## IMPORTANT NOTICE (FOR ELECTRONIC DELIVERY)

**IMPORTANT: You must read the following disclaimer before continuing.** The following disclaimer applies to the Offering Circular attached to this electronic transmission and you are therefore advised to read this disclaimer carefully before reading, accessing or making any other use of the attached Offering Circular. In accessing the attached Offering Circular, you agree to be bound by the following terms and conditions, including any modifications to them from time to time, each time you receive any information from the Joint Global Coordinators, the Company or the Principal Shareholder (each as defined in the attached Offering Circular) as a result of such access. You acknowledge that this electronic transmission and the delivery of the attached document is confidential and is intended for you only and you agree you will not forward this electronic transmission or the attached Offering Circular (electronically or otherwise) to any other person.

THE COMPANY'S SHARES MAY ONLY BE DISTRIBUTED IN "OFFSHORE TRANSACTIONS" AS DEFINED IN, AND IN ACCORDANCE WITH, REGULATION S UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT") OR WITHIN THE UNITED STATES TO QUALIFIED INSTITUTIONAL BUYERS ("QIBs") AS DEFINED IN AND IN ACCORDANCE WITH RULE 144A UNDER THE SECURITIES ACT ("RULE 144A").

**Confirmation of your representation:** In order to be eligible to view the document or make an investment decision with respect to the Company's shares, investors must be either (1) QIBs or (2) outside the United States transacting in an "offshore transaction" (in accordance with Regulation S under the Securities Act). By accepting electronic delivery or electronically accessing the attached Offering Circular, you shall be deemed to have confirmed to the Joint Global Coordinators, the Company and the Principal Shareholder, that (i) you have understood and agree to the terms set out herein, (ii) (a) you, any customers you represent, and the electronic mail address you have given to us are not located in the United States, its territories and possessions or (b) you and any customers you represent are QIBs, (iii) you consent to delivery by electronic transmission of the attached Offering Circular, (iv) you will not transmit the attached Offering Circular (or any copy of it or part thereof) or disclose, whether orally, electronically or in writing, any of its contents to any other person except with the consent of the Joint Global Coordinators and (v) you acknowledge that you will make your own assessment regarding any legal, taxation or other economic considerations with respect to your decision to purchase the Company's shares.

You are reminded that the attached Offering Circular has been delivered to you on the basis that you are a person into whose possession the attached Offering Circular may be lawfully delivered in accordance with the laws of the jurisdiction in which you are located and you may not, nor are you authorized to, deliver the attached Offering Circular, electronically or otherwise, to any other person and in particular to any person in the United States or to any U.S. address.

Failure to comply with this directive may result in a violation of the U.S. securities laws or the applicable laws of other jurisdictions.

**Restrictions:** NOTHING IN THIS ELECTRONIC TRANSMISSION CONSTITUTES AN OFFER OF SECURITIES FOR SALE IN ANY OTHER JURISDICTION WHERE IT IS UNLAWFUL TO DO SO.

THE COMPANY'S SHARES HAVE NOT BEEN AND WILL NOT BE REGISTERED UNDER THE SECURITIES ACT OR THE SECURITIES LEGISLATION OF ANY STATE OR OTHER JURISDICTION IN THE UNITED STATES AND MAY NOT BE OFFERED, SOLD, PLEDGED, RESOLD, ALLOTTED, DELIVERED OR OTHERWISE TRANSFERRED DIRECTLY OR INDIRECTLY WITHIN OR INTO THE UNITED STATES EXCEPT IN CERTAIN TRANSACTIONS EXEMPT FROM, OR NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN COMPLIANCE WITH THE SECURITIES LEGISLATION IN THE RELEVANT STATE OR ANY OTHER JURISDICTION OF THE UNITED STATES. THE COMPANY'S SHARES ARE BEING OFFERED OUTSIDE THE UNITED STATES IN RELIANCE ON REGULATION S UNDER THE SECURITIES ACT. ANY OFFERNG OF THE COMPANY'S SHARES IN THE UNITED STATES WILL BE MADE ONLY TO INVESTORS WHO ARE QIBS IN RELIANCE ON RULE 144A OR PURSUANT TO ANOTHER AVAILABLE EXEMPTION FROM, OR IN TRANSACTIONS NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT. PROSPECTIVE PURCHASERS ARE HEREBY NOTIFIED THAT THE PRINCIPAL SHAREHOLDER AND THE JOINT GLOBAL COORDINATORS MAY BE RELYING ON THE EXEMPTION FROM THE PROVISIONS OF SECTION 5 OF THE SECURITIES ACT PROVIDED BY RULE 144A. IF YOU HAVE GAINED ACCESS TO THIS TRANSMISSION CONTRARY TO ANY OF THE FOREGOING RESTRICTIONS, YOU ARE NOT AUTHORISED AND WILL NOT BE ABLE TO PURCHASE ANY OF THE COMPANY'S SHARES DESCRIBED IN THE ATTACHED OFFERING CIRCULAR.

THE ATTACHED OFFERING CIRCULAR MAY NOT BE FORWARDED OR DISTRIBUTED TO ANY OTHER PERSON AND MAY NOT BE REPRODUCED IN ANY MANNER WHATSOEVER. DISTRIBUTION OR REPRODUCTION OF THE ATTACHED OFFERING CIRCULAR IN WHOLE OR IN PART IS UNAUTHORIZED. FAILURE TO COMPLY WITH THIS DIRECTIVE MAY RESULT IN A VIOLATION OF THE SECURITIES ACT OR THE APPLICABLE SECURITIES LAWS OF OTHER JURISDICTIONS.

Under no circumstances shall the attached Offering Circular constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of the Company's shares in any jurisdiction in which such offer, solicitation or sale would be unlawful. Recipients of the attached Offering Circular who intend to purchase any of the Company's shares are reminded that any such purchase may only be made on the basis of the information contained in the attached Offering Circular.

No public offering of the Company's shares is made in any countries within the European Economic Area (the "**EEA**") other than Sweden. In other member states of the EEA, which have implemented the Prospectus Directive (as defined below), the

attached Offering Circular is only addressed to and is only directed at "qualified investors" in that member state in accordance with the definition under article 2.1 e) of the Prospectus Directive or under any other circumstances that do not require the Company, the Principal Shareholder or the Joint Global Coordinators to publish a prospectus in the relevant member state under article 3 of the Prospectus Directive. Each recipient of this Offering Circular will be deemed to have committed and guaranteed that they neither have nor will make a public offering in any member state of the EEA.

Each person in a relevant member state other than, in the case of paragraph (a), persons receiving offers contemplated in the attached Offering Circular in Sweden, who receives any communication in respect of, or who acquires any Company shares under, the offers contemplated in the attached Offering Circular will be deemed to have represented, warranted and agreed to and with each of the Joint Global Coordinators and the Company that:

- (a) it is a qualified investor as defined in the Prospectus Directive; and
- (b) in the case of any Company shares acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (i) such Company shares acquired by it in the Offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any relevant member state other than qualified investors, as that term is defined in the Prospectus Directive, or in circumstances in which the prior consent of the Joint Global Coordinators has been given to the offer or resale; or (ii) where such Company shares have been acquired by it on behalf of persons in any relevant member state other than qualified investors, the offer of those Company shares to it is not treated under the Prospectus Directive as having been made to such persons.

For the purposes of this representation, the expression an "offer" in relation to any of the Company's shares in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and any Company shares to be offered so as to enable an investor to decide to purchase any of the Company's shares, as the same may be varied in that relevant member state by any measure implementing the Prospectus Directive in that relevant member state, and the expression "Prospectus Directive" refers to Directive 2003/71/EC of the European Parliament and of the Council and includes any relevant implementing measure in each relevant member state (including implementing measures of Directive 2010/73/EU of the European Parliament and of the Council amending the Prospectus Directive, etc.).

The attached Offering Circular is being distributed only to and is directed only at, and any investment or investment activity to which the attached Offering Circular relates is available only to, and will be engaged in only with "qualified investors" (as defined in section 86(7) of the Financial Services and Markets Act 2000) and who are (i) persons having professional experience in matters relating to investments who fall within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order") or (ii) high net worth entities, and other persons to whom the attached Offering Circular may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). The Company's shares are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such Company shares will be engaged in only with, relevant persons. Persons who are not relevant persons should not take any action on the basis of the attached Offering Circular and should not act or rely on it.

The attached Offering Circular has been sent to you in an electronic form. You are reminded that documents transmitted via this medium may be altered or changed during the process of electronic transmission and consequently none of the Joint Global Coordinators, any person who controls any of the Joint Global Coordinators, the Company or the Principal Shareholder, any director, officer, employee or agent of any of them or any affiliate of any such person accepts any liability or responsibility whatsoever in respect of any difference between the attached Offering Circular distributed to you in electronic format and the hard copy version of such Offering Circular. Please ensure your copy is complete.

The materials relating to the offering do not constitute, and may not be used in connection with, an offer or solicitation in any place where offers or solicitations are not permitted by law. If a jurisdiction requires that the offering be made by a licensed broker or dealer and the Joint Global Coordinators or any affiliate of the Joint Global Coordinators is a licensed broker or dealer in that jurisdiction, the offering shall be deemed to be made by the Joint Global Coordinators or such affiliate on behalf of the Company and the Principal Shareholder in such jurisdiction.

The Company has furnished the information in the attached Offering Circular. The Joint Global Coordinators disclaim, to the fullest extent permitted by applicable law, any and all liability whether arising in tort, contract or otherwise which they might otherwise be found to have in respect of the attached Offering Circular or any such statement.

None of the Company, the Principal Shareholder or the Joint Global Coordinators, or any of their respective affiliates, representatives, advisers or selling agents, is making any representation to any offeree or purchaser of the Company's shares regarding the legality of an investment in the Company's shares. Each investor should consult with his or her own advisors as to the legal, tax, business, financial and related aspects of a purchase of the Company shares.

The Joint Global Coordinators are acting exclusively for Camurus AB (publ) and the Principal Shareholder and no one else in connection with the offer. They will not regard any other person (whether or not a recipient of this document) as their client in relation to the offer and will not be responsible to any other person for providing the protections afforded to their clients nor for giving advice in relation to the offer or any transaction or arrangement referred to herein.

You are responsible for protecting against viruses and other destructive items. Your receipt of this document and the attached Offering Circular via electronic transmission is at your own risk and it is your responsibility to take precautions to ensure that it is free from viruses and other items of a destructive nature.



## Invitation to acquire shares in Camurus AB (publ)

DISTRIBUTION OF THIS OFFERING CIRCULAR AND ACQUISITION OF SHARES IN CAMURUS ARE SUBJECT TO RESTRICTIONS IN CERTAIN JURISDICTIONS, PLEASE SEE THE SECTION ENTITLED "SELLING AND TRANSFER RESTRICTIONS ETC."

Joint Global Coordinators and Joint Bookrunners



Handelsbanken Capital Markets

### Important information

For definitions and the meaning of certain expressions used in the offering circular, see "Certain definitions" on the next page.

A separate prospectus in Swedish has been approved and registered by the Swedish Financial Supervisory Authority (the "SFSA") in accordance with Chapter 2, Sections 25 and 26 of the Swedish Financial Instruments Trading Act (1991:980) (Sw: lag (1991:980) om handel med finansiella instrument). Approval and registration do not imply that the SFSA guarantees that the information in the prospectus or this offering circular is accurate or complete.

The prospectus, this offering circular and the Offering are governed by Swedish law. Disputes arising out of the contents of the prospectus, this offering circular, the Offering and related legal matters shall be settled exclusively by the Swedish courts.

In the event of any conflict between the Swedish language prospectus and this offering circular, the Swedish version shall prevail.

In certain jurisdictions, distribution of this offering circular and participation in the Offering is subject to restrictions under law and other regulations. Camurus, the Principal Shareholder and the Joint Global Coordinators have not taken, and will not take any actions to allow a public offering in any jurisdiction other than Sweden. The offering is not made to persons resident in the United States, Canada, Japan, Australia or any other jurisdiction where participation would require additional prospectuses, registration or measures besides those required by Swedish law. Consequently, the offering circular, application forms or any other documents in respect of the Offering may not be distributed in or into the mentioned countries or any other country or any other jurisdiction in which distribution or the Offering require such measures or otherwise would be in conflict with regulations in such country or jurisdiction. Subscription or acquisition of shares in violation of the restrictions described above may be void. Recipients of this offering circular are required to inform themselves about, and comply with, such restrictions. Any failure to comply with the restrictions described may result in a violation of applicable securities regulations. See also "Selling and transfer restrictions etc.".

Certain risks apply when investments in shares are made (see the section entitled "Risk factors"). When an investor makes an investment decision, he or she must rely on his or her own analysis of Camurus and the Offering, including applicable facts and risks. Potential investors should, before making an investment decision, engage their own professional advisers and carefully evaluate and consider their investment decision. Investors may only rely on the information in this offering circular and any supplement(s) to this offering circular. No person is authorised to provide any information or make any statements other than those made in this offering circular, and should such information or statement nevertheless be provided or made it should not be considered to have been approved by Camurus, the Principal Shareholder or the Joint Global Coordinators, and none of them is responsible for such information or statements. Neither the publication or distribution of this offering circular or any transaction made in respect of the Offering shall be deemed to imply that the information this offering circular is accurate or applicable at any time other than on the date of the publication of this offering circular or that there have been no changes in Camurus' business since this date. If significant changes in the information in this offering circular occur, such changes will be announced in accordance with the provisions on prospectus supplements under the Swedish Financial Instruments Trading Act.

As a condition for subscribing or acquiring new shares under the Offering, each person applying to subscribe for or acquire new shares shall be deemed to have made or, in some cases, be required to make, certain representations and warranties that will be relied upon by Camurus, the Principal Shareholder and the Joint Global Coordinators and its contractors. See also "Selling and transfer restrictions etc.". Camurus, the Principal Shareholder and the Joint Global Coordinators reserve the right to declare null and void any subscription or acquisition for shares that they believe may give rise to a breach or violation of any law, rule or regulation in any jurisdiction.

The Joint Global Coordinators make no representation or warranty, explicit or implicit, as to the accuracy, completeness or verification of the information contained in the offering circular and the contents of the offering circular neither is nor shall be relied upon as a promise or representation by the Joint Global Coordinators in this respect, whether regarding the past or the future. The Joint Global Coordinators assume no liability for the accuracy, completeness or verification of the offering circular and the offering the past or the future. The Joint Global Coordinators assume no liability for the accuracy, completeness or verification of the offering circular and accordingly disclaim, to the greatest extent possible under applicable law, all liability that they otherwise may have been subject to for the information provided, regardless of whether such liability is based on contract law, tort law or other grounds.

#### Information to investors in the United States

The shares in Camurus have not been registered, and will not be registered, under the United States Securities Act of 1933 as amended (the "Securities Act") or the securities legislation of any state or other jurisdiction in the United States and may not be subscribed, offered, sold or otherwise transferred, directly or indirectly, in or into the United States except under an available exemption from, or a transaction not subject to, the registration requirements under the Securities Act and in compliance with the securities legislation in the relevant state or any other jurisdiction of the United States. The shares are being offered outside the United States in compliance with Regulation 5 under the Securities Act. A public offering will not be made in the United States. Any offering of the shares made in the United States will be made only to a limited number of investors who are deemed to be qualified institutional buyers as defined in Rule 144A under the Securities Act ("QIBs") in reliance on Rule 144A or pursuant to another available exemption from, or transaction not subject to, the registration requirements under the Securities Act. For a description of these and certain further restrictions regarding the shares and the distribution of this offering circular, see "Selling and transfer restrictions etc.". Prospective investors are hereby notified that Camurus and/or the Principal Shareholder may be relying on the exemption from the provision of Section 5 of the Securities Act.

The shares in Camurus have neither been approved nor rejected by the United States Securities and Exchange Commission (SEC), any state securities authority or any other authority in the United States. Furthermore, the foregoing authorities have not confirmed the Offering and the accuracy or determined the adequacy of this offering circular. To assert the contrary is a criminal offence in the United States.

#### NOTICE TO NEW HAMPSHIRE RESIDENTS ONLY

NEITHER THE FACT THAT A REGISTRATION STATEMENT OR AN APPLICATION FOR A LICENSE HAS BEEN FILED UNDER CHAPTER 421-B OF THE NEW HAMPSHIRE REVISED STATUTES ("RSA 421-B") WITH THE STATE OF NEW HAMPSHIRE NOR THE FACT THAT A SECURITY IS EFFECTIVELY REGISTERED OR A PERSON IS LICENSED IN THE STATE OF NEW HAMPSHIRE CONSTITUTES A FINDING BY THE SECRETARY OF STATE OF NEW HAMPSHIRE THAT ANY DOCUMENT FILED UNDER RSA 421-B IS TRUE, COMPLETE AND NOT MISLEADING. NEITHER ANY SUCH FACT NOR THE FACT THAT AN EXEMPTION OR EXCEPTION IS AVAILABLE FOR A SECURITY OR A TRANSACTION MEANS THAT THE SECRETARY OF STATE HAS PASSED IN ANY WAY UPON THE MERITS OR QUALIFICATIONS OF, OR RECOMMENDED OR GIVEN APPROVAL TO, ANY PERSON, SECURITY OR TRANSACTION. IT IS UNLAWFUL TO MAKE, OR CAUSE TO BE MADE, TO ANY PROSPECTIVE PURCHASER, CUSTOMER OR CLIENT, ANY REPRESENTATION INCONSISTENT WITH THE PROVISIONS OF THIS PARAGRAPH.

#### Information to investors in the EEA

No public offering of shares in Camurus is made to any countries within the European Economic Area ("EEA") other than Sweden. In other member states of the EEA which have implemented European Parliament and Council Directive 2003/71/EC (the "Prospectus Directive"), such offering may be made only under the exemption in the Prospectus Directive as well as every relevant implementation measure (including measures to implement European Parliament and Council Directive 2010/73/ EU). See also "Selling and transfer restrictions etc.".

#### Forward-looking information

The offering circular contains forward-looking information that reflects Camurus' present view of future events as well as financial and operational development. Words such as "intend", "assess", "expect", "may", "plan", "believe" and other expressions entailing indications or predictions of future development or trends, not based on historical facts, constitute forward-looking information. Forward-looking information is inherently associated with both known and unknown risks and uncertainties as it depends on future events and circumstances. Forward-looking information is not a guarantee of future results or development and actual outcomes may differ materially from the statements set forth in the forward-looking information.

Factors that may result in any difference in Camurus' future results and development from those set forth in the forward-looking information statements include, but are not limited to, those described in "Risk factors". Forward-looking information in this offering circular is only valid as per the date of the publication of this offering circular. Neither Camurus, the Principal Shareholder nor the Joint Global Coordinators undertake to announce any update or change in the forward-looking information as a result of new information, future events or similar circumstances other than as required by applicable laws and regulation.

#### Market and sector information

This offering circular contains certain market and sector information related to Camurus business and the market on which the Company is operating. Such information is based on the Company's analysis of several different sources.

Industry publications or reports often states that the information contained therein has been collected from sources considered to be reliable, however the accuracy and completeness of the information cannot be guaranteed. The Company has not independently verified, hence cannot guarantee, the accuracy in the market and sector information included in this offering circular that originates from such industry publications or reports. Inherently, market and sector information is forward-looking and therefore subject to uncertainty and do not necessarily reflect actual market conditions. Such information is based on market researches made on the basis of assortment and subjective assessments, including both the market researchers' and the respondents' assessments regarding what type of products and transactions that should be included in the relevant market.

The Joint Global Coordinators takes no responsibility for the accuracy of any market or sector information included in this offering circular. Information from third parties has been accurately reproduced and as far as the Company is aware of and can assure by comparing the information with other information published by the same third party, no facts have been omitted in a way which would render the reproduced information inaccurate or misleading.

## Presentation of financial information

Certain financial and other information that is presented in the offering circular has been rounded off in order to make the information more accessible for the reader. Consequently, in certain columns the numbers do not exactly correspond to the stated total amount.

#### Stabilisation

In connection with the Offering, Joint Global Coordinators may execute transactions aimed at supporting the market price of the shares at levels above those which might otherwise prevail in the open market. Such stabilisation measures may be executed on Nasdaq Stockholm, in the over-the-counter market or otherwise, at any time during the period starting on the date of commencement of trading in the shares on Nasdaq Stockholm and ending not later than 30 calendar days thereafter. See also "Stabilisation" in the section "Legal considerations and supplementary information".

The fact that Joint Global Coordinators have the possibility of implementing stabilisation measures does not mean that such measures will necessarily be taken. Furthermore, any such stabilisation measures that are undertaken may also be discontinued at any time. Once the stabilisation period (30 calendar days) has expired, Joint Global Coordinators will announce through the Company whether stabilisation measures were undertaken and, in that case, the dates on which those stabilisation measures were implemented, including the final date for such measures and the price range within which the stabilisation transactions were conducted.

#### Important information about the possibilities to sell allotted shares

Notifications about allotment to the general public in Sweden will be made through distribution of contract notes, expected to be distributed on or about 3 December 2015. After payments for the allotted shares have been processed by Carnegie or Handelsbanken, the duly paid shares will be transferred to the securities depository account or the securities account specified by the acquirer. The time required to transfer payments and transfer duly paid shares to the acquirers of shares in Camrus may imply that these acquirers will not have shares available in the specified securities depository account or the securities account specified securities depository account or the securities account or should a December 2015, at the earliest. Trading in Camurus' shares on Nasdaq Stockholm is expected to commence on or about 3 December 2015. Please note that, accordingly, shares are not available in an acquirer's securities account or securities depository account until 7 December 2015. Please note that, accordingly, shares are not available in the spares commences, but only once the shares are available in the securities depository account or the secu

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## The offer in brief

**Price range** SEK 51-61 per share

Application period for institutional investors 20 November – 2 December 2015

Announcement of Offering price 3 December 2015

First day of trading in the Camurus' shares 3 December 2015

## Settlement date

7 December 2015

## **Other information**

Ticker:	CAMX
ISIN code:	SE0007692850

## Financial calendar

Year-end report 2015:	17 February 2016
Annual general meeting:	3 May 2016
Interim report January-March 2016:	17 May 2016
Interim report January-June 2016:	14 July 2016

## **Certain definitions**

In this offering circular, the following definitions are used:

"Camurus" or the "Company" refers to either Camurus AB (publ) (Reg. No. 556667-9105) or the group of which Camurus AB is the parent company, as the context requires.

"Carnegie" refers to Carnegie Investment Bank AB.

The "Offering" refers to the offer to acquire shares in Camurus, in accordance with this offering circular.

"**Cornerstone Investors**" refers to Backahill Utveckling AB, Catella Fondförvaltning AB, Fjärde AP-fonden, Gladiator and Grenspecialisten Förvaltning AB.

"Euroclear Sweden" refers to Euroclear Sweden AB.

The "Principal Shareholder" refers to Sandberg Development AB, Reg. No. 556091-0712.

"Handelsbanken" refers to Handelsbanken Capital Markets, a business area within Svenska Handelsbanken AB (publ), or Svenska Handelsbanken AB (publ), as applicable.

"Joint Global Coordinators" and "Joint Bookrunners" refers to Carnegie and Handelsbanken.

The "Group" refers to Camurus AB and its subsidiaries.

"Nasdaq Stockholm" refers to either the regulated market Nasdaq Stockholm or Nasdaq OMX Stockholm AB, as the context requires.

"SEK", "EUR" and "USD" refers to Swedish kronor, euro and United States dollars, respectively. K refers to thousand and M refers to millions.

## Summary

Prospectus or offering circular summaries consist of information requirements presented in "items". The items are numbered in sections A–E (A.1–E.7).

The summary in this offering circular includes all of the items required in a summary for the relevant type of security and issuer. However, since certain items are not applicable to all types of prospectuses or offering circulars, there may be gaps in the numbering of the items.

Even if an item is required to be included in the summary for the relevant type of security and issuer, it is possible that no relevant information can be provided regarding the item. In such case, the information is replaced by a brief description of the item together with the indication "not applicable".

Sectio	n A – Introduction	and warnings
A.1	Introduction and warnings	This summary should be read as an introduction to the offering circular. Any decision to invest in the securities should be based on consideration of the offering circular as a whole by the investor. Where a claim relating to the information in this offering circular is brought before a court, the plaintiff investor might, under the national legislation of the Member States, have to bear the costs of translating the offering circular before the legal proceedings are initiated. Civil liability may attach to those persons who produced the summary, including any translation thereof, only if the summary is misleading, inaccurate or inconsistent with other parts of the offering circular or if, together with other parts of the offering circular, it fails to provide key information to help investors when considering investing in such securities.
A.2	Consent to use of the offering circular	Not applicable. Financial intermediaries are not entitled to use the offering circular for subsequent resale or final placement of securities.

Sectio	on B – Issuer	
B.1	Legal and com- mercial name	The Company's name (also trading name) is Camurus AB.
B.2	Domicile and legal form	The Board of Directors is domiciled in Lund, Sweden. The Company is a Swedish public limited company, which is formed in Sweden and governed by the Swedish Companies Act (2005:551).
B.3	Nature of operations and principal activities	Camurus is an R&D-focused pharmaceutical company committed to the development and commercialisation of new and innovative products for the treatment of serious and chronic diseases. By combining its proprietary drug delivery technologies (such as the FluidCrystal® Injection depot) with active ingredients that have proven efficacy and safety profiles, the Company develops new and patented medicines with improved properties and treatment outcomes. These may be developed with significantly lower cost and risk, compared with the development of completely new medicines. Camurus has a well-diversified research portfolio which currently includes five products in clinical trials, and a number of additional product candidates in the pre-clinical phase. The Company is working on these projects both in-house and in collaboration with international pharmaceutical companies, including Novartis and Braeburn. In 2014, Camurus had net sales of SEK 208 million and profit before tax of SEK 62.5 million. The Company is based in Lund, Sweden, and had, as per 30 September 2015, 48 employees.
B.4a	Recent trends	Since a number of years the major pharmaceutical companies have become increasingly dependent on cooperating with small, research-based biotech and pharmaceutical companies, to develop projects in their early phases, a trend which has continued to contribute positively to Camurus' preclinical pipeline with a number of new and promising research and development cooperation programs. Furthermore, the trend of an ongoing change in the way European authorities view opioid dependence, with increased possibilities for opioid dependent patients to combine medical treatment with other suitable care in order to return to a normal way of life, positively affects Camurus and the Company's planned commercialization of CAM2038 for opioid dependence on selected European markets.
B.5	The Group	Camurus is the parent company of the Group, which comprises four legal entities in two countries.

	Major shareholders, etc.	In Sweden, the lowest threshold for of all shares or voting rights in resp corresponding to at least five perc	pect of all shares. S	hown below are th	ne Company's sh	areholders	with holdings
		Shareholder				ber of	Percentage of shares and voting rights, %
		Sandberg Development AB			21,5	61,048	85.5
		Fredrik Tiberg			1,5	69,820	6.2
		Other shareholders			2,0	77,692	8.3
		Total			25,2	08,560	100
		Assuming that the Offering price i Offering own a minimum of 53.4 and a maximum of 57.9 percent o that the Principal Shareholder will are subject to approval from Came	percent of the share f the shares in Cam continue to have a	es in Camurus (if th urus (if the Overall	ne Overallotmen otment Option i	t Option is s not exerci	fully exercised) ised). This means
	2.7 Selected historical financial information	audited financial statements for th Act, IFRS, and RFR 1 <i>Supplementa</i> September 2014 and 2015 is deriv prepared in accordance with IAS 3 been reviewed by the Company's The offering circular contains cer assessment that these non-IFRS m The non-IFRS measures have not b	ry Accounting Rule: ed from Camurus' i4 Interim Financial auditors. 'tain financial key fi easures provides a	s for Groups. The i interim financial re <i>Reporting</i> and the gures that are non better understand	nformation rega port for the peri- Annual Account -IFRS measures. ing of the econo	rding the p od January ts Act. The It is the Co mic trends	eriod January- -September 2015 interim report ha ompany's of the Company.
		measures.			ered independer	itiy or to re	eplace IFKS
		measures. Consolidated statement of com	prehensive incon	ne	· · ·	-	
		measures. Consolidated statement of com SEK thousand	prehensive incon Jan-Sep 2015	ne Jan-Sep 2014	2014	201	3 2012
		measures. Consolidated statement of com SEK thousand Net sales	prehensive incon Jan-Sep 2015 118,459	ne Jan-Sep 2014 63,330	<b>2014</b> 208,207	<b>201</b> 197,71	3 2012 6 95,204
		measures. Consolidated statement of com SEK thousand	prehensive incon Jan-Sep 2015	ne Jan-Sep 2014	2014	201	<b>3 2012</b> 6 95,204 5 -3,321
		measures. Consolidated statement of com SEK thousand Net sales Cost of goods sold	<b>prehensive incon</b> Jan-Sep 2015 118,459 -132	ne Jan-Sep 2014 63,330 -523	<b>2014</b> 208,207 -656	<b>201</b> 197,71 -1,57	<b>3 2012</b> 6 95,204 25 -3,321 11 <b>91,883</b>
		measures. Consolidated statement of com SEK thousand Net sales Cost of goods sold Gross profit	Jan-Sep 2015 118,459 -132 118,327	ne Jan-Sep 2014 63,330 -523 62,807	<b>2014</b> 208,207 -656 <b>207,551</b>	<b>201</b> 197,71 -1,57 <b>196,14</b>	<b>3 2012</b> 6 95,204 15 -3,321 11 <b>91,883</b> 11 -2,385
		measures. Consolidated statement of com SEK thousand Net sales Cost of goods sold Gross profit Marketing and distribution costs	Jan-Sep 2015 118,459 -132 118,327 -12,425	ne Jan-Sep 2014 63,330 -523 62,807 -6,555	2014 208,207 -656 207,551 -11,402	<b>201</b> 197,71 -1,57 <b>196,14</b> -3,82	3         2012           6         95,204           '5         -3,321           11         91,883           '1         -2,385           '5         -14,505
		measures. Consolidated statement of com SEK thousand Net sales Cost of goods sold Gross profit Marketing and distribution costs Administrative expenses	<b>Jan-Sep 2015</b> 118,459 -132 <b>118,327</b> -12,425 -18,712 -111,940 41	ne Jan-Sep 2014 63,330 -523 62,807 -6,555 -15,996	<b>2014</b> 208,207 -656 <b>207,551</b> -11,402 -22,165	<b>201</b> 197,71 -1,57 <b>196,14</b> -3,82 -17,77	3         2012           6         95,204           '5         -3,321           11         91,883           '1         -2,385           '5         -14,505           '5         -54,818           -6         114
		measures. Consolidated statement of com SEK thousand Net sales Cost of goods sold Gross profit Marketing and distribution costs Administrative expenses Research and development costs Other operating income Other operating expenses	<b>Jan-Sep 2015</b> 118,459 -132 <b>118,327</b> -12,425 -18,712 -111,940 41 -904	ne Jan-Sep 2014 63,330 -523 62,807 -6,555 -15,996 -73,062	2014 208,207 -656 207,551 -11,402 -22,165 -114,146	<b>201</b> 197,71 -1,57 <b>196,14</b> -3,82 -17,77 -52,67 5,44	3         2012           6         95,204           '5         -3,321           11         91,883           :1         -2,385           :5         -14,505           :5         -54,818
		measures. Consolidated statement of com SEK thousand Net sales Cost of goods sold Gross profit Marketing and distribution costs Administrative expenses Research and development costs Other operating income	<b>Jan-Sep 2015</b> 118,459 -132 <b>118,327</b> -12,425 -18,712 -111,940 41 -904	ne Jan-Sep 2014 63,330 -523 62,807 -6,555 -15,996 -73,062 86	<b>2014</b> 208,207 -656 <b>207,551</b> -11,402 -22,165 -114,146 2,481	<b>201</b> 197,71 -1,57 <b>196,14</b> -3,82 -17,77 -52,67 5,44	3         2012           6         95,204           75         -3,321           11         91,883           11         -2,385           15         -14,505           15         -54,818           16         114           -         -1,527
		measures. Consolidated statement of com SEK thousand Net sales Cost of goods sold Gross profit Marketing and distribution costs Administrative expenses Research and development costs Other operating income Other operating expenses Operating profit/loss before item	<b>Jan-Sep 2015</b> 118,459 -132 <b>118,327</b> -12,425 -18,712 -111,940 41 -904	ne Jan-Sep 2014 63,330 -523 62,807 -6,555 -15,996 -73,062 86 -1,567	<b>2014</b> 208,207 -656 <b>207,551</b> -11,402 -22,165 -114,146 2,481	<b>201</b> 197,71 -1,57 <b>196,14</b> -3,82 -17,77 -52,67 5,44	3         2012           6         95,204           75         -3,321           11         91,883           11         -2,385           15         -14,505           15         -54,818           6         114           -         -1,527
		measures. Consolidated statement of com SEK thousand Net sales Cost of goods sold Gross profit Marketing and distribution costs Administrative expenses Research and development costs Other operating income Other operating expenses Operating profit/loss before item affecting comparability	Jan-Sep 2015 118,459 -132 118,327 -12,425 -18,712 -111,940 41 -904 15 -25,613	ne Jan-Sep 2014 63,330 -523 62,807 -6,555 -15,996 -73,062 86 -1,567	<b>2014</b> 208,207 -656 <b>207,551</b> -11,402 -22,165 -114,146 2,481	<b>201</b> 197,71 -1,57 <b>196,14</b> -3,82 -17,77 -52,67 5,44	3         2012           6         95,204           '5         -3,321           11         91,883           '1         -2,385           '5         -14,505           '5         -54,818           -6         114           -         -1,527           6         18,761           -         -
		measures. Consolidated statement of com SEK thousand Net sales Cost of goods sold Gross profit Marketing and distribution costs Administrative expenses Research and development costs Other operating income Other operating expenses Operating profit/loss before item affecting comparability Items affecting comparability	Jan-Sep 2015 118,459 -132 118,327 -12,425 -18,712 -111,940 41 -904 15 -25,613 -138,075	ne Jan-Sep 2014 63,330 -523 62,807 -6,555 -15,996 -73,062 86 -1,567 -34,287	2014 208,207 -656 207,551 -11,402 -22,165 -114,146 2,481 - -	201 197,71 -1,57 196,14 -3,82 -17,77 -52,67 5,44 127,31	3         2012           6         95,204           '5         -3,321           11         91,883           '1         -2,385           '5         -14,505           '5         -54,818           -6         114           -         -1,527           6         18,761
		measures. Consolidated statement of corr SEK thousand Net sales Cost of goods sold Gross profit Marketing and distribution costs Administrative expenses Research and development costs Other operating income Other operating expenses Operating profit/loss before item affecting comparability Items affecting comparability Operating profit/loss	Jan-Sep 2015 118,459 -132 118,327 -12,425 -18,712 -111,940 41 -904 15 -25,613 -138,075 -163,688	ne Jan-Sep 2014 63,330 -523 62,807 -6,555 -15,996 -73,062 86 -73,062 86 -1,567 -34,287 - -34,287	2014 208,207 -656 207,551 -11,402 -22,165 -114,146 2,481 - - 62,319	201 197,71 -1,57 196,14 -3,82 -17,77 -52,67 5,44 127,31	3         2012           6         95,204           '5         -3,321           '1         91,883           :1         -2,385           :5         -14,505           :5         -54,818           :6         114           -         -1,527           6         18,761           -         -           6         18,761           :3         1
		measures. Consolidated statement of com SEK thousand Net sales Cost of goods sold Gross profit Marketing and distribution costs Administrative expenses Research and development costs Other operating income Other operating expenses Operating profit/loss before item affecting comparability Items affecting comparability Derating profit/loss Finance income	Jan-Sep 2015 118,459 -132 118,327 -12,425 -12,425 -18,712 -111,940 41 -904 15 -25,613 -138,075 -163,688	ne Jan-Sep 2014 63,330 -523 62,807 -6,555 -15,996 -73,062 86 -1,567 -34,287 - -34,287 393	2014 208,207 -656 207,551 -11,402 -22,165 -114,146 2,481 - 62,319 - 62,319 -	201 197,71 -1,57 196,14 -3,82 -17,77 -52,67 5,44 127,31 127,31	3       2012         6       95,204         75       -3,321         11       91,883         121       -2,385         15       -14,505         15       -54,818         6       114         -       -1,527         6       18,761         -       -         6       18,761         13       1         1       -902
		measures. Consolidated statement of com SEK thousand Net sales Cost of goods sold Gross profit Marketing and distribution costs Administrative expenses Research and development costs Other operating income Other operating expenses Operating profit/loss before item affecting comparability Items affecting comparability Finance income Finance expenses	Jan-Sep 2015 Jan-Sep 2015 118,459 -132 118,327 -12,425 -18,712 -111,940 41 -904 15 -25,613 -138,075 -163,688 1 -21	ne Jan-Sep 2014 63,330 -523 62,807 -6,555 -15,996 -73,062 86 -1,567 -34,287 -34,287 -393 -108	2014 208,207 -656 207,551 -11,402 -22,165 -114,146 2,481 - - 62,319 - 62,319 - 394 -170	201 197,71 -1,57 196,14 -3,82 -17,77 -52,67 5,44 127,31 127,31 7 -127,31	3         2012           6         95,204           '5         -3,321           '1         91,883           '1         -2,385           '5         -14,505           '5         -54,818           -6         114           -         -1,527           6         18,761           -         -           6         18,761           '3         1           :1         -902           8         -901
		measures. Consolidated statement of com SEK thousand Net sales Cost of goods sold Gross profit Marketing and distribution costs Administrative expenses Research and development costs Other operating income Other operating expenses Operating profit/loss before item affecting comparability Items affecting comparability Items affecting profit/loss Finance income Finance expenses Net financial items	Jan-Sep 2015 118,459 -132 118,327 -12,425 -18,712 -111,940 41 -904 15 -25,613 -138,075 -163,688 1 -21 -20	ne Jan-Sep 2014 63,330 -523 62,807 -6,555 -15,996 -73,062 86 -1,567 -34,287 - -34,287 - 393 -108 285	2014 208,207 -656 207,551 -11,402 -22,165 -114,146 2,481 - 62,319 - 62,319 - 394 -170 224	201 197,71 -1,57 196,14 -3,82 -17,77 -52,67 5,44 127,31 127,31 7 -12 -12 -4	3       2012         6       95,204         '5       -3,321         '1       91,883         '1       -2,385         '5       -14,505         '5       -54,818         .6       114         -       -1,527         6       18,761         .3       1         :1       -902         :8       -901         :8       17,860

I .		Summary consolidated balance					
	historical financial	SEK thousand	30 September, 2015	30 September, 2014	31 December, 2014	31 December, 2013	31 December 2012
	nformation,	ASSETS					
c	continued	Fixed assets					
		Intangible assets	21,344	21,902	22,551	20,723	7,421
		Tangible assets	6,566	6,035	7,119	3,176	2,461
		Financial assets	27,936	3,653	406	406	406
		Total fixed assets	55,846	31,590	30,076	24,305	10,288
		Current assets					
		Inventories	2,570	3,126	702	3,688	2,270
		Current receivables					
		Receivables from Group companies	-	-	157,908	70,664	37,049
		Trade receivables	27,792	25,199	6,118	7,790	4,408
		Other receivables	2,149	2,636	1,883	2,305	2,282
		Prepayments and accrued income	9,516	1,599	10,925	2,305	1,105
		Cash and cash equivalents	112,347	49	56	2,055	1,103
		Total current assets	154,374	32,609	177,592	87,351	47,117
		TOTAL ASSETS	210,220	64,199	207,668	111,656	57,405
		EQUITY					
		Share capital	630	583	630	583	583
		Other contributed capital	58,634	33,617	58,634	33,617	33,617
		Retained earnings, including profit/ loss					
		for the period	43,801	-10,675	64,193	15,847	6,010
		TOTAL EQUITY	103,065	23,525	123,457	50,047	40,210
		LIABILITIES					
		Long-term liabilities	-	-	8,079	4,577	1,762
		Short-term liabilities	107,155	40,673	76,132	57,032	15,434
		Liabilities to Group companies	2	12,712	1,697	508	382
		Trade payables	14,177	5,785	9,938	7,769	6,288
		Deferred tax liabilities	458	344	458	-	
		Income taxes	8,936	-	9,600	0	(
		Other liabilities	1,292	1,595	1,287	1,172	1,031
		Accrued expenses and deferred income	82,290	20 227	ED 1ED	17 600	7,733
		Total short-term liabilities	107,155	20,237 40,673	53,152 76,132	47,583 57,032	15,434
		TOTAL EQUITY AND LIABILITIES	210,220	64,199	207,668		57,405
		Summary consolidated stateme					
		SEK thousand	Jan-Sep 2015	Jan-Sep 2014	2014	2013	2012
		Cash flow from operating activities	-45,195	-77,222	69,429	163,064	24,735
		Cash flow from investing activities	157,486	65,710	-94,442	-48,446	
		Cash flow from financing activities	-	11,556	25,064		
		Net cash flow for the period	112,291	44			
		Cash and cash equivalents at beginning of period	56	5	5		
		Cash and cash equivalents at end of period	112,347	49	56		

.7 Selected historical financial informatio continued	torical ancial ormation,	Key figures and data per share IFRS measures Audited information for financial years September 2015, together with compa reviewed).				,	
			Jan-Sep 2015	Jan-Sep 2014	2014	2013	2012
		Net sales, SEK thousand	118,459	63,330	208,207	197,716	95,204
		Operating profit/loss before items affecting comparability, SEK thousand	-25,613	-34,287	62,319	127,316	18,761
		Operating profit/loss, SEK thousand	-163,688	-34,287	62,319	127,316	18,761
		Cash and cash equivalents, SEK thousand <sup>1</sup>	112,347	49	56	5	3
		Equity, SEK thousand	103,065	23,525	123,457	50,047	40,210
		Total assets, SEK thousand	210,220	64,199	207,668	111,656	57,405
		Earnings per share before dilution, SEK <sup>2</sup>	-20.26	-4.55	8.24	17.01	2.28
		Earnings per share after dilution, SEK <sup>2</sup>	-20.26	-4.55	7.67	15.75	2.11
		Average number of shares	6,302,140	5,835,310	5,864,727	5,835,310	5,835,310
		Average diluted number of shares	6,458,579	6,302,140	6,302,140	6,302,140	6,302,140
		Non-IFRS measures Please note that the table and calculat	ions below have	not been audited			
		Please note that the table and calculat R&D costs in percentage of operating	Jan-Sep 2015	Jan-Sep 2014	2014	2013	2012
		Please note that the table and calculat R&D costs in percentage of operating expenses <sup>1</sup>	Jan-Sep 2015 78%	Jan-Sep 2014 76%	<b>2014</b> 77%	71%	76%
		Please note that the table and calculat R&D costs in percentage of operating expenses <sup>1</sup> Equity/assets ratio, % <sup>2</sup>	Jan-Sep 2015 78% 49%	Jan-Sep 2014 76% 37%	<b>2014</b> 77% 59%	71% 45%	76% 70%
		Please note that the table and calculat R&D costs in percentage of operating expenses <sup>1</sup> Equity/assets ratio, % <sup>2</sup> Equity per share, SEK <sup>3</sup>	Jan-Sep 2015 78% 49% 16.35	Jan-Sep 2014 76% 37% 4.03	<b>2014</b> 77% 59% 19.59	71% 45% 8.58	76% 70% 6.89
		Please note that the table and calculat R&D costs in percentage of operating expenses <sup>1</sup> Equity/assets ratio, % <sup>2</sup> Equity per share, SEK <sup>3</sup> Diluted equity per share, SEK <sup>3</sup>	Jan-Sep 2015 78% 49% 16.35 15.19	Jan-Sep 2014 76% 37% 4.03 3.73	<b>2014</b> 77% 59% 19.59 19.59	71% 45% 8.58 7.94	76% 70% 6.89 6.38
		Please note that the table and calculat R&D costs in percentage of operating expenses <sup>1</sup> Equity/assets ratio, % <sup>2</sup> Equity per share, SEK <sup>3</sup> Diluted equity per share, SEK <sup>3</sup> Number of employees at end of period	Jan-Sep 2015 78% 49% 16.35	Jan-Sep 2014 76% 37% 4.03	<b>2014</b> 77% 59% 19.59	71% 45% 8.58	76% 70% 6.89
		Please note that the table and calculat R&D costs in percentage of operating expenses <sup>1</sup> Equity/assets ratio, % <sup>2</sup> Equity per share, SEK <sup>3</sup> Diluted equity per share, SEK <sup>3</sup>	Jan-Sep 2015 78% 49% 16.35 15.19	Jan-Sep 2014 76% 37% 4.03 3.73	<b>2014</b> 77% 59% 19.59 19.59	71% 45% 8.58 7.94	76% 70% 6.89 6.38
		Please note that the table and calculat R&D costs in percentage of operating expenses <sup>1</sup> Equity/assets ratio, % <sup>2</sup> Equity per share, SEK <sup>3</sup> Diluted equity per share, SEK <sup>3</sup> Number of employees at end of period Number of employees in R&D at end of	Jan-Sep 2015 78% 49% 16.35 15.19 48 35 d by operating ex at the end of the <b>mber 2015</b> ng significant cha respectively, ext ciation entailing to on a share split 4	Jan-Sep 2014 76% 37% 4.03 3.73 39 28 spenses (marketing period, basic and inges in Camurus traordinary genera that the Company :1, resolved on two	2014 77% 59% 19.59 19.59 43 28 and distribution diluted. 'financial or ma al meetings in t y has become a yo directed shar	71% 45% 8.58 7.94 36 29 n costs, administ arket position h he Company re public compan re issues as part	76% 70% 6.89 6.34 3 21 rative expen ave occurre solved to y and the c of the

Phase II study assessing the opioid blockade of CAM2038 on the effects of other opioids.

B.7	Selected historical financial information, continued	Significant changes during the period covered by the historical financial information Camurus had a net sales of SEK 118.5 million for the period January to September 2015, compared with SEK 63.3 million in the same period in 2014, which represents an increase of 87 percent. The increase in net sales was principally attributable to payments for completed activities related to clinical trials and for two development-related milestone payments from Novartis, each amounting to USD 2.5 million. Camurus' net sales increased from SEK 197.7 million in 2013 to SEK 208.2 million in 2014, which was an increase of 5.3 percent. The increase is partly related to a first development milestones of SEK 18.0 million from Novartis and revenues from the development work performed under the collaboration agreement. Licensing revenues decreased by SEK 21.2 million in 2014 compared with 2013, explained by the difference in revenues from the agreement with Braeburn in 2014 with those coming from the agreement with Novartis in 2013. Camurus' net sales amounted to SEK 197.7 million in 2013, compared to SEK 95.2 million in 2012, which is an increase of 107.7 percent. The increase in net sales was mainly attributable to Camurus receiving licensing revenues in the year in connection with Novartis exercising its option to acquire an exclusive global license for the development and commercialization of CAM2029 and, to a lesser extent, increased remuneration for development work.
B.8	Selected pro forma financial information	Not applicable. The offering circular contains no pro forma financial information.
В.9	Profit forecast	Not applicable. The offering circular contains no profit forecast or calculation of anticipated earnings.
B.10	Qualification of audit report	Not applicable. There are no qualifications of audit reports.
B.11	Insufficient working capital	It is Camurus' assessment that its current working capital is insufficient for the Company's current needs for the next twelve months. Camurus' working capital requirements mainly relate to the further development and expansion of its clinical project portfolio and its commercial operations according to plan, including the initiation of clinical phase III trials and the planned preparations for the commercialization of CAM2038 on selected European markets. The Company assesses that the working capital deficit for the next 12 months is in the range of SEK 215-245 million. The existing working capital is assessed to be sufficient to fund Camurus' operations through May 2016. In order to satisfy Camurus' working capital requirements, a new share issue, which is estimated to provide Camurus with approximately SEK 500 million after expenses relating to the Offering, is being carried out as part of the Offering. The Offering is conditional upon the new share issue providing Camurus with at least SEK 400 million after expenses relating to the Offering. After the new share issue is carried out, Camurus considers that the working capital will be sufficient for current needs for at least the next twelve months.

Sectio	n C – Securities	
C.1	Securities offered and admitted to trading	Shares in Camurus (ISIN code SE0007692850).
C.2	Currency	The shares are denominated in Swedish kronor, SEK.
C.3	Number of shares in the issuer	Camurus' registered share capital amounts to SEK 630,214, divided into 25,208,560 ordinary shares. All shares are paid-up in full. Each share has a quota value of SEK 0.025.
C.4	Rights attached to the securities	Each share entitles the holder to one vote at general meetings. If the Company resolves to issue new shares through a cash or set-off issue, or to issue warrants or convertible instruments, the shareholders shall as a general rule enjoy pre-emptive rights to subscribe pro rata to the number of shares previously held. All shares carry equal rights to the Company's earnings and any surplus in the event of liquidation. Resolutions on dividends are taken at the general meeting, and disbursement is effected through Euroclear Sweden. The entitlement to dividends vests in any person who, on the record day for dividends determined at the general meeting, is registered as a holder of shares in the share register maintained by Euroclear Sweden.

C.5	Restrictions on transferability	Not applicable. The shares are not subject to any restrictions on transferability.
C.6	Admission to trading	Camurus has applied for the Company's shares to be admitted to trading Nasdaq Stockholm. The estimated first day of trading is 3 December 2015.
C.7	Dividend policy	According to the dividend policy adopted by the Board, Camurus will continue to focus on further developing and expanding of the Company's clinical portfolio and the planned commercial activities, and available financial resources are intended to be used for the financing of this strategy. Hence, the intention of the Board is to not propose any dividend to shareholders until the Company generates a sustainable profitability.

