings per share after dilution (thousands)	37,358	27,086	37,319	25,834	37,281

# 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.

Carrying amount, KSEK	31-03-2016	31-03-2015	31-12-2015
Loans and receivables			
Trade receivables	10,747	11,410	8,917
Receivables from Group companies	-	-	207
Other receivables	-	-	-
Cash and cash equivalents	548,983	136,276	716,096
Total	-559,729	147,686	725,220
Other liabilities			
Other financial liabilities	-	-	-
Liabilities to Group companies	-	215	-
Trade payables	7,571	12,356	31,641
Other current liabilities	191	191	191
Total	7,762	12,762	31,832

## Not 6 Related party transactions

Investor relations services have been acquired from Piir & Partners AB, whose representative is a member of the management team. Pricing is done in accordance with allocation of costs in relation to utilization rate and on market terms.

At the end of the period the company had a dept to Piir & Partner AB regarding these services that amounted to MSEK 0.3 (0). There were no other receivables or liabilities.

## Not 7 Items affecting comparability

Up and until first quarter this year, no items affecting comparability have arisen.

The costs charged to the previous year's results relate to listing expenses, in connection with preparations of the public listing of the company's shares on Nasdaq, Stockholm, and to the share bonus program, implemented in 2013 and fulfilled December 3, 2015 when Camurus' shares were listed on the stock exchange.

Following below is the consolidated income statement as it would have looked had the listing expenses and the cost for the share bonus program not been separated out.

KSEK	Note	2016 Apr - Jun	2015 Apr - Jun	2016 Jan – Mar	2015 Jan – Mar	2015 Jan - Dec
NOEK	Hote			Jun Mai	Jun Mu	Jun Dee
Revenues	3	25,834	22,659	46,080	81,227	154,799
Cost of goods sold		-303	27	-366	-1	-237
Gross profit		25,531	22,686	45,714	81,226	154,562
Marketing and distribution costs		-5,293	-15,840	-9,591	-18,770	-31,338
Administrative expenses		-5,812	-45,786	-9,526	-51,427	-74,790
Research and development costs		-40,963	-106,548	-76,357	-144,437	-251,937
Other operating income		655	13	32	28	57
Other operating expenses		0	-1,649	-1,011	-1,158	-658
Operating result	6	-25,881	-147,645	-50,739	-134,539	-204,104
Finance income		6	0	8	0	2
Finance expenses		-471	-9	-508	-17	-166
Net financial items		-465	-9	-501	-17	-164
Result before tax		-26,347	-147,654	-51,240	-134,556	-204,268
Income tax	9	5,796	32,484	11,273	29,602	44,727
Result for the period		-20,551	-115,170	-39,967	-104,954	-159,542

## Note 8 Other non-cash items

Adjustment for non-cash items:

	2016	2015	2016	2015	2015
KSEK	Apr - Jun	Apr - Jun	Jan – Mar	Jan – Mar	Jan - Dec
Depreciation	846	854	1,686	1,702	3,552
Costs of share bonus program	0	88,300	0	88,300	108,793
Total	846	89,154	1,686	90,002	112,345

## **Note 9 Deferred tax**

Tax for the period amounted to MSEK 5.8 (32.4), primarily attributable to the negative result for the period. The difference compared to the year earlier period is that the company reported a profit at that time.

## **Note 10 Equity**

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

This information is information that Camurus AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Swedish Securities Markets Act. The information was submitted for publication, through the agency of the chief executive officer, 07.00 AM CET on 14 July 2016.



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