Sect	tion D – Risks	
D.1	Key risks associ- ated with the issuer or the industry	Any investment in securities is associated with risk. Prior to any investment decision, it is important to carefully analyse the risk factors considered relevant to the future development of the Company and the share. Below are descriptions of the main industry and operations related risks.
		• Pharmaceutical development and projects in early stages of development: Camurus' projects require continued research and development, which are subject to standard risks that product development becomes delayed and that costs become higher than expected or that the products prove to be insufficiently effective or safe. The level of risk in the development of pharmaceuticals is generally high and a setback in any individual project could have a material adverse effect on Camurus.
		• Technology platform with limited regulatory validation: No product based on Camurus' FluidCrystal® Injection depot has yet achieved market approval. If products based on Camurus' technology were to display shortcomings in safety or efficacy, there is a risk that Camurus or its partners are forced to discontinue further development and commercialisation of one or several products based on this technology, which would have a material adverse effect on Camurus.
		• <b>Clinical trials:</b> Prior to launching a product candidate in the market, Camurus or its partner must carry out pre-clinical and clinical trials. The process usually requires extensive, costly and time-consuming study programs. Clinical product development can be affected by unforeseen delays, increased costs, unforeseen suspensions and unfavorable results, which would have a material adverse effect on Camurus.
		• Heavily dependent on the furthest advanced products: Camurus is dependent on the continued success of the products that are the furthest advanced in their development to market. Rejected applications for clinical trials or market approval for Camurus' products or assessments that the products cannot be successfully commercialised due to other reasons, could have a material adverse effect on the Company. Camurus' ability to receive milestone payments and generating revenue from product sales is also dependent to a significant extent on the continuation of successful clinical development and commercialisation of the furthest advanced products. Delays to or suspensions of these programs can have a material adverse effect on Camurus.
		• Product and technology collaborations with other pharmaceutical companies: Camurus is dependent
		upon agreements regarding development and commercialization of products. There is a risk that previously signed agreements are terminated or that Camurus is unsuccessful in signing other such agreements in the future. Camurus' ability to realise the value of its products could be delayed or hindered by the absence of such partnership agreements. Furthermore, projects and collaborations can suffer delays for various reasons. The risks associated with out-licensing to other companies could delay, hinder or make the continued development or commercialisation of products more difficult, which could have a material adverse effect on Camurus.
		• <b>Regulatory review and registration of new pharmaceuticals:</b> A licence or approval must be obtained from the relevant authorities in order to commence and carry out clinical trials for a product or to market and sell a pharmaceutical. Obtaining licences and approvals can be time-consuming and can further delay, hinder or make the development and commercialisation of a product more expensive. If the necessary licence or registration is not obtained or is associated with unpredictable conditions, it will have an adverse impact on the ability to commence sales of the product, which in turn could have a material adverse effect on Camurus. The same applies if Camurus' or its partners do not meet the applicable regulatory requirements, and hence become subject to various sanctions.

D.1	Key risks as- sociated with the issuer or the industry, continued	• Commercialisation, market acceptance and dependence on reimbursement systems: If a pharmaceutical product obtains market approval, the risk remains that the product is not commercially successful. The degree of market acceptance and sales depend on a number of factors, including product properties, clinical documentation and results, competing products, distribution channels, availability, price, reimbursement, and sales and marketing efforts. Several of the risks related to the commercialisation and sales of products and reimbursement systems could lead to an adverse effect on Camurus.
		• Revenue from partners and licensees: As significant portion of Camurus' revenue is expected to comprise revenue from partners and licensees. All such revenue is dependent on the successful development of the product and it achieving the agreed development and regulatory milestones, and that it is subsequently launched and sold in the market. If a licensee were to decide to discontinue the development of a product or end sales of a product – and such a decision can be expected to be outside Camurus' control – Camurus' could be materially adversely affected.
		• Ability to manage growth and own commercialisation: If and when CAM2038 secure market approval, Camurus intends to pursue commercialisation of the products in selected markets in Europe and the rest of the world itself and therefore establish a proprietary sales and marketing organisation in certain selected markets in Europe. Camurus has not previously pursued any equivalent establishment. There is a risk that the process of establishing a proprietary marketing and sales organisation is more time-consuming and costly than the Company has estimated and that the expected sales successes fail to materialize, something that could lead to an adverse effect on Camurus.
		• Patents and other intellectual property rights: There is a risk that existing and future patents, trademarks and other intellectual property rights held by Camurus will not comprise full commercial protection from infringement and competition. The patent position of pharmaceutical companies is generally uncertain and comprises complex assessments. There is a risk that the measures taken by Camurus to protect their rights will not be sufficient. If Camurus is forced to defend its rights, this could entail significant costs and delays to product development. In addition, there is a risk that Camurus becomes involved in court cases for alleged infringement of other parties' rights. Infringement disputes can be have an adverse effect on Camurus' operations, earnings and financial position.
D.3	Key risks associated with the securities	Below is a description of the main risks related to the Offering and the shares in Camurus.
		• Share-related risk: Risks and risk-taking are an inevitable aspects of owning shares, and because a share investment can both rise and fall in value, it is not certain that an investor will recover the capital invested.
		• Shareholders with significant influence: The Principal Shareholder will continue to have a significant influence over Camurus and most resolutions that are subject to voting at the general meeting, and there is a risk that the Principal Shareholder's interests may differ or be contrary to the interests of other shareholders.
		• Future sales of large shareholdings and new share issues: Substantial sales of shares by major shareholders may affect Camurus' share price negatively and a new share issues could lead to a dilution of the ownership of shareholders.

Secti	Section E – Offering			
E.1	Net proceeds and expenses	The new share issue in the Offering is expected to raise approximately SEK 500 million for Camurus, after expenses relating to the Offering which are estimated to amount to no more than SEK 55 million. Camurus will not receive any revenues from the Principal Shareholder's sales of shares.		
E.2a	Reasons for the Offering and use of the issue proceeds	Over the past 10 years Camurus has taken decisive steps in developing the Company's unique lipid-based FluidCrystal® technology platform and in the establishment of a diversified and highly advanced patent-protected portfolio of drug products within commercially attractive indications. Camurus has entered into strategically important collaboration agreements with Novartis and Braeburn for the Company's two most advanced products, CAM2029 for the treatment of acromegaly and neuroendocrine tumours (NETs) and CAM2038 for the treatment of opioid dependence, which not only contribute financially to the continued development and future commercialization of these products, but also validate the Company's technology platform and business model. Camurus is now at the next stage of its development and growth, in which the Company, on its own and with its collaboration partners, will take its most advanced products through clinical phase III development to registration and market launch. Now that Camurus stands before growth and establishment on new markets, the Principal Shareholder believes that it is the right time to apply for the Company's shares to be listed on Nasdaq Stockholm. A listing of the shares is the next logical step for the Company and its business and provide Camurus with access to Swedish and international capital markets. The Principal Shareholder will remain an long-term large owner of the Company but will, in connection with the listing, sell those shares that the Principal Shareholder acquires in connection with the Offering as part of the completion of the Company's share bonus program. In order to support Camurus' above-stated objectives and overall strategic direction to expand and advance its pipeline of clinical stage products on its own and through strategic partnerships, the Company has decided to carry out a new share issue in connection with the listing on Nasdag Stockholm. If the issue is fully subscribed, the net proceeds from the new share issue are estimated to amount to approximately S		
E.3	Terms and conditions of the Offering	The Offering         The Offering is directed to the general public in Sweden <sup>1</sup> and to institutional investors <sup>2</sup> . The Offering comprises up to 12,288,065 shares in Camurus, representing approximately 32.0 percent of the total number of shares in the Company after the Offering.         Overallotment Option         The Principal Shareholder has provided an Overallotment Option to the Joint Global Coordinators, meaning that the Joint Global Coordinators, within 30 days following the first day of trading in the Company's shares on Nasdaq Stockholm, have the right to acquire up to an additional 1,843,210 shares from the Principal Shareholder, equivalent to a maximum of 15 percent of the total number of shares in the Offering at a price which is equivalent to the Offering price. The Overallotment Option may only be exercised in order to cover any potential overallotment within the Offering.         Book-building procedure       In order to establish a market-based pricing of the shares in the Offering, institutional investors will be given the opportunity to participate in a book-building procedure. The book-building procedure will take place between 20 November – 2 December 2015. The Offering price will be determined within the framework of this procedure. The book-building procedure for institutional investors may be terminated in advance or extended. Notice of any such termination or extension will be provided in a press release before the end of the book-building period. <sup>1</sup> The general public in Sweden comprises private individuals and legal entities in Sweden who apply for the acquisition of up to 10,000 shares.		

E.3	Terms and conditions of the Offering, continued	Offering price         The Offering price will be established in the book-building procedure described above and is expected to be set within the range of SEK 51–61 per share and is expected to be published in a press release on or about 3 December 2015. The Offering price to the general public (Sweden only) will not exceed SEK 61 per share. No commission will be charged. The price range has been established by the Board of Directors of the Company and the Principal Shareholder in consultation with Joint Global Coordinators based on the estimated investment interest from institutional investors.         Allotment of shares         Decisions about the allotment of shares to the general public (Sweden only) and institutional investors will be made by the Board of Directors of the Company and the Principal Shareholder in consultation with He Joint Global Coordinators, where the aim is to ensure that Camurus obtains a good institutional shareholder base and a wide distribution of the shares among the general public (Sweden only) in order to facilitate a regular and liquid trading in the Company's shares on Nasdaq Stockholm. Among the institutional investors, interest registered by institutional investors who are deemed to be possible long-term shareholders in the Company may be given priority. However, the Cornerstone Investors are guaranteed allotment in accordance with their respective undertakings.         Conditions for the completion of the Offering         The Offering raising a minimum of SEK 400 million after expenses relating to the Offering to the Company, that the placing agreement is entered into, that certain conditions in the placing agreement are fulfilled and that the placing agreement is not terminated. The Joint Global Coordinators may terminate the placing agreement up until the settlement date, 7 December 2015, if any material adverse ev
E.4	Interests material to the Offering	agreement is not fulfilled.Carnegie and Handelsbanken are Camurus' and the Principal Shareholder's financial advisors in connection with the Offering and the listing on Nasdaq Stockholm. These advisors (and companies closely related to them) have provided, and may in the future provide, various banking, financial, investment and commercial services and other services for which they have received, and may in the future receive, compensation. Employees and Board members of Camurus (except Per Sandberg) will at completion of the Offering receive a bonus from the Company paid in the form of shares in the Company. The share bonus comprises a total of 1,909,483 newly issued shares, which are received by the participants at a subscription price corresponding to the shares' quota value of SEK 0.025 per share, i.e. essentially free of charge, and are divided between employees and Board members in accordance with bonus agreements entered into. The implementation of the share bonus program is conditional upon the Offering being completed. The same applies to the Principal Shareholder's share acquisitions in connection with the share bonus program, comprising of a directed share issue to the Principal Shareholder and share purchases from participants in the share bonus program. Further, the Company's CEO Fredrik Tiberg and the Principal Shareholder have entered into an agreement under which Fredrik Tiberg transfers shares equivalent to an amount of SEK 7,142,857 to the Principal Shareholder, at a price corresponding to the final Offering price. The agreement is conditional upon the Offering being completed. Board member Per Sandberg owns all shares in PGS Group AB, which in turn owns all the shares in the Principal 

E.5	Seller of the securities and lock up agreement	In connection with the Offering, the Principal Shareholder, certain minority shareholders, share-owning Board members and senior executives undertake to the Joint Global Coordinators, subject to customary reservations, that they shall not sell their respective holdings during a certain period of time after trading on Nasdaq Stockholm has commenced. The lock up-period will be 540 days for the Company's CEO and 360 days for the others comprised by the lock up (including the Principal Shareholder), with the exception of Camurus Lipid Research Foundation for which the lock up-period will be 180 days. The Joint Global Coordinators may grant exemptions from the undertakings in question.
E.6	Dilution	Provided that the new share issue is fully subscribed and assuming an Offering price corresponding to the mid value of the price range (i.e. SEK 56), the number of shares in Camurus will increase by 9,910,714 from 27,544,644 to 37,455,358, which corresponds to a 36.0 percent dilution of the total number of shares in the Company after the Offering.
E.7	Expenses charged to the investor	Not applicable. Camurus and the Principal Shareholder will not impose any charges or taxes on investors.

## **Risk factors**

Any investment in securities is associated with risk. Prior to any investment decision, it is important to carefully analyse the risk factors considered relevant to the future development of Camurus and the share. Described below are the risks judged relevant to Camurus, in no particular order of importance. Risks exist relating both to circumstances attributable to Camurus or the sector, as well as those of a more general nature, and risks associated with the share and the new share issue. Certain risks are beyond Camurus' control. The presentation below does not claim to be exhaustive and, naturally, not all risk factors can be foreseen or described in detail, which is why an overall assessment must also include other information in the offering circular, as well as a general assessment of external circumstances. The following risks and uncertainties could have a material adverse effect on Camurus' operations, financial position and/or earnings. They could also contribute to Camurus declining in value, which could lead to shareholders in Camurus losing all or part of their invested capital. Additional factors currently unknown to Camurus, or currently not deemed to constitute risks, could also have an equivalent negative impact.

## **Risks related to the industry and operations**

## Pharmaceutical development and projects in early stages of development

Camurus currently has, either itself or together with partners, five projects that are in the clinical development phase and a number of projects in pre-clinical trials. The projects require continued research and development, which is subject to standard risks that product development becomes delayed and that costs become higher than expected or that the products prove to be insufficiently effective or safe at any stage of their development. Negative, unclear or insufficient results increase the risk of Camurus not obtaining the necessary regulatory approvals, and may also make it more difficult for the Company to sell the products in the market or enter into partnerships for the continued development, sale or distribution of the products. Accordingly, it may be difficult to evaluate and predict the time and cost aspects, and future sales potential. The level of risk in the development of pharmaceuticals is generally high and a setback in any individual project could have a material adverse effect on Camurus' operations and future revenue and thus Camurus' financial position and earnings.

## Technology platform with limited regulatory validation

Most of the pharmaceutical candidates developed by Camurus, on a proprietary basis or in partnership with international pharmaceutical companies, are based on the Company's lipid-based technology platform FluidCrystal® Injection depot, which can be used, for example, to extend the duration and release of pharmaceutical substances in the body. No product based on Camurus' FluidCrystal® Injection depot has yet achieved market approval. There is a risk that products based on the Company's Injection depot or its other technology platforms are delayed to market or never reach it, and that problems identified make it more difficult to produce, or enter into partnerships for, additional products with future commercial value.

The long duration that characterises products based on Camurus' Injection depot can potentially, in certain cases,

increase the risk of complications compared to if the drug compound were to be released immediately and work for a short time. If products based on Camurus' technology were to display shortcomings in safety or efficacy in ongoing or future clinical trials or in the market, there is a risk that Camurus or its partners decide, or are forced, to discontinue further development and commercialisation of one or several products based on this technology. This could have a material adverse effect on Camurus' operations and ability to generate revenue and thus weaken Camurus' financial position and future earnings.

## **Clinical trials**

Prior to launching a product candidate in the market, Camurus or its partner must carry out pre-clinical and clinical trials to document and prove that the product gives rise to significant efficacy and has an acceptable safety profile. The process usually requires extensive, costly and time-consuming pre-clinical and clinical trial programs. Positive results in previously completed pre-clinical and clinical trials do not guarantee positive results in later stages of development. Camurus is also unable to predict with any certainty when planned clinical trials can be started or when ongoing trials can be completed since these are circumstances that are affected by numerous different factors outside Camurus' direct control, for example, regulatory approval, research ethics committee review, access to patients and clinical trial units, performing the clinical trial at the trial unit and the considerations of Camurus' partners. It is also difficult to accurately predict the costs associated with clinical trials. Actual costs for carrying out a trial may significantly exceed estimated and budgeted costs. Clinical trials may also give rise to results that do not confirm the intended treatment efficacy or an acceptable safety profile due to undesirable side effects or an unfavourable risk-benefit assessment of the product. This could lead to clinical trials being discontinued or cancelled, or the product not being granted the necessary regulatory approval for further clinical trials or sale in the market. In certain cases, the development programme of the product in question may need to be expanded with additional pre-clinical and/or clinical trials to enable market registration.

In summary, clinical product development can be affected by unforeseen delays, increased costs, unforeseen suspensions and unfavourable results, which could have a material adverse effect on Camurus' operations and ability to generate revenue from its projects and thus weaken Camurus' financial position and future earnings.

## Heavily dependent on the furthest advanced products

To date, Camurus has invested a significant portion of its human and financial resources in research and development of the products that are the furthest advanced in their development to market. Camurus is dependent on the continued success of these products and on negative results not arising or negative decisions not being made on the continuation of product development. Examples of events that could have serious consequences for the Company are rejected applications for clinical trials or market approval for Camurus' products or assessments that the products cannot be successfully commercialised due to other reasons. Camurus' partner Novartis Pharma AG ("Novartis") has prepared Phase III trials of CAM2029 for the treatment of acromegaly and neuroendocrine tumours (NETs), which are scheduled to commence subject to Novartis' successful completion of manufacturing and confirmation of stability of the final prefilled syringe product format. Camurus' assessment is that the phase III programs for acromegaly and neuroendocrine tumours will be completed within 3.5 years from study start. The Company and its partner Braeburn Pharmaceuticals Inc. ("Braeburn") have recently secured approvals from authorities to start registration trials of CAM2038 for opioid dependence in both the US and in EU, and the first patients are expected to be enrolled in these trials before yearend 2015. Even to the extent that these trials are being carried out and paid for by Novartis and Braeburn, the risks described above are nevertheless relevant for Camurus.

Camurus' ability to finance the operations by receiving milestone payments and generating revenue from product sales is also dependent to a significant extent on the continuation of successful clinical development and commercialisation of the furthest advanced products. Delays to or suspensions of these programmes can be expected to significantly reduce Camurus' future revenue opportunities and thus also have a material adverse effect on Camurus' operations, financial position and earnings. Many of these risk factors that are associated with the continued development and commercialisation of the products are also outside Camurus' control (for example, the launch of competing products).

### **Dependence on suppliers**

Camurus and its partners engage and enter into agreements with external parties for parts of the product development, for example, the production of pharmaceutical substances, performance of clinical trials and certain laboratory services. There is always a risk that such external parties do not perform their services satisfactorily, that delays occur or that a product does not meet quantitative or quality requirements for some unknown reason. If this were to occur, continued product development could become more expensive, be delayed or be hampered, which could have an adverse effect on Camurus' operations, financial position and earnings.

The trials being carried out and future sales require production of active ingredients and other pharmaceutical ingredients in both sufficient qualities and of the requisite quality. There is a risk that these requirements will not be met at a reasonable cost or at the planned point in time. The production processes are often complex and are also vulnerable to contamination, which can make the continued development of a product more expensive, and delay or hamper such development. In certain cases, only one or a small number of established manufacturers of specialist ingredients included in the products based on Camurus' drug delivery technology exist. Camurus may be dependent on such manufacturers, to the extent that the manufacturing processes are deemed to be complex and time-consuming and thus difficult to transfer to another manufacturer. It could be costly and time-consuming if the need to change a manufacturer were to arise, and could entail a material adverse effect on Camurus' operations, financial position and earnings. For future commercial requirements, the aim is that critical ingredients and product manufacturing are to be provided by at least two manufacturers. There is a risk that it will not be possible to achieve this goal for all ingredients and products or that it does not reduce Camurus' dependence on individual manufacturers to the desired extent.

## Product and technology collaborations with other pharmaceutical companies

Product and technology collaborations are a key component of Camurus' strategy for increasing its development capacity and commercial penetration, and for achieving profitability. Examples of this are the agreements with Novartis for CAM2029 and other undisclosed products, and the agreement with Braeburn for CAM2038. During 2014 the revenues under the agreement with Novartis and Braeburn accounted for more than 90 percent of Camurus turnover. Camurus is dependent on agreements signed with these and other companies regarding the development and commercialisation of the products and in those markets encompassed by these agreements. There is a risk that previously signed agreements are terminated or that Camurus is unsuccessful in signing other such agreements in the future. Camurus' ability to realise the value of its products could be delayed or hindered by the absence of such partnership agreements. There is also the risk that differences of opinion arise between Camurus and its partners or that such partners do not meet their contractual commitments. Furthermore, projects and collaborations can suffer delays for various reasons, something that is a common occurrence in pharmaceutical development since the schedules prepared when partnerships are entered into are indicative in nature. For example, the development of CAM2029 is delayed in comparison with the indicative development plan from when the parties entered into the collaboration, option and licence agreement in December 2011. The delay is primarily

related to the transition to Novartis' final product format for CAM2029 with confirmed stability, and there is always the risk that development activities are delayed further, which if materialised would result in a materially adverse effect on Camurus' operations, financial position and earnings. In addition, there is a risk that Camurus' collaboration partners and licensees may prioritise the development of alternative products that might also compete with the products featured in the collaboration with Camurus. This can, in turn, reduce the ability and willingness of the licensee to fulfil its obligations regarding the development and commercialisation of products included in the collaboration with Camurus.

A licensing agreement typically entails that the partner takes over main responsibility for the further development and commercialisation of a product in a defined market. This is the case for CAM2029 globally and CAM2038 in North America, which means that Camurus may have limited ability to exercise influence over the licensee's or collaboration partner's future development and commercialisation activities. The risks associated with out-licensing to other companies could delay, hinder or make the continued development or commercialisation of products more difficult, which could adversely affect future revenue opportunities and thus have a material adverse effect on Camurus' operations, financial position and earnings.

## Regulatory review and registration of new pharmaceuticals

A licence or approval must be obtained from the relevant authorities in each country or region in order to commence and carry out clinical trials for or to market and sell a pharmaceutical product. Various licences and approvals are also required for the manufacture and distribution of a drug. Obtaining licences and approvals can be time-consuming and can further delay, hinder or make the development and commercialisation of a product more expensive, for example, due to differing opinions on which clinical trials are required for registration, even between the authorities of different countries, or manufacturing not being deemed to meet the applicable requirements. Authorities may make different assessments compared with Camurus and Camurus' partners, e.g. regarding the interpretation of data from trials or the quality of data. Changes in authorities' practices or procedures, as well as new or changed rules, may require additional work or ultimately result in the necessary licence not being obtained or withdrawn. In the US, part of the strategy for obtaining market approval for the Company's products, including CAM2029 and CAM2038, is to apply to the US Food and Drug Administration (FDA) for approval via a simplified drug approval pathway known as 505(b) (2), which is based on utilising existing and available data for the safety and efficacy of the active substance established for a reference product. This may entail that the scope of the preclinical and clinical registration programme could be reduced, since reference may be made to pre-existing data. A similar approval pathway called a hybrid application is also applied by the European Medicines Agency (EMA) in the EU. If the authorities do not believe that the products qualify for this procedure, additional clinical trials may need to be carried out to meet the requirements for market approval. This could mean that the development time is extended, that development costs significantly more and that development risk increases.

If the necessary licence or registration is not obtained or is associated with unexpected conditions, it will have an adverse impact on the ability to commence sales of the product, which in turn could have a material adverse effect on Camurus' ability to generate revenue and on Camurus' financial position.

Camurus and its partners will be liable to meet certain regulatory requirements even after a product has been approved for marketing, including requirements for safety reporting and supervision of the marketing of the products. There is a risk of product side effects being manifested which have not been identified to the same extent in the earlier clinical trials. Furthermore, the Company's manufacturer will be responsible for continuing to follow the rules that apply to the various stages of manufacturing, testing, quality control and documentation of the product in question. Production facilities will be regularly inspected by regulatory bodies, which could lead to observations and new production requirements. If Camurus or its partners, including external manufacturers, do not meet the applicable regulatory requirements, Camurus may be subject to fines, withdrawal of regulatory approval, recalls or seizure of products, other operational restrictions and criminal sanctions that could have a material adverse effect on Camurus' operations, financial position and earnings.

## Handling narcotic substances

The CAM2038 pharmaceutical candidate contains narcotics that are classified as "controlled substances" therefore are subject to special regulatory rules, for example, regarding their production, handling, import and export. Failure on the part of Camurus, its collaboration partners, contract manufacturers or distributors to comply with these requirements could entail administrative, civil or criminal sanctions that could have a material adverse effect on Camurus' operations, financial position and earnings. Furthermore, it may also be difficult to find alternative manufacturers since the number of potential manufacturers holding the necessary regulatory licences for producing drugs may be limited.

## Commercialisation, market acceptance and dependence on reimbursement systems

If a pharmaceutical product obtains market approval, the risk remains that sales, regionally or globally, may not meet expectations and that the product is not commercially successful. The degree of market acceptance and sales of a drug depend on a number of factors, including product properties, clinical documentation and results, competing products, distribution channels, availability, price, reimbursement, and sales and marketing efforts.

Sales of prescription drugs are influenced by the price set and obtained from the responsible authorities (such as the Dental and Pharmaceutical Benefits Agency in Sweden), from reimbursement payers and by healthcare payors, including insurance companies, hospitals and regionally responsible authorities. The reimbursement rate that, from time to time, applies for a pharmaceutical product often depends on the value that the product is deemed to add for the patient and the healthcare system. There is a risk that the products do not qualify for subsidies from privately and publicly financed healthcare programmes or that reimbursement is lower than expected, which among other things may affect the market acceptance of the product or the operating margin. Reimbursement systems may also change from time to time, making it more difficult to predict the benefit and reimbursement that a prescription product may obtain. Various initiatives are in place in many countries to curb rising pharmaceutical costs, which could affect future sales margins and product sales for Camurus and its partners. Such measures are expected to continue and could result in fewer reimbursement possibilities and lower reimbursement levels in certain markets.

Several of the risks related to the commercialisation and sales of products and reimbursement systems could lead to an adverse effect on Camurus' revenues, operations, and financial position and earnings. Several of these risks are beyond the Company's control.

## Competition

The pharmaceutical industry is highly competitive and is characterised by rapid and significant innovation. Camurus' competitors can range from large multinational pharmaceutical companies, established biotech companies, specialist pharmaceutical companies and generic companies, to universities and other research institutions. Many of Camurus' competitors could have significantly greater resources, including research and development organisations, and more established marketing and manufacturing organisations. As a result, these companies can often allocate more resources to carrying out clinical trials, obtaining market approval and launching, retailing and marketing their products. Furthermore, competition regarding individual products can be significant and competitors may develop and market drugs with higher efficacy, that are safer and/or less expensive than Camurus and its partners' products, which could have an adverse effect on the competitive position of Camurus and its partners.

Several other companies have developed or are also developing drug delivery technology for simplified pharmaceutical administration or for extended release of active drug compounds in the body that compete with or may compete with Camurus' various technology platforms, such as the FluidCrystal® Injection depot. Camurus' current and any future partners and customers may presumably be evaluating and potentially develop such technologies themselves. Rapid technological advancement could lead to competition heightening and intensifying, and to new drug delivery technologies with enhanced properties replacing or competing with Camurus' technology as regards one or more pharmaceutical products in the market or under development, which could have an adverse effect on Camurus' operations, financial position and earnings.

#### **Revenues from partners and licensees**

As significant portion of Camurus' revenues are expected to comprise revenues from partners and licensees. These revenues may comprise milestone payments, which are dependent on the further development and future sales of the product, and sales-based royalties. All such revenues are dependent on the successful development of the product and it achieving the agreed development and regulatory milestones, and that it is subsequently launched and sold in the market. The level of future sales of Camurus' and its partners' products is uncertain and can vary significantly due to a wide variety of reasons, such as clinical results and marketing. If a licensee were to decide to discontinue the development of a product or end sales of a product – and decision over which Camurus can be expected to have no control – Camurus' revenues and financial position could be materially adversely affected.

## Dependence on key personnel and qualified employees

Camurus is dependent on its personnel and a number of key individuals. If a key individual were to leave the Company, this could have a short or long-term adverse effect on the Company's projects and thus its operations, financial position and earnings. Camurus' ability to retain and recruit qualified employees is of great importance to Camurus' future success and growth potential and there is significant competition from, for example, other industry companies, universities and other institutions.

## Ability to manage growth and own commercialisation

In its collaboration with Braeburn on CAM2038, Camurus has decided to retain all development and commercialisation rights in all markets apart from North America, China, Japan, Taiwan and Korea. If and when the products secure market approval, Camurus intends to pursue commercialisation of the products in selected markets in Europe and the rest of the world itself. For this purpose, the Company intends to establish a proprietary marketing and sales organisation in certain selected markets in Europe. Camurus has not previously pursued any equivalent establishment or expansion of a marketing and sales organisation in or outside Europe.

There is a risk that the process of establishing a proprietary marketing and sales organisation is more time-consuming and costly than the Company has estimated and that expected sales fail to materialise, completely or in part. In addition to company-specific and geographic risks (such as exposure to different and potentially overlapping legal systems and costs for compliance with such systems), the establishment and expansion of a new marketing and sales organisation may impose rigorous demands on Group management and on the operational and financial infrastructure. Camurus' existing control, governance, accounting and information systems may prove to be insufficient for pursuing continued growth and additional investments in these areas may therefore be necessary. If Camurus proves to be unable to efficiently control or provide for continued growth, it could have an adverse impact on Camurus' operations, financial position and earnings.

## Product liability and insurance

Camurus' operations are subject to various forms of liability risks that are normal for operations that carry out research development, manufacturing and sale of, pharmaceutical products and medical devices. These include the risk of product liability claims that may arise in connection with manufacturing, clinical trials and the marketing and sale of products, for example, volunteers and patients participating in clinical studies or in some other manner coming into contact with the products and suffering from side effects or being injured.

Although Camurus normally transfers large parts of the product liability to its partners and licensees and takes out insurance to the extent that is commercially warranted to cover its own liability, the amount and the scope of insurance coverage is limited. There is a risk that applicable insurance policies do not provide sufficient coverage in the event of a potential claim for damages, which could have an adverse effect on Camurus' operations, financial position and earnings.

## IT risks

Camurus' ability to effectively and securely manage and store project-related information, results and reports from clinical trials, and other business-critical activities is dependent on its IT systems and related processes working efficiently and without interruption. Such systems can be disrupted by, for example, software and hardware problems, computer viruses, data intrusion, sabotage and physical damage. There is a risk that IT failure or other problems with IT systems, depending on their length, scope and severity, could adversely affect Camurus' operations, financial position and earnings.

### Legal risks

#### Patents and other intellectual property rights

Camurus has an active intellectual property rights strategy, whereby the Company endeavours to protect its platform technologies and products in all important global markets. There is a risk that existing and future patents, trademarks and other intellectual property rights held by Camurus will not provide full commercial protection from infringement and competition. The patent position of pharmaceutical companies is generally uncertain and comprises complex technical, medical and patent-law assessments. The pharmaceutical industry is also characterised by rapid technological advances and a high level of innovation. Accordingly, there is always the risk that new technologies and products are developed that could mean that Camurus' current and future intellectual property rights for technologies and products could be circumvented or replaced. Patents are, by their nature, limited in time. The patents of other companies can also limit opportunities for Camurus or licensees to freely use a certain product or production method. Since patent applications are confidential

until they are published, it could be the case that Camurus' patent applications are not prioritised in relation to previously unknown patent applications and patents. Furthermore, it is not certain that Camurus' patent applications will result in patents being granted or that patent protection has the same scope as was stated in the original application. There is a risk that granted patents are declared null and void, for example, in a dispute with a third party. Based on licensing agreements, Camurus' partners have certain rights to patents that encompass the products included in the agreement. As a result, these patents are not always or fully under Camurus' direct control. Future sales of, for example, CAM2029 and CAM2038 are partly dependent on Novartis' and Braeburn's ability to renew and maintain the appropriate patent protection. If Camurus' partners fail in this respect, it could have a material adverse effect on Camurus' ability to generate revenue.

Despite Camurus investing significant resources in protecting its patents, trademarks and other intellectual property rights and taking legal action when deemed appropriate, there is a risk that the measures taken will not be successful or sufficient. There is also the risk that competitors and others may, intentionally or unintentionally, infringe Camurus' patents, trademarks or other intellectual property rights. Laws and practice regarding the protection of intellectual property rights vary extensively between countries and Camurus' rights may thus be more vulnerable in some countries than in others. If Camurus is forced to defend its patents, trademarks and other intellectual property rights, this could entail significant costs and delays to product development. There is also the risk that Camurus can be considered to have unintentionally infringed another party's intellectual property rights. In addition, there is a risk that for unknown reasons Camurus becomes involved in court cases for alleged infringement of other parties' rights. Companies may also be subjected to baseless lawsuits regarding patent infringement. Infringement disputes can, similar to other types of disputes, be costly and time-consuming and thus have an adverse effect on Camurus' operations, earnings and financial position.

## Know-how and trade secrets

Camurus is dependent on know-how and trade secrets, which are not protected by registration in the same way as other intellectual property. To protect its know-how, Camurus uses for example confidentiality agreements, but unauthorized disclosure or unauthorized use of Company information – by competitors, business partners, consultants, employees, among others – could still occur. There is also a risk that competitors and others could independently develop similar know-how, which could be detrimental to Camurus' operations.

### Disputes and legal proceedings

Camurus may from time to time be the subject of legal proceedings related to its operating activities. Such legal proceedings, in addition to the disputes referred to above regarding intellectual property infringement and validity of certain patents, may also include commercial disputes. Disputes and claims can be time-consuming, disrupt operations, involve considerable sums or principally important issues and entail significant costs, and thus adversely affect the Company's operations, earnings and financial position.

## Tax risks

Camurus' conducts operations involving several countries. As far as Camurus knows, this is done in compliance with applicable tax laws for operations carried out both in Sweden and abroad, including intra-group transactions. However, there is a risk that Camurus' interpretation of these tax rules may be incorrect or that the laws may change, possibly with retroactive effect. As a result of decisions by Swedish and foreign tax authorities, Camurus' previous or current tax situation could therefore change, which could have a negative impact on Camurus' operations, earnings and financial position.

Furthermore, as a result of the collaboration and licensing agreements that Camurus has entered into, the Company must make complicated assessments relating, inter alia, to revenue recognition. Important assessments include whether an agreement should be divided into different sub-transactions, how to allocate the price of these transactions, how the timing of the transactions should be reported and in what way (on one occasion or over time). Camurus must also determine whether a collaboration and license agreement should be recognized as revenue upon delivery, or if the agreement involves a lease agreement to be recognized as revenue over time. There is a risk that the estimates and assumptions made for accounting purposes prove not to correspond to actual results, which in turn may mean that substantial adjustments are needed to the carrying values for profit, assets and liabilities in prior and future periods, something that could have a negative impact on Camurus' operations, earnings and financial position.

In connection with the payment of the share bonus which the employees and board members of Camurus will receive subject to the completion of the Offering, an obligation arises for Camurus to pay social security contributions based on the value of the share bonus, see "Share information". There is a risk that the estimated cost of these social security contributions that Camurus recognized as an item affecting comparability in the results for the interim period for January-September 2015 will prove to be higher than Camurus estimated, which could have a negative impact on Camurus' financial performance.

## Corporate governance and CSR risks

Camurus is subject to the risk that executives may make decisions that are not consistent with Camurus' strategies, internal guidelines and policy documents. Furthermore, employees within Camurus and other persons related to Camurus, as well as its partners, may perform acts that are considered unethical, are criminal (e.g. violation of applicable bribery and anticorruption legislation) or otherwise contrary to applicable laws and regulations or Camurus' internal guidelines and policy documents. If Camurus' internal controls and other measures to ensure compliance with laws, regulations, internal guidelines and policy documents prove to be insufficient, Camurus' reputation may be harmed or the Company may be affected by public law sanctions, which could result in an adverse effect on its operations, financial position and earnings.

## **Financial risks**

### Operating losses and additional financing needs

With the exception of the 2012-2014 financial years, Camurus has reported operating losses since the Company's operations started, and cash flow is deemed to remain neutral or negative until such time as Camurus can generate annual revenues from products in the market. Going forward, Camurus will continue to require significant capital for continuing research and development of potential products. Both the extent and timing of Camurus' future capital requirements will depend on a number of factors, such as costs for the operations, the potential success of research and development projects and opportunities for entering into partnership and licensing agreements, the timing for the receipt and amount of milestone payments and royalties, and the market reception of potential products. Access to and the terms and conditions for additional financing are influenced by several factors, such as market conditions, the general availability of credit and Camurus' credit rating and credit capacity. Turmoil and uncertainty in the credit and capital markets can also limit access to additional capital. If the Company chooses to obtain additional financing by issuing shares or share-based instruments, the Company's shareholders who do not participate will have their holdings diluted, while debt financing, if such is available to the Company, may contain terms and conditions that restrict the Company's operational and financial flexibility. There is a risk that new capital cannot be obtained when such needs arise, that capital cannot be obtained on favourable terms or that no capital at all can be acquired. If Camurus is unable to obtain financing as required, the Company may be required to significantly curtail one or more of its research or development programmes or ultimately discontinue operations.

### Exchange rate risk

Camurus is exposed to foreign exchange risk in the form of transaction exposure. Camurus is based in Sweden and reports its financial position and results in SEK. Transaction exposure arises from the purchase and sale of goods and services in currencies other than SEK. A large portion of Camurus' revenues and expenses are, and are expected in the future to remain, denominated in foreign currencies. Camurus' finance policy allows hedging instruments to be used, but if Camurus' measures to address the impact of exchange rate fluctuations do not prove to be sufficiently effective, Camurus' financial position and earnings could be adversely affected.

## Credit risk

Credit risk refers to the risk that Camurus' counterparties cannot meet their payment obligations and thereby create a loss for Camurus. If Camurus' measures to manage credit risk are inadequate, this may adversely affect Camurus' financial position and earnings.

## Risks related to the share and the Offering

## Share-related risk

Risks and risk-taking are inevitable aspects of owning shares. Since a share investment can both rise and fall in value, there is a risk that an investor will not recover the capital invested. The share price for listed companies can be very volatile and its development is dependent on a number of factors, some of which are company-specific while others are tied to the stock market as a whole. It is impossible for an individual company to control all of the factors that may affect its share price, and consequently any investment in shares should be preceded by a careful analysis.

Prior to the Offering, there has been no organized market for shares in Camurus. There is a risk that an active trading market will not develop for the shares or that, even if developed, it will not be maintained after completion of the Offering. It is possible that the Offering price, as determined by the Principal Shareholder and the Company's Board of Directors in consultation with Joint Global Coordinators, does not correspond to the shares' market price after the shares are listed on Nasdaq Stockholm. In addition, there is a risk that the liquidity and price of the shares are subject to large fluctuations in the stock market in general. Such fluctuations can occur regardless of how Camurus actually performs or the conditions in its main markets, and may adversely affect the liquidity and price of the shares.

Further, the trading market for the shares in Camurus will be influenced by the research and reports that securities or industry analysts publish about the Company (if any). If one or more of the analysts who cover the Company, or the industry in which it operates, downgrades the Company's shares, the market price of the shares may decline. If one or more of these analysts ceases coverage of the Company or fails to regularly publish reports on the Company, the Company could lose visibility in the financial and share markets, which could cause the market price or trading volume of the Company's shares to decline.

## **Future dividends**

Those participating in the Offering may be entitled to any future dividends resolved following the completion of the Offering. To receive such potential future dividends, the holder must be a registered owner of shares in Camurus on the record date determined by the general meeting or the Board of Directors. The size of any future dividends depends on Camurus' future earnings, financial position, cash flows, working capital requirements and other factors. Historically, no dividend has been paid and the intention is to not propose dividend to the shareholders, unless when and if a long-term profitability is achieved in Camurus. Hence, there is a risk that no dividend will be paid in the future.

## Shareholders with significant influence

Assuming that the Offering price is set at the mid value of the price range, the Principal Shareholder will after the Offering own a minimum of 53.4 percent and a maximum of 57.9 percent of the shares in Camurus, depending on if the Overallotment Option is exercised. This means that the Principal Shareholder will continue to have significant influence over Camurus and most resolutions that are subject to voting at the general meeting. Such matters include the election of board members, the issuance of additional shares and share-related securities that could entail dilution for existing shareholders and resolutions on dividends, if any. There is a risk that the Principal Shareholder's interests may differ or be contrary to the interests of other shareholders.

## Future sales of large shareholdings and new share issues

Substantial sales of shares by major shareholders, as well as a general market expectation that additional sales will be made, may affect Camurus' share price negatively. Moreover, new share issues would lead to a dilution of the ownership of shareholders who for some reason are unable to participate in such a new issue or do not choose to exercise their right to subscribe for shares. The same applies in the event that new shares are issued directed at others than existing shareholders.

The Principal Shareholder, certain minority shareholders, share-owning Board members and senior executives within Camurus have committed not to sell their shares in the Company for a period of time from the first day of trading. The lock up-period will be 540 days for the Company's CEO and 360 days for the others who are comprised by the lock up, with the exception of Camurus Lipid Research Foundation for which the lock up-period will be 180 days. Even if the lock up commitments limit the possibility for concerned shareholders to sell their shares, the Joint Global Coordinators may decide to lift the restrictions on the sale of shares during the respective lock up period. After the respective lock up period expires, concerned shareholders are also free to sell their shares in Camurus. The sale of large quantities of shares by the concerned shareholders, along with the perception that such sales could occur, may cause the price of the shares in Camurus to drop.

## The Cornerstone Investors may not fulfill their undertakings

The Cornerstone Investors have undertaken to acquire shares in the Offering corresponding to a total of SEK 240 million. Based on full subscription in the Offering, that the Overallotment Option is fully exercised and an Offering price corresponding to the mid value in the price range (i.e. SEK 56), the undertakings correspond to 4,285,714 shares, equal to 32.9 percent of the number of shares comprised by Offering and 11.4 percent of the total number of shares in the Company after the Offering. However, the Cornerstone Investors' undertakings are not secured through bank guarantees, blocked funds or pledges of collateral or similar arrangement, why there is a risk that the Cornerstone Investors will not be able to fulfill their undertakings. Furthermore, the Cornerstone Investors' undertakings are associated with certain conditions. In the event that any of these conditions are not fulfilled, there is a risk that the Cornerstone Investors do not fulfill their undertakings, which could negatively affect the completion of the Offering.

## Specific risks for foreign shareholders

Camurus' shares will only be quoted in SEK and any dividends will be paid in SEK. This means that shareholders outside Sweden may incur a negative effect on the value of holdings and dividends when these are translated into other currencies if the SEK decreases in value against the currency concerned.

If, in the future, Camurus issues new shares with preferential right for existing shareholders, shareholders in certain countries may be subject to limitations preventing them from participating in such new share issues or otherwise impeding or limiting their participation. For example, shareholders in the United States may be prevented from exercising such preferential right unless an exemption from the registration requirements of the Securities Act is applicable. Shareholders in other jurisdictions outside Sweden may also be affected in a corresponding manner. To the extent that shareholders in jurisdictions other than Sweden are unable to subscribe for new shares in any rights issues, their proportionate ownership in Camurus will decrease.

## The Offering

In order to promote Camurus' continued growth and development, the Board of Directors of Camurus and the Principal Shareholder have decided to carry out a new share issue in the Company and also broaden the shareholder base by selling existing shares. In order to provide the broadened shareholder base with the necessary conditions for appropriate trade in Camurus shares and to provide the Company with access to Swedish and international capital markets, Camurus' Board of Directors has also decided to apply for the Company's shares to be traded on Nasdag Stockholm.

The Offering comprises between 9,098,361 and 10,882,353 newly issued shares in Camurus and 1,405,712 of the Principal Shareholder's existing shares in Camurus, in total between 10,504,073 and 12,288,065 shares. The newly issued shares are offered by the Company, and the Principal Shareholder is selling those shares which the Principal Shareholder acquirus in direct connection with the Offering as a part of the completion of the Company's share bonus program. The Offering consists of two parts; an offering to the general public in Sweden and an offering to institutional investors.<sup>1</sup>

The Offering price (and thereby the exact number of shares in the Offering) will be established through a book-building procedure and will therefore be based on demand and general market conditions. The Offering price will be established by the Company's Board and the Principal Shareholder in consultation with Joint Global Coordinators and is expected to be established in the range of SEK 51 to SEK 61 per share, based on the order book prepared in the book-building process. The Offering price to the general public (Sweden only) will not exceed SEK 61. The final Offering price is expected to be published in a press release around 3 December 2015.

As part of the Offering, an extraordinary general meeting of the Company on 18 November 2015 resolved to increase the share capital in the Company through a new share issue, with authorization for the Board of Directors to determine the final terms. The new share issue is expected to raise around SEK 500 million for Camurus after expenses related to the Offering<sup>2</sup>. The subscription price in the new share issue will be the same as the Offering price. The general public in Sweden and institutional investors shall, with deviation from the shareholders' preferential right, be entitled to subscribe for the new shares. Provided that the new share issue is fully subscribed and assuming an Offering price of the median of the price range (i.e. SEK 56), the number of shares in Camurus will increase by 9,910,714 from 27,544,644 to 37,455,358, which corresponds to a 36.0 percent dilution of the total number of shares in the Company after the Offering.

Backahill Utveckling AB, Catella Fondförvaltning AB, Fjärde AP-fonden, Gladiator and Grenspecialisten Förvaltning AB have undertaken to acquire shares in the Offering corresponding to a total of SEK 240 million. Based on full subscription in the Offering, that the Overallotment Option is fully exercised and an Offering price corresponding to the mid value in the price range (i.e. SEK 56), the undertakings correspond to 4,285,714 shares, equal to 32.9 percent of the number of shares comprised by Offering and 11.4 percent of the total number of shares in the Company after the Offering.

In order to cover any over-subscription resulting from the Offering, the Principal Shareholder has, at the request of Joint Global Coordinators, undertaken to sell up to an additional 1,843,210 shares (the "**Overallotment Option**"), corresponding to not more than 15 percent of the number of shares covered by Offering and not more than 4.8 percent of the total number of shares in the Company after the Offering. If the Overallotment Option is fully utilized, the Offering will comprise up to 14,131,275 shares in Camurus, corresponding to approximately 36.8 percent of the total number of shares in the Company after the Offering.

Based on the price range, the total value of the Offering amounts to approximately SEK 627 million to SEK 641 million and approximately SEK 721 million to SEK 737 million if the Overallotment Option is fully utilized.

In other respects, reference is made to the full particulars in this offering circular, which has been prepared by the Board of Directors of Camurus in connection with the application for listing of the Company's shares on Nasdaq Stockholm and the Offering made in connection therewith.

> Lund on 18 November 2015 Camurus AB (publ)

Malmö on 18 November 2015 Sandberg Development AB

<sup>1</sup> The Principal Shareholder, the Company, Carnegie and Handelsbanken intend to enter into an agreement on the placing of shares in Camurus on or about 2 December 2015 (the "**Placing agreement**"). The Offering is conditional upon the new share issue within the Offering raising a minimum of SEK 400 million after expenses relating to the Offering to the Company, that the Placing agreement is entered into, that certain conditions in the Placing agreement are fulfilled and that the Placing agreement is not terminated. Pursuant to the Placing agreement, the Joint Global Coordinators' commitment to designate purchasers of or, if the Joint Global Coordinators fail to do so, themselves acquire the shares comprised by the Offering is conditional upon, inter alia, that no events occur which have such a materially adverse effect on the Company that it would be inappropriate to complete the Offering ("material adverse events") and certain other conditions. The Joint Global Coordinators may terminate the Placing agreement up until the settlement date, 7 December 2015, if any material adverse events occur, if the warranties that the Company have given the Joint Global Coordinators should not be true and correct or if any other condition stipulated by the Placing agreement. In such event, neither delivery of nor payment for shares under the Offering will be effected. For more information regarding the Placing agreement, see "Placing agreement" in "Legal considerations and supplementary information".

<sup>&</sup>lt;sup>2</sup> Camurus' expenses for the Offering are estimated to amount to no more than SEK 55 million, see "Expenses for the Offering" in the "Legal considerations and supplementary information" section.

## Background and reasons

Over the past 10 years Camurus has taken decisive steps in developing the Company's unique lipid-based FluidCrystal® technology platform and in the establishment of a diversified and highly advanced patent-protected portfolio of drug products in commercially attractive indications. Camurus has entered into strategically important cooperation agreements with Novartis and Braeburn for the Company's two most advanced products, CAM2029 for the treatment of acromegaly and neuroendocrine tumours (NETs) and CAM2038 for the treatment of opioid dependence, which not only contribute financially to the continued development and future commercialization of these products, but also validate the Company's technology platform and business model.

Camurus is now at the next stage of its development and growth, in which the Company, on its own and with its collaboration partners, will take its most advanced products through clinical phase III development to registration and market launch. As part of the Company's business plan to obtain marketing approval and commercialize CAM2038, Camurus intends to establish its own marketing and distribution organization, with initial focus on selected European markets.

Camurus' principal shareholder Sandberg Development is owned in the second generation by Per Sandberg, the son of Gunnar Sandberg who through his company Elektro Sandberg laid the foundation of the Company. Sandberg Development's business concept is to use its long-term ownership to create optimum conditions for the growth of the portfolio companies, and has invested in Camurus since it started operating in 1991. Now that Camurus stands before growth and establishment on new markets, the Principal Shareholder believes that it is the right time to apply for the Company's shares to be listed on Nasdaq Stockholm. A listing of the Camurus share is the next logical step for the Company, which will not only widen Camurus' shareholder base but will also contribute to raising the profile of the Company and its business and provide Camurus with access to Swedish and international capital markets. The Principal Shareholder will remain an long-term large owner of the Company but will, in connection with the listing, sell those shares that the Principal Shareholder acquires in connection with the Offering as part of the completion of the Company's share bonus program<sup>1</sup>.

In order to support Camurus' above-stated objectives and overall strategic direction to further develop preclinical candidates towards clinical programs and registration, or as candidates for strategic partnerships, the Company has decided to carry out a new share issue in connection with the listing on Nasdaq Stockholm. If the issue is fully subscribed, the net proceeds from the new share issue are estimated to amount to approximately SEK 500 million<sup>2</sup> after expenses related to the Offering. Camurus intends to use the net proceeds from the share issue in the following order of priority, with the approximate percentage of issue proceeds stated in brackets:

- i. clinical and market access supporting phase III trials for registration of CAM2038 for the treatment of opioid dependence in Europe (20-25 percent);
- ii. implementation of the Company's marketing plan for the launch, marketing and sale of CAM2038 on Camurus' markets e.g. in Europe, including establishing a supply chain and commercial presence on selected European markets (20-25 percent);
- iii. continued development and implementation of trials for approval and registration on Camurus' markets of CAM2038 for the treatment of chronic pain (15-20 percent);
- iv. continued development of the Company's clinical and pre-clinical programs, and transfer of new drug candidates from preclinical to clinical development (15-20 percent);
- v. further development and identification of new areas of application for the FluidCrystal® technology platform, including the assessment and application of new injection devices, such as autoinjectors (5-10 percent).

Camurus' total costs for implementing its development programs will largely depend on the ability of the Company and its partners to implement and complete individual project activities successfully and on time. Drug development is always associated with risks and uncertainties. Some of the elements of development, such as assessments and decisions by regulatory authorities, will be beyond the control of the Company and may therefore affect schedules and costs. As a result, it is difficult to estimate with complete precision the costs for completing Camurus' development program and at what point in time these costs will occur. Correspondingly, the is a risk that that the process of establishing a proprietary marketing and sales organisation is more timeconsuming and costly than the Company has estimated and that expected sales targets are not achieved.

The Board of Directors of Camurus is responsible for the contents of this offering circular. The Board of Directors hereby declares that, having taken all reasonable care to ensure that such is the case, information in this offering circular is, to the best of the Board of Directors' knowledge, in accordance with the facts and contains no omissions likely to affect its import.

Lund on 18 November 2015 Camurus AB (publ) Board of Directors

<sup>&</sup>lt;sup>1</sup> See also "Share bonus agreements" in the "Legal considerations and supplementary information section and "Ownership structure" in the "Share capital and ownership structure" section.

<sup>&</sup>lt;sup>2</sup> See also "Statement regarding working capital" in the "Capitalisation and other financial information" section.

# Business description and industry overview

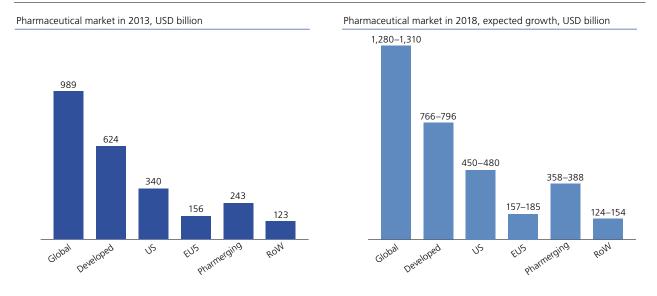
## Introduction

Camurus is an R&D-focused pharmaceutical company committed to the development and commercialisation of new and innovative products for the treatment of serious and chronic diseases. By combining its proprietary drug delivery technologies (such as the FluidCrystal® Injection depot) with active ingredients that have proven efficacy and safety profiles, the Company develops new and patented medicines with improved properties and treatment outcomes. These may be developed with significantly lower cost and risk, compared with the development of completely new medicines. Camurus has a well-diversified research portfolio which currently includes five products in clinical trials, and a number of additional product candidates in the pre-clinical phase. The Company is working on these projects both in-house and in collaboration with international pharmaceutical companies, including Novartis and Braeburn. In 2014, Camurus had net sales of SEK 208 million and profit before tax of SEK 62.5 million. The Company is based in Lund, Sweden, and had, as per 30 September 2015, 48 employees.

## The pharmaceutical industry

General growth trends

The global pharmaceutical market is expected to grow to USD 1,280-1,310 billion by 2018, representing an increase of approximately 30 percent compared with 2013. Developed pharmaceutical markets are expected to grow to USD 766–796 billion in 2018, an increase of about 23-28 percent compared with 2013. Relative market growth is expected to be significantly higher in pharmerging markets (pharmaceutical emerging markets)<sup>1</sup> where medicine spending is expected to reach USD 358-388 billion by 2018, an increase of 50-60 percent compared with 2013.<sup>2</sup>



Source: IMS Institute for Healthcare Informatics, The Global Outlook for Medicines Through 2018, November 2014.

A significant driver for the increase is demographic trends in both developed and emerging pharmaceutical markets. In developed pharmaceutical markets, an increase and improvement in the diagnosis and treatment of chronic conditions combined with an aging population are expected to drive market growth. Currently, growth in these markets, particularly in the US, is also stimulated by launches of a relatively high number of new medicines combined with fewer patent expirations for marketed medicines. Growth in emerging markets is expected to be driven primarily by increasing populations, improved access to healthcare and medicines, as well as governmentfunded economic stimulus packages.<sup>3</sup>

In addition to these broader market trends, specific factors are affecting pharmaceutical market growth in each region. In the US, the key growth drivers are fewer patent expirations, implementation of the Affordable Care Act and, to some

<sup>&</sup>lt;sup>1</sup> 21 growth markets that IMS Health predicts will account for the greatest value added to the total pharmaceutical market.

<sup>&</sup>lt;sup>2</sup> IMS Institute for Healthcare Informatics, The Global Outlook for Medicines Through 2018, November 2014.

<sup>&</sup>lt;sup>3</sup> IMS Institute for Healthcare Informatics, The Global Outlook for Medicines Through 2018, November 2014.

extent, an aging population and price increases. In Europe (Germany, France, Italy, Spain and the UK), growth is expected to be moderate due to austerity measures and the continued economic recession, as well as changes to benefit systems and price cuts in some countries. Market growth in Japan is also expected to remain at the comparatively moderate level of 1-4 percent until 2018, mainly driven by new medicines and an older population. Growth in emerging markets is expected to be driven mainly by increased sales of generic products, which are anticipated to grow at twice the rate of branded products.<sup>4</sup>

## The role of R&D companies in the pharmaceutical industry's development process

Historically, large pharmaceutical companies have undertaken the entire development process in-house, from R&D to commercialisation.<sup>5</sup> However, the major pharmaceutical companies are now increasingly dependent on collaboration with smaller research-oriented biopharmaceutical companies that increasingly conduct early-stage projects and then license their product candidates to larger companies with the capacity to conduct major drug trials and commercialise the products in the global market. These joint ventures can streamline product development from idea to market, and reduce risks and costs for both parties. Licensing agreements for new product candidates often entitle the R&D company to down payments, milestone payments and royalties. Such agreements usually also include collaborations in which employees from both sides are involved in the development project. Other typical agreement factors may be joint marketing and sales, or exclusive rights in certain markets. Technology-related agreements may sometimes cover multiple future product candidates.

## **Overview of Camurus**

## **Company description**

Camurus is an R&D-focused pharmaceutical company committed to the development and commercialisation of innovative specialty medicines to provide patients suffering from serious disease with better treatment outcomes and quality of life. Camurus is active in all phases of pharmaceutical research where the Company's technology platform can provide an advantage, from the early pre-clinical phase to pivotal clinical trials and product launch. The Company conducts several projects, both in-house and in partnership with international biotech and pharmaceutical companies.

Camurus has a well-diversified research portfolio that includes products for treating cancer and the side effects of cancer treatment, endocrine diseases and pain, as well as drug addiction. Camurus uses its own patented drug delivery technologies in most of these developments, such as the long-acting FluidCrystal<sup>®</sup> Injection depot. By combining the Company's technologies with active ingredients that have proven efficacy and safety profiles, Camurus creates new and patented medicines with improved properties and treatment outcomes. This is achieved by means of a cost- and time-effective process, using the 505(b)(2) regulatory pathway in the US and the hybrid application in the EU. A New Drug Application (NDA) that is submitted under the provisions of 505(b)(2) contains full safety and effectiveness reports but allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant. This can result in a much less expensive and faster route to approval, compared with a traditional development path.

To exploit the full potential of its technologies and expertise and to extend its development capacity and commercial reach, Camurus also engages actively in strategic partnerships and collaborations with pharmaceutical corporations, contract research organisations and universities around the world. These collaborations are based on the Company's technology and may also include the development of new medicines based on completely new ingredients and mechanisms of action within the traditional regulatory process, Marketing Authorization Application (MAA) and/or NDA (see "Regulatory Overview").

## **Product portfolio**

Over the past ten years, Camurus has invested significant resources in its R&D and the long-term building of its proprietary technologies and portfolio of pharmaceutical product candidates based on these technology platforms. The diagram below shows Camurus' current pipeline of pre-clinical and clinical product candidates, including the Company's marketed medical device episil<sup>®</sup>.

Pivotal Phase II/III trials are being prepared or started for Camurus' two most advanced product candidates:

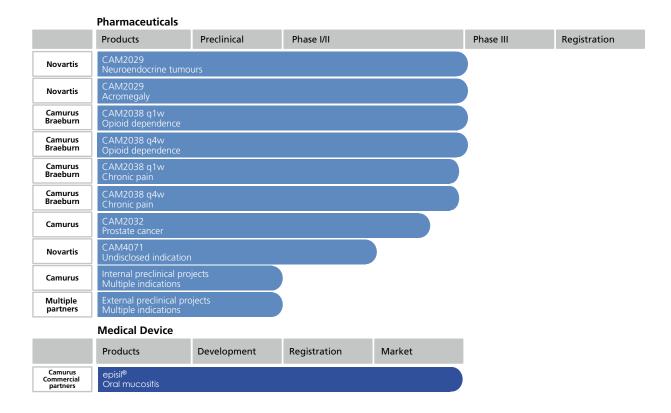
- CAM2029, a long acting octreotide chloride injection depot for the treatment of acromegaly and neuroendocrine tumours (NETs), which has been developed by Novartis under a joint venture and licensing agreement with Camurus.
- CAM2038, buprenorphine injection depots for the treatment of opioid dependence, developed by Camurus in collaboration with its US partner Braeburn under a joint venture and licensing agreement.

CAM2038 is also being developed for the treatment of chronic pain, with the intention of initiating registration trials prior to mid-year 2016.

The Company is also pursuing other clinical-stage product opportunities, including CAM2032, a leuprolide acetate injection depot in development for the treatment of prostate cancer. This product candidate is currently being assessed in a Phase II trial of repeat-doses in patients with prostate cancer,

<sup>4</sup> IMS Institute for Healthcare Informatics, The Global Outlook for Medicines Through 2018, November 2014.

<sup>&</sup>lt;sup>5</sup> Pharma 2020: Challenging business models. Which path will you take? PricewaterhouseCoopers.



and the results are expected in early 2016. Concurrently, Camurus is also conducting a Phase I trial of CAM4071, an additional product to be assessed within the framework of the collaboration with Novartis. The product comprises a peptide substance (undisclosed) formulated with Camurus' FluidCrystal® Injection depot.

In addition to clinical projects, Camurus' pipeline also includes a number of in-house products in the pre-clinical phase (optimisation phase) focused on the treatment of inflammation, pain, central nervous system (CNS) disorders, diabetes, cancer and cancer side effects. The further development of these projects is intended to create new clinical projects and to expand Camurus' pipeline of innovative and differentiated product candidates in attractive market areas.

In addition to the above projects, Camurus is also engaged in a number of R&D collaborations with several international biotech and pharmaceutical companies, based on Camurus' unique FluidCrystal<sup>®</sup> delivery platform. The aim of these joint ventures is to develop new medicines, or to further develop existing products in order to extend their lifecycles and optimise their long-term market value. Several ongoing collaboration projects are focused on diabetes, obesity, viral infections and endocrine diseases. If the outcomes and evaluations are positive, these collaborations may result in new clinical-stage projects under licensing agreements with opportunities for license revenues, future development and sales-related milestone payments and royalties on any product sales.

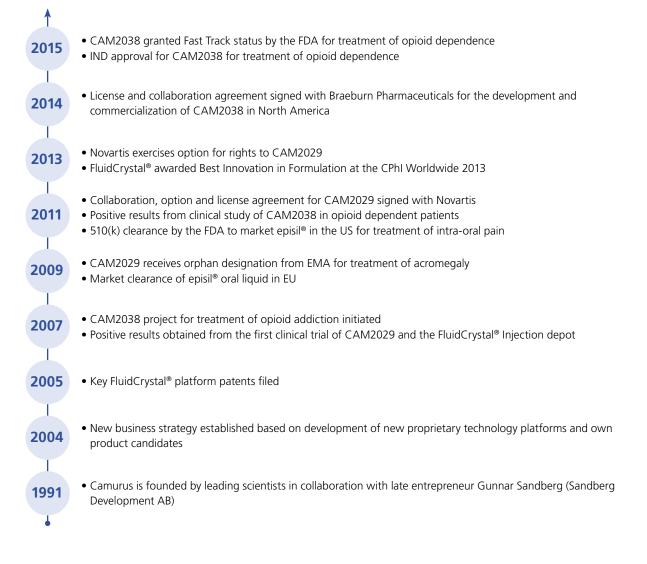
Finally, Camurus has also developed the medical device product episil® for treating pain in the oral cavity, including pain caused by oral mucositis, a common and debilitating side effect of chemo and radiotherapy. episil® is registered in several markets, including the EU and the US, where it was launched in 2013. Sales and distribution of episil® are mainly conducted through partners, although Camurus has recently initiated its own sales efforts in Sweden, Denmark and the UK.

## History

Camurus was founded in Lund in 1991 by a group of leading scientists in physical and biophysical chemistry, including Professors Kåre Larsson (Lund Institute of Technology) and Björn Lindman (Lund University), in collaboration with the entrepreneur and business leader Gunnar Sandberg. As pioneers in research on lipid-phase nanostructures and being aware of the drug delivery challenges in pharmaceutical development, they recognised the potential of certain liquid crystalline structures for solubilisation, stabilisation and delivery of active pharmaceutical ingredients.

Initially, Camurus followed a service-based approach in which the Company was active in R&D projects for other companies, which led to the first registered product, Elyzol® dental gel, for the treatment of periodontitis. Elyzol® was developed through a collaboration with the Danish company Dumex-Alpharma and subsequently licensed to Colgate Oral Pharmaceuticals. In addition to these companies, Camurus also collaborated with a range of industrial partners, but did not pursue its own clinical-stage product development.

In 2004, after further research innovations and development of new lipid formulation technologies, Camurus instigated a new strategic direction and began the development of its proprietary FluidCrystal® technology platforms along with a number of novel proprietary product candidates. Based on these initiatives, Camurus has now developed what the Company considers to be a leading position in lipid-based drug formulations, and on the basis of these, also created a broad and diversified pipeline of clinical-stage product candidates, developed in-house or in partnership with leading international pharmaceutical companies. A brief history of the company, including a few milestones in Camurus' history is presented below.



## Strategy

Camurus' goal is to develop and commercialise innovative and differentiated pharmaceutical products, based on the Company's proprietary and patented drug delivery technologies, including the FluidCrystal® Injection depot. By combining the Company's technologies with active ingredients with proven efficacy and safety profiles, new patented medicines are developed, with better properties and meaningful improvements in the treatment of patients suffering from serious and chronic diseases. This may encompass simplified dosage regimens, better medication compliance and better treatment outcomes, due to a more precise and steady release of the active drug compound. The use of established active ingredients enables the development of new and improved medicines at significantly lower cost and risk, compared with the development of new compounds. Camurus' strategy encompasses both research and development of new product candidates, and sales and marketing of medicines and medical devices utilizing a lean and efficient commercial infrastructure dedicated to a select niche product opportunities, indications and regional markets. In order to increase the R&D capacity and to fully exploit the commercial potential and range of Camurus' various technologies and product opportunities, the Company also intends to continue working actively in strategic partnerships with leading pharmaceutical companies. Key highlights of Camurus' strategy are:

## Expand the Company's pipeline with important and differentiated product candidates in commercially attractive indications

Camurus intends to continue expanding its pipeline of new and differentiated pharmaceutical candidates by capitalising on the unique advantages of the Company's patented FluidCrystal® technology platforms. The Company will continue to focus on commercially attractive indications with significant unmet medical needs and where meaningful improvements in relation to existing alternatives may be achieved under conditions of market exclusivity. This development is reinforced by continuous improvements and validation of the FluidCrystal® technology platform, and occurs in tandem with the progress of the Company's late-stage product candidates toward market registration.

## Continue technological development and leadership

Camurus will continue to invest significant resources in R&D in further refining and improving its' proprietary FluidCrystal® technology platforms to secure continued technological advancement and new product applications. The goal is to secure the Company's leading position in advanced drug formulations and continued development of innovative and differentiated pharmaceutical products in attractive commercial markets. Examples of development areas include new customised delivery components tailored to specific pharmaceutical ingredients and product requirements. Another example of development of the Company's technologies is the focus on add-on technologies, such as safety mechanisms and auto-injectors, which simplify the administration of medicine for both healthcare professionals and patients.

## Advance Camurus' late-stage product candidates to approval and commercial launch

The advancement of in-house and partnered development programmes through to approval and launch is a key objective for Camurus. With the support of Camurus, Novartis has prepared global Phase III trials of CAM2029 for the treatment of acromegaly and NETs, which are planned to start subject to Novartis completion of manufacturing and confirmation of stability of the final prefilled syringe product format. Camurus and its partner Braeburn have in parallel initiated the Phase III programme for the registration of CAM2038 for opioid dependence in the US and Europe. A further key strategic component is the planning and initiation of the clinical registration programme of CAM2038 for the treatment of chronic pain. For both of these indications, Braeburn is responsible for development and registration in North America, with an option for China, Japan, Korea and Taiwan, while Camurus has retained all product rights in Europe and the rest of the world (RoW).

## Grow the business through strategic partnerships

To further enhance the Camurus' development capacity and commercial reach, the Company will continue to actively seek new strategic partnerships with pharmaceutical companies with leading positions and/or a strategic focus on relevant markets and therapeutic categories. This will enable the Company to continue expanding its pipeline with several value-generating product candidates and increase the geographic reach of its products, while maintaining a cost-effective operational structure.

## Build a commercial sales force for CAM2038 and add-on products in Europe

Camurus has retained all development and commercialisation rights for CAM2038 in Europe and several other markets, except for North America, China, Japan, Korea and Taiwan. Based on Camurus' market assessments and long-term strategic objectives, the Company has decided to conduct its own marketing and sales of CAM2038 for the treatment of opioid dependence in selected markets, including Germany, the UK, France, Italy and the Nordic countries. Camurus may also expand its marketing and sales efforts to selected RoW markets, such as Australia. Camurus believes that CAM2038 for opioid dependence represents an attractive opportunity to establish a cost efficient commercial organisation that is focused on a limited prescriber base and with a potential for significant and long-term future revenues. In addition to CAM2038, the Company intends to retain and/or secure commercialisation rights for auxiliary product candidates in its strategic focus areas fit, based on therapeutic area, market dynamics, development costs and other factors.

## **Competitive strengths**

Camurus believes that the Company has several key strengths that have contributed to its positive development, and that will enable the Company to realise its future goal of becoming an integrated and long-term profitable pharmaceutical company through the development and commercialisation of innovative and differentiated medicines for the treatment of serious and chronic conditions. Camurus' competitive advantages include:

## An efficient and diversified business model that combines in-house and partnered pharmaceutical development based on Camurus' proprietary, patented and broadly applicable FluidCrystal® technology platform

Camurus' business model is to develop new differentiated medicines by combining the Company's proprietary and patented drug delivery technologies with active ingredients that have proven efficacy and safety profiles. The Company believes that this approach to drug development has several key benefits, such as shorter development timelines from start to market, lower costs and lower risk of failure compared with traditional drug research and development. Camurus therefore believes that, over time, the Company will be able to generate a favourable return on its development investments.

Camurus' business model is supported by the fact that the Company has completed and reported more than ten clinical trials of products based on the Company's patented FluidCrystal® technology platform, in addition to a number of trials that are ongoing and under initiation, both in-house and in collaboration with partners. Camurus also believes that recently concluded collaboration agreements with companies such as Braeburn and Novartis, and the market registration of episil® in the US and the EU, further demonstrates the commercial potential of Camurus' technologies and product candidates, as well as the Company's ability to develop new and differentiated treatment options.

## CAM2029 and CAM2038 – late-stage product candidates with potential for differentiated positioning in commercially attractive markets Camurus considers that its two most advanced product candidates have potential for differentiated best-in-class positioning in commercially attractive markets.

CAM2029 is being developed for the treatment of acromegaly and NETs, markets that exceeded USD 2 billion in 2014. CAM2029 is a novel pharmaceutical formulation of the somatostatin analogue (SSA) octreotide, which is also included in Novartis' product Sandostatin® LAR®, the current market leader in acromegaly and NETs, which generated sales of some USD 1.65 billion in 2014.

CAM2029 is being further developed by Novartis, with the support of Camurus, and is assessed to have several key benefits compared with both Sandostatin<sup>®</sup> LAR<sup>®</sup> as well as the current second highest selling SSA, Somatuline<sup>®</sup> Autogel<sup>®</sup> from Ipsen. The product is designed to be administered as a single subcutaneous injection, compared with Sandostatin<sup>®</sup> LAR<sup>®</sup> which requires intramuscular administration and Somatuline<sup>®</sup> Autogel<sup>®</sup>, which requires deep subcutaneous injection with a thick needle. CAM2029 comes in a pre-filled syringe stored at room temperature and therefore, does not require any reconstitution or conditioning to room temperature before administration, while Sandostatin<sup>®</sup> LAR<sup>®</sup> requires six-step reconstitution and both Sandostatin<sup>®</sup> LAR<sup>®</sup> and Somatuline<sup>®</sup> Autogel<sup>®</sup> must be brought to room temperature before injection. CAM2029 is also compatible with auto-injectors, which may further enhance the ease of self-administration.

In addition to the above improvements, CAM2029 has demonstrated around 500 percent higher octreotide bioavailability compared with Sandostatin<sup>®</sup> LAR<sup>®</sup>, which may enhance treatment efficacy in patients who do not respond satisfactorily to Sandostatin<sup>®</sup> LAR<sup>®</sup>. CAM2029 also demonstrates considerably faster absorption of octreotide and thus a more rapid initial suppression of high IGF-1levels. This, in turn, leads to faster therapeutic effects compared with Sandostatin<sup>®</sup> LAR<sup>®</sup>, where treatment efficacy is not achieved for one to two weeks due to the delay in octreotide absorption.

The other late-stage and promising product candidate developed by Camurus is CAM2038 for the treatment of opioid dependence. Opioid dependence is a growing, global public health problem, but only a small percentage of the world's opioid addicts currently have access to effective treatment. In Europe, an estimated 250,000 patients, of approximately 1.3 million opioid addicts, receive buprenorphine maintenance treatment. The corresponding figure for the US is approximately 700,000 patients, from a total of about 5 million addicts.

The current products for treating opioid dependence are delivered intraorally in the form of a sublingual tablet or film, which has significant disadvantages in the form of extensive abuse, diversion and illicit trade, as well as inadvertent consumption among minors and children. To avoid these problems and improve medical compliance, patients often receive their daily medication under supervision according to various treatment schedules, resulting in high costs, encroachment on the lives of patients and violations of personal integrity. CAM2038, which is administered once a week or once a month by a healthcare professional, has a clear potential to solve all the above mentioned problems reduce and unnecessary healthcare costs associated with daily treatment. In addition, patients will not experience the daily discomfort associated with the intake of sublingual tablets and films, i.e. the bitter taste while the product is dissolving in the mouth, which can take up to ten minutes.

CAM2038 has also demonstrated 600-800 percent higher bioavailability compared with sublingual buprenorphine, which indicates more efficient use of the active ingredient, and also reduces the amount of buprenorphine circulating in the treatment system, which can potentially be misused. In summary, Camurus considers the long-acting buprenorphine injection depot, CAM2038, to have highly favourable, competitive and user-friendly properties.

### Strong strategic partnerships

Camurus has a worldwide partnership with Novartis for the development and commercialisation of CAM2029, and other related products based on somatostatin analogues in combination with Camurus' FluidCrystal® Injection depot technology. As one of the world's largest pharmaceutical companies, and the current market leader in the treatment of acromegaly and NETs, Camurus is confident that Novartis represents the strongest possible partner for CAM2029 and related product opportunities.

For CAM2038, Camurus has selected Braeburn as its development and commercialisation partner in North America and in selected Asian markets. Based on the company's clear focus on the US opioid-dependence market, a complementary product portfolio including the Probuphine<sup>®</sup> implant for treating opioid dependence, and a management with proven development and commercial track-record, including the commercial development of Abilify<sup>®</sup> for treating schizophrenia, generating annual sales of more than USD 8 billion in 2014. Camurus believes that Braeburn represents an ideal partner for CAM2038, particularly since the two companies have common strategic objectives and complementary strengths in each market.

## A growing pipeline with major opportunities

Beyond its two most advanced product candidates, Camurus has several other promising product candidates in clinical and pre-clinical phase, all of which, in the Company's assessment address great medical unmet needs and have significant commercial potential.

In partnership with Braeburn, Camurus is developing both CAM2038 and variations of CAM2038 for additional indications beyond opioid dependence treatment, including the treatment of moderate to severe chronic pain. Camurus expects that clinical trials with pain patients will commence within three to six months, with the objective of registering the product first in the US and then in Camurus' markets.

In addition to the development of CAM2029, the partnership with Novartis includes the evaluation of additional product candidates based on the FluidCrystal® Injection depot, including CAM4071, containing an as yet undisclosed active peptide ingredient, which is currently being evaluated by Camurus and Novartis in a Phase I trial in Europe. Camurus expects this will be completed during the first half of 2016.

The fact that both Braeburn and Novartis have elected to include additional product candidates and/or indications in their respective collaborations confirms, in the Company's view, the value they both place on their partnership with Camurus, and the potential of Camurus' unique delivery technology and expertise.

In addition to the above collaborations, Camurus is also conducting an in-house project in clinical development – CAM2032 for the treatment of prostate cancer. This product is based on the active ingredient leuprolide acetate, a gonadotropin-releasing hormone (GnRH) agonist, and is currently being evaluated in a Phase II trial in patients with advanced prostate cancer. Annual global sales of the four leading GnRH- based products were in 2014 estimated to be more than USD 3 billion. Current treatment options require costly efforts by healthcare professionals for reconstitution and injection, normally on a quarterly or monthly basis. CAM2032 can be self-administered with a single subcutaneous injection, with the possibility of using the auto-injector once a month. The properties of CAM2032 may also prove highly valuable for other groups of patients now being treated with GnRH agonists, particularly children and adolescents affected by precocious puberty, and women with endometriosis.

Camurus is preparing to bring another new product candidate into clinical development in 2016, based on the results of pre-clinical trials and market analyses. The Company continually evaluates a number of product candidates as well as the respective product candidate's suitability for in-house or partner development, and various options for future commercialisation in relation to the Company's commercial strategy and capabilities.

Finally, Camurus is also involved in several promising collaboration projects with international pharmaceutical companies in the pre-clinical evaluation phase, typically based on its proprietary FluidCrystal<sup>®</sup> delivery technology, in combination with the relevant partner's patented active ingredient. These partnerships could lead to new product candidates entering clinical development with the potential to generate down payments, milestone payments, reimbursement of R&D costs and royalties on future sales.

## Attractive opportunity for own commercialisation of CAM2038 by Camurus in European and selected RoW markets

Camurus believes that CAM2038, a long-acting injectable depot formulation of buprenorphine, is a highly promising and suitable treatment option for opioid-dependent patients in Europe, compared with current sublingual buprenorphine products and methadone, with the potential to reduce abuse, diversion and healthcare costs, and to improve treatment compliance and outcomes.

On the basis of these improvements, Camurus has assessed that CAM2038, with both weekly and monthly products and flexible dosing, has the potential to capture significant market share for medication-based treatment in Europe and other markets. Many European countries apply a relatively high degree of supervised drug administration and substitution treatment for opioid dependence, which leads to increased healthcare costs and encroachments on the patient's life.

Since doses of CAM2038 are only required once a month or once a week, the costs of drug administration are reduced, while the patient avoids unnecessary visits for supervised administration associated with daily tablet administration. The dosing flexibility of CAM2038, with weekly and monthly products, means that treatment can be adapted to local treatment conditions, where the treatment frequency varies between countries, and depending on the patient's needs and stability.

In addition to potentially reducing costs for administration and enhancing quality of life for patients compared with current daily treatment options, CAM2038 may improve medication adherence since the medicine is slowly and continuously released over time and is not affected by day-to-day patient decisions. By extension, this provides opportunities for significant treatment gains, as relapse into drug abuse is common and may have serious implications for both the individual and society.

Together with external experts and advisors, Camurus has conducted thorough market assessments of the potential to commercialising CAM2038 in Europe, in which treatment costs, the preferences of prescribers and opinion leaders, payment structures, as well as price and benefit aspects have been examined. Camurus has concluded that own commercialisation of CAM2038 in the EU represents a compelling opportunity for the Company and holds major potential for future revenue and profitability.

### **Strong IP position**

Camurus has an active patent strategy covering all major geographic markets, including the US, EU5 and Japan. The Company has secured some 35 patent families, comprising more than 350 patents and patent applications, covering all of its technology platforms and products. The duration of Camurus' patents for the FluidCrystal<sup>®</sup> technology platform varies, depending on the technology, product application and geography. The earliest patent expirations are expected in 2025, while several patents and patent applications extend until 2032 and possibly longer. In addition to its technology platform patents, Camurus also has a large number of product-specific patents to protect the Company's various pharmaceutical candidates. In addition to providing more product-oriented protection for various properties, compositions and applications, these patents and patent applications also allow more flexibility in the management of patents and intellectual property issues in the Company's many collaboration agreements with various partners.

Camurus also has extensive know-how in all critical aspects of its proprietary FluidCrystal<sup>®</sup> drug delivery technology, including the components, manufacturing aspects, various applications, packaging and stability. This know-how will continue to grow as Camurus and its partners further develop their different products and achieve market approval.

### Experienced management team

Camurus' management team comprises of highly qualified individuals with considerable industry experience and expertise in all key areas of pharmaceutical development relevant to the Company. The average term of employment for members of the Company's management team is a little more than six years at Camurus, and approximately 20 years in the pharmaceutical industry. Several team members have been instrumental in the invention of Camurus' patented FluidCrystal® delivery technology, as well as many other products in the Company's pipeline. In addition, Camurus' management has been instrumental in negotiating a significant number of major commercial agreements with international biotech and pharmaceutical companies over the years, including the partnership agreements with Braeburn and Novartis.

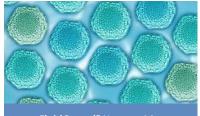
## Camurus' technology platforms



FluidCrystal<sup>®</sup> Injection depot



FluidCrystal® Topical bioadhesive



FluidCrystal® Nanoparticles

An increasing number of therapeutics are now based on proteins and smaller protein sequences, known as peptides. In 2013, 22 percent of all drugs on the market were peptides or proteins. This figure is expected to rise to 25 percent of the total market by 2020. Among the top 100 prescription products in 2020, biological products are expected to account for more than 50 percent of sales.<sup>6</sup> Peptides or protein drugs often require frequent intravenous or subcutaneous injections, which encroaches on the lives of patients, may cause discomfort and inconvenience, and ultimately lead to lower medication adherence and a greater burden on the healthcare system. Many peptide and protein drugs have been modified to extend their half-lives, but still have to be administered relatively often. Other peptide or protein drugs are combined with depot technologies (e.g. controlled and long-acting release) that give adequate and stable medication over time. The efficacy of small-molecule pharmaceuticals can also, in many cases, be substantially improved by applying controlled release instead of one or more daily oral intakes. Long-acting injections can increase bioavailability, improve medication adherence among patients and reduce the risk of diversion, abuse and illicit trading of drugs. Another advantage of long-acting products is that they are often difficult and expensive to copy, which enhances their market exclusivity.

By combining patented drug delivery technologies for controlled or long-acting release with established active ingredients, new patented medicines, with improved properties and treatment efficacy, can be developed with faster time to market, lower risk of failure in clinical trials and lower development costs compared with medicines developed through traditional pharmaceutical R&D.

Injection depot systems must be safe, stable and reliable, since they may contain potentially harmful or lethal doses of drugs, and the drug release profile must therefore be consistent, without sudden or severe effects, in order to achieve a clinically relevant effect with a minimum of side effects. The depot must also offer a stable environment for the active ingredient, to avoid decomposition during storage or in vivo during the intended treatment period.

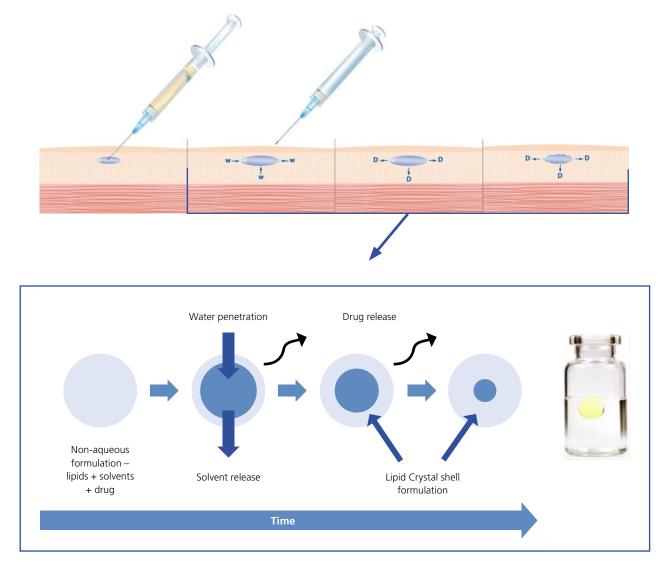
Since 2004, Camurus has developed three technologies that are all based on special combinations of polar and non-polar lipid mixtures, and their ability to spontaneously form liquid crystal structures in aqueous solutions. The technologies are marketed under the registered trademark FluidCrystal<sup>®</sup>.

## FluidCrystal<sup>®</sup> Injection depot

Traditional long acting injection products often comprise polymeric microparticles, where the active ingredient is encapsulated in an emulsion process according to relatively complicated reconstitution procedures. Since microparticles do not form stable and homogenous dispersions, the products generally require reconstitution before they can be administered in one or more steps. Most microparticle-based products have to be injected intramuscularly with relatively long and thick needles. Compared with these microparticle-based systems, FluidCrystal® Injection depot offers a simple and uncomplicated alternative, in terms of both manufacturing and administration. Since the system is based on homogenous solutions and the actual depot structure is not formed until after the product enters the body, products can be manufactured through a relatively simple process followed by sterilisation and transfer to a vial, ampule or syringe.

The FluidCrystal<sup>®</sup> Injection depot is easily and conveniently administered in small doses by injection with a pre-filled standard syringe with a thin needle. The technology can also be complemented with a needle stick prevention device, for example, or an auto-injector. Camurus' depot technologies make life easier for both patients and healthcare professionals. Products based on this technology are also well-suited for home-based administration by the patient or family members.

<sup>6</sup> EvaluatePharma "World Preview 2014, Outlook to 2020," 2014.



## Illustration of functional principle of Camurus FluidCrystal® injection depot

The FluidCrystal<sup>®</sup> Injection depot comprises a liquid lipid solution that, when in contact with minute quantities of water, self-assembles into a slow and controlled release liquid crystalline gel matrix at the site of injection. The drug compound is thereby effectively encapsulated in a depot that is released as it biodegrades, which provides long-acting drug release. By controlling the depot formulation, the release time can be adjusted from a few days to several months, partly dependent on the active ingredient. The depot system is ideal for relatively potent ingredients that require small dosage amounts, such as peptides and small molecules that are active at low concentrations. The FluidCrystal® system does not demonstrate disadvantages such as high initial release, limited chemical and physical product stability, complex handling and administration, and costly manufacturing, which are often associated with traditional microparticle-based depot systems. Liquid crystalline gels are effective encapsulating matrices for a broad range of active ingredients and as the gelling process starts immediately on injection, the initial drug release is typically low. The liquid crystalline structure has a stability-enhancing effect on many sensitive ingredients, which probably explains the high bio-availability documented for the FluidCrystal® system compared with, for example, microparticles. The low-viscosity liquid nature of Camurus' depot makes products based on this technology not only simple to handle and administer through thin needles, but also straightforward to produce. The following list sets out the principal characteristics of the FluidCrystal<sup>®</sup> Injection depot system:

- Long-acting technology that provides a slow and steady release of active ingredients in the body
- The release can be controlled from a few days to several months
- The products are ready to use and do not require reconstitution
- Easily injected in small dose volumes with a thin needle
- Administration can be subcutaneous or intramuscular, with a similar drug-release profile
- The system is compatible with pre-filled syringes and injection aids (such as auto-injectors)
- Good local tolerance has been demonstrated in pre-clinical and clinical trials
- Good safety and systemic tolerance have been demonstrated in pre-clinical and clinical trials
- Room-temperature stable
- Simple and standardised manufacturing process

More than 1,000 injections of products based on the Fluid-Crystal<sup>®</sup> Injection depot system have been documented in clinical trials and several more trials are in the start-up phase.

## FluidCrystal<sup>®</sup> topical bioadhesive

FluidCrystal® topical bioadhesive is another invention and advanced delivery technology from Camurus. The formulation is a simple liquid that is applied to topical surfaces, where it spreads to form a thin bioadhesive film, an "invisible patch," that protects the tissue and can be used for the local release of pharmaceutical ingredients. The system is suitable for extended local release of, for example, peptides and small molecules on mucous membranes in the mouth, nose, throat, vagina, rectum and skin.

The formulation is applied as a low-viscosity liquid, which transforms into a thin and strongly bioadhesive liquid crystalline film at the biosurface through absorption of minute amounts of water. The nanostructure of the film can be controlled to achieve an optimal delivery profile and bioadhesive strength. The formulation has a high solubilising capacity, which allows small dosage volumes to achieve therapeutic effects with the active ingredient.

FluidCrystal<sup>®</sup> topical bioadhesive is compatible with several applicators, such as disposable pipettes, tubes and spray bottles.

The system is used in Camurus' marketed medical device episil<sup>®</sup>, which has been granted 510(k) market approval in the US by the FDA, and has also been approved for sales in Europe and other markets (see "Medical device – episil<sup>®</sup>"). The mechanism of action of episil<sup>®</sup> is based on the product spontaneously forming a protective film around damaged mucous membranes in the mouth, thereby relieving pain caused by oral mucositis, for example, which is a serious side effect of cancer treatment. The following list sets out the principal characteristics of the FluidCrystal<sup>®</sup> topical bioadhesive technology:

- Strongly bioadhesive
- · Protection of sensitive biosurfaces and local pain relief
- High solubilising capacity of active ingredients
- Extended local drug release
- Good local tolerance demonstrated in clinical trials
- Simple and standard manufacturing process

## FluidCrystal® nanoparticles

Unlike the other systems, FluidCrystal® nanoparticles are usually water-based and comprise a stable emulsion of nanoparticles with a liquid crystalline structure. The technology has been designed to increase the bioavailability of amphiphilic and lipophilic drugs with low aqueous solubility and biodegradation-sensitive drugs such as peptides and proteins.

Products based on this technology are either preformed to stable dispersions for intravenous, subcutaneous, intramuscular or intracavital injection, or applied to the skin or mucous membranes in spray form.

The following list sets out the principal characteristics of the FluidCrystal<sup>®</sup> nanoparticle system:

- Prolonged systemic drug circulation (parenteral administration)
- Enhanced transmucosal flux (topical administration)
- Protection of sensitive pharmaceutical ingredients
- High solubilising capacity
- Based on safe excipients
- Good systemic and local tolerance demonstrated in preclinical and early-phase clinical assessments

## Intellectual property strategy

All of Camurus' technology platforms are protected by a broad and, in Camurus' view, solid patent portfolio with several granted patents in all major markets, including the US, Europe, China, Japan, Korea and Australia. Camurus' portfolio of technology and product patents is constantly being expanded with new applications and approvals as applications are processed and new innovations are made, such as specific compositions, enhancements and new therapeutic applications. New patents can extend market exclusivity for both technologies and products, and are therefore highly significant for the Company. Moreover, building strong know-how in all aspects of Camurus' various technology platforms is a top priority. Camurus closely monitors all developments regarding its IP rights in all relevant areas, as well as competing technologies and companies. The patent strategy for intellectual property rights has been developed in close and long-standing collaborations with Camurus' external international patent agents.

#### **Product candidates**

## CAM2029 – subcutaneous injection depot of octreotide for acromegaly and NETs *Introduction*

CAM2029 is a long-acting subcutaneous injection of the active ingredient octreotide, formulated with Camurus' patented FluidCrystal® Injection depot. The product is being developed by Novartis, with the support of Camurus, and is considered by Camurus to have several key benefits compared with current products – Sandostatin® LAR® from Novartis and Somatuline® Autogel® from Ipsen.

Octreotide is a synthetic peptide analogue of the natural peptide hormone somatostatin. Somatostatin analogues (SSAs) represent the current standard for safe and effective medical therapy for acromegaly and symptom control in NETs. In addition, SSAs have demonstrated anti-tumour effects and are a treatment option for patients with unresectable NETs. Currently marketed SSA products include octreotide immediate release (Sandostatin® from Novartis, as well as generic versions) and the market-leading long-acting formulation octreotide LAR (Sandostatin® LAR® from Novartis), as well as two long-acting formulations of lanreotide (Somatuline® LA® and Somatuline® Autogel® from Ipsen).

CAM2029 is being developed by Novartis as a future treatment alternative to the current market leader Sandostatin® LAR<sup>®</sup>. The product is designed to be administered as a single subcutaneous injection, while Sandostatin® LAR® needs to be reconstituted from a powder in a six-stage process and injected intramuscularly by a healthcare professional using a 40 mm long and 20 gauge (0.91 mm) needle. Somatuline® Autogel<sup>®</sup> requires refrigerated storage and must be conditioned to room temperature before it can be administered as a deep subcutaneous administration using a 20 mm long and 18/19 gauge (1.27 mm) needle. CAM2029 has the advantage of being ready to use and is easily injected with a pre-filled syringe equipped with a 12.5 mm long and 22 gauge (0.72 mm) or thinner needle. The product can also be equipped with an auto-injector which, in future, may further enhance the ease of self-administration.

The extended release of octreotide with CAM2029 has been demonstrated in three completed clinical trials featuring a total of about 250 individuals. In two of the trials, octreotide LAR (Sandostatin<sup>®</sup> LAR<sup>®</sup>) was also included as a reference product. Compared with octreotide LAR, CAM2029 demonstrated faster onset and 500 percent higher octreotide bioavailability compared with Sandostatin<sup>®</sup> LAR<sup>®</sup>. The safety profile of CAM2029 was generally comparable to the safety profile of Sandostatin<sup>®</sup> LAR<sup>®</sup>.<sup>7</sup>

#### Overview of target indications for CAM2029 – acromegaly and NETs Symptoms and prevalence

Acromegaly is a rare and chronic hormonal disorder that occurs when the pituitary gland produces excess growth hormone. The disease is insidious, and more than 90 percent of cases are due to the hypersecretion of growth hormone in a benign pituitary tumour (pituitary adenoma). Acromegaly most commonly affects middle-aged adults, with equal distribution between men and women as well as ethnic populations. Acromegaly is associated with reduced quality of life, shortened life expectancy and an increased prevalence of cardiovascular mortality risk factors. The clinical symptoms of acromegaly include progressive skeletal growth and soft tissue enlargement, mainly of the extremities (hands and feet) and head. The prevalence of acromegaly in the US and Europe is estimated to be around 4 to 7 per 100,000<sup>8</sup>, meeting the orphan disease prevalence criteria. The annual incidence rate has been calculated at 3 to 4 cases per 1,000,000 people.9

NETs (previously termed carcinoids) are a heterogeneous group of rare and malignant neoplasms that originate from regulatory hormone-producing neuroendocrine cells and that can arise throughout the body. Depending on their histology and primary origin, these tumours can secrete various bioactive amines and hormones, causing the classical carcinoid syndrome of diarrhoea, flushing and sometimes wheezing. The symptoms are due to the overproduction and uncontrolled release of serotonin. Most NETs are malignant and they commonly metastasise to lymph nodes and the liver. They can remain asymptomatic for years, presenting at a relatively late stage with symptoms of mass effect or distant (usually hepatic) metastases. Although functioning tumours result in distinct syndromes, individual symptoms are commonly non-specific, often leading to a delay in diagnosis of several years (five to seven years on average) and increasing the probability of metastatic disease.<sup>10</sup> The incidence rate of NETs has significantly increased in recent years and is now estimated to be five per 100,000 per year, with an estimated prevalence of 35 per 100,000 in the US.11

#### **Current treatments**

Surgery is the most effective option to achieve a rapid and complete cure of both acromegaly and NETs. However, for a majority of patients, surgery is not possible due to the tumour's location, size and degree of malignancy. For these patients, pharmacological therapy with the SSAs octreotide

<sup>&</sup>lt;sup>7</sup> Tiberg F, Roberts J, Cervin C, et al. Octreotide sc depot provides sustained octreotide bioavailability and similar IGF-1 suppression to octreotide LAR in healthy volunteers. Br J Clin Pharmacol. 2015;80:460-472.

<sup>&</sup>lt;sup>8</sup> Chanson P, Salenave S. Acromegaly. Orphanet J Rare Dis. 2008;3:17.

<sup>&</sup>lt;sup>9</sup> Holdaway IM, Rajasoorya C: Epidemiology of acromegaly. Pituitary 1999, 2:29-41.

<sup>&</sup>lt;sup>10</sup> Modlin IM, Oberg K, Chung DC, et al; Gastroenteropancreatic neuroendocrine tumours. Lancet Oncol. 2008;9:61-72.

<sup>&</sup>lt;sup>11</sup> Fraenkel M, Kim M, Faggiano A, de Herder WW, Valk GD; Knowledge NETwork. Incidence of gastroenteropancreatic neuroendocrine tumours: a systematic review of the literature. Endocr Relat Canc. 2014;21:R153-163.

and lanreotide is the standard treatment option. For metastatic NETs, the treatment mainly aims to control tumour growth and symptoms. Although both octreotide and lanreotide were primarily developed to palliate symptoms, new clinical data indicates that these substances also inhibit tumour growth.<sup>12</sup> To summarise. SSAs are used in inoperable patients, patients undergoing non-curative surgery, and as chronic postoperative medical management with the aim of relieving symptoms and suppressing tumour growth and spread.<sup>13</sup> For many NET-patients, the effect of SSAs gradually decreases due to desensitisation, while other responsive patients can have their disease controlled for several years.<sup>14</sup> Some cases have demonstrated that desensitisation can be overcome by increasing the dosage of octreotide, which has also been shown to stabilise hormone production and reduce tumour growth, and to significantly reduce symptoms such as diarrhoea, flushing and abdominal pain.15

Acromegaly is treatable in most patients and the therapeutic strategy can include surgery, radiotherapy and medical treatment.<sup>16</sup> The aim of the treatment is to reduce long-term morbidity and mortality by reducing the tumour mass and controlling its growth. The biochemical goals are to restore growth hormone secretion and the insulin-like growth factor-1 (IGF-1) to normal levels. By reducing the concentration of these growth hormones to normally circulating levels, the mortality rate of acromegaly patients can be reduced to the same levels as for the general population.<sup>17</sup> The treatment of acromegaly with SSAs has proven safe and effective and is now the standard treatment.

SSAs have an effective normalising impact on growth hormone and IGF-1 in about 55 percent of patients with acromegaly, while about 40 percent of NETs patients experience therapeutic effects for carcinoid syndrome in the form of reduced flushing and diarrhoea.<sup>18</sup> Although NET patients sometimes do not receive maximum benefits before ten years of therapy,<sup>19</sup> they normally respond directly to initial doses provided that an SSA with fast onset is used. The initiation of treatment involves relatively simple titration procedures to identify the optimal treatment dose of SSA. Due to rapid onset, dose-proportional kinetics and prolonged effect, CAM2029 is therefore expected to be suitable for both the initiation of treatment and for replacing treatment with other SSAs.

#### Competitive landscape and market opportunity Limitations of current products

Three different SSAs are currently approved for the treatment of acromegaly or NETs: i) octreotide, in Sandostatin<sup>®</sup> and Sandostatin<sup>®</sup> LAR<sup>®</sup> from Novartis; ii) lanreotide, in Somatuline<sup>®</sup> LA<sup>®</sup> and Somatuline<sup>®</sup> Autogel<sup>®</sup> from Ipsen; and iii) pasireotide, in Signifor<sup>®</sup> LAR<sup>®</sup> from Novartis. In addition, generic versions of the immediate release version of octreotide are available on several markets.

Sandostatin<sup>®</sup> LAR<sup>®</sup> is a long-acting depot of octreotide. Available as a powder for suspension, the product is based on polymeric microparticles and is administered once-monthly as an intramuscular injection. The product requires refrigeration and must therefore be conditioned to room temperature before administration. The reconstitution procedure comprises six different stages of preparation, including very gentle handling to ensure homogenous suspension of the product before it can be injected. Due to its complex reconstitution procedure and the need for intramuscular injection, Sandostatin<sup>®</sup> LAR<sup>®</sup> requires administration by a specially trained healthcare professional. Treatment with Sandostatin<sup>®</sup> LAR<sup>®</sup> usually takes place in specialist centres in major hospitals and patients often need to travel long distances to receive their therapy.

Somatuline<sup>®</sup> Autogel<sup>®</sup> is a depot formulation of lanreotide, in the form of a viscous paste in a pre-filled syringe for deep subcutaneous injection once a month. Due to the high viscosity of the product, the custom-made syringe has a relatively thick needle and the injection time is long. Compared to Sandostatin<sup>®</sup> LAR<sup>®</sup>, Somatuline<sup>®</sup> Autogel<sup>®</sup> reaches therapeutic effect levels faster. Like Sandostatin<sup>®</sup> LAR<sup>®</sup>, Somatuline<sup>®</sup> Autogel<sup>®</sup> requires refrigeration and must be conditioned to room temperature before administration.

Signifor<sup>®</sup> LAR<sup>®</sup> is a relatively new, long-acting pasireotidebased SSA, which has similar pharmaceutical presentation to Sandostatin<sup>®</sup> LAR<sup>®</sup>, meaning it requires reconstitution in six steps and must be injected intramuscularly by a healthcare professional. The product binds to four of the five somatostatin receptor subtypes and, at present, is only approved for the treatment of patients with acromegaly who, as a second line medical treatment, respond inadequately to surgery (US), or not at all to octreotide or lanreotide (Europe).

The table below shows a comparison between Sandostatin<sup>®</sup> LAR<sup>®</sup>, Somatuline<sup>®</sup> Autogel<sup>®</sup> and Signifor<sup>®</sup> LAR<sup>®</sup>.

<sup>&</sup>lt;sup>12</sup> Strosberg, J, Kvols L. Antiproliferative effect of somatostatin analogs in gastroenteropancreatic neuroendocrine tumors. World J Gastroenterol. 2010;16:2963-2970.

<sup>&</sup>lt;sup>13</sup> Oberg KE. The management of neuroendocrine tumours: current and future medical therapy options. Clin Oncol (R Coll Radiol). 2012;24:282-293.

<sup>&</sup>lt;sup>14</sup> Hofland LJ, Lamberts SW. The pathophysiological consequences of somatostatin receptor internalization and resistance. Endocr Rev. 2003;24:28-47.

<sup>&</sup>lt;sup>15</sup> Al-Efraij K, Aljama MA, Kennecke HF. Association of dose escalation of octreotide long-acting release on clinical symptoms and tumor markers and response among patients with neuroendocrine tumors. Cancer Med. 2015;4:864-870. IS Pap. Scheme A. Melmed S. Astronomical Metab. Clin Nath Among 2009;7:101-122.

<sup>&</sup>lt;sup>16</sup> Ben-Shlomo A, Melmed S. Acromegaly. Endocrinol Metab Clin North Am. 2008;37:101-122.

 <sup>&</sup>lt;sup>17</sup> Kauppinen-Makelin R, Sane T, Reunanen A, et al. A nationwide survey of mortality in acromegaly. J Clin Endocrinol Metab. 2005;90:4081-4086.
 <sup>18</sup> Modlin IM, Pavel M, Kidd M, Gustafsson BI. Review article: somatostatin analogues in the treatment of gastroenteropancreatic neuroendocrine (carcinoid) tumours. Aliment Pharmacol Ther. 2010;31:169-188.

<sup>&</sup>lt;sup>19</sup> Ayuk J, Sheppard MC. Growth hormone and its disorders. Postgrad Med J. 2006;82:24-30.

Indication	Sandostatin <sup>®</sup> LAR <sup>®</sup>	Somatuline <sup>®</sup> Autogel <sup>®</sup>	Signifor <sup>®</sup> LAR <sup>®</sup>
Company	Novartis	lpsen	Novartis
Needle size	20G x 40 mm	18/19G x 20 mm	20G x 40 mm
Injection volume	2.0 mL	0.2-0.5 mL	2.0 mL
Presentation	Powder vial + prefilled syringe with diluent solution + vial adapter + injection needle	Prefilled syringe	Powder vial + prefilled syringe with diluent solution + vial adapter + injection needle
Injection route	Intramuscular, after reconstitution in six steps	Subcutaneous	Intramuscular, after reconstitution in six steps
Storage	Refrigerated, bring to room temperature between 30-60 minutes before reconstitution	Refrigerated, conditioning at room temperature for at least 30 minutes before injection	Refrigerated, bring to room temperature between 30-60 minutes before reconstitution
Administration	Must be administered by a trained healthcare provider	Approved for partner and self injection	Must be administered by a trained healthcare provider

#### Comparison of SSA-based products on the market

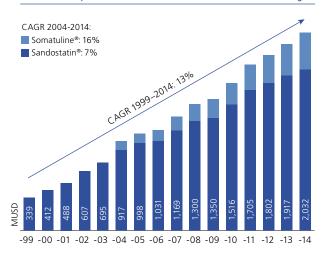
#### Somatostatin analogues in development

Camurus is not currently aware of any other SSA depot formulations in clinical development in Europe or the US. The Company is only aware of one SSA product in clinical development for the treatment of acromegaly or NETs – an oral octreotide formulation developed by Chiasma Pharmaceuticals. According to Chiasma, the company has submitted a market approval application in 2015 which is currently being processed by the FDA. In 2014, the company's former partner, Roche, returned the product rights to Chiasma. The relative bioavailability of oral octreotide following oral administrations is approximately 200 times lower than after subcutaneous injection<sup>20</sup>, meaning that very high doses of octreotide need to be administered daily.

#### Market opportunity

The global market for leading SSA products Sandostatin® LAR® and Somatuline® Autogel® has more than quintupled over the past 15 years, with a compound annual growth rate (CAGR) of 13 percent. In 2014, the global market for these products was valued at more than USD 2 billion, with total sales of USD 1.65 billion for Sandostatin® LAR® and of USD 382 million for Somatuline® Autogel®.<sup>21,22</sup>

Despite several patent expiries between 2010 and 2014, sales of Sandostatin<sup>®</sup> LAR<sup>®</sup> continued to rise steadily. At the same time, increased awareness and diagnosis rate of rare endocrine disorders are leading to market expansion.<sup>23</sup> Growth may be further strengthened by potential new therapeutic indications for SSA products. Such applications include diabetic complications such as retinopathy, nephropathy and obesity<sup>24</sup>, polycystic kidney disease<sup>25</sup>, pancreatitis and pancreatic fistulas<sup>26</sup>. Market development for Sandostatin® LAR® and Somatuline® Autogel®



Source: Medtrack

<sup>26</sup> Jin K, Zhou H, Zhang J, et al. Systematic review and meta-analysis of somatostatin analogues in the prevention of postoperative complication after pancreaticoduodenectomy. Dig Surg. 2015;32:196-207.

<sup>&</sup>lt;sup>20</sup> Tuvia S, Atsmon J, Teichman SL, et al. Oral octreotide absorption in human subjects: comparable pharmacokinetics to parenteral octreotide and effective growth hormone suppression. J Clin Endocrinol Metab. 2012; 97:2362-2369.

<sup>&</sup>lt;sup>21</sup> Medtrack.

<sup>&</sup>lt;sup>22</sup> Sales data for Somatuline<sup>®</sup> Autogel<sup>®</sup> is only available from 2004.

<sup>23</sup> GBI Research, http://www.prweb.com/pdfdownload/8052240.pdf.

<sup>&</sup>lt;sup>24</sup> Rai U, Thrimawithana TR, Valery C, Young SA. Therapeutic uses of somatostatin and its analogues: Current view and potential applications. Pharmacol Ther. 2015;152:98-110.

<sup>&</sup>lt;sup>25</sup> Woon C, Bielinski-Bradbury A, O'Reilly K, Robinson P. A systematic review of the predictors of disease progression in patients with autosomal dominant polycystic kidney disease. BMC Nephrol. 2015;16:140.

## CAM2029 – a new treatment alternative for acromegaly and NET

CAM2029 is a novel pharmaceutical formulation of octreotide. It is based on Camurus' patented FluidCrystal® injection depot technology and considered to have major benefits compared with existing products – Sandostatin® LAR® and Somatuline® Autogel®. CAM2029 comes in a pre-filled syringe equipped with an automatic needle-stick prevention device and can easily be injected subcutaneously, also by patients themselves, without need for complex reconstitution or conditioning to room temperature before administration. The FluidCrystal® Injection depot technology used for CAM2029 has also been demonstrated to be compatible with the use of auto-injectors, which, if developed, could further enhance the ease of selfadministration.

CAM2029 for treatment of acromegaly has been granted orphan designation by the European Commission, a status that is granted for medicines of significant benefit to patients with rare diseases. Obtaining orphan designation provides a number of benefits during product development, such as scientific advice and protocol assistance, as well as additional market exclusivity once the medicine is on the market. Reductions of regulatory fees are also available, depending on the status of the sponsor and the type of service required.

#### Product features, handling and administration

CAM2029 comes ready-to-use with two doses, 10 mg and 20 mg, in a standard pre-filled syringe with a thin fixed needle and an external needle-stick prevention device. The product is easily administered as a subcutaneous injection by a healthcare

professional or by the patient. When CAM2029 is injected, the depot formulation absorbs interstitial aqueous fluid, resulting in a rapid in situ transformation from a viscous liquid to a viscous liquid crystalline gel, which effectively encapsulates the pharmaceutical substance octreotide. Formation of the encapsulating gel structure is a spontaneous process that begins immediately when CAM2029 is injected into the body. The gel-formation results from the self-assembly of the lipid components of the FluidCrystal® formulation, where a nanostructured liquid crystalline phase structure is formed immediately on contact with minute quantities of water present at the site of injection.

In addition to the benefits mentioned in relation to the handling and administration of CAM2029, the product also demonstrates a rapid onset of therapeutic octreotide concentrations, followed by long-acting release phase as the lipid-based depot is biodegrading in the subcutaneous tissue. In contrast, it takes between one and two weeks before therapeutic octreotide levels are established after first dosing with Sandostatin<sup>®</sup> LAR<sup>®</sup>; see the figure in the "Clinical results" section below. In addition to faster onset, CAM2029 has been shown to provide about 500 percent higher bioavailability, compared to Sandostatin<sup>®</sup> LAR<sup>®</sup>. The higher octreotide exposure achieved with CAM2029 may potentially improve efficacy in some patient populations with acromegaly and NETs, as well as potentially providing opportunities in other therapeutic areas.

The safety profile of CAM2029 is generally comparable with the safety profile of Sandostatin<sup>®</sup> LAR<sup>®</sup>.<sup>27</sup> Due to the thinner needle, Camurus expects injections of CAM2029 to be less painful than injections of Sandostatin<sup>®</sup> LAR<sup>®</sup> and Somatuline<sup>®</sup> Autogel<sup>®</sup>, which use thicker 20 and 18/19 gauge needles, re-

#### Illustration of product design for CAM2029 and marketed SSA-based products



\* Illustrative. Final product configuration may be different.

<sup>27</sup> Tiberg F, Roberts J, Cervin C, et al. Octreotide sc depot provides sustained octreotide bioavailability and similar IGF-1 suppression to octreotide LAR in healthy volunteers. Br J Clin Pharmacol. 2015;80:460-472.

<sup>\*\* 22</sup>G or thinner.

spectively. Furthermore, Sandostatin<sup>®</sup> LAR<sup>®</sup> requires multi-step reconstitution from a powder before administration as a 2.0 mL intramuscular injection by a trained healthcare professional. The image below shows a product design comparison be-

tween Sandostatin<sup>®</sup> LAR<sup>®</sup>, Somatuline<sup>®</sup> Autogel<sup>®</sup> and CAM2029.

Overall, CAM2029 is expected to simplify treatment for patients, through allowing easy self-administration and avoiding frequent and sometimes long journeys to specialist clinics for injections, with the further potential to reducing healthcare costs and workloads for healthcare professionals. In addition, CAM2029 is expected to provide faster, and potentially better, treatment efficacy in certain groups of patients with acromegaly and NETs.

Camurus believes that the many positive features of CAM2029, combined with Novartis' position as the market leader in acromegaly and NETs, create the potential the product, if approved, to capture a significant future share of the global SSA market.

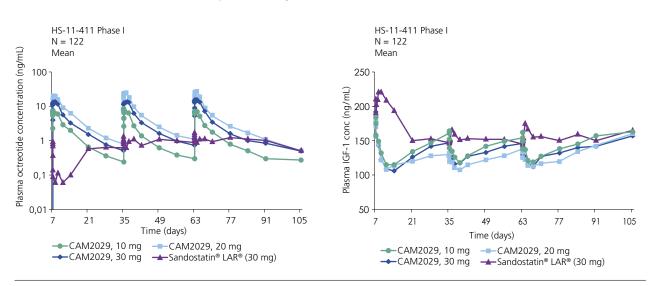
#### **Clinical results**

To date, CAM2029 has been documented in three clinical trials in healthy volunteers after single (HS-05-194) and repeat doses (HS-07-291 and HS-11-411). More than 250 subjects participated in these three trials, which have also included immediate release Sandostatin<sup>®</sup> and Sandostatin<sup>®</sup> LAR<sup>®</sup> as a reference products. In total, more than 400 injections of CAM2029 were characterised in relation to the pharmacokinetics of octreotide, effect on the growth factor IGF-1, as well as safety and local tolerance.<sup>28</sup>

The figures below show the plasma concentration profiles of octreotide and IGF-1 after repeat doses of CAM2029 as well as Sandostatin® LAR®. Doses were administered once monthly (days 7, 35 and finally 63) in the form of subcutaneous and intramuscular injections, respectively. As shown in the figure below on the left, CAM2029 demonstrates more rapidly increasing and higher octreotide concentrations, while it takes about one to two weeks before Sandostatin® LAR® demonstrates higher concentrations following a short initial release of octreotide. CAM2029 provides a significantly higher octreotide bioavailability, about 500 percent, compared to the reference product Sandostatin® LAR®. The difference in bioavailability is also reflected in the pharmacodynamic effects on the insulin-like growth factor 1 (IGF-1). The figure below on the right shows how a much faster suppression, and generally lower levels, of IGF-1 is obtained with CAM2029 than with Sandostatin® LAR®. Notably, IGF-1 is a well-established surrogate biomarker for treatment efficacy in acromegaly patients.

Although CAM2029 demonstrates about 500 percent higher octreotide exposure and a faster and more powerful suppression of IGF-1, the safety profile after repeat doses of CAM2029 is comparable with that of Sandostatin<sup>®</sup> LAR<sup>®,29</sup>

#### Pharmacokinetics (octreotide) and pharmacodynamics (IGF-1) for CAM2029 and Sandostatin® LAR®



<sup>&</sup>lt;sup>28</sup> Brabant G. Insulin-like growth factor-I: marker for diagnosis of acromegaly and monitoring the efficacy of treatment. European Journal of Endocrinology 148 S15–S20, 2003.

<sup>&</sup>lt;sup>29</sup> Tiberg F, Roberts J, Cervin C, et al. Octreotide sc depot provides sustained octreotide bioavailability and similar IGF-1 suppression to octreotide LAR in healthy volunteers. Br J Clin Pharmacol. 2015;80:460-472.

Overall, the safety profile of CAM2029, including systemic and local tolerance, was characterised in three clinical trials, see below, and was reported to be good. The most commonly reported side effects were gastrointestinal disorders associated with the active ingredient octreotide.

Completed and ongoing clinical trials featuring CAM2029 are shown in the table below.

Trial no.	Subjects	Key results / Study	/ design	Status		
HS-05-194 Phase I	32 volunteers		Rapid and long-acting release of octreotide and suppression of the IGF-1 growth factor. Comparable results obtained after intramuscular and subcutaneous injections	~		
HS-07-291 Phase I	95 volunteers	Demonstrated good safety profile, including local tolerability, in all clinical trials	Rapid and long-acting release of octreotide and suppression of the IGF-1 growth factor. Dose proportional octreotide exposure with a 7-fold increase in bio-availability compared with Sandostatin LAR after repeated dosing abdominally or in the butock	~		
HS-11-411 Phase I	122 volunteers		Rapid and long-acting release of octreotide and suppression of the IGF-1 growth factor. Dose proportional octreotide exposure with a 5 times higher bio-availability compared with Sandostatin LAR 30 mg	•		
HS-12-455 Phase II	24 patients <sup>1</sup> in two groups with acromegaly and NETs	efficacy and safety of	Randomised multi-centre study of the pharmacokinetics, pharmacodynamics, efficacy and safety of CAM2029 in two patients groups with acromegaly and neuroendocrine tumours (NET) previously treated with Sandostatin® LAR®			

<sup>1</sup> Planned number of patients.

#### **Pre-clinical trials**

The pre-clinical development programme for CAM2029 comprises studies of pharmacokinetics, pharmacodynamics, toxicity and local tolerance. The pharmacokinetics of CAM2029 have been characterised in several pre-clinical in vivo trials following single or repeat dosing, and compared against relevant marketed medicines. The results of these trials show comparable pharmacokinetic profiles in various pre-clinical animal models, with a relatively rapid absorption phrase, in which a maximum plasma concentration (Cmax) level is achieved within a few hours of administration, followed by a slowly declining release over the 28-day period for which the product is intended. No pre-clinical trials showed any signs of dose dumping after administration. Over longer periods of time, the octreotide concentration continued to decrease before finally falling under the limit of quantification. In pre-clinical trials, CAM2029 also demonstrated dose proportionality in relation to plasma concentrations and exposure, and exhibited similar pharmacokinetic profiles following subcutaneous and intramuscular administration.

#### Partnership with Novartis

In December 2011, Novartis and Camurus signed a collaboration, option and licensing agreement regarding further development and commercialisation of CAM2029. Novartis is an affiliate of Novartis AG, a global pharmaceutical company based in Basel, Switzerland.

Upon signing of the agreement in 2011, Camurus received an option payment of USD 10 million from Novartis. Two years later, in September 2013, Novartis exercised its option to license and acquire the rights to CAM2029 for further development and worldwide commercialization, including the treatment of patients with acromegaly and neuroendocrine tumours (NETs). As part of the agreement, Novartis is obliged to make milestone payments to Camurus upon the completion of various development and regulatory milestones with respect to the first and second indications for CAM2029, in either the US or EU. Under the Agreement, these milestone payments could total up to a maximum of USD 105 million. Of this amount, USD 32.5 million was paid to Camurus at the time of the exercise of the option in 2013, and a further USD 7.5 million in development milestones has been received after Novartis exercised its option.

In the event that CAM2029 achieves regulatory approval in the US or EU, sales of CAM2029 by Novartis would be subject to milestone payments to Camurus upon reaching certain annual sales thresholds up to a maximum of USD 150 million, in addition to the above development and regulatory milestones.

In the event of regulatory approval and commercialization, Novartis shall also pay tiered royalties to Camurus on annual net sales of CAM2029, ranging between mid to high single digit percentage, with the lowest royalty level applying to annual sales up to USD 500 million and with the highest royalty level applying to annual sales above USD 1,000 million.

In addition to CAM2029, the agreement with Novartis also covers additional future products based on the Camurus FluidCrystal<sup>®</sup> Injection depot technology. The total eligible potential payments to Camurus, including for CAM2029, amount to USD 700 million, subject to achievement of predefined development, regulatory and commercial milestones for the products included in the agreement. In addition, Camurus is entitled to royalties on global product sales.

## *Further development and the path to market registration*

Following the option exercise in September 2013, Novartis assumed responsibility for the further clinical development, including pivotal studies, product registration and worldwide commercialization for CAM2029. Based on available data, including stability, PK/PD profiles at different CAM2029 doses, safety/tolerability and injectability, a formulation of the CAM2029 drug product candidate has been selected for continued clinical development.

Camurus and Novartis have successfully conducted end of Phase II meetings with EU and US health authorities, with alignment achieved on the registration programs for CAM2029 in both acromegaly and NET. Novartis has informed Camurus that it expects Phase III programs in acromegaly and NETs to each include a non-inferiority study versus Sandostatin<sup>®</sup> LAR<sup>®</sup> as the main registration-supporting study. Novartis has prepared the Phase III studies, which are scheduled to commence subject to Novartis' successful completion of manufacturing and confirmation of stability of the final prefilled syringe product format. Camurus estimates that the Phase III program in acromegaly and in NETs may take approximately 3.5 years to complete from inclusion of the first patient in the respective study.

Pursuant to the agreement, Camurus and Novartis are also conducting an early clinical study to evaluate a formulation of a second peptide product candidate, CAM4071, based on Camurus' FluidCrystal<sup>®</sup> Injection depot.

#### CAM2038 – injection depots of buprenorphine for treatment of opioid dependence Introduction

Opioid dependence is a serious and rapidly growing medical and social problem all over the world. CAM2038 comprises two long-acting, subcutaneous buprenorphine products for the maintenance treatment of opioid dependence, intended for once-weekly (q1w) or once-monthly (q4w) dosages. The products have been developed to address several shortcomings in currently available medicines, such as poor adherence and frequent relapses as well as diversion, abuse and misuse.

CAM2038 combines the established and well-documented

active ingredient buprenorphine with Camurus' long-acting FluidCrystal® Injection depot. Due to the long-acting efficacy of CAM2038, the medicine only needs to be administered 12 or 52 times per year. This reduces the burden of daily medication, which usually requires supervision by healthcare professionals, and is therefore time-consuming and costly for both patients and society. CAM2038 is designed for administration as a single subcutaneous injection by a healthcare professional and can therefore not be misused, diverted or sold on the illegal market.

CAM2038 is developed in multiple doses, both for weekly or monthly administration. This flexibility enables the product to meet all phases of maintenance therapy for opioid dependence, from initiation of treatment to stabilisation and long-term maintenance. The dosing flexibility is important for addressing individual patient needs, such as treatment phase, history of abuse and other factors. CAM2038 will be available in pre-filled syringes with a needle-stick prevention device. The products are injected subcutaneously in small volumes and do not need any reconstitution before administration.

CAM2038 has been evaluated in three clinical trials to date, comprising a total of 188 subjects, of which 176 have been dosed with CAM2038. Good safety profile, including local tolerance, has been demonstrated in all trials. The clinical trials also demonstrated the desired pharmacological and pharmacodynamic profiles for weekly and monthly dosing. Direct comparisons with marketed products have further supported the target product profile for CAM2038. Following completion of these three clinical Phase I and II trials, Camurus and its partner Braeburn have initiated the pivotal registration program for CAM2038 in opioid dependence. First dosing in a Phase III trial is planned for the fourth quarter of 2015.

#### Overview of opioid dependence Opioid dependence statistics

Dependence on prescription and illicit opioid drugs, including heroin, is a complex and growing global public health challenge. More than 30 million people worldwide are estimated to use opioids, and opioids also top the list of drugs with the largest disease burden on society and the highest number of drug-related deaths worldwide.<sup>30</sup> In monetary terms, the ordinance of prescription analgesic opioid products increased from USD 76 in 1991 to USD 207 in 2013, in the US alone.<sup>31</sup> Opioid dependence has a very profound negative effect on people's health and can severely impair quality of life. Alongside the risk of overdose, opioid dependence and abuse is also associated with risks of infection with HIV or hepatitis B or C, sometimes linked to the use of infected needles and syringes.

A recently published study by Degenhardt et al.<sup>32</sup> showed that globally in 2010, drug dependence was responsible for about 3.6 million years of life lost through premature death and 16.4 million years of life lived with impaired quality of life or disability. Combined, this represented 20 million disability-adjusted life

<sup>&</sup>lt;sup>30</sup> United Nations Office on Drugs and Crime, World Drug Report 2015 (United Nations publication, Sales No. E.15.XL.6).

<sup>&</sup>lt;sup>31</sup> US National Center for Health Statistics, http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-toopioids-heroin-prescription-drug-abuse.

<sup>&</sup>lt;sup>32</sup> Degenhardt L, Whiteford HA, Ferrari AJ, et al. Global burden of disease attributable to illicit drug use and dependence: findings from the Global Burden of Disease Study 2010. Lancet. 2013;382:1564-1574.

years, an increase of more than 50 percent from an estimated 13 million disability-adjusted life years in 1990. Opioid dependence was by far the largest contributor to the disease burden. Of around 78,000 deaths in 2010 attributed to illicit drug use, more than half (55 percent) were thought to be due to opioid dependence.

Total societal costs of opioid dependence in the US were estimated at USD 56 billion in 2007.33 Consequently, there is a strong health-economic argument in favour of opioid dependence treatment. In the US, it has been estimated that for every dollar spent on opioid dependence treatment, 12 dollars are saved in other healthcare and societal costs.<sup>34</sup>

Buprenorphine is one of the most commonly used medications for the treatment of opioid dependence and has since it was first launched at the start of the 21st century successively gained increasing recognition and market share. Sublingual buprenorphine tablets are currently marketed in more than 30 countries. The market leading buprenorphine product Suboxone® had global sales of around USD 1.4 billion in 2013.35

More than 5 million individuals in the US<sup>36</sup> are estimated to abuse opioids, of whom approximately half have been diagnosed with opioid dependence. Approximately 1.1 million individuals are currently receiving opioid dependence treatment in the US.37 In 2012, approximately 700,000 patients were treated with buprenorphine products and approximately 312,000 patients with methadone.<sup>38</sup> In Camurus' assessment, the market will continue to grow in future years, primarily driven by sustained, increased growth in the use of opioid painkillers, increased access to maintenance treatment, and increased political awareness of and interest in the medical and social consequences of opioid drug dependence.

Under the Drug Addiction Treatment Act of 2000 (DATA 2000), US office-based physicians with the appropriate training are able to prescribe and dispense opioid medications to up to 100 patients in their medical office. Only buprenorphine-based products have been approved for this office-based treatment of opioid dependence. Prior to DATA 2000, the treatment options for opioid dependence were either ineffective or associated with social stigma, resulting in a large number of untreated opioid-dependent individuals. The enactment of DATA 2000 and the ability to offer treatment in the privacy of a physician's office meant that opioid-dependent individuals could gain access to treatment in a similar manner as for other patients with chronic diseases.

The US Department of Health and Human Services (HHS) recently announced that it would increase the availability of medically supported treatment of opioid dependence as one of several initiatives to reduce opioid-related overdoses and dependence. HHS will also change the federal laws governing the prescription of buprenorphine for the treatment of opioid dependence in a bid to improve the availability of medicine and simultaneously reduce the risk of supply and abuse.

In Europe, the illicit use of opioids is also responsible for a disproportionately large share of morbidity and mortality resulting from drug use. Opioids account for approximately three quarters of all fatal overdoses in Europe.<sup>39</sup> The main opioid used in Europe is heroin, although a range of other synthetic opioids, such as oxycodone, fentanyl, methadone and buprenorphine are also available in the illicit market. In 2012, it was estimated that there were around 1.3 million problem opioid users in Europe, approximately 740,000 of whom received opioid substitution treatment<sup>40</sup>. The estimated average treatment period for patients receiving opioid substitution treatment in Europe was 3.7 years in 2012.<sup>41</sup> In France, Germany, Italy and the UK, approximately 500,000 patients were on substitution treatment, mainly using methadone and buprenorphine. In the EU, approximately 36 percent of the patients on substitution treatment are estimated to receive buprenorphine (or buprenorphine combined with naloxone), while methadone accounts for approximately 60 percent and other patients receive different types of substitution treatments.<sup>42</sup> Buprenorphine is by far the most common form of maintenance treatment in France, where the substance was registered for opioid dependence in the late 1990s.

To a certain extent, treatment methods are different in the EU than in the US. Due to price pressure and a longer maintenance treatment tradition, methadone and generics remain market leaders in the EU, while buprenorphine is the market leader in the US. Maintenance treatment is also more highly regulated in the EU, with more restrictions, for example, limiting directto-patient promotion and requirements for supervised dosing, resulting in daily clinic visits for many patients.

It is estimated that 15.8 million people in the rest of the world currently use opioids.43 Treatment services are, with the exception of Australia and New Zealand, generally underdeveloped. Asia has about 12 million opioid users<sup>44</sup>, and China has 1.2 registered opioid-dependent individuals.<sup>45</sup> Compared with the global average prevalence of 0.7 percent, opioid use is high in

<sup>33</sup> Birnbaum HG, White AG, Schiller M, Waldman T, Cleveland JM, Roland CL.. Societal costs of prescription opioid abuse, dependence, and misuse in the United States. Pain Med. 2011;12:657-67.

<sup>&</sup>lt;sup>34</sup> World Health Organization, United Nations Office on Drugs and Crime, UNAIDS, Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention: position paper 2004.

<sup>&</sup>lt;sup>35</sup> http://www.drugs.com/stats/top100/2013/sales <sup>36</sup> https://braeburnpharmaceuticals.com/opioid-dependence-recovery/about/.

<sup>&</sup>lt;sup>37</sup> National Institute on Drug Abuse (NIDA). CDC Wonder

<sup>38</sup> Jones CM, Campopiano M, Baldwin G, McCance-Katz E. National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment. Am J Public Health. 2015;105:e55-63.

<sup>&</sup>lt;sup>39</sup> European Monitoring Centre for Drugs and Drug Addiction, European Drug Report 2015.

<sup>40</sup> European Monitoring Centre for Drugs and Drug Addiction, European Drug Report 2015

<sup>&</sup>lt;sup>41</sup> Dale-Perera A, Goulão J, Stöver H. Quality of care provided to patients receiving Opioid Maintenance Treatment in Europe: Results from the EQUATOR analysis. Heroin Addict Relat Clin Probl. 2012;14: 23-38

<sup>&</sup>lt;sup>42</sup> Dale-Perera A, Goulão J, Stöver H. Quality of care provided to patients receiving Opioid Maintenance Treatment in Europe: Results from the EQUATOR analysis. Heroin Addict Relat Clin Probl. 2012;14: 23-38. <sup>43</sup> United Nations Office on Drugs and Crime, World Drug Report 2015 (United Nations publication, Sales No. E.15.XL.6).

<sup>&</sup>lt;sup>44</sup> United Nations Office on Drugs and Crime, World Drug Report 2015 (United Nations publication, Sales No. E.15.XL.6).

<sup>&</sup>lt;sup>45</sup> China Anti-drug Abuse Agency 2011.

Oceania, with a prevalence rate of 3 percent in 2010.<sup>46</sup> Some 47,000 people in Australia receive opioid pharmacotherapy every day.<sup>47</sup> About 68 percent of patients in Australia received methadone, while the remaining 32 percent received buprenorphine or buprenorphine combined with naloxone.<sup>48</sup>

#### Buprenorphine treatment benefits

Buprenorphine was initially developed for the treatment of pain and has many properties that make it suitable for the treatment of opioid dependence. The potency of buprenorphine is 25 to 50 times higher than that of morphine but unlike morphine and methadone for example, buprenorphine is a partial mu-opioid receptor agonist, which means that it does not have the full opioid effects. Unlike methadone for example, buprenorphine does not normally lead to respiratory depression and thus the risk of overdose is low, even for high buprenorphine doses. Buprenorphine produces milder euphoric and sedative effects compared with morphine and methadone, for instance, while still occupying opioid receptors, thus effectively preventing withdrawal symptoms. Moreover, buprenorphine has a higher affinity for the mu receptor than other opioids and can therefore block the effects of other opioids, such as heroin. Compared with morphine and other opioids, use of buprenorphine also leads to a lower incidence of constipation.49

Buprenorphine treatment for opioid dependence typically consists of three phases:

- Induction (usually about one week), during which the patient is weaned off illicit opioids and is titrated for withdrawal symptoms. The goal of the induction phase is to find the minimum dose of buprenorphine at which the patient discontinues or markedly diminishes use of other opioids and experiences no withdrawal symptoms.
- Stabilisation (usually one to two months), when patients are closely monitored by regular, often weekly, clinical visits, and the maintenance dose is adjusted as required. The stabilisation phase aims at ensuring that patients are considerably reducing if not eliminating illicit opioid use.
- Long-term maintenance treatment (usually over several years or a lifetime), involves continued buprenorphine treatment until dependence ceases or the patient has a relapse. Endeavours are often made to gradually taper doses during this phase. Close attention is paid to the patient's psychosocial situation and family relationships, and on monitoring opioid cravings and withdrawal symptoms, to avoid relapse. The goal of the maintenance phase is to achieve an enduring recovery from opioid dependence and freedom from illicit opioid use for the patient.

Opioid maintenance therapy with buprenorphine is associated with substantial benefits for patients and society, such as reductions in illicit opioid use, criminal activity, fatalities and the transmission of infectious diseases, such as HIV.<sup>50</sup> Buprenorphine treatment also leads to fewer emergency room visits and improved quality of life for the individual. Like methadone, buprenorphine has been shown to reduce hospital admissions, morbidity and mortality. Additionally, buprenorphine treatment is associated with a lower risk of overdose and diversion compared with methadone treatment (as described above), and thus offers improved safety and flexibility to both patients and physicians.<sup>51</sup>

#### Competitive landscape and market opportunity Current buprenorphine products

All current buprenorphine pharmaceuticals are administered intraorally under the tongue (sublingual administration) or through the inside of the cheek (buccal administration) as a tablet or film. Suboxone® and Subutex® (Indivior) are the market-leading products in the US and Europe respectively. ZubSolv® (Orexo) and Bunavail® (Biodelivery Sciences) are new products in the US market that have both received approval in the last few years. These products have comparable characteristics to Suboxone®, though certain differences exist in terms of flavour, shape and dissolution time.

Subutex<sup>®</sup> is a sublingual buprenorphine tablet, which was first approved for opioid dependence treatment in 1995, and is currently marketed in 24 countries. Suboxone<sup>®</sup>, which contains both buprenorphine and naloxone, was developed to deter misuse by injection and is currently marketed in the form of sublingual tablets or film. Suboxone<sup>®</sup> Film was launched in the US in 2010 and currently maintains a share of approximately 60 percent of the US market for buprenorphine-based opioid dependence treatment (based on prescribed milligrams). In addition to the US, Suboxone<sup>®</sup> Film is also marketed in Australia and Malaysia but is not yet approved in Europe. In the US, Suboxone<sup>®</sup> in tablet form was approved in 2002 as an orphan drug for maintenance treatment of opioid dependence, a status which it lost in 2009. The product is currently marketed in 41 countries worldwide.

ZubSolv<sup>®</sup> is a relatively new sublingual product based on buprenorphine and naloxone. The product is marketed using arguments, such as an improved flavour and a shorter dissolution time. Bunavail<sup>®</sup> is a recently registered buprenorphine and naloxone buccal film that is applied daily to the oral mucosa. In addition to these products, there are currently a number of generic, sublingual, tablet products based on buprenorphine and naloxone in the US market.

<sup>&</sup>lt;sup>46</sup> United Nations Office on Drugs and Crime, World Drug Report 2015 (United Nations publication, Sales No. E.15.XL.6).

<sup>&</sup>lt;sup>47</sup> AIHW 2014, National Opioid Pharmacotherapy Statistics 2013. Drug treatment series 23.

<sup>&</sup>lt;sup>48</sup> AIHW 2014, National Opioid Pharmacotherapy Statistics 2013. Drug treatment series 23.

<sup>&</sup>lt;sup>49</sup> Harcus AW, Ward AE, Smith DW. Buprenorphine: experience in an elderly population of 975 patients during a year's monitored release. Br J Clin Pract. 1980;34:144-146.

<sup>&</sup>lt;sup>50</sup> World Health Organization, United Nations Office on Drugs and Crime, UNAIDS, Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention : position paper, 2004.

<sup>&</sup>lt;sup>51</sup> Connery HS. Medication-Assisted Treatment of Opioid Use Disorder: Review of the Evidence and Future Directions. Harvard Review of Psychiatry Volume 23, Number 2, March/April 2015.

Even if it has been possible to establish efficacy of these products in the treatment of patients with an opioid dependence, a number of disadvantages have been reported, including: incorrect use, misuse, deviation from the dosage regimen, the need for daily administration, sometimes supervised, and limited treatment adherence. All of the above products are essentially bioequivalent, in other words, display comparable pharmacokinetic buprenorphine profiles and exposures. The table below compares the key features of currently

marketed buprenorphine products.

Features	Subutex	Suboxone	ZubSolv	Bunavail	Generika
Company	Indivior	Indivior	Orexo	BioDelivery Sciences Int'l	Several companies
Pharmaceutical form	Sublingual tablet	Sublingual tablet and film	Sublingual tablet	Buccal film	Sublingual tablets
Geographic presence	Available in Europe	<ul> <li>Tablet is available in Europe</li> <li>Film is available in the US</li> </ul>	Available in the US	Available in the US	EU and US
Administration supervision	Only qualified doctors with the necessary DEA identification number are able to start in-office treatment	Only qualified doctors with the necessary DEA identification number are able to start in-office treatment	Treatment should be initiated with supervised administration, progressing to unsupervised administration	Treatment should be initiated with supervised administration, progressing to unsupervised administration	Only qualified doctors with the necessary DEA identification number are able to start in-office treatment
Storage	Storage between 15 and 30 degrees Celsius	Room temperature	Storage between 20 and 25 degrees Celsius	Storage between 20 and 25 degrees Celsius	Room temperature
Key features	Daily administrations	<ul> <li>Daily administrations</li> <li>Film is available in four different doses</li> </ul>	<ul> <li>Daily administrations</li> <li>Improved flavour</li> <li>Short dissolve time</li> </ul>	Daily administrations	Daily administrations

Source: Camurus

In addition to the buprenorphine-based treatment alternatives for opioid dependence, Alkermes is marketing the long-acting injection product, Vivitrol<sup>®</sup>, in the US market. Vivitrol<sup>®</sup> is based on the opioid antagonist naltrexone encapsulated in polymeric microparticles and injected as a 3.4 mL intramuscular injection once monthly using a 40 or 50 mm long, 20 gauge needle. The product must be stored refrigerated and needs to be conditioned for at least 45 minutes prior to injection. Naltrexone is an opioid antagonist and is used after opioid detoxification as a treatment to prevent relapses. Naltrexone is also available in oral dosage forms but the product has a very limited use in opioid dependence treatment.

## Long-acting buprenorphine treatments in clinical development

Camurus is aware of two other companies who are working on developing long-acting formulations of buprenorphine in clinical phase.

Probuphine<sup>®</sup> is a buprenorphine implant developed by Camurus' partner Braeburn and Titan Pharmaceuticals for opioid dependence treatment. The product is implanted in the form of four polymer-based implants (ProNeura<sup>™</sup>), which release buprenorphine for a period of six months. Probuphine<sup>®</sup> requires surgical insertion and removal of the implants every six

52 www.clinicaltrials.gov

months. The products offer a relatively limited buprenorphine exposure range and is intended for a subset of highly stable opioid-dependent patients undergoing maintenance treatment with sublingual buprenorphine doses of 8 mg or lower. Braeburn's intended positioning of Probuphine® is discussed further in the Partnership with Braeburn section below.

RBP-6000 is a buprenorphine injection depot in Phase III development by Indivior that is used for opioid dependence treatment. The product is based on the Atrigel® drug delivery technology and comprises a lactic acid polymer dissolved in the solvent N-methyl pyrrolidone (NMP). Upon subcutaneous injection, the solvent is absorbed by the body and the polymer diffuses and solidifies in the subcutaneous tissue. This means that the drug is encapsulated in the amorphous matrix and then slowly released as the matrix degrades. According to Indivior, RBP-6000 is being developed as a product candidate for once-monthly injection. In the ongoing Phase III trials, the product is administered in buprenorphine doses of 100 and 300 mg respectively, in the form of an 18 percent solution,<sup>52</sup> which correspond to injection volumes of approximately 0.55 and 1.66 mL, respectively.

To the best of Camurus' knowledge, no other long-acting buprenorphine treatments are in active clinical development in either EU or the US. While current sublingual buprenorphine products have been proven effective in treating opioid dependence, this approach has several shortcomings. For example, the limited absolute bioavailability of sublingual products of approximately 15 percent,<sup>53</sup> means that a higher effect can be achieved if the product is injected, when a bioavailability closer to 100 percent is achieved. The relatively high dosages of sublingual products can also be misused through snorting. Since not all buprenorphine administration is supervised, there is extensive diversion, misuse and abuse of sublingual buprenorphine tablets. In addition to intentional misuse of buprenorphine tablets, there is also a risk that children and adolescents may accidentally ingest buprenorphine tablets. Supervised administration solves some of these problems and is common in many European countries and in Australia, but entails severe restrictions in patients' lives and additional healthcare costs. Moreover, daily medication also means daily decisions and the risk that patients could discontinue treatment and, instead, temporarily take illicit drugs (referred to as "drug holiday").

High levels of attrition from treatment have been observed during the early induction and stabilisation phases of maintenance treatment of opioid dependence with sublingual buprenorphine. A large database study of 5,992 patients (3,349 on sublingual buprenorphine and 2,643 on methadone) entering their first episode of treatment found that 36 percent of buprenorphine recipients and 12 percent of methadone recipients abandoned treatment during the first two weeks.<sup>54</sup> Any non-adherence to treatment may lead to relapse, treatment failure and mortality in the opioid-dependent population.

Given the aforementioned shortcomings and the fact that close to one million people in the US and Europe are currently being treated with buprenorphine for opioid dependence Camurus is of the opinion that significant market potential exists for products that can address the medical needs and shortcomings of current products. In addition, such products could, in Camurus' assessment, also be an important alternative for patients currently being treated with methadone, in particular given the issues with supervised administration, serious side effects, high relapse rate and the risk of fatal respiratory depression associated with methadone treatment.

## *CAM2038 – a new treatment alternative of opioid dependence*

CAM2038 comprises two long-acting injection depot buprenorphine products developed for maintenance treatment with dosages administered once weekly and once monthly respectively. The products are available in several dosages and are intended for treatment during all phases of opioid dependence treatment, from induction and stabilisation to long-term maintenance treatment. The dosages are chosen to cover the approved doses of existing buprenorphine products, to be able to replace these in all treatment phases of opioid-dependent patients.

CAM2038 is intended to be administered by healthcare personnel to eliminate uncertainty about patients' compliance with treatment and, thereby, to virtually eliminate the risks of diversion, abuse, and misuse associated with current buprenorphine pharmaceuticals. Furthermore, the risk of children and adolescents being due to the storage of the pharmaceuticals in the patients' home environment is avoided.

CAM2038 also enables physicians to safely evaluate the need for dose titration, since there is no possibility of incorrect use of the medicine. Patients and physicians are also relieved from the burdens of daily, sometimes supervised, medication. CAM2038 can also lead to significant savings for the healthcare system and society as a whole, since the number of patient visits for supervised doses is substantially reduced.

The US Food and Drug Administration (FDA) recently granted CAM2038 fast track designation in the US for opioid dependence treatment signifying that CAM2038 has the potential to address a significant medical need in the treatment of serious or life-threatening conditions.

Camurus is unaware of any other company that is developing buprenorphine pharmaceuticals for weekly administration. The Company believes the combination of these dosing alternatives to be of substantial value since it enables medication to be adapted to both the patient's individual needs and the different care providers' treatment practices.

#### Product presentation, handling and administration

CAM2038 has been developed using Camurus' lipid-based drug delivery technology FluidCrystal® Injection depot; refer to the "FluidCrystal® Injection depot" section. Following the injection of CAM2038, the injected fluid spontaneously transforms into a liquid crystalline gel that releases buprenorphine at a steady rate during the period in which the depot slowly degrades in the subcutaneous tissue. CAM2038 comprises both weekly and monthly product versions, with compositions adapted to give release rates suitable for dosing once a week or once a month respectively.

Both products are presented in a prefilled syringe (1mL) with a relatively thin 23 gauge injection needle. The products are also equipped with a needle safety device that automatically covers the needle following injection. The products are ready to be injected, with no need for mixing or temperature adjustment prior to administration. Both weekly and monthly products are available in different doses to maximise flexibility and utility.

Relapse into dependence increases mortality risks in opioiddependent patients.<sup>55</sup> The vulnerability is particularly high during the induction phase of maintenance treatment. The use

<sup>&</sup>lt;sup>53</sup> NDA 020732 & 020733, Clinical Pharmacology and Biopharmaceutics Review.

<sup>&</sup>lt;sup>54</sup> Bell J, Trinh L, Butler B, Randall D, Rubin G. Comparing retention in treatment and mortality in people after initial entry to methadone and buprenorphine treatment. Addiction. 2009;104:1193-1200.

<sup>&</sup>lt;sup>55</sup> Cornish R, Macleod J, Strang J, Vickerman P, Hickman M. Risk of death during and after opiate substitution treatment and primary care: prospective observational study in UK General Practice Research Database. BMJ. 2010;341:c5475.

of CAM2038 in early treatment may enable to improve treatment, since the patient receives a long-acting product that also blocks the effects of other opioids, including heroin. Given this and the many other potential advantages of CAM2038 products, Camurus believes that CAM2038 can result in a paradigm shift in the treatment of opioid-dependent patients and could become an attractive alternative to daily sublingual/ buccal products during all stages of maintenance treatment of opioid-dependent patients. This may result in a reduction in the burden on patients as well as physicians, when compared with daily administration of existing buprenorphine and methadone drugs. Uncertainties with regard to patients' medication compliance and diversion, misuse and abuse of tablet and film products are also avoided.

#### **Clinical results**

The safety and efficacy profile of sublingual products based on buprenorphine and buprenorphine/naloxone for the maintenance treatment of opioid dependence has been well documented.<sup>56</sup> Each year, about one million individuals in the US and Europe undergo maintenance treatment with sublingual buprenorphine products. The CAM2038 weekly and monthly products are being developed in compliance with the hybrid application in the EU and the 505(b)(2) regulatory pathway in the US, refer to the Regulatory Overview section. These pathways for registration allow the referencing to the efficacy and safety data of for existing reference products.

To date, Camurus has concluded three clinical trials for CAM2038 weekly and monthly products in a total of 188 individuals, opioid-dependent patients and healthy volunteers and under Naltrexone blockage (of which 176 have been dosed with CAM2038); refer to the following table.

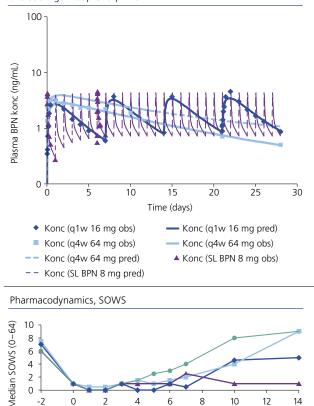
Trial no.	Subjects	Title	Status
HS-11-426 Phase I	60 volunteers	Randomised, three-way treatment trial assessing pharmacokinetics, bioavailability and safety of three doses of CAM2038 q1w versus intravenous and sublingual buprenorphine in healthy volunteers under naltrexone blockage	~
HS-13-487 Phase I	87 volunteers	Randomised trial assessing pharmacokinetics, bioavailability and safety of four single doses of CAM2038 q4w and four repeat doses of CAM2038 q1w versus intravenous and sublingual buprenorphine in healthy volunteers under naltrexone blockage	•
HS-07-307 Phase I/II	41 patients	Single-blind, single-dose, dose-escalation, parallel-group trial to investigate the safety, pharmacokinetics and pharmacodynamics of CAM2038 in patients with opioid dependence	~

The results from these trials have shown that the CAM2038 products (q1w and q4w) provide a rapid establishment of elevated buprenorphine plasma concentrations which peak during the first 24 hours and then slowly decay over one to four weeks, respectively. Both products have demonstrated dose-proportional plasma exposures in the dose intervals studied: 7.5 mg to 32 mg for the weekly product and 64 mg to 192 mg for the monthly product.

Doses were selected based on the comparability of plasma concentrations with those obtained with registered doses of the currently marketed buprenorphine products, Subutex<sup>®</sup> and Suboxone<sup>®</sup>, with the aim to ensure adequate exposure throughout the dosing period. This is illustrated in the following figure, which compares observed (obs) plasma concentrations of four repeated doses of CAM2038 q1w with one single dose of CAM2038 q4w and seven repeated doses of Subutex<sup>®</sup>. To facilitate comparison following repeated dosing with steady-state profiles, simulated curves based on predicted (pred) data are also shown.

The diagram clearly indicates that buprenorphine plasma concentrations after single and repeated steady-state dosing lies within the same intervals as the sublingual reference product Subutex<sup>®</sup>, but without the daily variations that are seen in plasma concentrations for Subutex<sup>®</sup>. Since both CAM2038 products give dose-proportional buprenorphine levels, dose adjustments is easily made to match the corresponding sublingual doses or as needed according to patients' needs. Dose conversion tables, from sublingual buprenorphine products to CAM2038 weekly and monthly products and vice versa, have been developed based on the pharmacokinetic studies performed to date.

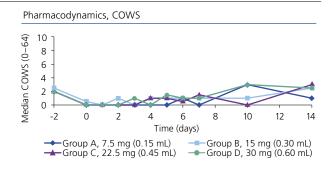
<sup>56</sup> Johnson RE, Jaffe, JH, Fudala, PJ JAMA – Journal of the American Medical Association, 1992, 267, 2750-2755, Fudala, PJ; Bridge, TP; Herbert, S; et al. New England Journal of Medicine Volume, 2003, 349, 949-958.



Pharmacokinetic profiles for CAM2038 q1w, CAM2038 q4w and sublingual buprenorphine

In addition to pharmacokinetics, pharmacodynamic properties have been assessed in opioid-dependent patients treated with CAM2038 q1w in the HS-07-307 trial. This includes subjective opiate withdrawal symptoms (SOWS), clinical opiate withdrawal symptoms (COWS) and the use of rescue medication, which were evaluated following single-dose administration of CAM2038 g1w, after a 48-hour washout of the previous maintenance treatment with sublingual buprenorphine.

Modest SOWS and COWS values were noted for all patients, which increased over the 48-hour washout period before rapidly diminishing following single-dose administration of CAM2038 g1w to zero or close to zero within about two to three hours. Low SOWS and COWS values were measured until day 7, or longer, following single-dose administration of CAM2038 g1w, which indicates that the product is effective in treating abstinence.



HS-07-307 also studied the time taken before patients took rescue medication in the form of sublingual buprenorphine. A Kaplan-Meier plot of time to first intake of buprenorphine rescue medication is shown in the diagram below. Only a few patients (5 of 41) took their first rescue dose before day seven. The median time from single-dose administration of CAM2038

0 -2

0

2

Group A, 7.5 mg (0.15 mL)

Δ

6

Time (days)

8

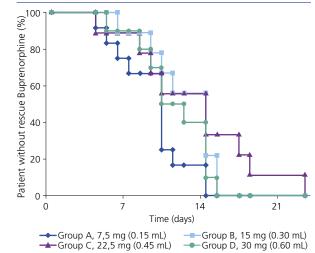
10

--- Group D, 30 mg (0.60 mL)

Group B, 15 mg (0.30 mL)

12

Time to intake of rescue medication (sublingual buprenorphine) after single-dose administration of CAM2038 q1w



q1w until the first rescue dose of buprenorphine was ten days, while the longest time following a single dose of CAM2038 q1w was 23 days.

Safety, including local tolerance at the site of injection, for CAM2038 g1w and/or CAM2038 g4w was studied in the three clinical trials performed to date. The results from all of the trials, for a total of 188 individuals (of which 176 have been dosed with CAM2038), unanimously showed a good safety profile and very good local tolerability at the site of injection. Only a few adverse effects related to injection site tolerability have been observed in the clinical trials conducted to date, and the effects have been transient and in most cases mild. In the pharmacokinetic trials (HS-11-426 and HS-13-487), the safety profiles for CAM2038 g1w and g4w have been reported as comparable to the corresponding safety profiles for the reference products: intravenous buprenorphine (Temgesic®) and sublingual buprenorphine (Subutex<sup>®</sup>).

#### Pre-clinical trials

The pre-clinical trials of CAM2038 g1w and g4w were designed to provide primary data pertaining to safety and pharmacokinetics, and to compare the existing record of safety and efficacy of buprenorphine. A further, key target has been to generate of adequate local tolerance data for long-term use of CAM2038, and to complete risk assessments for the FluidCrystal® technology and the FluidCrystal® components.

The pre-clinical pharmacokinetic data shows that subcutaneous administration of CAM2038 q1w and CAM2038 q4w results in rapid establishment of plasma concentrations of buprenorphine and that CAM2038 q1w and CAM2038 q4w are both suitable for one-week and four-week release, respectively, with no indication of dose dumping. The high measured bioavailability of buprenorphine indicates complete release of the buprenorphine substance from the CAM2038 depot matrix. The CAM2038 products have also been demonstrated to be robust in terms of the in-vivo release of buprenorphine, with no effects from external influence at the injection site (pressure and rubbing) on the pharmacokinetic profile. Similar pharmacokinetic profiles have been obtained for subcutaneous and intramuscular administration respectively.

The treatment-related findings in single- and repeat-dose toxicity studies of CAM2038 have been limited to reversible clinical toxicity effects compatible with the known pharmacological effects of buprenorphine. The local effects at the injection site have been generally transient and mild, and are characterised as foreign-body responses. No novel toxicological aspects have arisen for buprenorphine in the CAM2038 formulations. No indications of systemic toxicity (histopathological organ findings) have been identified.

#### Partnership with Braeburn

In November 2014, Camurus entered into an exclusive licensing agreement for CAM2038 with Braeburn. Braeburn thereby obtained exclusive rights to CAM2038 for the treatment of opioid dependence and pain in North America, with option rights in Japan, Korea, Taiwan and China. Camurus retained all rights in Europe and the rest of the world, including Australia.

Braeburn is a US pharmaceutical company that focuses on novel, long-acting, implantable and injectable therapies for severe neurological and psychiatric disorders, including addiction, pain and schizophrenia. Braeburn focuses on addressing conditions with significant negative public health dimensions, where enduring stigma complicates the treatment paradigm, and where effective, long-acting, therapeutic options are essential to improving outcomes for patients and the healthcare system. Braeburn has undertaken significant research on the US opioid dependence market, resulting in extensive local market knowledge. Braeburn is owned by Apple Tree Partners, a US-based venture capital firm with an investment capital of approximately USD 1.67 billion, dedicated for development of companies in the health care sector.<sup>57</sup> Apple Tree Partners invests in pharmaceuticals, biotech, medtech and healthcare services.

Under the licensing agreement, Camurus received an upfront licence fee of USD 20 million from Braeburn. In addition, Camurus is eligible for a further USD 35 million in development milestones linked to the clinical development and registration of CAM2038 for opioid dependence in the US, and USD 21 million for the development of the pain indication in the US. Camurus is also entitled to receive up to an additional USD 75 million in sales milestones, and a mid-double digit percentage of royalties on product sales.

In December 2012, Braeburn licensed the US and Canadian development and commercialisation rights for Probuphine®, a buprenorphine sub-dermal implant for the maintenance treatment of opioid dependence. Braeburn recently completed a Phase III clinical trial of Probuphine® and an NDA was submitted to the FDA in August 2015. Probuphine® comprises four implants that are inserted and removed from the tissue with the help of a minor surgical procedure. The product is intended for the treatment of stable opioid-dependent patients that receive maintenance treatment with sublingual buprenorphine doses of 8 mg or lower.

Probuphine® is expected to be used by a subset of stable opioid-dependent patients, including those living far from treatment clinics, where access to other treatment forms is limited. Camurus and Braeburn both considers Probuphine® to complement CAM2038 well in the market place, and expect to benefit from market synergies between the products. The commercialisation of CAM2038 is also assessed to benefit from the marketing and sales organisation, the marketing experience and the commercial infrastructure being established by Braeburn for the launch of Probuphine®.

Braeburn's executive team has decades of experience of successfully launching and growing commercially successful pharmaceutical product franchises on the market, including Abilify<sup>®</sup>, with current global sales in excess of USD 8 billion. The company also has extensive experience of clinical and regulatory development in areas including addiction and psychiatric disorders.

## *Further development and the path to market registration*

The Phase III programme for CAM2038 q1w and CAM2038 q4w has been designed to meet the requirements for the hybrid application in the EU and the 505(b)(2) regulatory pathway in the US. In addition, Camurus and Braeburn may conduct further clinical trials to support future pricing and reimbursement. CAM2038 has received fast track designation in the US for the treatment of opioid dependence. The Fast Track process is intended to facilitate and expedite the development and registration of new drugs to address unmet medical needs in the treatment of serious life-threatening conditions.

The clinical development programme for the EU and US market registrations of CAM2038 for the treatment of opioid dependence is assessed as comprising three pivotal clinical trials: the recently started Phase II trial assessing the opioid blockade of CAM2038 q1w on the effects of other opioids, a Phase III trial documenting the long-term safety of CAM2038 q1w and q4w, and a randomised, active-controlled, Phase III efficacy trial for CAM2038 q1w and q4w in comparison with sublingual buprenorphine designed to demonstrate "non-inferiority" in treatment efficacy. In addition to these trials, a further Phase III/ IV trial is planned to, among other things, support the price and reimbursement of CAM2038 in the EU and other territories.

<sup>57</sup> http://www.appletreepartners.com, October 2015.

Camurus' partner Braeburn is responsible for all development pertaining to registration of CAM2038 products in North America, including the US. Braeburn also holds option rights for China, Korea, Taiwan, and Japan. If Braeburn exercises its option, the company will have responsibility for clinical development and product registration in these countries. Camurus has retained all rights for the EU and other territories. Both companies have exclusive rights, in their territories, to each other's development results and all regulatory data related to CAM2038 and other injectable products containing buprenorphine.

During 2015, Camurus and Braeburn have conducted and completed "CHMP Scientific Advice" and "End of Phase II" meetings with the EMA and the FDA, respectively, in relation to the planned Phase III program for CAM2038 for treatment of opioid dependence. The FDA recently approved the start of Phase III registration trials, which will commence before yearend 2015. In addition, an open Phase III trial of CAM2038, which will document long-term safety, has been approved by health authorities in Europe. The Phase III program is estimated to be completed within 18 months from when the first patient is included in the trials.

#### Further products in clinical development

In addition to the Company's most advanced product candidates, CAM2029 for acromegaly and NET and CAM2038 for opioid dependence, Camurus has three more products in clinical development phase, both in-house and in collaboration with its' partners.

In collaboration with Braeburn, Camurus is developing depot injections of buprenorphine under the CAM2038 product label for the treatment of chronic pain. The two companies plan to start the clinical registration program in patients with chronic pain in three to six months. Camurus' product CAM2032 is currently being assessed in a repeat-dose Phase II trial for patients with advanced prostate cancer. The results of the trial are expected in during the first quarter of 2016. As part of the collaboration with Novartis, a Phase I clinical trial is being conducted of CAM4071, a long-acting, subcutaneous injection based on FluidCrystal® Injection depot and an as yet undisclosed peptide. The trial is expected to be concluded in the beginning of 2016.

Camurus' early, pre-clinical product candidates are described in the *Additional collaborations* and *In-house pipeline* sections, respectively.

#### CAM2038 for pain The market for chronic pain

Chronic pain represents a significant, global health problem and causes deterioration in general health, decreased capacity for work and reduced quality of life and, following medication with strong opioids, it also causes dependence and misuse. In the US, chronic pain is estimated to affect approximately 116 million people. The associated societal costs, including the costs of healthcare and lost productivity, are estimated at about USD 560-635 billion annually.<sup>58</sup> In Europe, it is estimated that one in every five adults suffers from chronic pain, corresponding to around 100 million people.<sup>59</sup> Worldwide, the corresponding figure is estimated at 1.5 billion people.<sup>60</sup>

The global market for chronic pain exceeded USD 20 billion in 2012, with the US market accounting for about half of the market at USD 10.8 billion.<sup>61</sup>

Chronic pain is often defined as pain lasting longer than three months or beyond the normal time for tissue healing. Common types of chronic pain include lower back pain, arthritis, headache, and face and jaw pain. Moderate pain may prevent a person from participating in his or her daily activities, while severe pain typically stops a person from participating in those activities and prompts the patient to exhibit painavoidance behaviour. Chronic pain management is one of the most difficult clinical challenges in medicine today, with limited treatment options available and a high unmet medical need.

#### Opioid treatment of chronic pain

Opioids are recommended for the management of moderate to severe acute and chronic pain that cannot be adequately controlled by means of non-opioid analgesics. Opioids fill an extremely important role in the treatment of moderate to chronic pain, but the healthcare system also struggles with the risks and consequences of liberal prescription and high consumption of addictive opioids. The World Health Organization (WHO) has prepared a number of recommendations with the aim of optimising pain therapy with opioids. These recommendations include keeping plasma opioid concentrations as stable as possible to ensure long-acting, effective and lasting pain relief, and thereby improved quality of life.

Based on the need for extended pain relief, a large number of extended-release opioid products exist on the market in the form of tablets and patches, which are typically based on full opioid agonists, such as morphine, oxycodone and fentanyl among others. These products are widely used for the

<sup>61</sup> Decision Resources.

<sup>&</sup>lt;sup>58</sup> Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. National Academies Press, 2011.

<sup>&</sup>lt;sup>59</sup> Breivik H, Collett B, Ventafridda V, Cohen R, Gallacher D. Survey of chronic pain in Europe: prevalence, impact on daily life, and treatment. Eur J Pain. 2006;10:287-333.

<sup>&</sup>lt;sup>60</sup> Global Industry Analysts, Inc. Report, 2011.

treatment of chronic pain, but are also associated with limited compliance, over-dosage, misuse, abuse, and diversion.<sup>62, 63</sup>

Buprenorphine is an effective analgesic with a potency at least 30 times that of morphine. Dose-dependent pain relief has been observed with intramuscular doses of up to 10 mg, and in parallel, respiratory depression is minimised since buprenorphine is a partial mu-opioid receptor agonist, which means that it exhibits a ceiling on some opioid effects.<sup>64</sup> Clinically, buprenorphine also has a less significant effect on gastrointestinal activity, resulting in a lower incidence of constipation compared with full mu-opioid agonists. In addition, the slow dissociation of buprenorphine from receptors results in an extended effect and also minimises withdrawal symptoms upon discontinuation of therapy.<sup>65</sup>

Buprenorphine is currently available in injectable formulations to treat moderate to severe acute pain (for example, Temgesic® and Buprenex®) and transdermal patches for chronic pain (for example, BuTrans®/Norspan® from Purdue Pharma/ Mundipharma and Transtec® from Grünenthal). These products provide stable and relatively low buprenorphine concentrations over a period of seven and four days, respectively. As with tablets, patches are associated with compliance issues, abuse, misuse and diversion, where the active content can be extracted and thereafter injected for increased effect. Buprenorphine patches, such as BuTrans<sup>®</sup>, demonstrate a slow initial delivery rate of buprenorphine and, accordingly, have a delayed effect. In clinical pharmacological trials, the median time for Norspan® to deliver detectable buprenorphine concentrations (25 picogramme/mL) was about 17 hours. During this period, other analgesic products are needed. The plasma concentrations reached with patches are also limited, which results in an inadequate analgesic effect for certain patients, particularly those receiving high opioid doses, 80 mg/day or above.<sup>66</sup> Due to the limited transdermal delivery rate, relatively large patches are required, 18-50 cm<sup>2</sup>. Skin irritation and erythema, including at the application area, are very common side effects of BuTrans®/Norspan® and Transtec® patches. Analysis of residual buprenorphine in patches after seven days' use demonstrate that only 15 percent of the original content has been delivered.<sup>67</sup> The remaining 85 percent of the buprenorphine in the patch should be folded and disposed of at a suitable location, which also entails a risk of misuse, abuse and diversion.

**CAM2038** - a new treatment alternative for chronic pain CAM2038 is a subcutaneous injection depot of buprenorphine for simple and safe pharmaceutical administration with the aid of a pre-filled syringe with a needle-stick prevention device. In addition to the treatment of opioid dependence, CAM2038 is also being developed as weekly and monthly products for the treatment of chronic pain. Initially, this development is targeted at treatment of opioid-experienced patients, but product variants for opioid naive patients are also being prepared.

CAM2038 provides a rapid onset and dose-proportional, long-term exposure without the same risks of overdoses and respiratory depression that are associated with full muagonists, such as morphine, oxycodone and fentanyl among others. The product's profile corresponds well with the target profile for medications for treatment of chronic pain and addresses a significant medical need to combine effective pain relief with a reduced risk of misuse and an improved safety. The subcutaneous route of administration is assumed to increase compliance and reduce the risks of incorrect use, even when compared with transdermal opioid formulations, indicating that CAM2038 may be particularly well suited for chronic pain patients with a history of misuse. While chronic pain and substance abuse disorders often occur concurrently, these patients are particularly difficult to treat using existing opioid products.<sup>68</sup> CAM2038 allows high and stable buprenorphine exposure and, therefore, can be used for patients who need high opioid doses, equivalent to 80 mg/day or more of morphine. In comparison, the product specification for Butrans® states that the maximum dose in the US of 20 mcg/hour may be insufficient for treatment of this group of patients.<sup>69</sup>

In summary, CAM2038 is expected to be an effective alternative to existing opioid medications for patients with chronic pain indications, combining enhanced safety and a reduced risk of misuse. Braeburn and Camurus are developing several customised treatment candidates and plan to document these sequentially for different pain conditions and patient populations.

The product development has many synergies with the CAM2038 q1w and q4w programmes against opioid dependence, and exploits the extensive existing non-clinical information and data as well as results from three completed clinical trials; see "Clinical trials" under "CAM2038 – a new treatment alternative for opioid dependence" above. The primary pivotal programme comprises two trials in patients with chronic pain: a Phase II clinical trial that is expected to commence within three to six months, and a Phase III efficacy trial that is expected to start before mid-year 2016.

<sup>68</sup> Weaver MF, Schnoll SH. Opioid treatment of chronic pain in patients with addiction. J Pain Palliat Care Pharmacother. 2002;16:5-26.

69 BuTrans® Prescribing Information, June 2014.

<sup>&</sup>lt;sup>62</sup> Salinas GD, Robinson CO, Abdolrasulnia M. Primary care physician attitudes and perceptions of the impact of FDA-proposed REMS policy on prescription of extended-release and long-acting opioids. J Pain Res. 2012;5:363-369.

 <sup>&</sup>lt;sup>63</sup> The Joint Commission and the FDA take steps to curb adverse events related to the use and misuse of opioid drugs. ED Manag. 2012;24:112-116.
 <sup>64</sup> Dahan A, Yassen A, Bijl H, et al. Comparison of the respiratory effects of intravenous buprenorphine and fentanyl in humans and rats. Br J Anaesth. 2005;94:825-834..

<sup>&</sup>lt;sup>65</sup> Tompkins DA, Smith MT, Mintzer MZ, Campbell CM, Strain EC. A double blind, within subject comparison of spontaneous opioid withdrawal from buprenorphine versus morphine. J Pharmacol Exp Ther. 2014;348(2):217-26.

<sup>66</sup> BuTrans<sup>®</sup> Prescribing Information, June 2014.

<sup>&</sup>lt;sup>67</sup> Norspan® transdermal drug delivery system product information, http://secure.healthlinks.net.au/content/mf/pi.cfm?product=mfpnorsp.

#### CAM2032

## The market for prostate cancer, precocious puberty and endometriosis

Prostate cancer is one of the major global health problems and the fourth most commonly diagnosed cancer type worldwide, with an estimated 1.1 million new cases in 2012.<sup>70</sup> In the US, around 220,000 new cases of prostate cancer are expected to be identified in 2015 and it is the second leading cause of cancer deaths in men.<sup>71</sup> In the EU, approximately 190,000 new cases of prostate cancer are diagnosed each year.<sup>72</sup> The prevalence of prostate cancer has steadily increased over the past decade and this trend is expected to continue due to enhanced diagnosis and changed life habits. Increased survival thanks to earlier diagnosis, improved therapy and an increased life expectancy are also expected to increase the prevalence of the disease. The global prostate cancer market is forecast to grow rapidly from USD 2.6 billion in 2013 to more than USD 8.0 billion in 2023, at a CAGR of 12.4 percent. The Brazilian and Japanese markets are expected to grow fastest and, for example, the sales of pharmaceuticals for prostate cancer treatment in Brazil are estimated to increase to USD 1.6 billion by 2023, corresponding to a CAGR of 25 percent.73

Precocious puberty is a condition referring to the appearance of pubertal development at an earlier age than is considered normal. This can cause problems with bone growth (short adult stature) and emotional distress for the children. The incidence and prevalence of precocious puberty depends on the definition of what is a normal onset of puberty. Data from the US indicate that about 1 in 5,000 children are affected and that it is ten times more common in girls than in boys.<sup>74</sup>

Endometriosis is a serious medical issue that affects many women of reproductive age and happens when the lining of the uterus (endometrium) grows outside the uterus. Endometriosis often leads to various pain conditions, including chronic pain. Other common symptoms are bleeding disorders, bowel disorders such as irritable bowel syndrome (IBS) and cystitislike disorders. Many suffer from a general feeling of illness, lack of energy and tiredness. Endometriosis also often results in impaired fertility. Despite this, the percentage of people with endometriosis who have their own biological children is almost the same as for people without endometriosis, but a larger proportion of those with endometriosis become pregnant with the help of in-vitro fertilisation. Women with endometriosis have a higher risk of ovarian cancer.

Many studies show that most people who suffer from endometriosis develop symptoms in their teenage years. After themselves realising that their pain is abnormal, it takes approximately eight to ten years before women with endometriosis get their diagnosis. Around 10 percent of all women are affected by endometriosis during their reproductive years, corresponding to more than 170 million women around the world.<sup>75, 76</sup>

## GnRH treatment of prostate cancer, precocious puberty and endometriosis

There are different standard treatments for prostate cancer, including surgery, radiation therapy, hormone therapy, chemotherapy and biologic therapy. Hormone therapies (or androgen deprivation therapy), such as CAM2032, aim to reduce the level of male sex hormones (androgens) and thereby stop cancer cells from growing. There are various types of hormonal therapies for prostate cancer treatment, including drugs with gonadotropinreleasing hormone (GnRH) agonist or antagonist action. GnRH agonists, including the peptides leuprolide, goserelin, triptorelin, and histrelin, work initially through a transitory increase in the gonadotropins (LH and FSH), which leads to raised levels of testosterone in men and estradiol in women. After about three weeks of treatment, the production of LH and FSH declines through suppression of the pituitary gland's gonadotropin production. This results in a decline in serum testosterone in men and in serum estradiol in women. Levels of serum testosterone in men decline after about 21 days' treatment to the castration level. These levels remain constant if treatment is continued, which will lead to prostate tumour regression and symptomatic improvement for most patients. In the treatment of patients with metastatic prostate cancer in comparative clinical trials, GnRH agonists have proven to deliver survival rates comparable to those obtained through surgical castration.

GnRH agonists are also used to treat gonadotropin-dependent (or central) precocious puberty, which accounts for about 80 percent of all cases of precocious puberty.<sup>77</sup>

Hormonal treatments, such as hormonal birth control or GnRH agonists, are generally first-line treatments for endometriosis. GnRH agonists work by stopping the production of oestrogen, which causes the endometriosis tissue to become inactive and degenerate.<sup>78</sup>

Synthetic GnRH agonist peptides have been available in the market for decades and are considered to be safe and well tolerated. There are a number of approved extended-release GnRH agonist products, including the leuprolide preparations Eligard® (Tolmar, Astellas), Lupron® Depot (Procren® Depot in Europe; Abbvie, Takeda) and Leuprorelin Sandoz® (Sandoz), the goserelin depot Zoladex® (AstraZeneca), the triptorelin depot Decapeptyl® (Ipsen) and the histrelin implant Vantas® (Endo Pharmaceuticals). These products have depot dura-

<sup>&</sup>lt;sup>70</sup> http://www.cancerresearchuk.org/health-professional/cancer-statistics/worldwide-cancer/incidence#heading-One.

<sup>&</sup>lt;sup>71</sup> http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-key-statistics.

<sup>&</sup>lt;sup>72</sup> Damber JE, Aus G. Prostate cancer. Lancet. 2008;371:1710-1721.

<sup>&</sup>lt;sup>73</sup> GlobalData, PharmaPoint: Prostate Cancer – Global Drug Forecast and Market Analysis to 2023.

<sup>&</sup>lt;sup>74</sup> Cesario SK, Hughes LA. Precocious puberty: a comprehensive review of literature. J Obstet Gynecol Neonatal Nurs. 2007;36:263-274.

<sup>&</sup>lt;sup>75</sup> Rogers PA, D'Hooghe TM, Fazleabas A, et al. Priorities for endometriosis research: recommendations from an international consensus workshop. Reprod Sci. 2009;16:335-346.

<sup>&</sup>lt;sup>76</sup> Adamson GD, Kennedy S, Hummelshoj L. Creating solutions in endometriosis: global collaboration through the World Endometriosis Research Foundation. J Endometriosis 2010:2:3-6.

<sup>&</sup>lt;sup>77</sup> Kappy MS, Ganong CS. Advances in the treatment of precocious puberty. Adv Pediatr. 1994;41:223-261.

<sup>&</sup>lt;sup>78</sup> Schweppe K-W, Hummelshoj L. Recommendations on the use of GnRH in the management of endometriosis. I: Lunenfeld B (ed). GnRH Analogs in Human Reproduction. UK: Francis & Taylor. 2005:53-66.

tions ranging from one to 12 months, but all products require reconstitution prior to administration and should therefore be administered by healthcare professionals.

The graph below shows global sales in millions of US dollars for some of the leading GnRH agonist products since 2004.<sup>79</sup> In 2014, the market for these products was USD 3.26 billion. The total, global GnRH market is substantially larger, since several of the marked GnRH products from private companies, where public information is not available, are not included.



## CAM2032 - a new treatment alternative for prostate cancer

Camurus' CAM2032 is a long-acting leuprolide formulation with rapid onset and extended release of leuprolide acetate. CAM2032 was initially developed for long-term treatment of advanced prostate cancer, but the product can also be used

Product design of CAM2032 vs. competitors

for treatment of precocious puberty and endometriosis. The product is based on the Company's FluidCrystal® Injection depot system and is designed for easy and convenient selfadministration by patients, using a pre-filled syringe equipped with a thin 27 gauge needle and an automatic needle guard. CAM2032 is compatible for use with auto-injectors to further simplify administration as part of the product life-cycle management. Once injected, the lipid constituents immediately begin to self-assemble into a slow-release crystalline gel that delivers therapeutic levels of leuprolide for a period of one month.

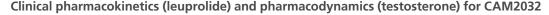
CAM2032 is to Camurus' knowledge the first long-acting GnRH agonist developed to enable patients to administer the product themselves, which has the potential to increase flexibility for patients while also reducing the burden of scheduling injections. Thanks to the product's user-friendly design, CAM2032 does not require reconstitution or temperature conditioning prior to administration in a small-volume (0.2 or 0.4 mL) liquid with a thin needle. The development of an autoinjector version is expected to further simplify handling and administration of CAM2032.

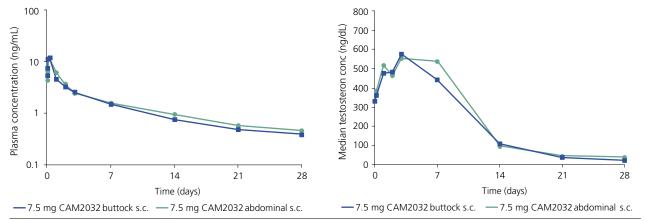
Compared with other injectable GnRH agonist products on the market, CAM2032 has several potential advantages, including its simple administration, small injection volume, thin needle and the possibility of self-administration by patients; see the comparison in the figure below. In addition, Camurus assesses that CAM2032 may have lower manufacturing costs than competing products, and therefore the possibility for price advantages compared to such products.



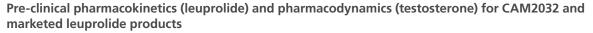
79 Medtrack.

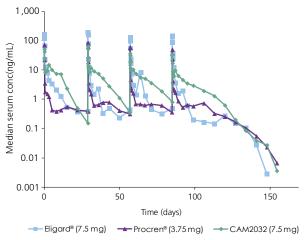
The pharmacokinetics of CAM2032 were studied in a completed Phase II trial in patients with prostate cancer (HS-06-230). The trial duration was 112 days for each patient and consisted of three separate doses ranging between 7.5 and 30 mg of leuprolide acetate. The trial demonstrated a favourable safety profile with very good local tolerance after subcutaneous injection in the abdomen or buttocks. The pharmacokinetic and pharmacodynamic profiles (effect on plasma testosterone) after administration of CAM2032 demonstrated the release of leuprolide over a one-month period for a 7.5 mg dose, with similar results recorded by the different injection locations; refer to the following results from the HS-06-230 trial. The trial also demonstrated an extended release period with an increased dose.

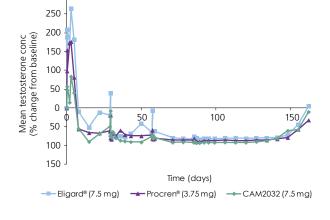




In pre-clinical trials, the leuprolide plasma concentration against time for CAM2032 has been compared with other leuprolide products on the market, namely Eligard<sup>®</sup> and Procren<sup>®</sup>. Comparable pharmacokinetics after subcutaneous injection are illustrated in the following diagrams.







CAM2032 is being developed in-house by Camurus, and the Company has retained all development and commercialisation rights to the product. The product is currently being assessed with an active comparator in a randomised, repeat-dose Phase Il trial in patients with advanced prostate cancer. All patients have been enrolled in the trial. The results of the trial will be analysed and reported during the first quarter of 2016. Further development and commercialisation, including global and regional partnerships, are assessed on the basis of the structure and dynamics of the prostate cancer market and an assessment of market opportunities within other indication areas.

#### CAM4071

300

CAM4071 is another product candidate in clinical development under the option, collaboration and licensing agreement with Novartis. The product is a long-acting formulation of an undisclosed peptide based on Camurus' FluidCrystal® Injection depot. The product candidate is currently under evaluation in a Phase I clinical trial exploring pharmacokinetics, safety and local tolerability, expected to be completed during the first half of 2016.

#### Additional collaborations

In addition to the different clinical stage development projects being conducted by Camurus both in-house and under collaboration agreements, the Company also has a number of developments in pre-clinical evaluation phase in collaboration with various international biotech and pharmaceutical companies. These collaborations include both clinical and marketed, patented active ingredients, where Camurus' collaboration project can be a part of the life-cycle management, and entirely new active ingredients where Camurus' technology is included in product development strategy from the start of clinical development. A significant advantage of the FluidCrystal® technology, as compared to other competing extended release technologies, is that it does not require chemical modification of the active pharmaceutical ingredient, nor does it require use of special non-standardised manufacturing process steps. This enables time and cost-efficient assessments of the technology for a wide range of product opportunities. Camurus has streamlined the feasibility study process, enabling the Company to relatively quickly and effectively study and evaluate key properties and criteria pertaining to the target product profile for a specific product candidate, including solubility, formulation optimisation, stability and in vitro and in vivo release profiles of the active ingredients. These are criteria that typically drive the decision to proceed with further product development and starting preparation of clinical trials. Aside from co-funding Camurus' research and development of its technologies and further boosting its' know-how, these cooperations may also result in new collaboration and licensing agreements with possibilities of future revenues in the forms of development and sales milestones and royalty on future product sales. In the case of successful projects, such revenues

#### may be substantial.

Camurus has more than five ongoing partnerships in the pre-clinical evaluation phase, where the Company's FluidCrystal® Injection depot system is being evaluated together with the respektive partners' drug compound. Collaborations include large pharmaceutical corporations as well as a smaller biotech company with research leading position in its field. Indication areas for currently ongoing collaboration projects include diabetes, obesity, viral infections and endocrine diseases.

#### In-house pipeline

Camurus' early stage product pipeline also comprises a number of promising internal product candidates in late pre-clinical development, based on the proprietary, patented drug delivery technologies, FluidCrystal<sup>®</sup> Injection depot and topical bioadhesive, respectively. The evaluation and selection process of new product candidates comprises a key set of criteria, including:

- the possibility of fulfilling an important unmet medical need;
- technology matching;
- expeditious clinical development and market registration process;
- the possibility of market exclusivity, including patent protection; and
- attractive markets.

Furthermore, development and commercial synergies with Camurus' other projects and future commercial interests are also taken into consideration.

The above evaluation and selection criteria are illustrated in the following figure.

#### Unmet medical need

- Patients and prescribers in focus
- Better treatment outcomes; efficacy and safety, convenience, compliance, health care cost savings
- Best-in-class potential

#### Attractive market

- Potential for pricing and reimbursement
- Concentrated customer base, prescribers
- Large market potential
- Commercial synergies

#### Patent protection

- Existing platform patents
- Product directed patent opportunities

#### Technology match

- Value creation by use of FluidCrystal<sup>®</sup> technology platforms
- Technology fit (solubility, stability, and *in vitro* and *in vivo* release)

#### Expeditious clinical development and market authorization

- 505(b)(2) registration pathway
- Accelerated approvals

Fulfilling a medical need can be achieved by enabling stable and sustained exposure, for example, of drug compounds with short biological half-life and/or poor oral bioavailability, which in turn can benefit treatment outcomes and medication compliance. In the pre-clinical development phase, all evaluable criteria for the desired product target profile are evaluated, including manufacturing, physical and chemical stability, in vitro and in vivo release profiles and, in parallel with this, the clinical, regulatory and market-related aspects. Provided a positive total outcome, technology transfer is initiated for clinical development, and the planning of the clinical trials programme is initiated in accordance with the expected regulatory and market-based requirements. As a rule, an abbreviated regulatory pathways such as 505(b)(2) in the US are utilised.

With regard to market exclusivity, new products are often protected by existing technology patents, which are supplemented with new patent applications as new product-specific innovations are realised. An initial freedom to operate analysis is normally conducted when the product's properties are available in a tangible form with regards to composition and use. Commercial assessments, including evaluations of market potential and dynamics, pricing, etc., are all conducted in parallel with the clinical and regulatory development processes.

Camurus has a number of preclinical product candidates that the Company, on the basis of completed trials, assesses as meeting the criteria listed in the above diagram, and which are assessed as addressing key unmet medical needs in areas of inflammation and pain (CAM2041), diabetes (CAM2046), cancer supportive care (CAM2047), and post-operative pain (CAM 2048). Camurus intends to initiate clinical trials for at least one of these products during 2016.

#### **Research and development strategy**

Research and development and continued innovation are key strategic priorities for Camurus. The Company's long-term success is largely dependent on its continued innovation and development of new and enhanced, patented technologies and attractive drug products that improve treatment outcomes and the quality of life of patients, while reducing the burden on the healthcare system.

Camurus' R&D organisation comprises pre-clinical, pharmaceutical and analytical, and clinical and regulatory development units, each headed by an experienced and highly qualified senior research director. All units have state-of-theart laboratory facilities and experimental equipment. In 2014, Camurus invested in an additional new analytical laboratory with capacity for both advanced pharmaceutical analysis and bioanalysis.

New product ideas and development come from a deep understanding of the different possibilities offered by Camurus' technology platforms and from interaction with scientists, physicians, regulatory bodies and other experts. The input from these sources is complemented by scientific documentation and market assessments to identify and evaluate attractive product candidates and development projects. New development projects must be firmly rooted in clinical practice and at the forefront of medical research. They should be aimed at solving medical problems within indication areas that can be addressed by Camurus' development organisation and/or commercial capabilities, and should also have significant global market potential.

In addition to candidates identified in-house, new ideas also come from other biotech and pharmaceutical companies. In these cases, Camurus always makes an internal assessment of whether the project is of strategic interest to Camurus. Thereafter, a feasibility study is carried out, where key properties of the target product profile are evaluated and assessed, prior to entering into a more extensive clinical collaboration in the form of, for example, collaboration and licensing agreements. Camurus has developed a highly effective feasibility study process, enabling the evaluations of new product candidates within six to 12 months. Costs for conducting these studies are typically borne by the partner.

Assessments of in-house ideas and feasibility studies for third parties typically comprise a number of standard steps, such as formulation optimisation, stability assessment, the determination of in vitro and in vivo release profiles, and a basic toxicology evaluation. Most of the early work is conducted by Camurus' internal teams and experts. However, toxicology studies will be outsourced to contract laboratories and research organisations under service agreements and close supervision by Camurus' staff, and after applicable regulatory and ethical reviews and approval.

Following positive results from in-house assessments and feasibility studies, Camurus or its partner may decide to initiate clinical trials, which initially comprise smaller Phase I and Phase Il trials, depending on the critical questions to be addressed and the possibilities of conducting trials in healthy volunteers and patients, respectively. Preparation and execution of early clinical trials involves all R&D units at Camurus, and also the technical operation function for technology transfers of manufacturing under good manufacturing practice (GMP) to one of Camurus' contracted manufacturers of investigational medical products. External experts such as regulatory experts are engaged as needed. Provided the establishment of positive results in terms of, for example, pharmacokinetics and safety, where after the project may proceed to a late development phase including the preparation and execution of pivotal trials (Phase III trials) for market registration (based, for example, on advice from the EMA and FDA) and the transfer of manufacturing to a commercial scale. Depending on the disease area, size and costs of the clinical program, and the market dynamics, Camurus may engage a partner in parts of or all late-stage clinical development. However, the starting point is often to retain rights to in-house projects for as long as possible to maximise the increase in value. When a cooperation agreement is entered into, the cooperation is structured to utilise the specific expertise of the respective partners to the greatest extent possible.

Following registration submission and approval, Camurus intends to continuously evaluates possibilities for conducting post-marketing studies and initiating life-cycle planning.

#### Medical device – episil®

The medical device episil<sup>®</sup> has been developed and registered by Camurus under its own management. episil<sup>®</sup> is a lipid-based liquid that is sprayed over the oral mucosa and immediately transforms into a strongly bioadhesive film protecting the sore and sensitised mucosa. The product has been studied in several clinical trials that have demonstrated positive treatment outcomes for, among other conditions, mouth pain in cases of oral mucositis, and has been registered in the US and European markets following the granting of 510(k) market approval by the FDA and CE marking in Europe.

#### **Oral mucositis**

Oral mucositis is a painful inflammation and ulceration of the oral mucosa. It is a frequent side effect of radiotherapy and chemotherapy, affecting nearly all head and neck cancer patients receiving radiotherapy and a large proportion, 30 percent to 75 percent, of patients undergoing chemotherapy for other cancer types, including breast cancer. In severe cases, oral mucositis may be treatment limiting, necessitating a reduction in dosage or delays in the delivery of therapy. Furthermore, oral mucositis can in advanced stages be extremely painful, preventing the patient from eating and requiring hospitalisation for re-hydration, opioid analgesia and total parenteral nutrition. Destruction of the protective mucous membrane may further place the patient at a serious risk of infection.<sup>80</sup>

The global oral mucositis market is estimated to exceed USD 700 million.<sup>81</sup>



#### episil®

Despite the development of various medications and targeted therapeutic interventions for the treatment of oral mucositis; a substantial medical need remains for effective pain control and to mitigate the symptoms of the disease. episil® has been developed to reduce pain in the oral cavity and works by spreading and adhering to the oral mucosa as a thin bioadhesive film, which acts as a long-acting protective barrier that reduces pain and may protect against infections. episil® can thereby maintain the patient's ability to eat and drink and potentially reduce the need for total parenteral nutrition and opioid analgesics.82

The product is based on Camurus' FluidCrystal® topical bioadhesive delivery technology. Clinical trials on cancer patients with oral mucositis have demonstrated that the lipid film, which is formed a few minutes after administration of episil<sup>®</sup>, strongly adheres to the mucosal surfaces and thereby protects them. In clinical trials, episil<sup>®</sup> has been demonstrated to rapidly reduce intraoral pain by an average of about 40 percent in cancer patients treated for head and neck cancer with radiation treatment, with a long-lasting effect of up to 8 hours.83 episil® has been shown to be safe with no systemic effects and very good local tolerability has been demonstrated in clinical trials and pre-clinical trials.84 episil® has obtained 501(k) market approval from the FDA in the US and a CE marking (class 1) in the EU. Camurus is ISO 13485-certified, thereby ensuring that the applicable quality requirements for the design and manufacture of episil® are met.

episil® is currently marketed in Europe, the US and the United Arab Emirates. Its sales and distribution are conducted through a broad spectrum of distribution partners and through Camurus' own sales efforts in Sweden, Denmark, Norway, the UK and Germany. Camurus recently signed a licensing agreement with Solasia Pharma K.K. for China and Japan.

#### Sales & marketing

#### Introduction

Camurus is in the early stages of establishing a commercialisation structure to market the Company's products in those countries where the Company has chosen to retain commercialisation rights and where Camurus has made the assessment that the market dynamics support its own sales activities. Initially, Camurus aims to create a platform for the market launch and sale of CAM2038 for the treatment of opioid dependence in selected European markets.

The Company has recently established a limited capacity for the distribution, sales and marketing of episil<sup>®</sup>, which is primarily aimed at sales to hospitals in Sweden, Denmark, Germany and the UK. Following extensive analysis of the European market for CAM2038 for the treatment of opioid dependence, Camurus has decided to establish a marketing and marketing and sales organisation with initial focus on selected markets in the Nordic region, Germany, the UK, France and Italy, potentially followed by further expansion into other European and RoW markets, for example, the attractive Australian market. The Company has made significant investments in mapping the market dynamics, interviewing opinion builders, identifying stakeholders and treatment practices, analysing pricing and benefit values, as well as logistics and distribution channels.

<sup>&</sup>lt;sup>80</sup> Al-Ansari S, Zecha JAEM, Barasch A, de Lange J, Rozema FR, Raber-Durlacher JE. Oral Mucositis Induced By Anticancer Therapies. Curr Oral Health Rep 2:202–211, 2015.

<sup>&</sup>lt;sup>81</sup> GlobalData, 2010.

<sup>&</sup>lt;sup>82</sup> Svanberg A, Birgegård G, Öhrn, K. The effect of oral lipid solution and cryo-therapy on severe side effects of intensive chemotherapy. Abstracts of the 2010 International MASCC/ISOO Symposium. Support Care Cancer. 2010;18:P114-115.

<sup>&</sup>lt;sup>83</sup> Tiberg F, Cavallin-Ståhl E, Linden M, Thuresson K, Hadjieva T. Treatment of oral mucositis pain by a bioadhesive barrier forming lipid solution. Abstracts of the 2009 International MASCC/ISOO Symposium. Support Care Cancer. 2009;17:918.

<sup>84</sup> Patient information leaflet (PIL) for episil®.

Camurus' strategy of establishing its own sales organisation for CAM2038 is based on a number of specific features of the European opioid dependence market that the Company assesses as attractive. The market comprises a concentrated target group of prescribing physicians who have shown substantial interest in the product concepts represented by CAM2038. Camurus has also made the assessment that potential exists for favourable pricing and attractive reimbursement levels, since the product is deemed to fulfil a substantial medical need and generate significant healthcare savings. The combination of value-creating treatments for both patients and society together with a concentrated and well-defined target group of physicians and decision-makers, means that Camurus has identified possibilities for effectively establishing CAM2038 as the first choice for the treatment of opioid dependence. CAM2038 addresses all phases of the treatment of opioid dependence, from induction and stabilisation to long-term maintenance treatment, with both weekly and monthly products, thereby making it viable in all European markets despite the partial differences in the countries' treatment procedures. This is considered to further strengthen Camurus' strategy of commercialising CAM2038 itself in selected European markets.

With a concentrated and well-defined target group, Camurus' assessment is that the market can be addressed through a costeffective marketing and marketing and sales organisation by centralising all key functions that do not require deep local market knowledge, while leveraging dedicated and scalable resources for market access and sales in countries and regional markets.

The marketing and sales organisation being built around CAM2038 for opioid dependence is expected, in the long term, to be utilised for other commercial opportunities, both related to Camurus' own products and for complementary product rights in the form of licenses and acquisitions. Camurus expects that significant synergies may be realised by also utilising the commercial infrastructure for CAM2038 for other matching product opportunities in complementary therapy areas, whether developed in-house, such as CAM2038 for chronic pain, or in-licensed from partners without their own regional coverage in Camurus' territories.

For countries and markets where Camurus does not have its own marketing presence and where the potential profitability of own sales is not considered satisfactory, the Company intends to continue to actively engage in establishing commercialisation partnerships, which could comprise shared marketing or licensing and distribution agreements in order to fully exploit the value potential of its proprietary drug product assets.

## The European opioid addiction market and CAM2038

Camurus has carefully assessed the prerequisites, dynamics and potential of the opioid dependence market in Europe and other parts of the world. The market is large and growing, partly as a consequence of the growing use of opioid analgesics. There is also an ongoing paradigm shift in Europe, where the traditional abstinence and harm-reduction treatment approaches are gradually changing towards an increasing recognition of opioid dependence as a chronic disease that requires long-term medical intervention in combination with psychosocial intervention, to allow patients to regain a normal lifestyle. In 2013, the number of patients on opioid substitution treatment (OST) is estimated at about 77,300 in Germany (75,000 in 2012), 163,000 in France (152,000), 172,500 in the UK (171,000) and 94,500 in Italy (98,000).85 Of these patients, approximately 21 percent in Germany are treated with buprenorphine, 66 percent in France and 15 percent in Italy. In the UK, methadone is predominant but no exact statistics are available. The average maintenance treatment duration is 4.6 years in Germany, 2.7 years in the UK and 4.4 years in Italy (no data is available for France).<sup>86</sup> In the Nordic countries, the estimated number of patients on substitution treatment is about 20,000, where patients on buprenorphine varies from about 15 percent in Denmark to approximately 60 percent in Norway and Finland.

In addition to the aforementioned potentially favourable aspects in terms of the opioid dependence market in Europe and CAM2038, additional features of the product exist that make it particularly suitable for the European market. In many European countries, substitution therapy requires closely monitored dispensing and intake of medication, which encroaches on patients' lives and is costly for healthcare systems. Since CAM2038 only requires once weekly or once monthly doses, unlike existing products which are given daily, the preconditions are in place for costs savings for healthcare system and an increased quality of life for patients. CAM2038 has also potential to for improving treatment compliance and reducing in the risk of diversion, misuse, and abuse, as well as, avoiding the exposure of children and teenagers to the medications. Variations of treatment practices, with differing intervals for psychosocial consultation, etc., in the various patient categories and between the different countries, makes CAM2038, with its flexible dose and dosing intervals, an attractive potential future treatment alternative in large parts of Europe.

<sup>85</sup> European Monitoring Centre for Drugs and Drug Addiction, European Drug Report 2015.

<sup>86</sup> Dale-Perera A, Goulão J, Stöver H. Quality of care provided to patients receiving Opioid Maintenance Treatment in Europe: Results from the EQUATOR analysis. Heroin Addict Relat Clin Probl. 2012;14: 23-38.

## The establishment of a commercial organisation for CAM2038 in Europe

Camurus intends to build an efficient and specialised marketing and sales organisation in key European markets, with a clear initial focus on CAM2038 products for the treatment of opioid dependence. Camurus' assessment is that CAM2038 has a significant market opportunity that can be exploited with a costefficient commercial organisation and infrastructure that the Company is currently in the early stages of establishing. As a first step, Camurus will focus on patients receiving maintenance treatment with buprenorphine and new entrants to medication assisted treatment. Over time, the Company also sees opportunities to expand its focus towards the methadone market.

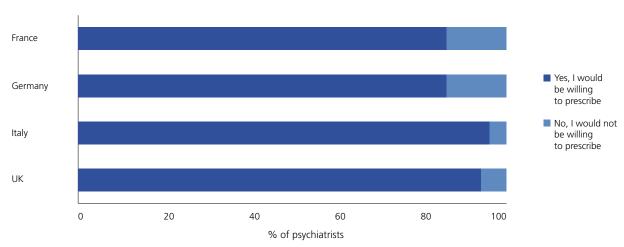
According to the Company's assessment of the European market, the treatment of opioid dependence is largely concentrated to specialised clinics located in highly populated areas. In France, there are about 600 specialist physicians, primarily located at various specialised treatment centres, and about 4,000 general practitioners prescribing buprenorphine. Germany has close to 700 specialist physicians treating patients within the primary healthcare system and at treatment centres, and a further approximately 2,100 general practitioners prescribing opioid substitution treatment. In Italy, treatment is handled by about 650 specialist physicians working out of "servizi tossicodipendenze" (separate drug treatment centres), as well as by private and non-profit organisations, while in the UK, around 700 specialists located at community health clinics or working at different NHS providers form the prescribing base. Neither Italy nor the UK allow prescription of buprenorphine for opioid substitution therapy by GPs.

In a recent survey across the EU5 (the UK, Germany, France, Italy and Spain), a majority of surveyed psychiatrists responded that they would be willing to prescribe the long-acting buprenorphine injection CAM2038 to their opioid addiction patients, provided that the therapy established documented efficacy, safety, and a tolerability profile similar to that of existing buprenorphine products.<sup>87</sup> The responses from the psychiatrists in France, Germany, Italy and the UK are illustrated in the table below.

Camurus intends to build an organisation comprising specialised medical advisors and educators, pharmaceutical consultants and market-access specialists. The company will focus on a concentrated prescriber base of specialists and, later, expand to general practitioners in Germany and France. Core marketing, regulatory and medical functions will be centralised to support the regional markets with qualified PR, training and marketing initiatives. A process for the recruitment of a chief commercial officer have been started. Collaborations with opinion builders and academic centres have also been initiated, for example, in conjunction with planning and initiating the Phase III trial of CAM2038 in Europe.

The size of the Camurus commercial organisation is intended to be expanded successively along with the expansion of the customer base and anticipated time points of pricing and reimbursement approvals in the respective countries. In the next stage, the Company plans to increase contact with prescribing specialists and treatment centres. Later, if and when CAM2038 has established a certain level of recognition among specialists, the Company intends to also increase its activity levels vis-á-vis general practitioners who have specialised in the treatment of opioid dependence in countries like France and Germany. This initiative could also include various types of sales partnership.

Fully expanded in 2020-2021, Camurus' commercial organisation for CAM2038 for opioid dependence could consist of between 50 and 100 people across France, Germany, the UK, Italy and the Nordic region.



#### Specialist physicians' willingness to prescribe CAM2038

Source: Market Access Dynamics in Opioid Addiction: Probing Prescriber Preferences and Payer Strategies for Current and Emerging Agents in the EU5, Decision Resources, 2015.

<sup>87</sup> Market Access Dynamics in Opioid Addiction: Probing Prescriber Preferences and Payer Strategies for Current and Emerging Agents in the EU5, Decision Resources, 2015.

#### **Pricing and reimbursement**

The EU is a differentiated market where the governing medical agencies of the respective member states have different guidelines and criteria for pricing and reimbursement levels. In most countries, there is a deliberate push towards generics to increase control of costs, either by way of doctors being required to prescribe generic medicines or by way of pharmacies substituting generic products for brand-name versions when they are available. To obtain a certain price and reimbursement level, most countries require the pharmaceutical companies to demonstrate the cost advantages of their products, for example, with the support of data from clinical trials comparing the cost-effectiveness of the companies' own products to currently available therapies.

The daily cost of substitution medication for opioid dependency differs significantly between countries in the EU. For both methadone and buprenorphine, the highest price was calculated for Finland. This was due to the relatively high doses used in this country combined with the high price of the medications. In four of the five countries reporting price data for both buprenorphine and methadone, the cost of a daily dose of methadone was considerably lower than that of buprenorphine. However, pharmaceutical costs generally represent a small portion of total treatment costs, of which the largest portion is personnel costs in the care chain.

Currently, the monthly cost of 16 mg/day Suboxone®

sublingual tablets is USD 310 in Germany. The corresponding monthly cost is about USD 140 in France, about USD 230 in the UK and about USD 270 in Italy. The monthly cost in Sweden is about USD 280.<sup>88</sup>

In the US, generic versions of Subutex<sup>®</sup> were approved in 2009. Generic Suboxone<sup>®</sup> tablets were approved in 2013. The monthly cost of 16 mg/day Suboxone<sup>®</sup> tablets is about USD 422. To date, the prices for generics have not dropped significantly below those of brand-name products and, in some cases, they are even more expensive.<sup>89</sup>

CAM2038 for treatment of opioid dependence is anticipated to deliver improved adherence to treatment, since patients no longer need to remember or take daily decisions with respect to their medication. The product can also substantially reduce the risks of diversion, misuse, abuse associated with current buprenorphine products. CAM2038 also has the potential to improve treatment efficacy and eliminate the risk of paediatric exposure, e.g. in patient homes. A reduction in the need for supervised dispensing and administration of medication compared with existing products for daily dosage could also significantly reduce costs and the treatment burden for healthcare providers and patients. Camurus believes that the various advantages of CAM2038 should secure advantageous prices and reimbursement levels for CAM2038 relative to existing sublingual buprenorphine products in the market.

<sup>88</sup> Camurus.

<sup>89</sup> https://www.naabt.org/buprenorphine-cost.cfm

#### **IP rights**

Camurus has an active intellectual property rights strategy and strives to effectively maximise the protection of its inventions, technologies and products with both patents and know-how in all major global markets. Camurus has made numerous innovations, resulting in more than 350 patents and patent applications distributed between some 35 patent families. Camurus' patents cover both technology platforms and products. The main patent families are WO2005/117830 for the FluidCrystal® Injection depot, WO2006/075123 for the FluidCrystal® topical bioadhesive system, and WO2006/075125 (CAM2032), WO2006/075124 (CAM2029) and WO2014/016428 (CAM2038) for product-specific aspects. In addition to maximising the protection of the Company's technologies and product enhancements, the Company's patent strategy aims to simultaneously allow the licensing of products to major pharmaceutical companies in specific product areas without losing overall control of the Company's core IP assets.

Camurus' material patents for the FluidCrystal® technology platform and the Company's various pharmaceutical candidates are set out in the table below with regard to the main markets.

			Geographic area granted/pending		Patent te	rm expiry		
Technology/ Product	Publication no. (US & EP and/or international)	US	Europe (EPO & national)	Rest of world	US (forecast)	EPO/Rest of world	_ Description	
FluidCrystal® Injection depot	US8236292, EP1768650	1/0	13/0	11/2	2027	2025	Liquid depot formulations comprising at least one bioactive agent	
	US8097239, EP2052716	1/0	5/1	0/1	2028	2028	Liquid-based controlled-release composition, comprising at least one polyhydroxy component and at least one bioactive agent	
	US8865021, EP1682091	1/0	0/1	1/0	2028	2024	Compositions containing one active cationic peptide agent and structure-forming amphiphiles	
	WO2013083460	0/1	0/1	0/13	(2032)	2032	Lipid compositions comprising at least 50% phosphatidyl ethanola- mine and optionally, at least one bioactive agent	
	WO2012160213	0/1	0/1	0/16	(2032)	2032	Lipid compositions comprising up to 20 wt.% polar solvent	
Fluid Crystal® topical bioadhesive	WO2006/07512, EP2206495	0/3	12/0	2/0	(2025)	2025	Bioadhesive lipid compositions that may comprise one bioactive agent	
FluidCrystal® nanoparticles	US9060935, WO2006077362	1/0	0/1	6/1	2029	2025	Particulate lipid composition of non-lamellar structure	
	US8182834, EP1713446	1/0	8/0	2/0	2027	2025	Particulate lipid composition with one structure-forming amphi- phile, one structure swelling amphiphile and one dispersion stabilizing amphiphile	
	US8187629	1/0	3/0	2/0	2026	2025	Particulate lipid compositions comprising dioleoyl phosphatidyl ethanolamine (DOPE) and poly- sorbate 80 (P80).	

			Geographic a granted/pend		Patent te	rm expiry	
Technology/ Product	Publication no. (US & EP and/or international)	US	Europe (EPO & national)	Rest of world	US (forecast)	EPO/Rest of world	Description
CAM202990	US8871712, EP1843746	1/0	11/0	4/0	2027	2025	Pre-formulations of a low viscosity mixture containing one diacyl glycerol, one phosphatidyl choline, one oxygen containing organic solvent and one somato- statin analogue.
	WO2008152401	0/1	0/1	4/2	(2028)	2028	Controlled release compositions for specific peptide active agent salts, especially of somatostatin analogues
	WO2012160213	-	-	1/22		2032	Lipid compositions comprising up to 20 wt.% polar solvent
CAM2038	US8236755	1/0	-	-	2026	-	Pre-formulations comprising non- liquid crystalline lipid composi- tions with low viscosity in which at least one opioid bioactive agent is dissolved or dispersed
	US20130190341	1/0	-	-	(2032)	-	An opioid depot precursor formu- lation with high bioavailability
	WO2014016428	0/1	0/1	0/20	(2033)	2033	Depot precursor formulation comprising at least 12 wt.% of at least one active agent selected from buprenorphine and salts thereof.
CAM2032	US20090170782, EP1845942	0/1	20/0	2/2	(2025)	2025	Lipid compositions comprising at least one GnRH analogue
episil®	US8920782 EP1848403	1/0	8/0	3/1	2030	2025	Bioadhesive compositions

Camurus utilises advanced research and sophisticated and unique technologies to enable the development of innovative and differentiated products that provide significant value for patients, healthcare professionals and partner companies. Research and development requires substantial resources, and also places stringent requirements on efficient patent management to ensure adequate patent protection in order to capitalise on the future value of the products by establishing an exclusive market position. Camurus has built long-standing relationships with leading international IP firms to be able to efficiently protect its inventions and submit new patent applications, as well as to maintain and defend its existing patents and trademarks, and ultimately the commercial value of the Company's various commercial assets.

#### Manufacturing

Camurus' manufacturing strategy is based on partnerships and outsourcing, where in-house know-how and expertise are combined with external contractors' best practices, process experience, infrastructure and production capacity. Camurus has established a network of preferred contract manufacturing partners in both Europe and the US to support its manufacturing needs, ranging from the supply of small batch sizes of investigational medicinal products to large-scale commercial product supply. Camurus has substantial experience of technology transfers to contract manufacturers and through such collaborations manufactured a number of products released for use in clinical trials and on the market. These partnerships often include the production of different types of products, ranging from ampules and prefilled syringes to spray pump bottles/vials. Furthermore, Camurus has established a full supply chain for all key components and ingredients, and continuously explores new possibilities to increase the efficiency and quality of its suppliers and contract manufacturers.

Generally, FluidCrystal<sup>®</sup> technology platform products are liquid products with the active pharmaceutical ingredient dissolved in a lipid solution matrix. The manufacturing includes standard pharmaceutical processing steps, including mixing and sterile filtration, followed by filling the primary packaging containers, e.g., vials, ampules or prefilled syringes. Several products based on FluidCrystal<sup>®</sup> Injection depot technology have been successfully manufactured in accordance with GMP

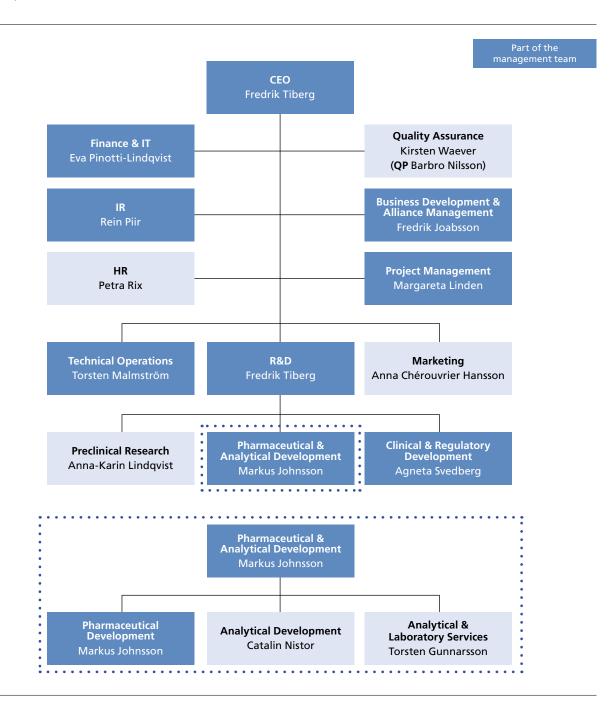
<sup>90</sup> The Company's agreement with Novartis includes a transfer of product specific patents for CAM2029 to Novartis.

for clinical trials, including for Phase III trials and registration stability studies, by different European and US-based contract manufacturers.

The Company also manufactures on a commercial scale through contract manufacturers. episil® is manufactured on a 400-litre commercial scale, demonstrating the scalability of Camurus' products.

#### **Organisational overview**

The chart below presents an overview of Camurus' organisational structure



As of 30 September 2015, Camurus had 48 employees. At the end of 2014, the Company had 43 employees, of whom 29 were women and 14 men.

No. of employees	Jan–Sep 2015	2014	2013	2012
At the end of period	48	43	36	31
Women/men	31/17	29/14	22/14	18/13

Camurus' head office, where all employees are based, is located at the Ideon Science Park in Lund, Sweden. The Company's premises consist of approximately 2,000 m<sup>2</sup> of offices and laboratories. The division of employees by function is depicted below.

Employees by function



#### **Sustainability**

Sustainability is a prioritised area for Camurus. The Company strives to be recognised for the added value it brings to patients, healthcare professionals, society, customers and partners, and to always be trusted and respected for the way Camurus conducts its operations: research, development and marketing.

Camurus has identified a number of specific areas where the Company will continuously strive to ensure that it upholds high ethical standards and full compliance with all applicable legislation and regulations. These areas include research and development, product and service information, product safety and quality, interaction with healthcare professionals and government regulatory bodies, procurement, anti-corruption and anti-bribery, and a safe and secure work environment. The identified areas are all addressed in the Company's Code of Conduct, where detailed guidelines are provided for Camurus' employees and suppliers to secure compliance with applicable standards and ensure that the Company thereby always acts in a way that promotes long-term sustainability.

#### Industry and market information

This offering circular contains certain industry and market information sourced from third parties, including statistics and data from industry publications and other publicly available information. Even if the information has been accurately reproduced and Camurus considers the sources reliable, Camurus has not independently verified the information and, accordingly, cannot provide any assurances as to its accuracy and completeness. As far as Camurus is aware and can ascertain by comparison with other information published by these sources, no information has been omitted that could render the reproduced information inaccurate or misleading.

# Pharmaceutical development and regulatory overview

#### **Development process for pharmaceuticals**

Pharmaceutical development is a time consuming process, which requires substantial financial resources. In order to obtain authorisation for the marketing of a pharmaceutical products, the developer must carry out extensive studies and comply with a rigorous regulatory framework. The studies are divided into pre-clinical studies and clinical trials, which aim at gathering information about the pharmaceutical product and, among other things, information on its safety and efficacy, best usage, other effects and potential adverse reactions.

#### **Discovery phase**

New drugs are typically discovered through one of the following steps:

- new insights into a disease process that allow researchers to design a product to stop or reverse the effects of the disease;
- a broad range of tests of molecular compounds to find possible beneficial effects against any of a large number of diseases;
- existing treatments that have unanticipated effects; or
- new technologies, for example such that provide new ways to target medical products to specific sites within the body or new ways to manipulate genetic material.

Once researchers identify a promising compound for development, they commence experiments to gather more information about the product and its effects through pre-clinical studies.

Pre-clinical studies and preparation for clinical trials

Before testing a drug on humans, the developer must investigate whether there is a risk that the drug can lead to serious harm or toxicity. The pre-clinical studies constitute the first step of the process and they include laboratory evaluation of product chemistry, toxicity and formulation, through studies of appropriate laboratory trials and animal models.

Following satisfactory pre-clinical study results, to be able to proceed with studies in humans in the US, the developer must apply for authorisation from the FDA. Such an application regarding clinical studies on a new study substance, a so called IND application, must be submitted to the FDA before clinical trials on humans can commence. In the IND, the drug developer or the sponsor must, among other things, include the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature data, together with the protocols of the clinical trials that are to be conducted. The clinical trial can proceed 30 days after the IND application, unless the FDA has raised questions or concerns related to the clinical trials during that time period. In such case, the drug developer or sponsor must take account of and amend these issues before the clinical trials can be initiated.

Pharmaceutical product development in the EU and the EEA is subject to extensive regulations by competent authorities at both EU and national level. In addition to this, specific national regulations on controlled substances may apply. All clinical trials of pharmaceuticals in the EU must be conducted in accordance with EU and national regulations, as well as with Good Clinical Practice (GCP). The EU regulations entail that the rules for conducting clinical trials are consistent throughout the EU and that any interventional clinical trials that are conducted in the EU/EEA, as well as clinical trials conducted outside the EU/ EEA that are linked to European paediatric-medicine development, must be registered with the EU Clinical Trials Database (EudraCT). The information in EudraCT is publically available and allows searches for trial protocols and results information. However, with regard to commercial confidential information, it does not provide full insight into e.g. the on-going clinical trials and clinical trial results.

#### **Clinical trials**

In a clinical trial, a new pharmaceutical product is introduced to humans under the supervision of qualified investigators in accordance with GCP requirements. A central requirement is for instance the informed written consent to participate in the trial provided by all research subjects. A clinical protocol must be submitted to the relevant supervisory authority for each clinical trial. The protocol shall e.g. include the purpose of the trial, what parameters are to be used in monitoring safety, and the effectiveness criteria to be evaluated, among many other things. In addition to the regulatory authority, an independent ethics committee or institutional review board consisting of scientists and non-scientists in hospitals and research institutions will also review and approve the clinical trial plan for the study from an ethical perspective.

Human clinical trials are typically conducted in three or four sequential phases, which may overlap or be combined. The different phases are:

- Phase I: Phase I trials are usually conducted on healthy volunteering individuals, but can also involve patients with the targeted disease. The goal is to determine how the drug is tolerated and how it is absorbed, distributed, metabolised and excreted. The initial doses are often low and may gradually be increased. Phase I trials can also yield important information of the drug's pharmaceutical effects. The number of subjects typically range from 20 to 80.
- Phase II: While the emphasis in Phase I is on safety and drug exposure, the emphasis in Phase II is on efficacy and establishing an appropriate dosage for later large scale testing of the drug. This phase aims at obtaining preliminary data on whether the drug works, is efficacious, in patients with the disease or condition to be targeted by the drug. Safety aspects are continuously monitored and short-term side effects are studied. The number of subjects in Phase II trials typically range from a few dozen to about 300.

- Phase III: Phase III trials are commenced only if Phase II, or in some cases Phase I, results are promising, i.e. if evidence of efficacy and safety is obtained. Phase III trials gather further information to document safety and tolerance and statistically significant treatment efficacy, studying different populations and different dosages and sometimes studying the drug in combination with other drugs. In controlled trials, patients receiving the drug are compared with patients receiving a different treatment, usually an inactive substance (placebo), or a different authorised drug in the double-blind randomised model. The number of subjects typically range from a few hundred to a few thousand patients.
- Phase IV: Phase IV trials are typically trials that are conducted after trials required to obtain product approval. If the relevant supervisory authority, e.g. FDA or EMA, approves the developer's or the sponsor's application for market authorisation of the new drug (which attaches a significant amount of data gathered from previous Phase I-III clinical trials as supporting documentation), it may condition the approval with undertakings for the market authorisation holder to conduct additional clinical trials after the receipt of approval. A developer may also voluntarily conduct additional trials, in order to get more information about the drug's long-term effects and health economic aspects. In both cases, such post-approval trials are known as Phase IV clinical trials or post-marketing surveillance studies.

During the Phase I-III clinical trials, update reports on the trial persons' safety must be submitted to the authorities at least annually and more often if major adverse events occur. If it is found that the research subjects are being exposed to unacceptable health or safety risks, the clinical trial can be suspended or terminated by the competent authority at any time.

The developer of the pharmaceutical product must also develop a process for product manufacturing in commercial quantities in accordance with current GMP requirements. It is important that the manufacturing process is capable of consistently producing the product with high quality and that there are methods for testing the identity, strength, quality and purity of the final product. In addition, appropriate packaging must be selected and evaluated, and stability studies performed in order to demonstrate that the product does not undergo unacceptable deterioration over its shelf life.

#### **Regulatory overview**

#### Approval process

The regulatory framework for development and receipt of marketing authorisation for pharmaceutical products is very extensive. The competent authorities regulate, among other things, research, development, testing, manufacturing, safety surveillance, efficacy, quality control, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, sale, import, export and the reporting of safety and other post-marketing information of the pharmaceutical product. Before a pharmaceutical product can be sold and promoted, it must be approved by the national competent authority in the relevant country or region. Once the product is manufactured in accordance with applicable legal and quality requirements and is introduced on the market, there are subsequent requirements that the manufacturer has to comply with, including appropriate market surveillance, pharmacovigilance, and sometimes requirements for conducting post-marketing studies.

#### **US Regulations**

In the US, drug development and marketing is regulated under the Federal Food, Drug and Cosmetic Act (FDCA) along with its implementing regulations, and under regulations from federal, state and local regulatory authorities. The FDCA and its implementing regulations contain requirements for the research, testing, development, manufacture, guality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of drugs, which the company must adhere to. If failing to comply with the regulation, an applicant in an application process or a manufacturer who after receipt of marketing authorization is obliged to comply with applicable requirements, may at any time during the process be subject to a variety of administrative or judicial sanctions, e.g. the FDA's refusal to approve pending "new drug applications" or NDAs, withdrawal of an approval, product recalls, total or partial suspensions of production or distribution, injunctions, refusals of government contracts, disgorgement or civil or criminal penalties.

Under the provisions of section 505(b)(2), an NDA can rely on data not developed by the applicant itself. These provisions of section 505(b)(2) were created, in part, to help avoid unnecessary duplication of studies already performed on a previously approved ("referenced" or "listed") drug. A 505(b)(2) NDA contains full safety and effectiveness reports but allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant. This way, the traditional steps of formula development and extensive pre-clinical studies may largely be avoided, and the clinical program may be reduced to fewer trials, including at least one Phase III trial. As a result, the route to an approval may be much less expensive and faster compared with a traditional development path. Marketing authorisation can be granted after approximately 5-8 years if the section 505(b)(2) procedure is used, varying primarily depending on substance and indication, which compares to approximately 10-15 years if development is carried out in accordance with the traditional route.

#### **Regulations within the EU/EEA**

In the EU/EEA, a marketing authorisation application (MAA) approval is required before a pharmaceutical product can be placed on the EU market. The cooperation in EU/EEA when it comes to approval of pharmaceuticals for marketing is well developed and depending on the product, the application can go through the centralised procedure, the decentralized procedure, the mutual recognition procedure or the national procedure. Depending on the choice of application procedure, the MAA is submitted for assessment to the EMA or to the national competent authority. A marketing authorisation (MA) is initially valid for five years and can be renewed on the basis of a re-evaluation of the risk-benefit balance.

A MA issued through the centralised procedure gives the marketing authorisation holder (MAH) access to every member state of the EEA. To obtain such a MA, the MAA must be submitted to the EMA in order for a scientific evaluation to be conducted.

A MA issued through the decentralised procedure or the mutual recognition process is based on the mutual recognition by national competent authorities. If the pharmaceutical product has not been granted a MA in any member state within the EEA at the time of application, the applicant can through the decentralised procedure submit an application in all the member states where it intends to obtain a MA at the same time. One of the member states must be chosen as a reference member state where the assessment will be made. If the pharmaceutical product has already received a MA in a member state at the time of application, the member states concerned must under the mutual recognition process recognise the MA granted by the reference member state. The maximum turnaround time for granting a MA through the centralised procedure, the decentralised procedure and the mutual recognition process is 210 days.

A MA granted through the national procedure will give the MAH access to only one particular member state.

Data from pre-clinical tests as well as from clinical trials must as a general rule be included in the abovementioned application procedures. An exception from this requirement can however be made when application is made by way of the decentralised procedure or the mutual recognition process. If the applicant can demonstrate that the active substances of the pharmaceutical product have been in well-established medicinal use within the EEA for at least ten years, with recognised efficacy and an acceptable level of safety, the test and trial results may be replaced by appropriate scientific literature. For pharmaceutical product candidates where this so called hybrid pathway is applicable, there is consequently a possibility of a shortened development process, as the MA applicant can rely in part on pre-clinical and clinical data already submitted for a reference product.

#### **Post-approval requirements**

Pharmaceutical products distributed or manufactured in accordance with an approval from the FDA or a national competent authority in the EEA or the EMA, are subject to extensive and continuously updated regulations with several requirements, e.g. requirements regarding record keeping, periodic safety reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. The manufacturers must continue to spend time, money and effort on production and quality controls in order to ensure GMP compliance. If any non-compliance with regulatory requirements occurs or if there are other problems with the product in the market, the competent authority at hand may withdraw the approval.

If the drug developer, after the approval, seeks to modify the approved product, e.g. adding new indications, a preview and approval of the change is required from the competent authority. In addition to this, there are annual user fee requirements for all marketed products, as well as new application fees for supplemental applications with clinical data. As a condition of approval for an NDA or a MA, as applicable, the FDA or the competent authority in the EEA may impose several post-approval requirements. Such requirements can include additional testing, including Phase IV clinical trials, and additional surveillance to assess and monitor the safety and effectiveness of the product.

In the US, drug manufacturers and others involved in the process must register their establishments with the FDA as well as relevant state authorities. In addition, they might be subject to periodic unannounced inspections by the FDA and the relevant state authorities, for evaluation of the GMP compliance. If a deviation from the GMP requirements occurs, the regulations require an investigation and correction of the deviation which in turn imposes reporting and documentation requirements.

The holder of a MA in the EEA must establish and maintain a pharmacovigilance system and appoint a qualified individual person who is responsible for the supervision of this system, who also has an extended duty to report suspected serious adverse reactions and to submit periodic safety update reports. As regards the advertising and promotional activities for the product, all off-label promotion and direct-to-consumer advertising of prescription pharmaceuticals is prohibited in the EU. In both EU/EEA and the US, an approved drug must only be promoted for the approved indications and in accordance with the provisions of the approved label.

Non-compliance with the regulations or the discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, may result in, for example, an obligation to add new safety information to the product, restrictions regarding the import or export of products, an obligation to conduct post-market studies or clinical trials, withdrawal of the product and/or injunctions or the imposition of civil or criminal penalties.

#### **US Regulation on controlled substances**

Camurus' product CAM2038 contains buprenorphine, which is a so called controlled substance, subject to extensive regulation under the US Controlled Substances Act of 1970 (CSA). The CSA and its implementing regulations establish a framework through which the use of controlled substances for legitimate medical, scientific, research and industrial purposes is regulated. The regulations shall prevent the controlled substances from being diverted for illegal purposes. In the CSA, a specific drug is assigned to one of five schedules, based on the medical use of the substance, potential for abuse, and safety or dependence liability. Schedule I contains substances that have no accepted medical use and cannot be made available to the public under a prescription in a safe manner, while Schedules II, III, IV and V include substances that have recognised medical uses and may be manufactured, distributed, and used in accordance with the CSA.<sup>1</sup>

Any person who handles controlled substances, e.g. drug manufacturers, wholesale distributors and scientific researchers, must register with the Drug Enforcement Administration (DEA) in the US Department of Justice. The registrants are obliged to establish and maintain updated and complete records of all transactions involving controlled substances, to maintain detailed inventories of the substances in their possession and to periodically file reports with the DEA. In addition, they are obliged to ensure that controlled substances are securely stored and safeguarded in accordance with DEA regulations. If a non-compliance with the CSA regulation occurs in the possession, manufacture or distribution of a controlled substances criminal sanctions may apply.<sup>2</sup>

## EU regulation on the wholesale of pharmaceutical products, including narcotic substances

The Directive 2001/83/EG (the "Directive") establishes that all wholesale distributors of pharmaceutical products within the EEA need to apply for a permit for wholesale with the national competent authority. Such permit will be issued if stipulated minimum requirements on e.g. premises, installations and security systems are met, and will only include the pharmaceuticals applied for by the wholesaler. In the Directive, it is further established that EU member states can apply more stringent rules in relation to narcotic substances on a national level.

As set out in the Directive, the European Commission has issued its Guidelines for Good Distribution Practice for pharmaceuticals for human use, 2013/C 343/01. These guidelines include rules on quality control and risk management, appointment of a responsible person within the wholesaling entity and other matters relating to staff, hygiene, premises, equipment, documentation, warehousing, transport and return policies which must be complied with.

<sup>1</sup> Brian T. Yeh, The Controlled Substances Act: Regulatory Requirements. https://www.fas.org/sgp/crs/misc/RL34635.pdf.

<sup>&</sup>lt;sup>2</sup> Brian T. Yeh, The Controlled Substances Act: Regulatory Requirements. https://www.fas.org/sgp/crs/misc/RL34635.pdf.

# Selected historical financial information

The selected consolidated financial statements presented below relating to full years is derived from Camurus' audited financial statements for the financial years 2012-2014, prepared in accordance with the Annual Accounts Act, IFRS, and RFR 1 Supplementary Accounting Rules for Groups. The information regarding the period January-September 2014 and 2015 is derived from Camurus' interim financial report for the period January-September 2015, prepared in accordance with IAS 34 Interim Financial Reporting and the Annual Accounts Act. The interim report has been reviewed by the Company's auditors. For further information on how the accounting has been conducted, please see note 1 ("Summary of key accounting policies") at p.136 onwards in the "Historical financial information" section.

The offering circular contains certain financial key figures that are non-IFRS measures. It is the Company's assessment that these non-IFRS measures are an important supplement, since they enable a better evaluation of the economic trends of the Company. The non-IFRS measures have not been audited and are not to be considered independently or to replace IFRS measures.

The information below should be read together with Camurus' financial statements for the financial years 2012-2014 and for the period January-September 2015, which are included in this offering circular (see "Historical financial information").

	Jan-Sep	Jan-Sep			
SEK thousand	2015	2014	2014	2013	2012
Net sales	118,459	63,330	208,207	197,716	95,204
Cost of goods sold	-132	-523	-656	-1,575	-3,321
Gross profit	118,327	62,807	207,551	196,141	91,883
Marketing and distribution costs	-12,425	-6,555	-11,402	-3,821	-2,385
Administrative expenses	-18,712	-15,996	-22,165	-17,775	-14,505
Research and development costs	111,940	-73,062	-114,146	-52,675	-54,818
Other operating income	41	86	2,481	5,446	114
Other operating expenses	-904	-1,567	-	-	-1,527
Operating profit/loss before items affecting comparability	-25,613	-34,287	62,319	127,316	18,761
Items affecting comparability	-138,075	-	-	-	-
Operating profit/loss	-163,688	-34,287	62,319	127,316	18,761
Finance income	1	393	394	73	1
Finance expenses	-21	-108	-170	-121	-902
Net financial items	-20	285	224	-48	-901
Profit/loss before tax	-163,708	-34,002	62,543	127,268	17,860
Income tax	36,016	7,480	-14,197	-28,032	-4,543
Profit/loss for the period <sup>1</sup>	127,692	-26,522	48,346	99,235	13,317

#### Consolidated statement of comprehensive income

Earnings per share based on earnings attributable to parent company shareholders for the year						
Earnings per share before dilution, SEK	-20.26	-4.55	8.24	17.01	2.28	
Earnings per share after dilution, SEK	-20.26	-4.55	7.67	15.75	2.11	

<sup>1</sup> Comprehensive income is the same as profit/loss for the year as the consolidated group contains no items that are recognized under other comprehensive income.

#### **Consolidated balance sheet**

SEK thousand	30 September, 2015	30 September, 2014	31 December, 2014	31 December, 2013	31 December, 2012
ASSETS					
Fixed assets					
Intangible assets					
Capitalized product development expenditure	21,344	21,902	22,551	20,723	7,421
Tangible assets					
Equipment	6,566	6,035	7,119	3,176	2,461
Financial assets					
Non-current receivables on Group companies	-	406	406	406	406
Deferred tax receivables	27,936	3,247	-	-	-
Total fixed assets	55,846	31,590	30,076	24,305	10,288
Current assets					
Inventories					
Finished goods and goods for resale	2,570	3,126	702	3,688	2,270
Current receivables					
Receivables from Group companies	-	-	157,908	70,664	37,049
Trade receivables	27,792	25,199	6,118	7,790	4,408
Other receivables	2,149	2,636	1,883	2,305	2,282
Prepayments and accrued income	9,516	1,599	10,925	2,899	1,105
Cash and cash equivalents	112,347	49	56	5	3
Total current assets	154,374	32,609	177,592	87,351	47,117
TOTAL ASSETS	210,220	64,199	207,668	111,656	57,405
EQUITY					
Equity attributable to parent company shareholders					
Share capital	630	583	630	583	583
Other contributed capital	58,634	33,617	58,634	33,617	33,617
Retained earnings, including profit/loss					
for the period Total equity	43,801 103,065	-10,675 <b>23,525</b>	64,193 <b>123,457</b>	15,847 <b>50,047</b>	6,010 <b>40,210</b>
lotal equity	105,005	25,525	125,457	50,047	40,210
LIABILITIES					
Long-term liabilities					
Deferred tax liability Total long-term liabilities	-	-	8,079 <b>8,079</b>	4,577 <b>4,577</b>	1,762 1,762
-	-	-	0,075	4,577	1,702
Short-term liabilities					
Liabilities to Group companies	2		1,697	508	382
Trade payables	14,177	5,785	9,938	7,769	6,288
Deferred tax liabilities	458		458	-	-
Income taxes	8,936		9,600	0	0
Other liabilities	1,292	1,595	1,287	1,172	1,031
Accrued expenses and deferred income	82,290	20,237	53,152	47,583	7,733
Total short-term liabilities	107,155		76,132	57,032	15,434
TOTAL EQUITY AND LIABILITIES	210,220	64,199	207,668	111,656	57,405

#### Consolidated statement of cash flow

SEK thousand	Jan-Sep 2015	Jan-Sep 2014	2014	2013	2012
Operating activities					
Operating profit/loss before financial items	-163,688	-34,287	62,319	127,316	18,761
Adjustments for non-cash items	109,888	914	1,427	814	699
Interest received	1	393	394	73	1
Interest paid	-21	-108	-170	-121	-902
Income taxes paid	-664	-552	37	0	20
	-54,484	-33,640	64,007	128,082	18,539
Changes in working capital					
Increase/decrease in inventories	-1,868	562	2,986	-1,418	-1,412
Increase/decrease in trade receivables	-21,673	-17,408	1,672	-3,382	65,819
Increase/decrease in other current receivables	1,143	1,521	-8,278	-1,817	-735
Increase/decrease in trade payables	4,239	-1,982	2,169	1,482	3,571
Increase/decrease in other current operating liabilities	27,448	-26,275	6,873	40,117	-61,047
Cash flow from changes in working capital	9,289	-43,582	5,422	34,982	6,196
Total cash flow from operating activities	-45,195	-77,222	69,429	163,064	24,735
Investing activities					
Acquisition of intangible assets	-355	-1,179	-1,828	-13,302	-3,855
Acquisition of tangible assets	-473	-3,775	-5,370	-1,529	-1,261
Divestment/amortization of other financial assets	406	-	-	-	-
Increase/decrease in current financial investments (intercompany account for cash handling)	157,908	70,664	-87,244	-33,615	-37,049
Cash flow from investing activities	157,486	65,710	-94,442	-48,446	-42,165
Financing activities					
Increase/decrease in current financial liabilities (intercompany account for cash handling)	-	11,556	-	-	-3,393
New share issue		-	25,064	-	-
Group contributions received/paid	-	-	-	-114,616	20,824
Cash flow from financing activities	-	11,556	25,064	-114,616	17,431
Net cash flow for the period	112,291	44	51	2	1
Cash and cash equivalents at beginning of period	56	5	5	3	2
Cash and cash equivalents at end of period	112,347	49	56	5	3

#### Key figures and data per share

#### **IFRS** measures

Audited information for financial years 2012-2014 and reviewed information for the period 1 January – 30 September 2015, to-gether with comparative figures for the corresponding period in 2014.

	Jan-Sep 2015	Jan-Sep 2014	2014	2013	2012
Net sales, SEK thousand	118,459	63,330	208,207	197,716	95,204
Operating profit/loss before items affecting comparability, SEK thousand	-25,613	-34,287	62,319	127,316	18,761
Operating profit/loss, SEK thousand	-163,688	-34,287	62,319	127,316	18,761
Cash and cash equivalents, SEK thousand	112,347	49	56	5	3
Equity, SEK thousand	103,065	23,525	123,457	50,047	40,210
Total assets, SEK thousand	210,220	64,199	207,668	111,656	57,405
Earnings per share before dilution, SEK	-20.26	-4.55	8.24	17.01	2.28
Earnings per share after dilution, SEK	-20.26	-4.55	7.67	15.75	2.11
Average number of shares	6,302,140	5,835,310	5,864,727	5,835,310	5,835,310
Average diluted number of shares	6,458,579	6,302,140	6,302,140	6,302,140	6,302,140

#### **Non-IFRS** measures

Please note that the tables and calculations below have not been audited.

	Jan-Sep	Jan-Sep			
	2015	2014	2014	2013	2012
R&D costs in percentage of operating expenses	78%	76%	77%	71%	76%
Equity/assets ratio, %	49%	37%	59%	45%	70%
Equity per share, SEK	16.35	4.03	19.59	8.58	6.89
Diluted equity per share, SEK	15.19	3.73	19.59	7.94	6.38
Number of employees at end of period	48	39	43	36	31
Number of employees in R&D at end of period	35	28	28	29	25

#### Definitions

#### **R&D** costs as a percentage of operating expenses

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

#### Cash and cash equivalents

Cash and cash equivalents refers to cash and cash bank balances.

#### Equity/assets ratio

Equity divided by total capital.

#### Earnings per share before and after dilution

Profit/loss divided by the average number of shares, basic and diluted.

#### Equity per share before and after dilution

Equity divided by the number of shares at the end of the period, basic and diluted.

## Operating and financial review

The following information should be read together with the sections "Selected historical financial information" and "Historical financial information". The following review contains forward-looking information subject to various risks and uncertainties. Camurus' actual result may differ significantly from those predicted in the forward-looking statements due to multiple different factors, including, but not limited to, those specified under "Forward-looking information" on the inside cover of this offering circular and in the section "Risk factors".

#### Factors affecting the result of operations

Camurus' profits/losses have been affected, and will be affected, by a number of factors, some of which are outside of Camurus' control. This section describes the key factors that Camurus considers to have affected the result of operations over the period covered by this section and that could be expected to continue to affect Camurus' profits/losses.

#### **Research and development**

Research and development is an important strategic priority for Camurus. The Company's long-term success depends to a great extent on continued innovation and development of new technology and attractive pharmaceutical products. Camurus currently has, either itself or together with cooperation partners, five projects in clinical development phase, and a number of projects in preclinical phase (see "Product candidates" in the "Business description and industry overview" section). These projects require continued research and development, which is subject to common risks including delays in product development and cost overruns or that products at some stage of development do not prove to be sufficiently effective or safe. For further details about risks relating to Camurus' research and development operations, see the "Risk factors" section.

Camurus' research and development organization comprises preclinical, pharmaceutical, analytical, clinical and regulatory functions (see also "Research and development strategy" in the "Business description and industry overview" section). In 2014, research and development costs totaled SEK 114.1 million (SEK 52.7 million in 2013), which corresponds to 77 percent (71 percent in 2013) of the operating expenses.

The total cost of completing Camurus' current pharmaceutical projects is expected to be significant. However, both the annual development costs and the total cost of completing each program will largely depend on Camurus and its partners' ability to successfully carry out and complete various project activities at the right time. This will in turn depend on regulatory acceptance (see "Legal regulation" below), as well as the type and extent of potential new cost- sharing arrangements. Delays and unforeseen events are common in the development of pharmaceuticals and the level of risk is generally high. It is therefore not possible to precisely estimate the costs attributable to the completion of Camurus' product development program, either in total or for the respective programs.

#### License and cooperation agreements

Camurus is dependent on license and cooperation agreements relating to the development and commercialization of the products on those markets covered by such agreements. These include the agreements with Novartis regarding CAM2029 and other undisclosed products as well as the agreement with Braeburn regarding CAM2038. See the "Description of operations and industry overview" section for further details of these agreements. In 2014, revenues attributable to the agreements with Novartis and Braeburn accounted for more than 90 percent of Camurus' net sales.

Revenues from license and collaboration agreements may consist of one-time payments, license, royalty and milestone payments, as well as the sale of development-related goods and services. In addition, under the agreements, Camurus may also be entitled to compensation for costs incurred. All revenues, with the exception of remuneration for research services and agreed incurred costs, are dependent on the product in question developing successfully and reaching the agreed development and regulatory milestones, as well as on the products then being launched and sold on the market. The size of future sales of Camurus' and its partners' products is uncertain and may vary significantly for a number of reasons, such as clinical results and marketing efforts. See also "Product and technology collaboration with other pharmaceutical companies" and "Revenues from partners and licensees" in the "Risk factors" section.

#### Protection of intellectual property rights

Camurus' operations depend on the ability to obtain, retain and protect patents and other intellectual property rights. Camurus' research operations have created a large number of innovations that have resulted in more than 350 patents and patent applications, divided into around 35 patent families covering Camurus' technology platform and products. The Company's intellectual property rights are aimed at both protecting technology and product improvements and enabling the out-licensing of products to companies within specific product areas without giving up overall control of the Company's main intangible assets. For further information, see "IP rights" in the "Business description and industry overview" section.

The research and development conducted by Camurus places stringent requirements on both the practical and strategic work in ensuring patent protection is in place so that Camurus can capitalize on the value generated by its products. The position of pharmaceutical companies under patent law is generally uncertain and includes complex technical, medical and patent law considerations. In addition, the pharmaceutical industry is characterized by rapid technological development and a high level of innovation. If Camurus, or its collaboration partners, do not succeed in obtaining, retaining or protecting significant patents and other intellectual property rights this could have a considerably adverse effect on Camurus' ability to generate revenues. See "Patents and other intellectual property rights" in the "Risk factors" section for further information.

#### Legal regulation

The pharmaceutical industry is subject to extensive public law and other regulation in Sweden and abroad (see also "Regulatory overview" in the "Pharmaceutical development and regulatory overview" section). This regulation imposes requirements regarding matters such as clinical trials, regulatory trials and permissions, market approval, manufacturing, marketing, distribution, packaging, labelling, product safety and quality control. The sale of prescription medicines is also governed by the reimbursement and subsidy systems established by the responsible authorities, reimbursers and healthcare payors, including insurance companies, hospitals and regions.

Changes to regulatory practice and procedures such as new or stricter rules can result in significant costs and could have a material adverse impact on Camurus' ability to generate revenues. For further information, see "Regulatory review and registration of new pharmaceuticals" and "Commercialisation, market acceptance and dependence reimbursement systems" in the "Risk factors" section.

#### Sales and marketing

If and when CAM2038 is granted market approval, Camurus intends to commercialize the related drugs on selected European and other markets itself. For that purpose, Camurus has decided to establish a sales organization in the EU with an initial focus on CAM2038 for the treatment of opioid dependence and a long-term objective to also market additional products on selected European specialist markets. The Company's strategy is to develop the sales organization gradually in an efficient and structured way and Camurus has already started recruiting key functions to the Company's existing commercial organization for episil®. Development of the future commercial structure for CAM2038 has started for certain centralized functions at the headquarters in Lund and, when appropriate, Camurus intends to establish a local presence in important markets. See "The establishment of a commercial organisation for CAM2038 in Europe" under the "Business description and industry overview" section for further details.

Camurus has not previously conducted this type of establishment and expansion of a marketing and sales organisation within or outside Europe. Establishment and expansion of a new marketing and sales organisation may place significant demand on the Group management and on operating and financial infrastructure (see "Ability to manage growth and own commercialisation" in the "Risk factors" section).

#### Segments

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.

#### Income statement items

#### Net sales

Net sales comprise the Company's revenues in the form of licensing revenues, milestone payments, sales of development-related goods and services, the sale of goods and royalties.

#### Costs and other revenues Marketing and distribution costs

The Company's marketing and distribution costs mainly consist of costs for the episil<sup>®</sup> sales organization and business development, which mainly comprises costs relating to staff, marketing tools, trade fairs and exhibitions.

#### Administrative expenses

Administrative expenses include costs for the finance function, IT and the portion of wages and other administrative costs that are not directly attributable to research and development operations.

#### Research and development costs

Research and development costs mainly comprise personnel expenses, costs for preclinical and clinical trials and regulatory development, as well as amortization of intellectual property rights.

#### Other revenues and costs

Other revenues and costs consist of the Company's foreign exchange gains and losses.

#### **Operating profit/loss**

Operating profit is calculated by deducting the cost of sales, marketing and distribution costs, administrative expenses, research and development costs and other operating expenses from net sales.

#### Finance income and expenses

Finance income and expenses mainly comprise interest income and interest expense from the Company's subaccount of the Principal Shareholder's Group-wide cash management (so called cash-pool), from which the Company was deregistered in March 2015. During the time the Company was connected to the Princial shareholder's cash management, the Principal Shareholder had full disposition of the proceeds of the Company's sub-account, which was included in the Principal Shareholder's currency-pooling and used to optimize the liquidity of the Principal Shareholder. The balance on the Company's subaccount of the Principal Shareholder's cash pool is not included in cash equivalents. That the Company had a positive balance on its sub-account in the cash pool meant that the Company had a receivable on the Principal Shareholder, while a negative balance meant a liability to the Principal Shareholder.

#### Profit/loss for the period before and after tax

Profit/loss for the period before and after tax refers to the Company's earnings for the period before and after income

tax. Comprehensive income is the same as profit/loss for the period as the consolidated group contains no items that are recognised under other comprehensive income. Comprehensive income is attributable to parent company shareholders.

#### **Income tax**

Income tax consists of current and deferred income tax for the period.

### Comparison of January-September 2015 and January-September 2014

#### Net sales

Camurus had net sales of SEK 118.5 million for the period January to September 2015, compared with SEK 63.3 million in the same period in 2014, which represents an increase of 87 percent. The increase in net sales was principally attributable to payments for completed activities related to clinical trials and to two development-related milestone payments from Novartis, each amounting to USD 2.5 million. The increase is shown in the sale of development-related goods and services, SEK 68.0 million, compared to SEK 18.9 million in the corresponding period in 2014, and in the milestone payment of SEK 42.7 million compared with SEK 18.0 million in the same period 2014. For the same time period the licensing revenue decreased to SEK 7.2 million, a decrease of SEK 16.8 million compared to January-September 2014. The decrease is related to the accrued license revenue from the agreement with Novartis, which was settled in 2014. The license revenues primarily relate to an initial license payment from Solasia Pharma in a new license and distribution agreement for episil®.

#### Costs and other revenues

Camurus had marketing and distribution costs of SEK 12.4 million for the first three quarters of 2015, compared with SEK 6.6 million for the year-earlier period, which is an increase of 88 percent. SEK 1.5 million of the increase is due to a redistribution of costs, in particular between administrative expenses and sales and marketing expenses, implemented in order to provide a more accurate picture of how costs should be allocated between the functions. The remaining underlying increase is mainly due to the Company's overall growth. The administrative expenses were increased by 17 percent and amounted to SEK 18.7 million for January to September 2015, compared with SEK 16.0 million for the year-earlier period. However, for a fair comparison, the administrative expenses had been SEK 10.4 million higher if there had not been a redistribution between administrative costs and marketing and selling expenses, and research and development costs. The underlying increase relates to increased personnel costs and the ongoing process preparing the Company for listing on the stock exchange. The research and development costs amounted to SEK 111.9 million for the first nine months of 2015, compared with SEK 73.1 million for the year-earlier period,

which is an increase of 53 percent. The increase mainly relates to high activity levels in the lead development programs and costs of clinical trials. However, SEK 8.9 million is related to the redistribution between administrative expenses and research and development costs. Other revenues amounted to SEK 0,0 million for January to September 2015, compared with SEK 0.1 million for the year-earlier period.

#### **Operating profit/loss**

Camurus' operating result for the first three quarters of 2015 was SEK -163.7 million, compared with SEK -34.3 million for the year-earlier period. The operating result before items affecting comparability (see below) amounted to SEK -25.6 million for the first three quarters of 2015, compared with SEK -34.3 million for the year before. The increase was largely attributable to the reasons stated under "Net sales" and "Costs and other revenues" above.

In connection with the payment of the share bonus due to Camurus employees and Board members on the day of listing the Company on the stock exchange, Camurus will be obliged to pay social security contributions, based on the value of the share bonus. This program has now been recognized as an expense in accordance with IFRS 2 because of the expected public listing of the Company's shares on Nasdag Stockholm. The total cost of the bonus program charged to earnings as of 30 September 2015 is estimated<sup>1</sup> at SEK 138.1 million before tax, with a corresponding increase in equity of SEK 107.3 million and a social security liability of SEK 30.8 million. This cost has been classified as an item affecting comparability. The Principal Shareholder has undertaken to contribute an amount to Camurus corresponding to the Company's final cost for social security payments net after tax, by way of subscribing for new shares in Camurus at a total price corresponding to such costs, calculated based on the mid value of the price range in the Offering (see further "Share bonus agreement"). Other costs for the bonus program are accounting cost (not affecting liquidity).

#### Finance income and expenses

Consolidated net financial items amounted to SEK -20 thousand for the first three quarters of 2015, compared with SEK 285 thousand for the year-earlier period. The net deterioration was due to the generally lower interest rates on the Company's transaction account.

#### Profit/loss before and after tax

Camurus had pre-tax income of SEK -163.7 million for January to September 2015, compared with SEK -34.0 million for the year-earlier period. Income after tax for the first nine months of 2015 was SEK -127.7 million, compared with SEK -26.5 million for the year-earlier period.

<sup>&</sup>lt;sup>1</sup> See also "Share bonus agreements" and "Tax risks".

#### **Income tax**

Deferred income tax for the Group amounted to SEK 36.0 million for the first nine first months of 2015, compared with SEK 7.5 million for the year-earlier period, which corresponds to an effective, flat rate tax rate of 22.0 percent for the period of 2015, compared with 22.0 percent for the year-earlier period. The increase of deferred income tax was mainly due to increased negative earnings before tax compared with the year-earlier period.

#### **Cash flow**

Cash flow includes cash flow from operating activities, investing activities and financing activities. Camurus had total cash flow of SEK 112.3 million for January to September 2015, compared with SEK 0.0 million for the year-earlier period, of which cash flow from operating activities was SEK -45.2 million for January to September 2015, compared with SEK -77.2 million for the year-earlier period. The change was primarily due to improved operating income before items affecting comparability and that the Company as per 30 September 2014 had relatively lower deferred income. Cash flow from investing activities generated a net inflow of SEK 157.5 million for the first three guarters of 2015, compared with a net inflow of SEK 65.7 million for the year-earlier period. The increased inflow was mainly related to current financial investments decreasing in the relevant period of 2015 as a result of the withdrawal of cash and cash equivalents from the Principal Shareholder's cash pool. Cash flow from financing activities amounted to SEK 0.0 million for January to September 2015, compared with an inflow of SEK 11.6 million for the year-earlier period. The change was due to the fact that the Company per 30 September 2014 temporarily had a negative balance on the Company's sub-account of the Principal Shareholder's cash pool.

#### **Financial position**

At 30 September 2015, consolidated equity amounted to SEK 103.1 million, compared with SEK 23.5 million at 30 September 2014. At 30 September 2015, total assets amounted to SEK 210.2 million, compared to SEK 64.2 million at 30 September 2014. At 30 September 2015 Camurus had cash and cash equivalents of SEK 112.3 million compared to SEK 0.0 million at 30 September 2014. As per 30 September 2014, Camurus has had available liquidity through its share of the Principal Shareholder's cash pool, from which the Company was deregistered in March 2015.

#### Comparison of 2014 and 2013 financial years Net sales

Camurus' net sales increased from SEK 197.7 million in 2013 to SEK 208.2 million in 2014, which was an increase of 5.3 percent. The increase is partly related to a first development milestone of SEK 18.0 million from Novartis and revenues from the development work performed under the collaboration agreement. Licensing revenues decreased by SEK 21.2 million in 2014 compared with 2013, explained by the difference in revenues from the agreement with Braeburn in 2014 with those coming from the agreement with Novartis in 2013.

#### Costs and other revenues

Camurus had marketing and distribution costs of SEK 11.4 million in 2014, compared with SEK 3.8 million in 2013, which is an increase of 198.4 percent. This was mainly as a result of Camurus expanding its focus on establishing own sales of episil® in Sweden, Denmark and the UK in 2014. Administrative expenses amounted to SEK 22.2 million in 2014, compared with SEK 17.8 million in 2013. This 24.7 percent increase was mainly related to Camurus strengthening its organization and expanding its premises in 2014 to enable the Company's further expansion. Research and development costs amounted to SEK 114.1 million in 2014, compared with SEK 52.7 million in 2013, which is an increase of 116.7 percent. This change was mainly related to Camurus performance of a number of clinical trials in 2014, on its own and with its partners, and starting preparations of registration program, including Phase III trials of CAM2029 and CAM2038. Other revenues (exchange rate effects) amounted to SEK 2.5 million in 2014, compared with SEK 5.4 million in 2013.

#### **Operating profit/loss**

Camurus reported operating profit of SEK 62.3 million in 2014, compared with SEK 127.3 million in 2013, which is a decrease of 51.1 percent. The decrease was largely due to what is stated in the "Net sales" and "Costs and other revenues" sections above.

#### Finance income and expenses

Consolidated net financial items amounted to SEK 224 thousand for the 2014 year, compared with SEK -48 thousand for 2013. The net improvement is explained by Camurus having a positive cash flow and consequently to a larger extent, a positive balance in the Company's sub-account of the Principal Shareholder's cash pool than in 2013.

#### Profit/loss before and after tax

Camurus' profit before tax for 2014 was SEK 62.5 million, compared with SEK 127.3 million in 2013, which is a decrease of 50.9 percent. Profit after tax (profit for the year) was SEK 48.3 million in 2014, compared with SEK 99.2 million in 2013, which is a decrease of 51.3 percent.

#### **Income tax**

The Group's tax expense for 2014 was SEK 14.2 million compared with SEK 28.0 million in 2013, which corresponds to an effective tax rate of 22.7 percent for 2014 versus 22.0 percent for 2013. The decrease in income tax was mainly due to lower earnings before tax than the previous year.

#### Cash flow

Camurus had total cash flow of SEK 51 thousand 2014, compared with SEK 2 thousand in 2013, of which cash flow from operating activities was SEK 69.4 million in 2014 compared with SEK 163.1 million in 2013. The change was mainly explained by a lower operating profit in 2014 but also by the fact that the operating profit in 2013 contained a paid accrued

licensing revenue of SEK 31.7 million which then strengthened cash flow as working capital changed. Cash flow from investing activities generated a net outflow of SEK 94.4 million in 2014, compared with a net outflow of SEK 48.4 million in 2013. The increased outflow was mainly due to current financial investments increasing in 2014 as a result of the deposit of cash and cash equivalents to the Principal Shareholder's cash pool. Investments in intangible assets in 2014 relating to a clinical after-market study for episil® amounted to SEK 1.8 million. Investments in property, plant and equipment, tangible assets, amounted to SEK 5.4 million. These related to a new analysis laboratory and several new advanced analysis instruments and extended premises in Lund. Cash flow from financing activities generated an inflow of SEK 25.1 million in 2014, compared to an outflow of SEK 114.6 million in 2013. The change was attributable to the issue of new shares as part of a warrant program for Camurus' CEO and that fact that no group contribution was either received from or paid to the Principal Shareholder in 2014.

#### **Financial position**

Consolidated equity at year-end amounted to SEK 123.5 million, compared with SEK 50.0 million at year-end 2013. Total assets at year-end amounted to SEK 207.7 million, compared with SEK 111.7 million at year-end 2013. At year-end, Camurus had cash and cash equivalents of SEK 56 thousand, compared with SEK 5 thousand at year-end 2013. Camurus' receivables from Group companies mainly relate to its share of the Principal Shareholder's cash pool, which amounted to SEK 158.1 million compared with SEK 70.3 million at year-end 2013.

#### Comparison of 2013 and 2012 financial years Net sales

Camurus' net sales amounted to SEK 197.7 million in 2013, compared with SEK 95.2 million in 2012, which is an increase of 107.7 percent. The increase in net sales was mainly attributable to Camurus receiving licensing revenues during the year in connection with Novartis exercising its option to acquire an exclusive global license for the development and commercialization of CAM2029 and, to a lesser extent, increased remuneration for development work in project collaborations.

#### Costs and other revenues

Camurus had marketing and distribution costs of SEK 3.8 million in 2013, compared with SEK 2.4 million in 2012, which is an increase of 60.2 percent. This was mainly due to Camurus taking initial steps during the year to begin its own sales of the medical device product episil<sup>®</sup>. Administrative expenses amounted to SEK 17.8 million in 2013, compared with SEK 14.5 million in 2012, which is an increase of 22.5 percent. This was mainly due to Camurus strengthening its organization in 2013 to enable further development and expansion of its business. Research and development costs amounted to SEK 52.7 million in 2013, compared with SEK 54.8 million in 2012, which is a decrease of 3.9 percent. Overall, the Company's research and development costs increased in 2013, and the decrease in costs was due to a higher share of capitalized expenses. Other revenues (exchange rate effects) amounted to SEK 5.4 million in 2013, compared with other costs SEK -1.4 million in 2012.

#### **Operating profit/loss**

Camurus reported operating profit of SEK 127.3 million in 2013, compared with SEK 18.8 million in 2012, which is an increase of 578.6 percent. The increase was largely due to what is stated in the "Net sales" and "Costs and other revenues" sections above.

#### Finance income and expenses

Consolidated net financial items amounted to SEK -48 thousand for the 2013 year, compared with SEK -901 thousand for 2012. The net increase was due to Camurus having positive cash flow and to a larger extent having a positive balance in the Company's sub-account of the Principal Shareholder's cash pool than in 2012.

#### Profit/loss before and after tax

Camurus' profit before tax for 2013 was SEK 127.3 million, compared with SEK 17.9 million in 2012, which is an increase of 612.6 percent. Profit after tax (profit for the year) was SEK 99.2 million in 2013, compared with SEK 13.3 million in 2012, which is an increase of 645.2 percent.

#### Income tax

The Group's tax expense for 2013 was SEK 28.0 million, compared with SEK 4.5 million in 2012, which corresponds to an effective tax rate of 22.0 percent for 2013 versus 25.4 percent for 2012.<sup>2</sup> The increased tax expense was principally the result of improved earnings before tax compared with the previous year.

#### **Cash flow**

Camurus had cash flow of SEK 2 thousand in 2013, compared with SEK 1 thousand in 2012. Cash flow from operating activities was SEK 163.1 million in 2013 compared with SEK 24.7 million in 2012. The change in cash flow was mainly due to the improved operating profit as well as an increase in other current operating liabilities in the form of a paid but accrued license revenue of SEK 31.7 million. Cash flow from investing activities generated a net outflow of SEK 48.4 million in 2013, compared with a net outflow of SEK 42.2 million in 2012. The increased outflow was mainly related to increased investments in intangible assets (mainly the conduct of an after-market study for episil®). Cash flow from financing activities generated an outflow of SEK 114.6 million in 2013, compared with an inflow of SEK 17.4 million in 2012. The change was mainly due to Camurus paying a group contribution in 2013 to, and receiving a group contribution in 2012, from the Principal Shareholder.

<sup>2</sup> The higher tax rate in 2012 was due in part to the cut in corporate tax in Sweden from 26.3% to 22% on 1 January 2013.

#### **Financial position**

Consolidated equity at year-end amounted to SEK 50.0 million, compared with SEK 40.2 million at year-end 2012. Total assets at year-end amounted to SEK 111.7 million, compared with SEK 57.4 million at year-end 2012. At year-end Camurus had cash and cash equivalents of SEK 5 thousand, compared with SEK 3 thousand at year-end 2012. Camurus' receivables from Group companies mainly relate to its share of the Principal Shareholder's cash pool, which was SEK 70.3 million compared with SEK 36.9 million at year-end 2012.

# Capitalisaton and other financial information

The tables in this section account for Camurus' capital structure at Group level as per 30 September 2015. For information on the Company's share capital and shares (including changes in connection with the Offering), please see "Share capital and ownership structure". The tables in this section should be read together with "Operating and financial review" and Camurus' financial reports and the related notes, which are to be found in the "Historical financial information" section.

#### **Equity and liabilities**

Set forth below is Camurus' capitalisation as of 30 September 2015.

SEK thousand	30 September 2015
Total short-term liabilities	107,155
Against guarantee or surety	-
Against security	-
Without guarantee/surety or security	107,155
Total long-term liabilities	-
Against guarantee or surety	-
Against security	-
Without guarantee/surety or security	-
Total equity	103,065
Share capital	630
Other contributed capital	58,634
Retained earnings, including profit for the period	43,801

#### Net indebtedness

Set forth below is Camurus' net indebtedness as of 30 September 2015.

SEK thousand	30 September 2015
(A) Cash	0
(B) Cash equivalents	112,347
(C) Current financial investments	-
(D) Cash and cash equivalents (A)+(B)+(C)	112,347
(E) Current financial receivables	27,792
(F) Current bank loans	-
(G) Current share of long-term liabilities	-
(H) Other current financial liabilities (non-interest bearing)	14,177
(I) Total current financial liabilities (F)+(G)+(H)	14,177
(J) Net current financial indebtedness (I)– (E)–(D)	-125,962
(K) Non-current bank loans	-
(L) Issued bonds	-
(M) Other non-current liabilities	-
(N) Non-current financial indebtedness (K)+(L)+(M)	-
(O) Net financial indebtedness (J)+(N)	-125,962

#### Statement regarding working capital

It is Camurus' assessment that its current working capital is insufficient for the Company's current needs for the next twelve months.

Camurus' working capital requirements mainly relate to the further development and expansion of its clinical project portfolio and its commercial operations according to plan, including the initiation of clinical phase III trials and the planned preparations for the commercialization of CAM2038 on selected European markets. The Company assesses that the working capital deficit for the next 12 months is in the range of SEK 215-245 million. The existing working capital is assessed to be sufficient to fund Camurus' operations through May 2016. In order to satisfy Camurus' working capital requirements, a new share issue, which is estimated to provide Camurus with approximately SEK 500 million after expenses related to the Offering, is being carried out as part of the Offering. The Offering is conditional upon the new share issue providing Camurus with at least SEK 400 million after expenses relating to the Offering. If that will not occur, the Offering will be cancelled and the listing of the Company on Nasdag Stockholm will not be implemented. After the new share issue is carried out, Camurus considers that the working capital will be sufficient for current needs for at least the next twelve months.

#### **Research and development**

Camurus' business model is based on the Company's research and development activities and Camurus' ability to succeed in the long term is largely dependent on continued successful innovation and development work on new technologies and pharmaceutical products. Camurus' research and development work is described in more detail in the "Research and development strategy" section.

Owing to the high degree of risk with which the Company's development projects are associated, all development work is considered to be research until the product has gained market approval, as it is only then that a product is considered to fulfil all the criteria for being recognized as an intangible asset. Research expenditures are expensed as they occur. See also note

1.6 ("Intangible assets") on p.137 of this offering circular.

The table below shows Camurus' research and development costs for the 2012–2014 financial years and for the periods January to September 2014 and 2015.

SEK thousand	Jan–Sep 2015	Jan–Sep 2014	2014	2013	2012
Research and development costs	111,940	73,062	114,146	52,675	54,818
Total	111,940	73,062	114,146	52,675	54,818

#### Investments

The table below summarizes Camurus' total investments for the 2012-2014 financial years and for the periods January to September 2014 and 2015. The investments mainly consist of after-market studies for episil<sup>®</sup>, as well as an analysis laboratory and related analysis instruments.

	Jan–Sep	Jan–Sep			
SEK thousand	2015	2014	2014	2013	2012
Tangible assets	473	3,775	5,370	1,529	1,261
Intangible assets	355	1,179	1,828	13,302	3,855
Total	828	4,954	7,198	14,831	5,116

#### Ongoing and future investments

Camurus has no ongoing or committed future significant investments. The Company's planned use of the net proceeds of the new share issue is detailed in the "Background and reasons" section.

#### **Tangible assets**

Camurus' tangible assets amounted to SEK 6.6 million as per 30 September 2015 and consists mainly of inventory, primarily laboratory equipment. No material tangible assets have been financed by way of leasing. There were no pledged assets relating to tangible assets at 30 September 2015.

#### **Financial exposure and risk management**

As a result of its business, the Group is exposed to a number of different financial risks: market risk (including foreign exchange risk), credit risk and liquidity risk. Camurus' finance policy allows for hedging instruments to be used. See also note 2 ("Financial risk management") on p.140 of this offering circular.

#### Significant trends

Since a number of years the major pharmaceutical companies have become increasingly dependent on cooperating with small, research-based biotech and pharmaceutical companies, to develop projects in their early phases and then license their products to large companies that have the capacity to conduct large-scale pharmaceutical trials and commercialize the drugs globally. This general trend has continued to contribute positively to Camurus' business and performance, and over the past year the Company's preclinical pipeline has been replenished with a number of new and promising research and development cooperation programs with large pharmaceutical companies with the general objective to create new clinical development projects. One example of these is CAM4071 in collaboration with Novartis, which started a clinical phase I trial during the year.

Further, the trend of a change in the way European authorities view opioid dependence, with the traditional focus on abstinence and harm reduction gradually shifting towards an illness- and treatment-based approach, has become further established. The ability for opioid dependent patients to combine medical treatment with other suitable care in order to return to a normal way of life, is one of a number of core elements supporting Camurus' planned commercialization of CAM2038 for opioid dependence on selected European markets.

In addition to these general trends, with the support of revenues from partnership cooperation, Camurus has also been able to make planned investments in the Company's in-house clinical development projects and to intensify its preparations to establish a commercial organization in Europe.

#### Significant events since 30 September 2015

Since 30 September 2015, the following significant events in Camurus' financial or market position have occurred. On 7 October and 18 November 2015, respectively, extraordinary general meeting in the Company resolved to amend the Company's articles of association entailing that the Company has become a public company and the inclusion of a CSD provision, resolved on a share split 4:1, resolved on two directed share issues as part of the Company's share bonus program and resolved on the new share issue within the Offering. Additionally, on 4 November 2015 the Company and Braeburn announced that the FDA has granted Fast Track designation in the US for CAM2038 for opioid dependence treatment and that the first patient at the same time has been dosed in a Phase II study assessing the opioid blockade of CAM2038 on the effects of other opioids.

## Board of Directors, Group management and auditors

#### **Board of Directors**

According to Camurus' articles of association, the Board of Directors shall consist of three to ten members elected by the general meeting. In addition, Camurus' employees have the right to representation on the Board by law. The Board of Directors currently consists of nine elected members (elected by the 2015 annual general meeting and the extraordinary general meeting in August 2015 for the period until the 2016 annual general meeting).

				Audit	Remuneration	Share-
Name	Function	Elected	Independent	Committee	Committee	holdings <sup>1</sup>
Per Olof Wallström	Chairman	2010	Yes	•	•	52,748
Per-Anders Abrahamsson	Member	2006	Yes			39,561
Marianne Dicander Alexandersson	Member	2015	Yes			10,550
Martin Jonsson	Member	2013	No <sup>2</sup>	•	•	22,682
Svein Mathisen	Member	2010	Yes	•	•	41,143
Björn Olsson	Member	2010	No <sup>2</sup>	•		52,748
Per Sandberg	Member	2006	No <sup>2</sup>			-
Fredrik Tiberg	Member, CEO	2003	No <sup>3</sup>			1,510,313 <sup>4</sup>
Kerstin Valinder Strinnholm	Member	2015	Yes			5,908

<sup>1</sup> Refers to own and related natural and legal persons' holdings as per the date of this offering circular, and includes the shares which in connection with the listing will be received within the share bonus program (less the number of shares that will be sold to pay the tax attributable to the benefit).

<sup>2</sup> Not independent in relation to major shareholders of the Company.

<sup>3</sup> Not independent in relation to the Company and its management.

<sup>4</sup> Refers to holdings in accordance with footnote 1 above, and after the sale of shares to the Principal Shareholders that takes place on the first day of trading, calculated based on the assumption that the Offering price corresponds to the mid value of the price range. See also "Interests of importance for the Offering" in the "Legal considerations and supplementary information" section.

#### Per Olof Wallström

Born 1949. Chairman of the Board since 2015 and member since 2010. Chairman of the Remuneration Committee and member of the Audit Committee.

Education and work experience: M.Sc. in Pharmacy from Uppsala University. Senior management at Merck Sharpe & Dohme, AstraZeneca, Pharmacia and Bristol Myers Squibb. CEO of Q-Med, Melacure and Karo Bio AB.

**Other current appointments:** Chairman of the Board of MB Erikssons Bygg & Fastighet AB, Arosgruppen Fastigheter Fjärdingen AB, Arosgruppen Holding AB, Neo Dynamics AB and Patients Pending Ltd. Board member of Hansa Medical AB and Arosia Communication AB. Deputy Board member of Reabyrån AB.

**Previous appointments (last five years):** Chairman of the Board of Aros Arkitekter AB and Chemilia AB. Board member of Mediplast AB and Aggal Invest AB.

#### Holdings: 52,748

Independent in relation to the Company and its management and the Company's major shareholders.

#### Per-Anders Abrahamsson

Born 1949. Board member since 2006.

Education and work experience: Doctor of Medicine from Lund University, Ph.D., associate professor and professor of urology. Physician at Skåne University Hospital and former Secretary General of the European Association of Urology (EAU). Other current appointments: Board member of Medisport AB and GOAR Holding A/S. Executive Medical Director of Ferring Pharmaceutical.

#### Previous appointments (last five years):

#### Holdings: 39,561

Independent in relation to the Company and its management and the Company's major shareholders.

#### Marianne Dicander Alexandersson

Born 1959. Board member since 2015.

Education and work experience: M.Sc. in Chemical Engineering from Chalmers University of Technology. Many years of experience in the life science industry and from board work, including as CEO of Kronans Droghandel, Global Health Partner and the Sixth AP Fund, deputy CEO of Apoteket AB and positions in quality and market development at Pharmacia, Imperial Chemical Industries and Volvo.

**Other current appointments:** Enzymatica AB (publ), Recipharm AB (publ) and West Atlantic, Chairman of the Board and CEO of MDA Management AB, member of the council at Skandia, Chairman of Sahlgrenska Science Park and member of the Advisory Council of the Dental and Pharmaceutical Benefits Agency.

**Previous appointments (last five years):** Chairman of the Board for Global Health Partner Swe AB. Board member in Apoteksakademin i Sverige AB, Bariatric and Diabetes Center Ajman AB, Castellum Aktiebolag, Chalmers Tekniska Högskola Aktiebolag, Easy Lighting Scandinavia AB, Ideella föreningen Svenskt Näringsliv med firma Svenskt Näringsliv, Mölnlycke AB, Mölnlycke Holding AB and MHC Sweden AB. CEO of Global Health Partner AB, external CEO of GHP Specialty Care AB (publ), external CEO of the Sixth AP Fund and external deputy CEO of Apoteket AB (publ).

#### Holdings: 10,550

Independent in relation to the Company and its management and the Company's major shareholders.

#### **Martin Jonsson**

Born 1961. Board member since 2013. Chairman of the Audit Committee and member of the Remuneration Committee. Education and work experience: M.Sc. in Business Administration from Lund University. Over 25 years of combined experience in corporate governance and working in senior positions in various industries such as medical devices, biotechnology and industrial kitchens.

Other current appointments: Board member of Camurus Development AB, Bioimplant Scandinavia AB, Aimpoint AB and Granuldisk AB. Board member and CEO of Sandberg Development AB. Deputy for Ögårdsros AB, Lesurak AB and ANORK AB. External signatory for Aimpoint Sweden AB. Previous appointments (last five years): Deputy for Bioimplant Scandinavia Aktiebolag. External signatory for Bioimplant Scandinavia AB, Camurus AB, Camurus Development AB, Granuldisk AB, Aimpoint AB and Sandberg Development AB. Holdings: 22,682

Independent in relation to the Company and its management, but not in relation to the Company's major shareholders.

#### **Svein Mathisen**

Born 1956. Board member since 2010. Member of the Audit Committee and the Remuneration Committee.

Education and work experience: M.Sc. in engineering physics from the Norwegian University of Science and Technology. More than 25 years of experience in various senior positions in the Norsk Hydro Group and as CEO of BioInvent International AB. Other current appointments: Chairman of the Boards of iCell Science AB and Gabather AB. Board member of Athera Biotechnologies AB, Genagon Technologies AB and Arild Capital AB.

**Previous appointments (last five years):** Board member and CEO of BioInvent International AB, Chairman of the Board of Biotec Pharmacon ASA and Board member of the industry organization Sweden Bio.

#### Holdings: 41,143

Independent in relation to the Company and its management and the Company's major shareholders.

#### **Björn Olsson**

Born 1945. Board member since 2010. Member of the Audit Committee.

Education and work experience: M.Sc. in Business Administration specializing in Accounting and Finance from Lund University. Many years of experience in senior management and board work in Sweden and the US, including 10 years as CEO of Harmon Industries Inc. Other current appointments: Chairman of the Board of Aimpoint AB, Aimpoint Inc. and Granuldisk AB. Board member of Sandberg Development AB and Davinci Roofspace LLC. Board member of and Lead Independent Director for Saia Inc. Previous appointments (last five years): Chairman of the Board of Camurus AB. Board member of Hexiron AB, Lås & Larmteknik Europe AB and Scan Coin Group AB. Taught International Management at the University of Central Missouri. Holdings: 52,748

Independent in relation to the Company and its management, but not in relation to the Company's major shareholders.

#### Per Sandberg

Born 1962. Board member since 2006.

Education and work experience: M.Sc. in Mechanical Engineering from Lund Institute of Technology. Former CEO of Granuldisk, Aimpoint AB and Sandberg Development AB. Other current appointments: Chairman of the Board of Sandberg Development AB and Aimpoint Sweden AB. Board member of Ögårdsros AB, ANORK AB, Lesurak AB, PGS Group AB, Aimpoint AB, Granuldisk AB and Fosieby Företagsgrupp Ekonomisk Förening.

**Previous appointments (last five years):** Chairman of the Board of Camurus AB, Heptahelix AB, Pegubijo AB, Pegubijo Invest AB and Dansören 3 AB. Board member of Noxys Invest AB. Board member of Lundatraktorn Fastighets AB and Viptop Aktiebolag. Partner in E & G Sandberg Handelsbolag. Holdings: –

Independent in relation to the Company and its management, but not in relation to the Company's major shareholders.

#### **Fredrik Tiberg**

Born 1963. Board member and CEO since 2003. See 'Group management' below. Independent in relation to the Company's major shareholders,

but not in relation to the Company s major shareholders

#### Kerstin Valinder Strinnholm

Born 1960. Board member since 2015.

Education and work experience: Degree from the School of Journalism at the University of Gothenburg, many years of experience in sales, marketing and business development from senior positions at Astra/AstraZeneca and Nycomed/Takeda. Other current appointments: Board member of Corline Biomedical AB, KVS Invest AB and Cavastor AB.

**Previous appointments (last five years):** EVP Business Development for the Nycomed Group.

#### Holdings: 5,908

Independent in relation to the Company and its management and the Company's major shareholders.

#### Group management

Name	Title	Member of Group Management since	Employed by Camurus since	Share- holding <sup>1</sup>
Fredrik Tiberg	CEO	2003	2002	1,510,313 <sup>3</sup>
Eva Pinotti-Lindqvist	Chief Financial Officer	2014	2014	36,291
Margareta Lindén	argareta Lindén Vice President, Project Management and Planning		2004	36,291
Markus Johnsson	Vice President, Pharmaceutical and Analytical Development	2009	2004	45,363
Torsten Malmström	Vice President, Technical Operations	2013	2013	36,291
Agneta Svedberg	Vice President, Clinical and Regulatory Development	2015	2015	9,073
Fredrik Joabsson	Vice President, Business Development and Alliance Management	2015	2001	36,291
Rein Piir	Vice President, Investor Relations	2015	2015 <sup>2</sup>	5,275

<sup>1</sup> Refers to own and related natural and legal persons' holdings on as per the date of this offering circular and includes the shares which in connection with the listing will be received within the share bonus program (less the number of shares that will be sold to pay the tax attributable to the benefit). Assignments on a consultancy basis.

Refers to holdings in accordance with footnote 1 above, and after the sale of shares to the Principal Shareholders that takes place on the first day of trading, calculated based on the assumption that the Offering price corresponds to the mid value of the price range. See also "Interests of importance for the Offering" in the "Legal considerations and supplementary information" section.

#### **Fredrik Tiberg**

#### Born 1963. CEO since 2003.

Education and work experience: M.Sc. in Chemical Engineering from Lund Institute of Technology. Ph.D. in physical chemistry and associate professor of physical chemistry (surface chemistry) from Lund University. Section manager at the Institute for Surface Chemistry, adjunct professor of surface chemistry at Lund University, and visiting professor of physical and theoretical chemistry at the University of Oxford

Other current appointments: Board member and CEO of Camurus Development AB and Bioimplant Scandinavia AB. Board member of Medicon Valley Alliance.

Previous appointments (last five years):

CEO of Heptahelix AB.

Holdings: 1,510,313 shares

#### **Eva Pinotti-Lindqvist**

Born 1963. Chief Financial Officer since 2014.

Education and work experience: M.Sc. in Business Administration from Lund University. CFO and Vice President Business Development for EQL Pharma AB. Market analyst for Nordic Drugs AB and financial consultant for Poolia AB. Controller of Svedala Svenska AB and Finance Manager for Poseidon Yath Charter AB.

Other current appointments: Owner of JOCE Häst & Hö. Previous appointments (last five years): Board member of EQL Pharma OY. Board member of EQL Pharma Int AB. Holdings: 36,291

#### Margareta Lindén

Born 1954. Vice President, Project Management and Planning since 2004.

Education and work experience: B.Sc. in chemistry and biology and Ph.D. in zoophysiology from Lund University. Associate professor of experimental pulmonary medicine at Lund University. Many years of experience from various positions within preclinical and clinical research and development in the pharmaceutical industry (Draco, AstraZeneca).

#### Other current appointments: -

Previous appointments (last five years): Owner of BioLinden (sole trader).

Holdings: 36,291

#### Markus Johnsson

#### Born 1972. Vice President, Pharmaceutical and Analytical Development since 2009.

Education and work experience: Ph.D. in physical chemistry and M.Sc. in chemistry from Uppsala University. Postdoctoral researcher at the University of Groningen. Senior Scientist at Uppsala University. Senior Research Scientist and Manager for Parenteral Drug Delivery Systems at Camurus.

Other current appointments: -

Previous appointments (last five years): -Holdings: 45,363

#### Torsten Malmström

Born 1968. Vice President, Technical Operations since 2013. Education and work experience: Ph.D. in chemistry from Lund University. Team Manager at AstraZeneca.

#### Other current appointments:

Previous appointments (last five years): Director Pharmaceutical Development for Zealand Pharma and Director of Development for Polypeptide.

Holdings: 36,291

#### Agneta Svedberg

Born 1963. Vice President, Clinical and Regulatory Development since 2015. Development sedan 2015. Education and work experience: M.Sc. in radiophysics and Executive MBA, Executive Foundation Lund (EFL), B.Sc. in Medicine, all from Lund University. Over 20 years of experience in drug development, including two years as COO for Zealand Pharma A/S, two years as CEO of Cantargia AB and Senior Vice President, Clinical Development at Genmab A/S for ten years.

#### Other current appointments: -

**Previous appointments (last five years):** COO for Zealand Pharma A/S, CEO for Cantargia AB. **Holdings:** 9,073

#### Fredrik Joabsson

Born 1972. Vice President, Business Development and Alliance Management since 2015.

Education and work experience: Ph.D. in physical chemistry and M.Sc. in chemistry from Lund University. 14 years of experience in drug discovery through various positions in research and development and business development at Camurus.

#### Other current appointments:

Previous appointments (last five years): Holdings: 36,291

#### **Rein Piir**

Born 1958. Vice President, Investor Relations since 2015. Education and work experience: M.Sc. in Business Administration from Uppsala University. Many years of experience advising listed companies, including as head of research at Carnegie Investment Bank AB and strategist at Alecta. 14 years as CFO/Head of Investor Relations at Medivir AB, and three years as an auditor at PricewaterhouseCoopers AB.

**Other current appointments:** Chairman of the Board and CEO for Piir & Partner AB. Board member of Integrative Research Laboratories Sweden AB, Trygga Pengar i Mobilen Sverige AB and L. E. Svensson Snickeri AB.

**Previous appointments (last five years):** Board member of HW Svenskt Reklamscreen AB and Medivir Personal AB. **Holdings:** 5,275

### Other information concerning the Board of Directors and Group management

All members of the Board and Group management can be contacted via the Company's address, Camurus AB, Ideon Science Park, SE-223 70 Lund, Sweden.

There are no family ties between the member of the Board and/or senior executives. No director or senior executive has been convicted in any case involving fraud during the past five years. None of them has been involved in any bankruptcy, bankruptcy trusteeship or liquidation during the past five years. No accusations and/or sanctions have been issued by any agency authorised by law or regulation (including approved professional organisations) during the past five years against any of the members of the Board or the executive management. Nor, during the past five years, has any member of the Board or the executive management been prohibited by a court of law from being a member of a company's administrative, management or control body or from holding any senior or overarching position in a company.

No member of the Board or the executive management has any private interests which might conflict within Camurus' interests. However, as stated above, a number of Board members and the executive management have a financial interest in Camurus through shareholdings.

#### Auditors

Mazars SET Revisionsbyrå AB (Box 1317, SE-111 83 Stockholm, Sweden) is the Company's auditor since 2005, with Gunilla Malmsten as auditor in charge. PricewaterhouseCoopers AB (SE-113 97 Stockholm, Sweden) is the Company's auditor since 2015, with Ola Bjärehäll as auditor in charge. Gunilla Malmsten and Ola Bjärehäll are certified auditors and members of FAR, the accountants' professional body in Sweden.

### Corporate governance

#### **Corporate governance within Camurus**

Prior to the listing on Nasdaq Stockholm, corporate governance within Camurus has proceeded primarily based on the Swedish Companies Act, other applicable laws and regulations, the Company's articles of association and Camurus' internal governance documents. These governance documents mainly include the Board of Directors' rules of procedure, instructions to the Remuneration Committee, the Audit Committee and the CEO, and the Company's finance policy.

Following Camurus' listing on Nasdaq Stockholm, the corporate governance will also be based on Nasdaq Stockholm's Rule Book for issuers and the Swedish Code of Corporate Governance (the "Code"), as well as other applicable rules and recommendations. Listed companies are not obliged to comply with all rules at all times in the Code, but have the possibility to choose alternative solutions which they consider to be better suited to their circumstances, provided that all derogations are reported, that they describe the alternative solution and explain why (in accordance with the "comply or explain" principle). Companies whose shares are admitted to trading on a regulated market, such as Nasdaq Stockholm, must apply the Code from the first day of trading. Camurus intends to apply the Code, without derogations, commencing the day on which the Company's shares are admitted to trading on Nasdaq Stockholm.

The picture below provides a general description of corporate governance within Camurus.



#### The structure of the corporate governance

#### **General meeting**

The right of the shareholders to make decisions regarding Camurus' affairs is exercised at the general meetings (annual general meeting and extraordinary general meetings), which is the highest decision-making body in Camurus. The annual general meeting shall be held in Lund each calendar year before the end of June. Extraordinary general meetings are held as required. Decisions are made at the general meeting on a number of issues, including adoption of the income statement and balance sheet, disposition of Camurus profit or loss, discharge of the members of the Board and the CEO from liability to the Company, composition of the Nomination Committee, election of members of the Board (including the Chairman of the Board) and the auditors. Further, the general meeting also makes decisions regarding remuneration to the members of the Board and the auditors, guidelines for remuneration to the CEO and other senior executives, and any amendments to the articles of association.

Notice convening the annual general meetings and extraor-

dinary general meetings where amendments to the articles of association are to be addressed must be done no earlier than six weeks and no later than four weeks prior to the meeting. Notice convening other extraordinary general meetings must be done no earlier than six weeks and no later than three weeks prior to the meeting. Notice must be given through an announcement in the Swedish Official Gazette (Sw. Post- och Inrikes Tidningar) and on the Company's website. Simultaneously therewith, the fact that notice has been given must be published in Svenska Dagbladet. In order to participate at a general meeting, a shareholder must be entered in the share register maintained by Euroclear Sweden no later than five weekdays prior to the general meeting and give notice of their intention to participate at the general meeting no later than the day stated in the notice to attend the general meeting. Such a day may not be a Saturday, Sunday, public holiday, Midsummer's Eve, Christmas Eve or New Year's Eve, and may not occur earlier than five weekdays prior to the general meeting.

#### **Nomination Committee**

According to the Code, Camurus shall have a Nomination Committee with duties including preparation and drafting of proposals regarding the election of members of the Board, the Chairman of the Board, the Chairman of the general meeting and auditor. In addition, the duties of the Nomination Committee shall include proposals concerning fees for the members of the Board, the members of any Board committees and the auditor.

The extraordinary general meeting held 7 October 2015 decided upon the following instruction for the Nomination Committee, to be valid until further notice. The Nomination Committee ahead of the coming annual general meetings shall be composed of the representatives of the three largest shareholders in terms of voting rights listed in the shareholders' register maintained by Euroclear Sweden as of 30 September each year<sup>1</sup> (the Nomination Committee ahead of the 2016 annual general meeting shall be composed of the representatives of the three largest shareholders in terms of voting rights as of 31 December 2015), together with the Chairman of the Board of Directors, who will also convene the first meeting of the Nomination Committee.

The member representing the largest shareholder in terms of voting rights shall be appointed Chairman of the Nomination committee, unless the Nomination Committee unanimously resolves otherwise.

If, earlier than two months prior to the annual general meeting, one or more of the shareholders having appointed representatives to the Nomination Committee no longer are among the three largest shareholders in terms of voting rights, representatives appointed by these shareholders shall resign, and the shareholder or shareholders who has then become one of the three largest shareholders in terms of voting rights may appoint one representative each. Should a member resign from the Nomination Committee before its work is completed and the Nomination Committee considers it necessary to replace him or her, such substitute member is to represent the same shareholder or, if the shareholder is no longer one of the largest shareholders in terms of voting rights, the largest shareholder in turn. Changes in the composition of the Nomination Committee shall be made public immediately.

The composition of the Nomination Committee for each annual general meeting is to be announced no later than six months before such meeting (the composition of the Nomination Committee for the annual general meeting 2016 is to be announced as soon as it has been appointed). Remuneration shall not to be paid to the members of the Nomination Committee. The company is to pay any necessary expenses that the Nomination Committee may incur in its work. The term of office for the Nomination Committee ends when the composition of the following Nomination Committee has been announced. The duty of the Nomination Committee include to leave proposals for amendments of the instruction to the Nomination committee, in such way deemed necessary.

#### Board of Directors

**Composition and independence** 

According to the articles of association, Camurus' Board of Directors shall consist of at least three and no more than ten members elected by the annual general meeting for a term of office until the end of the next annual general meeting. At the 2015 annual general meeting seven members were elected, and at the extraordinary general meeting held on 10 August 2015 another two members were elected. Camurus' CEO is a member of the Board and the Company's CFO serves as secretary of the Board. Other officers at Camurus participate in Board meetings to provide presentations on specific issues. In accordance with the Code, a majority of the members of the Board elected by the general meeting are to be independent in relation to the Company and its management. In order to determine whether a member of the Board is independent, an overall assessment must be made of all circumstances which might give reason to call into question the independence of the Board member in relation to Camurus or the Company management, e.g. if the Board member has recently been employed by Camurus or an affiliate. Furthermore, according to the Code at least two of the Board members who are independent in relation to the Company and Company management must also be independent in relation to the Company's major shareholders. In order to assess such independence, consideration must be given to the scope of the Board member's direct or indirect relationship to the Company's major shareholders. In the Code, "major shareholder" means a shareholder who, directly or indirectly, controls 10 percent or more of the shares or voting rights in the Company.

The Board of Director's assessment of the independence of the members of the Board in relation to the Company, its management and major shareholders is presented in "Board of Directors, Group management and auditors". Except for the Company's CEO Fredrik Tiberg, all Board members are deemed independent in relation to the Company and its management. Five of them also are independent in relation to the Company's major shareholders. Camurus thereby fulfills the Code's independence requirement.

#### The Board's responsibilities and work

The duties of the Board of Directors are governed by the Swedish Companies Act and the articles of association and, following the listing on Nasdaq Stockholm, the Code. In addition, the work of the Board of Directors is governed by the written rules of procedure that the Board of Directors adopts annually. Among other things, the rules of procedure regulate the allocation of work and responsibilities between the Board of Directors, the Chairman of the Board and the CEO. Furthermore, the rules of procedure regulate the decision-making within the Board, the Board's meeting schedule and the Board's work on accounting, auditing and financial reporting.

<sup>&</sup>lt;sup>1</sup> The shareholding statistics used shall be sorted by voting power (grouped by owners) and cover the 25 largest shareholders. Should this shareholding statistics include nominee registered shareholdings, such shareholdings shall only be considered if the nominee has reported the identity of the underlying shareholder to Euroclear Sweden or if the company – without taking any measures on its own – receives other information that evidences the identity of the underlying shareholder.

The Board has also adopted an instruction for the CEO and adopted other special policy documents.

The Board of Directors is responsible for the Group's organisation and management of its affairs, adoption of the Group's overall objectives, development and monitoring of the overarching strategies, decisions regarding major acquisitions, disposals and capital expenditures, decisions on investments and loans in accordance with the financial policy, regular monitoring of the operations, adoption of guarterly and annual accounts and the regular assessment of CEO and the Group management. The Board of Directors is also responsible for securing the quality of the financial reporting, including a systems for monitoring and internal control of Camurus' financial reporting and position (see "Internal control"). In addition, the Board of Directors shall ensure that the Camurus' external disclosure of information is characterised by openness and is correct, relevant and clear. The Board of Directors is responsible for adoption of necessary guidelines and other policy documents, e.g. communication policy and insider policy. At the Board meetings, the following constitute standing items on the agenda: business situation, project status, market questions, establishment of interim reports, strategic review, outlook and economic and financial reporting.

Through continuous contacts with the CEO, the Chairman of the Board continuously follows the business of Camurus. The Chairman organises and leads the work of the Board, and is responsible for that the other members of the Board receive adequate information and basis for decision making. The Chairman is further responsible for ensuring that new Board members update and deepen their knowledge about Camurus, and receive the necessary training to carry out their work efficiently. The Chairman is also responsible for contacts with major shareholders in respect of shareholder issues and for ensuring that the Board of Directors conducts an annual assessment of its work.

#### Internal control

The Board of Directors' responsibility for the internal control is governed by the Swedish Companies Act, the Swedish Annual Reports Act – which requires that information regarding the most important aspects of the Company's system for internal control and risk management in connection with financial reporting each year must be included in the Company's corporate governance report – and the Code. The Board of Directors is required to, among other things, ensure that Camurus has a sufficient internal control and formalised procedures ensuring compliance of established principles for financial reporting and internal control.

The procedures for internal control with respect to the financial reporting have been designed to ensure reliable overall financial reporting and external financial reporting in accordance with IFRS, applicable laws and regulations as well as other requirements, which may apply to companies listed on Nasdaq Stockholm. This work involves the Board of Directors, the Group management and other personnel.

#### Control environment

The Board of Directors has adopted instructions and governance documents aimed at regulating the roles and allocation of responsibility between the CEO and the Board of Directors. The way in which the Board of Directors monitors and ensures guality in the internal control is documented in the Board's rules of procedure and Camurus' finance policy, in which the Board has established a number of fundamental guidelines of importance for the internal control work. These include control and monitoring of results compared with expectations in previous years as well as supervision of, among other things, the accounting principles applied by Camurus. The responsibility for maintaining an effective control environment, and the day-to-day risk assessment and internal control work regarding the financial reporting, are delegated to the CEO. However, the Board of Directors is ultimately responsible. Managers at various levels within Camurus have, in turn, corresponding responsibility within their respective areas of responsibility. Group management reports regularly to the Board of Directors in accordance with established routines. Responsibilities and powers, instructions, guidelines, manuals and policies constitute - together with laws and regulations - the control environment.

#### Risk assessment

The Group conducts continuous risk assessment to identify key risks relating to financial reporting. These risks include, among other things, significant errors in the accounts (for example with regard to the reporting and valuation of assets, liabilities, revenues and costs or other discrepancies) as well as fraud and losses through embezzlement. Risk management is built into all processes and various methods are used to assess and limit risks and to ensure that the risks to which Camurus is exposed are managed in accordance with established policies, instructions and followup procedures.

#### Control activities

The design of the control activities is of significant importance in respect of Camurus efforts to prevent and detect risks and failures in the financial reporting. The control structure includes clear organizational roles that enable an efficient division of responsibilities for specific control activities, such as authorisation controls in IT systems and signature authentication. The continuous analysis of financial reporting is highly important in ensuring that financial reports are free of material errors.

#### Information and communication

Camurus has channels of information and communication that serve to safeguard completeness and accuracy in financial reporting. Policies, guidelines and internal instructions regarding financial reporting are available in electronic and printed format. The employees concerned are given access to and are notified of regular updates and messages regarding changes in accounting principles, reporting requirements or other provision of information. In respect of the external communication, there are guidelines developed in order to ensure that Camurus meets the requirements of spreading accurate information to the market.

#### Monitoring, assessment and reporting

The Board of Directors regularly assesses the information provided by Group management. Between Board meetings, the Board of Directors regularly receives updated information regarding Camurus' performance. The Group's financial position, strategies and capital expenditures are discussed at each Board meeting. The Board of Directors is also responsible for monitoring the internal control. This work includes, among other things, ensuring that measures are taken to address any deficiencies, as well as follow-up of proposals for measures to which attention has been drawn in connection with the external audit. Annually, the Company carries out a self-assessment of the risk management and internal control work. This process includes a review of the way in which established routines and guidelines are applied. The Board of Directors receives information regarding important conclusions drawn from this annual assessment process, as well as possible proposals on measures relating to the Company's internal control environment. In addition, the external auditors report regularly to the Board of Directors.

#### **Board committees**

Within itself, the Board of Directors has established two committees, an Audit Committee and a Remuneration Committee, which operates according to rules of procedure adopted by the Board of Directors.

#### Audit Committee

The main duties of the Audit Committee are to supervise the Company's financial reporting, monitor efficiency in its internal controls, internal audit and risk management, and apprise itself of information regarding the audit of the annual report and consolidated financial statements, review and monitor the auditor's impartiality and independence and, in so doing, take particularly into account whether the auditor provides Camurus with services other than audit services. The Audit Committee shall also assist the Nomination Committee with proposal to the general meeting for election of auditors. The Audit Committee has regular contacts with the auditors of Camurus.

The members of the Audit Committee are Martin Jonsson (Chairman), Per Olof Wallström, Svein Mathisen and Björn Olsson. The committee complies with the Companies Act's requirements for independence and accounting and auditing expertise.

#### Remuneration Committee

The main duties of the Remuneration Committee are to prepare decisions by the Board of Directors on issues concerning remuneration principles, remuneration and other employment terms for the CEO and other members of the Group management, and to monitor and assess ongoing programs for variable remuneration to the Group management, as well as such programs as have been completed during the year. Furthermore, the Committee shall monitor and assess the application of the guidelines for remuneration to the executive management resolved by the annual general meeting, as well as applicable remuneration structures and remuneration levels in the Company.

The members of the Remuneration Committee are Per Olof Wallström (Chairman), Martin Jonsson and Svein Mathisen. The Committee is assessed to comply with the Code's requirements for independence and appropriate knowledge and experience in questions related to remuneration of executive management.

#### **Remuneration to the Board of Directors**

Following a proposal from the Nomination Committee, fees to members of the Board elected by the general meeting are decided upon by the annual general meeting. The table below shows the fees paid during 2014 to the Board members elected by the general meeting.

Name	Function	Board fee (SEK)	Remuneration Committee fee (SEK)	Audit Committee fee (SEK)	Total (SEK)
Björn Olsson <sup>1</sup>	Chairman	170,000	_	-	170,000
Per-Anders Abrahamsson	Member	60,000	-	-	60,000
Martin Jonsson	Member	-	-	-	-
Svein Mathisen	Member	60,000	-	-	60,000
Per Sandberg	Member	_	-	-	-
Fredrik Tiberg	Member, President and CEO	-	-	-	-
Per Olof Wallström	Member	60,000	-	-	60,000
					350,000

<sup>1</sup> Björn Olsson was the Chairman of the Board up to and including 20 April 2015.

On the occasion of the Company's listing on the Nasdaq Stockholm, the extraordinary general meeting held on 10 August 2015 resolved that a fee of SEK 300,000 shall be paid to the Chairman of the Board and of SEK 150,000 to the other member of the Board not employed by the Company. For Per Sandberg and Martin Jonsson such fees shall apply from 1 January 2016 and be paid out proportionally. In addition, the extraordinary general meeting resolved that compensation for committee work shall amount to SEK 50,000 to the Chairman of the Audit Committee and SEK 25,000 to the other Committee members, whilst no compensation shall be paid for work in the Remuneration Committee.

#### **CEO and Group management**

The CEO is responsible for the day-to-day management and development of Camurus in accordance with applicable legislation and applicable rules, including Nasdaq Stockholm's Rule Book for issuers as well as the Code and the instructions and strategies adopted by the Board of Directors. The CEO shall ensure that the Board of Directors receives objective and relevant information required to enable the Board of Directors to make well-founded decisions. Furthermore, the CEO monitors compliance with Camurus' targets and policies, as well as the strategic plans adopted by the Board of Directors and is responsible for informing the Board of Directors about the Camurus' performance between Board meetings.

The CEO leads the work of the Group management, which is responsible for overall business development. In addition to the CEO, Group management comprises the CFO, Vice President Project Management, Vice President Pharmaceutical and Analytical Development, Vice President Technical Operations, Vice President Clinical and Regulatory Development, Vice President Business Development and Alliance Management and Head of Investor Relations, in total eight individuals.

#### **Remuneration to Group management**

Remuneration to Group management consists of basic salary, variable remuneration, pension benefits, other benefits as well as conditions for termination. The table below shows the salary and other remuneration paid to the CEO and other members of Group management in 2014.

SEK thousand	Basis salary	Variable remuneration	Pension <sup>2</sup>	Other benefits <sup>3</sup>	Total
President and CEO	1,754	800	646	76	3,276
Other Group management <sup>1</sup>	2,790	932	937	187	4,846
Total	4,544	1,732	1,583	263	8,122

<sup>1</sup> 4 persons in 2014.

<sup>2</sup> The Group has defined contribution and defined benefit plans. The pension cost refers to the cost that affected the net income. All pension benefits for senior executives are insured. Consequently, there are no amounts set aside or accrued in the Company provide pension or similar benefits to current senior executives after completion of service.

<sup>3</sup> Refers primarily to car benefits.

#### Guidelines

According to the Swedish Companies Act, the shareholders at the general meeting shall adopt guidelines regarding remuneration to the CEO and other executive managing. The following guidelines were adopted at the extraordinary general meeting on 7 October 2015.

The total remuneration and the terms and conditions for the senior executives should correspond to relevant market conditions and will include a balanced composition of fixed salary, variable remuneration, pension benefits, other benefits as well as conditions for termination. Cash remuneration shall consist of fixed salary and variable remuneration. The fixed salary and, if applicable, variable remuneration is to be linked to the executive's responsibility and authority. The variable remuneration is to be based on the outcome of predetermined well defined objectives. The variable cash remuneration is to be limited to thirty (30) percent of the fixed annual salary. Variable remuneration may also be paid in the form of long-term incentive programs. Share based programs shall be resolved by the general meeting. Programs for variable remuneration shall be designed in such a way as to enable the Board of Directors, if exceptional financial conditions prevail, to restrict or omit

payment of the variable remuneration if such action is deemed reasonable and consistent with the company's responsibility towards shareholders, employees and other stakeholders.

Pension benefits must be in accordance with the ITP-plan or otherwise premium-based and maximized at 35 percent of the total remuneration. Benefits other than fixed salary, variable remuneration and pension benefits must be applied restrictively. Fixed salary during the notice period and severance pay shall in total not exceed an amount equal to the fixed salary for 12 months; or for the CEO, the fixed salary for 18 months. The Board of Directors may derogate from these guidelines in certain cases if there are special reasons for doing so. Reasons for derogation must be reported at the next annual general meeting.

To the extent that a member of the Board performs work for the company, besides the board membership, consultant fee and other remuneration may be granted for such work. The remuneration shall correspond to relevant market conditions and shall, as well as other conditions, be determined by the Board.

#### Termination periods and severance pay

Between Camurus and the CEO a notice period of 12 months applies in respect of the Company and 6 month in respect of the CEO. In the event that the CEO's employment in the Company is terminated due to or in connection with a transfer of the Company to a new owner, a 24 month notice period applies from the Company's side. During this period the CEO is entitled to fixed monthly salary and other benefits in accordance with the current employment contract. In this situation, remuneration from the Company shall not be reduced by any other benefits as the CEO may receive during the notice period. Between the Company and other senior executives, a mutual notice period of three to six months applies. Upon termination, no severance payment is paid.

#### **External audit**

The shareholders at the annual general meeting elect auditors for one year each time. The auditors audit the annual report and the accounting as well as the management by the Board of Directors and the CEO, and operate based on an audit plan which is adopted in consultation with the Board's Audit Committee. In connection with the audit, the auditor's report their observations to the Group management for verification, and thereafter to the Board of Directors through the Audit Committee. Reporting back to the Audit Committee takes place following conclusion of the audit of the management and the review of the so called 'hard close' accounts. The Board of Directors meets the auditors at least once per year, when the auditors report back their observations directly to the Board of Directors without the CEO and CFO of Camurus being present. Finally, the auditors participate at the annual general meeting, presenting a brief description of the audit work and their recommendation in the audit report.

# Share capital and ownership structure

#### **Share information**

The Company's registered share capital was SEK 583,531 at 31 December 2014, divided into 5,835,310 shares (no change since 1 January 2014) with a quota value of SEK 0.10 per share. According to the articles of association that applied on 31 December 2014, the number of shares should be no less than 2,500,000 and no more than 10,000,000 and the share capital should be no less than SEK 250,000 and no more than SEK 1,000,000.

Since 31 December 2014, the number of shares in Camurus has increased by a total of 31,620,048 shares, as follows.

In January 2015 the number of shares was increased by 466,830 through the exercise of warrants, after which the total number of shares amounted to 6,302,140.

At the extraordinary general meeting of 7 October 2015, it was resolved to change the articles of association and to carry out a share split dividing each share into four shares (share split 4:1), after which the number of shares amounted to 25,208,560 and the quota value for each share amounts to SEK 0.025.

At the Company's extraordinary general meeting on 18 November 2015, it was resolved to carry out two directed share issues of a total of 2,336,084 new shares to employees, board members and the Principal Shareholder in connection with the share bonus program that is payable on the listing date. These share issues are conditional on the implementation of the Offering. Registration at the Swedish Companies Registration Office is estimated to occur around 7 December 2015, after which the number of shares will amount to a total of 27,544,644. For further information, see "Share bonus agreement" under "Legal considerations and supplementary information".

The new share issue in connection with the Offering entails, at full subscription and assuming that the Offering price corresponding to the mid value of the price range (i.e. SEK 56), that the number of shares in the Company is increased by 9,910,714 shares, from 27,544,644 to 37,455,358 shares, which would correspond to a 36.0 percent dilution of the total number of shares in the Company after the new share issue. Registration at the Swedish Companies Registration Office is estimated to occur around 7 December 2015.

Following the change to the articles of association made at the extraordinary general meeting on 7 October 2015, Camurus' share capital shall be no less than SEK 500,000 and no more than SEK 2,000,000 divided between no less than 20,000,000 and no more than 80,000,000 shares. The Company has only one share class. The shares in Camurus are issued in accordance with Swedish law, fully paid up and denominated in Swedish kronor.

#### Certain rights linked to the shares General meetings

Notice convening general meeting must be given through an announcement in the Swedish Official Gazette (Sw: *Post- och Inrikes Tidningar*) and on the Company's website. Announcement to the effect that notice convening general meeting has been issued shall be made in Svenska Dagbladet. Shareholders who are registered in Camurus' share register five weekdays prior to the meeting and have notified the Company of their participation not later than the date stated in the notice of the meeting shall be entitled to participate at the general meeting.

#### Voting right

Each share entitles the holder to one vote and each person entitled to vote may, at general meetings, vote the full number of shares owned and represented by him or her at the general meeting, without any limitation on voting rights.

#### Pre-emptive right to new shares etc.

If the Company resolves to issue new shares through a cash or set-off issue, or to issue warrants or convertible instruments, the shareholders shall enjoy pre-emptive right to subscribe pro rata to the number of shares previously held. However, the Company's articles of association contains no provision which restricts the possibility – pursuant to the provisions of the Swedish Companies Act – to issue new shares, warrants or convertible instruments with deviation from the shareholders' pre-emptive right.

### Entitlement to dividends and surplus in the event of liquidation

All shares carry equal rights to the Company's earnings and any surplus in the event of liquidation.

Resolutions on dividends are taken at the general meeting, and disbursement is effected through Euroclear Sweden. Dividends may only be distributed in such an amount that, after the dividend, there is full coverage for the Company's restricted equity, and only on condition that the dividend is defensible in light of (i) the requirements which the nature of the business, its scope, and risks impose as regards the size of equity, and (ii) the Company's and Group's need to consolidate, liquidity and financial position in general (the so called prudence rule). As a general rule, the shareholders may not decide on payment of a dividend which exceeds the amount proposed or approved by the Board of Directors. See also "Dividend policy" below.

The entitlement to dividends vests in any person who, on the record day for dividends determined at the general meeting, is registered as a holder of shares in the share register maintained by Euroclear Sweden.<sup>1</sup> Where a shareholder cannot

<sup>1</sup>The offered shares carry the right to dividend from the first dividend record date following the admission to trading of the Company's shares.

be reached through Euroclear Sweden, the shareholder's claim on the Company in respect of the dividend amount will remain in force and shall be limited in time only pursuant to the rules regarding a 10-year limitations period for claims. Where any claim is time-barred, the dividend shall inure to Camurus. Neither the Swedish Companies Act nor Camurus' articles of association contain any restrictions regarding the right to dividends of shareholders outside Sweden. Apart from any restrictions due to banking or clearing systems in relevant jurisdictions, disbursement to such shareholders shall take place in the same manner as payment to shareholders domiciled in Sweden. However, Swedish withholding tax is normally deducted with respect to shareholders with limited tax liability in Sweden, see "Certain tax considerations in Sweden".

#### **Development of the share capital**

The table below shows changes in the share capital since the Company was formed in 2004.

		Change, number of	Change, share capital,	Total number of	Total share capital,	Ouota value,
Year	Event	shares	SEK	shares	SEK	SEK
2004	Establishment	-	-	1,000,000	100,000.00	0.10
2005	New share issue	2,591,143	259,114.30	3,591,143	359,114.30	0.10
2005	New share issue	2,244,167	224,416.70	5,835,310	583,531.00	0.10
2015	Exercise of warrants <sup>1</sup>	466,830	46,683.00	6,302,140	630,214.00	0.10
2015	Changes prior to listing, share split	18,906,420	0	25,208,560	630,214.00	0.025
2015	Directed new share issue <sup>2</sup>	1,909,483	47,737	27,118,043	677,951	0.025
2015	Directed new share issue <sup>2</sup>	426,601	10,665	27,544,644	688,616	0.025
2015	New share issue in the Offering <sup>3</sup>	9,910,714	247,768	37,455,358	936,384	0.025

<sup>1</sup> The warrants were exercised in December 2014 and the new shares were registered in January 2015.

<sup>2</sup> Resolved on 18 November 2015, conditional upon the completion of the Offering.

<sup>3</sup> The calculation of the number of new shares in the Offering is based on the assumption that the new share issue is fully subscribed and that the Offering price will correspond to the mid value of the price range, i.e. SEK 56.

#### **Ownership structure**

As per the day of this offering circular, Camurus has nine shareholders. The largest shareholder is the Principal Shareholder with approximately 85.5 percent of the total number of shares and voting rights in the Company. In addition, the Company's CEO and other shareholders holds a total of approximately 14.5 percent of the total number of shares and voting rights in the Company. The first column in the table below describes Camurus' ownership structure immediately prior to the Offering.

The second column describes the Company's ownership structure at the time of the Offering, i.e. after participants in the Company's share bonus program have subscribed for a total of 1,909,483 new shares in the Company, after the Principal Shareholder has acquired 979,111 of those shares from the participants in the share bonus program for the purpose of cover the participants' tax liabilities resulting from the share bonus benefit, and after the Principal Shareholder has subscribed for 426,601 new shares of the Company in order to cover the Company's net cost social security payments applicable on the share bonus program. As described in "Background and reasons", the total number of 1,405,712 related to the share bonus program that the Principal Shareholder acquires in connection with the Offering, both from the participants in the share bonus program and through the subscription of new shares in Camurus, corresponds to the number of shares sold in the Offering by the Principal Shareholder. The ownership structure at the time of the Offering further comprises a transfer of shares, corresponding to a value of SEK 7,142,857, from Fredrik Tiberg to the Principal Shareholder at the listing day to a price corresponding to the final Offering price. All of the transactions described above are conditional upon the completion of the Offering, see also "Interests of importance for the Offering" under "Legal considerations and supplementary information". Following these transaction, and thus at the time of the Offering, the Principal Shareholder's ownership share amounts to approximately 83.8 percent and the other shareholders' ownership share amounts to approximately 16.2 percent.

Last, the third and fourth columns set forth Camurus' ownership structure immediately after completion of the Offering, divided between if the Overallotment Option is not exercised and if the Overallotment Option is fully exercised.

All calculations below are based on the assumption that the Offering price will be the mid value of the price range in the Offering.

	Owners immediately the Offer	prior to	Ownership after the Offering Ownership at the time (if the Overallotment of the Offering Option is not exercised)		Ownership after the Offering (if the Overallotment Option is fully exercised)			
Shareholder	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Shareholders with a holding of more than 5 percent								
Sandberg Development AB <sup>1</sup>	21,561,048	85.5	23,094,311	83.8	21,688,599	57.9	19,991,135	53.4
Fredrik Tiberg <sup>2</sup>	1,569,820	6.2	1,510,313	5.5	1,510,313	4.0	1,510,313	4.0
Other current shareholders, 7 shareholders	2,077,692	8.3	2,077,692	7.5	2,077,692	5.5	2,077,692	5.5
Other board members, 7 individuals	-	-	225,340	0.8	225,340	0.6	225,340	0.6
Other senior executies, 7 individuals		-	204,875	0.7	204,875	0.5	204,875	0.5
Other employees		-	432,113	1.6	432,113	1.2	432,113	1.2
Total	25,208,560	100.0	27,544,644	100.0	26,138,932	69.8	24,441,468	65.3
New shareholders	-	-	-	-	11,316,426	30.2	13,013,890	34.7
Total	25,208,560	100.0	27,544,644	100.0	37,455,358	100.0	37,455,358	100.0

<sup>1</sup> Jägershillsgatan 15, SE-213 75 Malmö

<sup>2</sup> c/o Camurus AB, Ideon Science Park, SE-223 70 Lund

In Sweden, the lowest threshold for mandatory reporting of changes in shareholdings (Sw: flagging) is five percent of all shares or voting rights in respect of all shares.

#### **Application for listing**

Camurus' Board of Directors has applied for the admission to trading of the Company's share on Nasdag Stockholm. On 3 November 2015, the Nasdag Stockholm listing committee decided to admit the shares in Camurus to trading on Nasdag Stockholm, subject to customary conditions, such as the distribution requirement for the Company's share being fulfilled no later than on the first day of trading. In case the Company's Board of Directors ultimately resolves to list the Company's share, trading in the Company's share is expected to begin on or about 3 December 2015. Consequently, trading is expected to commence before the shares have been transferred to the acquirer's VP-account or securities depository account and in some cases before the contract note has been received. This means that trading is expected to commence before the terms and conditions for the completion of the Offering have been fulfilled. Trading in the Company's share made before the Offering becomes unconditional will be cancelled if the Offering is not completed.

The trading symbol on Nasdaq Stockholm for the Company's share is CAMX.

#### **Central securities depository**

Camurus' articles of association contains a CSD-clause and the Company's shares are affiliated to the electronic securities system with Euroclear Sweden (Euroclear Sweden AB, Box 191, SE-101 23 Stockholm, Sweden) as central securities depository. The shares are registered in the name of the shareholder. No share certificates have been issued in respect of the shares or will be issued in respect of the new shares. The ISIN code for the Camurus shares is SE0007692850.

#### Shareholders' agreements

At the time of this offering circular there is a shareholders' agreement in place between the Principal Shareholder and the other current shareholders in the Company. This shareholders' agreement will terminate in conjunction with the listing of the Camurus share on Nasdaq Stockholm.

To the Board of Directors' knowledge, there are no other shareholders' agreements or any other agreements between the shareholders of the Company which aim to exercise joint influence over the Company. Nor is the Board of Directors aware of any agreements or equivalent which may result in any change of control over the Company.

#### Lock up- arrangement

In connection with the Offering, the Principal Shareholder, certain minority shareholders, share-owning Board members and senior executives, undertake to the Joint Global Coordinators not to sell their respective holdings during a certain period of time after trading on Nasdag Stockholm has commenced (the "lock up-period"). The lock up-period will be 540 days for the Company's CEO and 360 days for the others comprised by the lock up (including the Principal Shareholder), with the exception of Camurus Lipid Research Foundation for which the lock up-period will be 180 days. The undertaking is subject to customary reservations, mainly including a right for the shareholder to sell shares to certain closely related parties, sales pursuant to a public offer or a repurchase offer, sales of subscription rights within the scope of a rights issue, sales in connection with incentive programs or sales required by mandatory law or official decisions. Following expiry of the relevant lock up period, the shares can be offered for sale, which may affect the market price of the share. The Joint Global Coordinators may grant exemptions from the undertakings in question.

#### **Dividend policy**

Camurus' current sales and results are primary based on non-recurring revenues under the license and collaboration agreements that the Company has entered into. Camurus will continue to focus on further developing and expanding of the Company's clinical portfolio and the planned commercial activities, and available financial resources are intended to be used for the financing of this strategy. The intention of the Board is therefore to not propose any dividend to shareholders until the Company generates sustainable profitability.

## Articles of association

#### Articles of association adopted at extraordinary general meeting on 7 October 2015<sup>1</sup>

#### 1. Company name

The name of the company is Camurus AB. The company is a public company (publ).

#### 2. Object of business

The objective of the company's business is to conduct research and production primarily within the fields of chemistry and biotechnology, sales of know-how and products within these fields, and to acquire and manage securities and other personal property and to conduct business compatible therewith.

#### 3. Registered office

The registered office of the company shall be in the municipality of Lund.

#### 4. Share capital

The company's share capital shall amount to not less than SEK 500,000 and not more than SEK 2,000,000.

#### 5. Number of shares

The number of shares shall be not less than 20,000,000 and not more than 80,000,000.

#### 6. Board of directors

The board of directors shall consist of no less than three (3) and no more than ten (10) members.

#### 7. Auditors

The company shall have one (1) or two (2) auditors with no more than two (2) deputy auditors. As auditor shall be elected an authorized public accountant or a registered public accounting firm.

#### 8. Annual general meeting

The Annual general meeting shall be held no later than six (6) months after the end of the financial year. At the annual general meeting, the following matters shall be addressed:

- Election of the chairman of the meeting.
- Preparation and approval of the voting list.
- Election of one or two persons to approve the minutes.
- Determination of whether the meeting has been duly convened.
- Approval of the agenda.
- Presentation of the annual report and the auditor's report, and if applicable, the consolidated financial statements and the group auditor's report.

- Resolutions regarding:
  - (a) adoption of the income statement and the balance sheet, and if applicable, the consolidated income statement and the consolidated balance sheet;
  - (b) appropriation of the company's profit or loss according to the adopted balance sheet;
  - (c) discharge from liability for the members of the board of directors and the managing director.
- Resolution regarding fees for the members of the board of directors and fees for the auditors.
- Resolution regarding the number of members of the board of directors and auditors and deputy auditors.
- Election of members of the board of directors, as well as election of auditors and deputy auditors.
- Any other matter on which the annual general meeting is required to decide pursuant to the Swedish Companies Act or the articles of association.

#### 9. Notice

Notice convening a general meeting shall be published in the Swedish Official Gazette and on the company's website. It shall be advertised in Svenska Dagbladet that notice convening a general meeting has been made.

Shareholders that wishes to participate in a general meeting shall be recorded in a print-out or other representation of the entire share register as at the date falling five weekdays (Sw. *vardagar*) prior to the meeting and notify the company of their intention to participate by the date specified in the notice convening the meeting. The last mentioned day must not be a Sunday, other public holiday, Saturday, Midsummer's Eve, Christmas Eve or New Year's Eve and not fall earlier than the fifth weekday prior to the Meeting.

At a general meeting, shareholders may be accompanied by one or two assistants, however only if the shareholder has notified the company of the number of assistants in the manner stated in the previous paragraph.

#### 10. Financial year

The financial year of the company shall comprise the period 1 January to 31 December.

#### 11. CSD company

The company's shares shall be registered in a central securities depository register in accordance with the Swedish Financial Instruments Accounts Act (1998:1479).

<sup>1</sup> The articles of association will be registered at the Swedish Companies Registration Offices before the first day of trading in Camurus' shares.

# Legal considerations and supplementary information

#### General company and group information

The name of the Company (and its trading name) is Camurus AB. Camurus' registration number is 556667-9105 and the registered office is in the county of Lund, Sweden. The Company was founded in Sweden on 8 September 2004 and was registered with the Swedish Companies Registration Office on 8 October 2004. The business has been conducted since 1991, until 2005 in Camurus Development AB, today a wholly owned subsidiary of the Company. Camurus is a public limited liability company governed by the Swedish Companies Act (2005:551).

Camurus is the parent company of the Group, which comprises three legal entities in two countries, see the table below. Only Camurus is currently operational.

Subsidiaries	Country	Proportion of shares and votes, percent
Camurus Development AB	Sweden	100.0
Camurus Inc	USA	100.0
Cubosome Inc	USA	100.0

#### **Material agreements**

Camurus has entered into two agreements that the Company considers to be material to the Company and its business.

### Collaboration, option and license agreement with Novartis

In December 2011, Camurus entered into a collaboration, option and license agreement with Novartis. Under the agreement, Novartis acquired (i) an exclusive right to globally develop and commercialize CAM2029 (octreotide formulated using the FluidCrystal® technology) and somatostatin formulated using the FluidCrystal® technology, and (ii) an exclusive license for the FluidCrystal® technology for the development, manufacturing and commercialization of pharmaceutical products developed for administration by injection in human or animal subjects that contains a somatostatin receptor agonist and that principally works through direct interaction with one or more of the five subgroups of somatostatin receptors.

The agreement results in the transfer of product-specific rights regarding CAM2029 and the somatostatin covered by the agreement, as well as a license to relevant Camurus technology and know-how to further develop and commercialize the products under the agreement. Further, Novartis is also entitled, at any time, to exercise an option to acquire an exclusive right to certain other substances formulated with the Fluid-Crystal® technology, including CAM4071, (through the transfer and licensing based on the same model as for CAM2029).

Novartis's further development and commercialization of CAM2029 entitles Camurus to compensation in the form of development and sales related milestone payments and sales based royalties. In total, Camurus is entitled to payments of USD 105 million upon achievement of specific developmentrelated or regulatory intermediate goals in either the US or Europe. Of this amount, so far USD 32.5 million has been received in connection with Novartis exercising the option on the rights to CAM2029 and in total USD 7.5 million has been achieved in development milestone payments. In addition, Camurus is entitled to sales-related payments from Novartis totaling up to USD 150 million, which are due upon achievement of certain annual sales volumes. In addition to this, Novartis pays royalties to Camurus based on its annual net revenues for CAM2029. The level of royalties varies between mid to high single-digit percentages, with the lowest level of royalty being paid upon annual sales of up to USD 500 million and the highest levels being paid upon annual sales of over USD 1 billion. Any future development and sales of other products that may be developed based on the rights that Novartis receives under the agreement also entitle Camurus to both development and sales related milestone payments and royalties.

Novartis is entitled, at any given time, to terminate the agreement at its discretion with sixty days' notice. In the event of such termination, Novartis is obliged to transfer back the rights that were previously transferred from Camurus. If such cancellation occurs after a product has received regulatory approval, Camurus must pay royalties to Novartis based on future sales of the product.

#### License agreement with Braeburn

In November 2014, Camurus and Braeburn entered into a license agreement under which Camurus grants Braeburn an exclusive license to the FluidCrystal® technology and other related intellectual property rights for developing and commercializing pharmaceutical products consisting of a long-acting subcutaneously injected buprenorphine formulation, including but not restricted to CAM2038 (opioid dependence and chronic pain). The license covers the US, Canada and Mexico, and entitles Braeburn under certain circumstances to expand the license to include development and commercialization in Japan, Taiwan, South Korea and China.

Under the agreement, Braeburn is responsible, at its own cost and in accordance with agreed development plans, for developing CAM2038 within the rights granted.

Camurus received a one-time payment of USD 20 million upon entering into the agreement. In addition, Camurus is entitled to development-related milestone payments totaling USD 56 million, USD 35 million of which relates to CAM2038 for opioid dependence and USD 21 million relates to CAM2038 for pain. The agreement further entitles Camurus to salesbased milestone payments of up to USD 75 million based on the achievement of certain sales targets. Finally, royalties are paid at a mid double-digit percentage based on annual net sales.

Braeburn is entitled, at any given time, to terminate the

agreement at 90 days' notice. In the event of such termination, Braeburn must transfer or license joint inventions and information and intellectual property rights developed and controlled by Braeburn to Camurus. If termination occurs after the product has received NDA approval by the FDA, Camurus must pay royalties to Braeburn based on future sales of the product.

#### Share bonus agreement

All employees and Board members of Camurus (except Per Sandberg) will at completion of the Offering receive a bonus from the Company paid in the form of shares in the Company. The share bonus comprises a total of 1,909,483 newly issued shares, which are divided between employees and Board members in accordance with bonus agreements entered into. The share bonus is payable at a listing of the Company's share (performance criteria). The participants' part of the bonus depends on position and employment time (employment criteria). The shares are received by the participants by way of subscription of new shares in the Company at a subscription price corresponding to the shares' quota value of SEK 0.025 per share, i.e. essentially free of charge.

Upon payment of the share bonus, an obligation arises for Camurus to pay social security contributions based on the value of the share bonus. This cost is calculated to amount to 31.42 percent of the total value of the bonus shares based on the final Offering price. The Principal Shareholder has undertaken to contribute to Camurus an amount corresponding to Camurus' net cost for social security contributions based on the assumption that the Offering price is set at the mid value of the price range in the Offering. Consequently, the Principal Shareholder will subscribe for 426,601 new shares in Camurus at a price per share of SEK 56 (corresponding to the mid value of the price range in the Offering). The total issue proceeds amounts to SEK 23.9 million, equal to Camurus' net cost for social security contributions calculated based on the mid value of the price range in the Offering. See also "Development of the share capital".

When the share bonus is paid, the participants becomes li-

able to pay income tax based on the value of the share bonus. For the purpose of providing liquidity to cover the participants' tax cost attributable to the bonus benefit, the Principal Shareholder has offered to purchase up to 57 percent of the shares allotted to each participant within the share bonus program. As a result, the Principal Shareholder has purchased 979,111 shares from the participants (conditional upon the consummation of the Offering). The purchase price corresponds to the mid value of the price range in the Offering. See also "Ownership structure" and "Interests of importance for the Offering".

#### Legal and arbitration proceedings

The Group operates in several countries and will, from time to time and in the ordinary course of business, be subject to disputes, claims and administrative proceedings. However, Camurus has not been involved in any legal or arbitration proceedings (including cases that are pending or that Camurus is aware could arise) over the past 12 months that have recently had, or could have, material effects on Camurus' financial position or profitability.

#### **Related party transactions**

The Principal Shareholder holds 85.5 percent of the shares in Camurus and is therefore deemed to have a controlling influence over the Group. The remaining 14.5 percent of the shares are held by the Company's CEO, a foundation and the other shareholders. The Principal Shareholder is wholly owned by PGS Group AB, which is wholly owned by Per Sandberg. Others classified as related parties are the Group subsidiaries and Group senior executives, i.e. Board members and the management, as well as their family members.

The table below sets forth transactions between Camurus and related parties during the financial years 2012–2014 and the period January – September 2015. No transactions, which are material for the Company on either an individual or a joint basis, have occurred after 30 September 2015.

SEK thousand	Jan–Sep 2015	2014	2013	2012
Purchases of primarily IT and administrative services from the Principal Shareholder	1,505	2,789	2,790	2,604
Total	1,505	2,789	2,790	2,604

Products and services have been bought and sold on normal market terms. Transactions with the Principal Shareholder have occurred in relation to delivered services of IT and HR support, however all such transactions have ceased. Prices were set pursuant to the cost-sharing in relation to the utilization rate and in accordance with market conditions.

See also note 27 ("Related party transactions") on p.150 in this offering circular. For information on the remuneration of the members of the Board and Group management, see "Board of Directors, Group management and auditors".

#### **Placing Agreement**

Under the terms of an agreement regarding the placing of shares intended to be entered into on or about 2 December 2015 by and between the Company, the Principal Shareholder and the Joint Global Coordinators on (the "Placing agreement"), the Principal Shareholder undertakes to sell and the Company undertakes to issue, respectively, a total maximum of approximately 36.8 percent of the shares in the Company after the Offering to the purchasers as the Principal Shareholder determines in consultation with the Joint Global Coordinators. In the event that the Joint Global Coordinators fail to procure purchasers, the Joint Global Coordinators have undertaken to the acquire the shares comprised in the Offering, on the condition that the Offering is not cancelled before that (see below). The Principal Shareholder further intends to grant an Overallotment Option entailing a commitment to, at the request of the Joint Global Coordinators within 30 days from the first day of trading in the Company's shares, sell a further maximum of 1,843,210 shares, corresponding to not more than 15 percent of the Offering. The Overallotment Option may only be exercised to cover any overallotment under the Offering.

In order to enable the delivery of shares included in the Offering prior to the rights issue in the Offering have been registered with the Swedish Companies Registration Office and Euroclear Sweden, the Principal Shareholder has furthermore agreed with the Joint Global Coordinators to lend shares to the Joint Global Coordinators. As a result, the Principal Shareholders holding in Camurus may for a period of time fall below 30 percent of the total number of votes in the Company. When the Joint Global Coordinators return the shares borrowed to the Principal Shareholder, the Principal Shareholder's holding may increase to 30 percent or more of the total number of votes in the Company and thereby trigger the obligation to offer a mandatory bid. The Swedish Securities Counsel (Sw. Aktiemarknadsnämnden) has granted the Principal Shareholder exemption from such mandatory bid obligation in accordance with its statement AMN 2015:38.

Through the Placing Agreement, the Company provides customary representation and warranties to the Joint Global Coordinators, primarily regarding the accuracy of the information in this offering circular, that the offering circular and the Offering meet the relevant legal and regulatory requirements and that there are no legal or other impediments to the Company entering into the agreement or to the implementation of the Offering. The Placing Agreement prescribes that the Joint Global Coordinators' commitments to procure purchasers for the shares or, in the event that the Joint Global Coordinators fail in this, to themselves purchase the shares comprised in the Offering are conditional upon, among other things, no events occurring that materially impact the Company negatively to the extent that implementing the Offering becomes inappropriate ("material adverse events"), as well as on certain other customary terms. The Joint Global Coordinators may terminate the Placing Agreement up until the settlement date, 7 December 2015, if any material adverse events occur, if the Company's representations and warranties to the Joint Global

Coordinators should prove to be incorrect or if any of the other terms pursuant to the Placing Agreement are not met. If the Joint Global Coordinators terminate the Placing Agreement by reason of material adverse events, the Offering may be discontinued. In such case, neither the delivery of, nor payment for, the shares will be implemented under the Offering. According to the Placing Agreement, the Company will, with the usual reservations, undertake, under certain conditions, to indemnify the Joint Global Coordinators from certain claims.

With the exception of the transfers described in this offering circular, the Company undertakes, in accordance with the Placing Agreement, not to (i) offer, pledge, allot, issue, sell, undertake to sell, sell any options or forward contracts for, acquire put options for, issue subscription rights or warrants for, or otherwise, directly or indirectly, transfer or dispose of any shares in the Company or any other securities convertible into, or exercisable or exchange-able for such shares, or (ii) enter into swap agreements or other arrangements that transfer all or part of the financial risk associated with ownership of shares in the Company to another until at least 360 days after the day on which trading commences on Nasdaq Stockholm. However, the Joint Global Coordinators may grant exceptions from these restrictions.

#### **Stabilisation**

In connection with the Offering and the listing on Nasdag Stockholm, the Joint Global Coordinators may conduct transactions entailing that the share price maintains a higher level than what otherwise would have been the case. Stabilisation measures intended to support the share price may occur from the first day of trading in the shares on Nasdaq Stockholm and for a maximum period of 30 calendar days thereafter. Stabilisation transactions will not be conducted by the Joint Global Coordinators at a price higher than the Offering price. The stabilisation measures may entail that the market price of the shares reach a level that is not long term sustainable and that exceeds the price that would otherwise prevail in the market. The fact that the Joint Global Coordinators have the possibility of implementing stabilisation measures does not mean that such measures will necessarily be taken. Any such stabilisation measures that are undertaken may also be discontinued at any time. Once the stabilisation period (30 calendar days) has expired, the Joint Global Coordinators will announce through the Company whether stabilisation measures were undertaken and, in that case, the dates on which those stabilisation measures were implemented, including the final date for such measures and the price range within which the stabilisation transactions were conducted.

#### Interests of importance for the Offering

Carnegie and Handelsbanken are Camurus' and the Principal Shareholder's financial advisors in connection with the Offering and the listing on Nasdaq Stockholm. These advisors (and companies closely related to them) have provided, and may in the future provide, various banking, financial, investment and commercial and other services to Camurus and the Principal Shareholder for which they have received, and may in the future receive, compensation.

Employees and Board members of Camurus (except Per Sandberg) will at completion of the Offering receive a bonus from the Company paid in the form of shares in the Company. The share bonus comprises a total of 1,909,483 newly issued shares, which are received by the participants at a subscription price corresponding to the shares' guota value of SEK 0.025 per share, i.e. essentially free of charge, and are divided between employees and Board members in accordance with bonus agreements entered into. The implementation of the share bonus program is conditional upon the Offering being completed. The same applies to the Principal Shareholder's share acquisitions in connection with the share bonus program, comprising of a directed share issue to the Principal Shareholder and share purchases from participants in the share bonus program. Further, the Company's CEO Fredrik Tiberg and the Principal Shareholder have entered into an agreement under which Fredrik Tiberg transfers shares equivalent to an amount of SEK 7,142,857 to the Principal Shareholder, at a price corresponding to the final Offering price. The agreement is conditional upon the Offering being completed. The agreement is conditional upon the Offering being completed. For more information, see "Share information".

Board member Per Sandberg owns all shares in PGS Group AB, which in turn owns all the shares in the Principal Shareholder.

#### Subscription undertakings

Backahill Utveckling AB, Catella Fondförvaltning AB, Fjärde APfonden, Gladiator and Grenspecialisten Förvaltning AB have undertaken to acquire shares in the Offering corresponding to a total of SEK 240 million. Based on full subscription in the Offering, that the Overallotment Option is fully exercised and an Offering price corresponding to the mid value in the price range (i.e. SEK 56), the undertakings correspond to 4,285,714 shares, equal to 32.9 percent of the number of shares comprised by Offering and 11.4 percent of the total number of shares in the Company after the Offering.

The Cornerstone Investors will not receive any compensation for their respective undertakings. However, the Cornerstone Investors are guaranteed allotment in accordance with their respective undertakings. The Joint Global Coordinators, the Principal Shareholders and the Board of Directors of Camurus consider the Cornerstone Investors' have sound creditworthiness and that they will be able to meet their respective undertakings. However, the Cornerstone Investors' undertakings are not secured through bank guarantees, blocked funds or pledges of collateral or similar arrangement, why there is a risk that the Cornerstone Investors will not be able to fulfill their undertakings. Furthermore, the Cornerstone Investors' undertakings are associated with certain conditions. The undertaking of Fjäde AP-fonden is conditional upon the proceeds from the new share issue in the Offering amounting to not less than SEK 500 million. In the event that any of these conditions are not fulfilled, there is a risk that the Cornerstone Investors do not fulfill their undertakings.

Cornerstone Investors	Subscription undertaking (SEK million)	Number of shares <sup>1</sup>	Part of the Offering <sup>1</sup>
Backahill Utveckling AB <sup>2</sup>	50	892,857	6.86%
Catella Fondförvaltning AB <sup>3</sup>	50	892,857	6.86%
Fjärde AP-fonden⁴	40	714,286	5.49%
Gladiator⁵	50	892,857	6.86%
Grenspecialisten Förvaltning AB <sup>6</sup>	50	892,857	6.86%
Total	240	4,285,714	32.93%

<sup>1</sup> Based on full subscription in the Offering, that the Overallotment Option is fully exercised and an Offering price corresponding to the mid value in

the price range (i.e. SEK 56). Box 1159, SE-262 22 Ängelholm, Sweden. Box 7328, SE-103 90 Stockholm. Sweden.

<sup>4</sup> Box 3069, SE-103 61 Stockholm, Sweden.

c/o Max Mitteregger Kapitalförvaltning AB, Box 7472, SE-103 92 Stockholm, Sweden.

6 Box 4042, SE-203 11 Malmö, Sweden.

#### **Description of Cornerstone Investors** Backahill Utveckling AB

Backahill Utveckling AB, a business area of Backahill AB, invests in local and regional businesses which are expected to have great potential for development. Backahill AB is a family owned company founded in 1998 by Erik Paulsson, founder of Peab AB. Peab AB is a Nasdag Stockholm exchange listed company which is one of the leading Nordic construction and engineering companies with a market capitalization of approximately SEK 19 billion.

#### Catella Fondförvaltning AB

Catella Fonder, founded in 1997, is an active fund manager focusing on the Nordic markets. Catella manages equity funds, alternative funds, balanced funds and credit funds. Catella Fonder currently has approximately SEK 45 billion under management.

#### Fjärde AP-fonden

Fjärde AP-fonden (the Fourth Swedish National Pension Fund) is a Swedish government authority with the mission of contribution to the stability of the retirement pension system through the management of the fund capital. The fund is focused on creating long-term returns through active management and at the end of 2014 the fund had SEK 295 billion under management.

#### Gladiator

Gladiator is a hedge fund managed by Max Mitteregger Kapitalförvaltning AB. The fund pursues an investment strategy that defines it as a long/short equity fund. The management of the fund aims to provide the best possible return over time on the invested capital at a well-balanced level of risk, regardless of the overall performance of the market. As per 31 October 2015, Gladiator's assets under management was SEK 1.5 billion.

#### Grenspecialisten Förvaltning AB

Grenspecialisten Förvaltning AB is owned and managed by Martin Gren, co-founder of Axis Communications, together with Mikael Karlsson and Keith Bloodworth.

#### **Costs for the Offering**

The Company's costs related to the Offering and the listing on the Nasdaq Stockholm are estimated to amount to no more than SEK 55 million. In addition to the Company's part of the fixed and discretionary fee to the Joint Global Coordinators, the Company's costs primarily consist of expenses for auditors, legal advisers, printing of the prospectus and offering circular, costs of marketing materials for investors and similar.

The Principal Shareholder's costs in connection with the Offering are estimated to amount to no more than SEK 5 million, and primarily refer to fixed and discretionary fee to the Joint Global Coordinators.

#### Available documentation

Copies of the following documents are available at Camurus' headquarters at Sölvegatan 41 A i Lund, Sweden, during the validity of the offering circular (ordinary weekday office hours).

- Camurus' articles of association,
- Annual reports for the financial years 2013–2014 (including audit's reports) for Camurus and all of its subsidiaries, and
- Camurus' interim financial report for the Group for the period January – September 2015, which have been reviewed by the auditors and prepared in accordance with Annual Accounts Act and IAS 34 *Interim Financial Reporting*.

# Certain tax considerations in Sweden

The following is a summary of certain tax consequences that may arise from the Offering, applicable to individuals or limited liability companies tax resident in Sweden, unless otherwise stated. The summary does not purport to be a comprehensive description of all tax consequences that may be relevant in relation to the Offering. For instance, the summery does not address securities held by partnerships or held as current assets in business operations. Moreover, the summary does not address the specific rules on tax-exempt capital gains and dividends (including non-deductibility for capital losses) in the corporate sector that may be applicable when shares are considered to be held for business purposes (Sw. näringsbetingade andelar) by the shareholder. Neither are the specific rules covered that could be applicable to holdings in companies that are, or have previously been, closely held companies or shares acquired on the basis of such holdings. Moreover, the summary does not address shares or other equity-related securities that are held in a so-called investment savings account (Sw. investeringssparkonto) and that are subject to special rules on standardized taxation. Special tax rules apply to certain categories of taxpayers, for example, investment companies and insurance companies. The tax treatment of each individual shareholder depends on such investor's particular circumstances. Each holder of shares should therefore consult a tax advisor for information on the specific implications that may arise in their individual case, including the applicability and effect of foreign rules and tax treaties.

#### Shareholders who are tax resident in Sweden Individuals

#### Dividend taxation

For individuals, dividends on listed shares, which the shares will be once admitted to trading on Nasdaq Stockholm, are taxed as income from capital at a rate of 30 percent. A preliminary tax of 30 percent is generally withheld on dividends paid to individuals resident in Sweden. The preliminary tax is withheld by Euroclear Sweden or, regarding nominee-registered shares, by the Swedish nominee.

#### Capital gains taxation

Upon the sale or other disposal of listed shares, which the shares will be once admitted to trading on Nasdaq Stockholm, a taxable capital gain or deductible capital loss may arise. Capital gains are taxed as income from capital at a rate of 30 percent. The capital gain or loss is calculated as the difference between the sales proceeds, after deducting sales costs, and the tax basis. The tax basis for all shares of the same class and type is calculated together in accordance with the average cost method. Upon the sale of listed shares, the tax basis may alternatively be determined as 20 percent of the sales proceeds after deducting sales costs.

Capital losses on listed shares are fully deductible against taxable capital gains on shares and other listed equity-related securities realized during the same fiscal year, except for units in securities funds (Sw. värdepappersfonder) or special funds (Sw. specialfonder) that consist exclusively of Swedish receivables ("interest funds"). Up to 70 percent of capital losses on shares that cannot be offset in this way are deductible against other capital income. If there is a net loss in the capital income category, a tax reduction is allowed against municipal and national income tax, as well as against property tax and municipal property charges. A tax reduction of 30 percent is allowed on the portion of such net loss that does not exceed SEK 100,000 and of 21 percent on any remaining loss. Such net loss cannot be carried forward to future fiscal years.

#### Limited liability companies Dividend and capital gains taxation

For a limited liability company, all income, including taxable capital gains and dividends, is taxed as business income at a tax rate of 22 percent. Capital gains and capital losses are calculated in the same manner as described above with respect to individuals. Deductible capital losses on shares and other equity-related securities may only be deducted against taxable capital gains on such securities. Under certain circumstances such capital losses may also be deducted against capital gains in another company in the same group, provided that the companies can tax consolidate (Sw. koncernbidragsrätt). A capital loss that cannot be utilized during a given year may be carried forward and be offset against taxable capital gains on shares and other equity-related securities during subsequent fiscal years without any limitation in time.

#### Specific tax considerations for shareholders who are not tax resident in Sweden Dividend taxation

Dividends paid on shares in a Swedish limited liability company to shareholders not tax resident in Sweden are generally subject to 30 percent withholding tax. However, the tax rate is generally reduced for shareholders resident in other jurisdictions with which Sweden has entered a tax treaty. The majority of Sweden's tax treaties enable an at-source reduction of the Swedish withholding tax to the tax rate stipulated in the treaty at the time of payment of dividends, provided that necessary information is made available to Euroclear Sweden or the nominee in relation to the person entitled to such dividends. Under the US–Sweden tax treaty the tax rate is reduced to 5 percent for US resident companies owning shares representing at least 10 percent of the total voting rights in the Company, and to 15 percent in other cases. The tax rate for US resident companies and pension funds may be further reduced to 0 percent if certain requirements set out in the US - Sweden tax treaty are fulfilled. In Sweden, Euroclear Sweden, or in the case of nominee-registered shares, the nominee, generally carries out the deduction of withholding tax.

If a 30 percent withholding tax is withheld from a payment to a shareholder entitled to be taxed at a lower rate, or if too much withholding tax has otherwise been withheld, a refund can be claimed from the Swedish Tax Agency prior to the expiry of the fifth calendar year following the dividend distribution.

#### **Capital gains taxation**

Shareholders who are not tax resident in Sweden and not carries on business activities from a permanent establishment in Sweden are normally not liable for Swedish capital gains taxation on the disposal of shares. However, the shareholders may be subject to taxation in their country of residence. Under a specific tax rule, individual shareholders that are not tax resident in Sweden may, however, be subject to tax in Sweden on the sale of shares if they have been resident or stayed permanently in Sweden at any time during the calendar year of such disposal or during any of the previous ten calendar years. The applicability of this rule may, however, be limited by tax treaties between Sweden and other countries. However, the period is not reduced under the US–Sweden tax treaty.

# Certain US federal income tax considerations

The following is a summary of certain tax consequences that may arise from the Offering and is intended as general information only. The statements concerning US federal income tax laws set forth below, including concerning the Convention Between the Government of Sweden and the Government of the United States for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income (the "Treaty"), are based on the laws and regulations as at the date of this offering circular and are subject to any changes in Swedish or US law, or in the Treaty, occurring after that date, which changes may have retroactive effect.

The summary below does not purport to be a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire shares. This discussion applies only to a US Holder that holds shares as capital assets for tax purposes. In addition, it does not describe all of the tax consequences that may be relevant in light of the US Holder's particular circumstances, including alternative minimum tax consequences, the Medicare contribution tax, and tax consequences applicable to US Holders subject to special rules, such as:

- certain financial institutions;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding shares as part of a hedging transaction, straddle, wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to the shares;
- persons whose functional currency for US federal income tax purposes is not the US dollar;
- entities classified as partnerships for US federal income tax purposes;
- tax-exempt entities, "individual retirement accounts" or "Roth IRAs";
- persons that own or are deemed to own ten percent or more of the Company's voting stock; or
- persons holding shares in connection with a trade or business conducted outside of the United States.

If an entity that is classified as a partnership for US federal income tax purposes owns shares, the US federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships owning shares and partners in such partnerships should consult their tax advisers as to the particular US federal income tax consequences of owning and disposing of shares.

This discussion is based on the Internal Revenue Code of 1986, as amended (the "**Revenue Code**"), administrative pronouncements, judicial decisions, final, temporary and proposed Treasury regulations, and the Treaty, all as of the date hereof, any of which is subject to change, possibly with retroactive effect.

A "US Holder" is a shareholder who, for US federal income tax purposes, is a beneficial owner of shares and is:

- a citizen or individual resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia; or
- an estate or trust the income of which is subject to US federal income taxation regardless of its source.

US Holders should consult their tax advisers concerning the US federal, state, local and foreign tax consequences of owning and disposing of shares in their particular circumstances.

This discussion assumes that the Company is not, and will not become, a passive foreign investment company, as described below.

#### **Taxation of distributions**

Distributions paid on shares, other than certain pro rata distributions of ordinary shares, will be treated as dividends to the extent paid out of the Company's current or accumulated earnings and profits (as determined under US federal income tax principles). Because the Company does not maintain calculations of its earnings and profits under US federal income tax principles, it is expected that distributions generally will be reported to US Holders as dividends. Subject to applicable limitations, dividends paid to certain non-corporate US Holders may be taxable at favorable rates. The amount of a dividend will be treated as foreign-source dividend income, will not be eligible for the dividends-received deduction generally available to US corporations under the Revenue Code, and will include any amounts withheld by the Company in respect of Swedish taxes. Dividends will be included in a US Holder's income on the date of the US Holder's receipt of the dividend. The amount of any dividend income paid in Swedish Krona will be the USD amount calculated by reference to the spot rate of exchange in effect on the date of receipt, regardless of whether the payment is in fact converted into USD on that date. If the dividend is converted into USD on the date of receipt, a US Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A US Holder may have foreign currency gain or loss if the dividend is converted into USD after the date of receipt.

Subject to applicable limitations, Swedish income taxes withheld from dividends on shares at a rate not exceeding any applicable Treaty rate will be creditable against the US Holder's US federal income tax liability. Swedish taxes withheld in excess of the rate applicable under the Treaty will not be eligible for credit against a US Holder's federal income tax liability. The rules governing foreign tax credits are complex, and US Holders should consult their tax advisers regarding the creditability of foreign taxes in their particular circumstances.

#### Sale or other disposition of shares

For US federal income tax purposes, gain or loss realized on the sale or other disposition of shares will be capital gain or loss, and will be long-term capital gain or loss if the US Holder held the shares for more than one year. The amount of the gain or loss will equal the difference between the US Holder's tax basis in the shares disposed of and the amount realized on the disposition, in each case as determined in USD. This gain or loss will generally be US-source gain or loss for foreign tax credit purposes.

#### Passive foreign investment company rules

The Company does not expect to be a "passive foreign investment company" (a "**PFIC**") for US federal income tax purposes for its current taxable year or in the foreseeable future. However, because PFIC status depends on the composition of a company's income and assets and the market value of its assets from time to time, there can be no assurance that the Company will not be a PFIC for any taxable year, and neither the Company nor its legal counsel express an opinion on the Company's potential PFIC status.

If the Company were a PFIC for any taxable year during which a US Holder held shares, gain recognized by a US Holder on a sale or other disposition (including certain pledges) of the shares would be allocated ratably over the US Holder's holding period for the shares. The amounts allocated to the taxable year of the sale or other disposition and to any year before the Company became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for individuals or corporations, as appropriate, for that taxable year, and an interest charge would be imposed on the tax on such amount. Further, to the extent that any distribution received by a US Holder on its shares exceeds 125 percent of the average of the annual distributions on the shares received during the preceding three years or the US Holder's holding Tax considerations period, whichever is shorter, that distribution would be subject to taxation in the same manner as gain, described immediately above. Certain elections may be available that would result in alternative treatments (such as mark-to-market treatment) of the shares. US Holders should consult their tax advisers to determine whether any of these elections would be available and, if so, what the consequences of the alternative treatments the company were a PFIC.

### Information reporting and backup withholding

Payments of dividends and sales proceeds that are made within the United States or through certain US-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the US Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the US Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding. The amount of any backup withholding from a payment to a US Holder will be allowed as a credit against the holder's US federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the Internal Revenue Service.

# Selling and transfer restrictions etc.

The offer to acquire shares in Camurus to persons resident or citizens in countries other than Sweden may be affected by legislation in such jurisdictions and may be subject to restrictions. Investors should engage professional advisers to assess whether regulatory approvals or other authorisations are required, and whether other formal requirements must be complied with, in order for the investors to be able to acquire shares in Camurus. Measures in violation of the restrictions in this section may constitute a violation of applicable securities legislation.

#### General

Camurus, the Principal Shareholder and Joint Global Coordinators have not taken and will not take any actions to permit a public offering of shares in Camurus in any jurisdiction other than Sweden. The Offering is not made to persons resident in the United States, Australia, Hong Kong, Japan or Canada, or any other jurisdiction where participation would require additional prospectuses, registration or measures other than those required by Swedish law. In such jurisdictions, the receipt of this offering circular should not be deemed to be an offering.

In addition to what is explicitly stated in this offering circular, an investor who receives a copy of this offering circular in jurisdictions other than Sweden shall not (i) consider the offering circular as an offering to acquire shares, or (ii) trade in shares in Camurus comprised in the Offering, unless such offering may be lawfully made to the investor and that such shares may be lawfully traded in without the requirement for registration or that any other legal requirements in the concerned jurisdiction are met.

Consequently, the offering circular, application forms and any other documents in respect of the Offering may not be dispatched or otherwise distributed, and shares in Camurus may not be transferred, to any person in, or into, any jurisdiction in which such measure or the Offering would require additional prospectuses, registration or measures other than those required by Swedish law, or otherwise may entail a violation of local securities legislation or local regulations. If an investor forwards the offering circular to any such jurisdiction (regardless of whether it occurs under an agreement, requirements under statutory law or of any other reason), the investor must inform the recipient of the content of this section. Unless otherwise is explicitly stated in this offering circular, the following shall apply:

- Shares in Camurus may not be offered, sold or otherwise transferred, directly or indirectly, in or into the United States, Australia, Hong Kong, Japan, Canada or any other jurisdiction where an Offering of the shares is not permitted or where such action would require additional prospectuses, registration or measures other than those required by Swedish law ("Unauthorised Jurisdictions"), and
- The offering circular may not be distributed to any person in an Unauthorised Jurisdiction ("Unauthorised Persons").

As a condition to acquire shares under the Offering, each person applying to acquire shares in Camurus will be deemed

to have made or, in some cases, be required to make, inter alia, the following representations and warranties that will be relied upon by Camurus, the Principal Shareholder and the Joint Global Coordinators (unless they waive this requirement).

- that the investor does not reside in any Unauthorised Jurisdiction,
- that the investor is not an Unauthorised Person,
- that the investor does not act on behalf of, or for the benefit of, an Unauthorised Person,
- that the investor provided that such investor is not a QIB

   resides outside of the United Sates and that potential persons that he is acting on behalf of, or for the benefit of, (on a non-discretionary basis) reside outside the United States and that the investor and such potential persons will reside outside the United States when carrying out a transaction in the shares,
- that the investor understands that the shares neither have been nor will be registered under the Securities Act and that they may not be offered, pledged, sold, resold, delivered or otherwise transferred within the United States, nor on behalf of or for the benefit of persons residing in the United States, except under an available exemption from, or transaction not subject to, the registration requirements under the Securities Act, and
- that the investor is lawfully entitled to be offered, acquire and receive the shares in the jurisdiction where the person concerned is domiciled or currently resides.

If a person acts on behalf of an investor (e.g. as a fiduciary, legal guardian or trustee), such person shall make the abovementioned representations and warranties to Camurus, the Principal Shareholder and the Joint Global Coordinators in respect of the acquisition of shares on behalf of the holder. If such person does not make or cannot make the above-mentioned representations and warranties, Camurus, the Principal Shareholder and the Joint Global Coordinators are not obligated to execute any allotment of shares to such person or any person who is acting on behalf of such person.

Taking account of the specific restrictions that are presented below, investors, (including their fiduciary, legal guardian and trustee) who are resident outside of Sweden and wish to acquire shares in Camurus, are responsible for compliance with applicable legislation in the relevant jurisdiction, including obtaining any required regulatory approvals or other authorisations, observing any other potential formalities as well as paying any taxes required in such jurisdictions.

The information in this section is only intended to serve as general guidance. If any doubts exist on whether an investor is entitled to acquire shares, the investor should immediately engage professional advisers.

With some exceptions, applications to acquire shares from any Unauthorised Jurisdiction will be considered invalid and shares will not be delivered to recipients in Unauthorised Jurisdictions. Camurus, the Principal Shareholder and the Joint Global Coordinators reserve the right to disregard or declare null and void any applications to acquire shares that are made by order of persons who (i) have stated an address in an Unauthorised Jurisdiction, (ii) are unable to undertake or guarantee that they are not residing in an Unauthorised Jurisdiction and/or are not an Unauthorised Person, or (iii) Camurus, the Principal Shareholder or the Joint Global Coordinators understand has signed his application to acquire shares in, or sent it from, an Unauthorised Jurisdiction. Furthermore, Camurus, the Principal Shareholder and the Joint Global Coordinators reserve the right to declare null and void an application to acquire shares that seems to be executed or otherwise carried out in a way that may entail a violation or breach of laws or regulations of any jurisdiction.

Regardless of what is otherwise stated in this offering circular, Camurus, the Principal Shareholder and the Joint Global Coordinators reserve the right to allow an investor to acquire shares if they consider the transaction in question to be exempt from, or not subject to, the laws and regulations that give rise to the relevant restrictions. The applicable exemptions are described below. In these cases, Camurus, the Principal Shareholder and the Joint Global Coordinators do not undertake any liability for any actions made by the investors nor for any consequences that the investor may suffer that may be caused by Camurus, the Principal Shareholder and the Joint Global Coordinators allowing the investor's acquisition of shares.

Neither Camurus, the Principal Shareholder nor any of the Joint Global Coordinators guarantees that an investment in shares in Camurus is permitted under applicable legislation. Every investor should engage own advisers and complete an independent assessment of the legal, tax, commercial, financial and other implications that follow an acquisition of shares in Camurus.

Certain risks apply to an investment in shares. See the section entitled "Risk factors" for a report on certain risks that should be observed by potential investors prior to an investment in Camurus.

#### **United States**

The shares in Camurus have not been, and will not be, registered under the Securities Act or the securities legislation of any state or other jurisdiction in the United States and may not be offered, pledged, sold, resold, allotted, delivered or otherwise transferred, directly or indirectly, within the United States except in certain transactions exempt from, or not subject to, the registration requirements under the Securities Act and in compliance with the securities legislation in the relevant state or any other jurisdiction of the United States. The shares are being offered outside the United States in reliance of Regulation S under the Securities Act. A public offering will not be made in the United States. Any offering of the shares in the United States will be made only to a limited number of investors who are deemed to be QIBs in reliance on Rule 144A or pursuant to another available exemption from, or transaction not subject to, the registration requirements under the Securities Act.

The shares in Camurus have neither been approved nor recommended by the SEC, any state securities authority or any other authority in the United States. Furthermore, the foregoing authorities have not confirmed the accuracy or determined the adequacy of this offering circular. To assert the contrary is a criminal offense in the United States.

Each investor in the United States who receives this offering circular or is offered shares in Camurus in the United States in reliance on Rule 144A or pursuant to another available exemption from, or transaction not subject to, the registration requirements under the Securities Act, is considered to have represented and agreed that it has received a copy of this offering circular and such other information as it deems necessary to make an informed investment decision and that:

- such investor understands that the shares have not been and will not be registered under the Securities Act or any securities legislation in any state or other jurisdiction in the United States and are subject to significant transfer restrictions,
- such investor is a QIB and the person, if any, for whose account or benefit the investor is acquiring the shares, is aware that a sale of shares to the investor is being made in reliance on Rule 144A or pursuant to another available exemption from, or transaction not subject to, the registration requirements under the Securities Act and that the shares are acquired for such investor's own account or for the account of a QIB, and
- the investor is aware that the shares are being offered in the United States in a transaction not involving any public offering within the meaning of the Securities Act,
- if, in the future, the investor decides to offer, resell, pledge or otherwise transfer such Shares, such Shares may be offered, sold, pledged or otherwise transferred only (i) to a person whom the beneficial owner and/or any person acting on its behalf reasonably believes is a QIB in a transaction meeting the requirements of Rule 144A, (ii) in an offshore transaction in accordance with Regulation S, or (iii) pursuant to another exemption from, or in a transaction not subject to, the registration requirements under the Securities Act, in each case in accordance with any applicable securities laws of any state of the United States or any other jurisdiction,

- the shares are "restricted securities" within the meaning of Rule 144(a)(3) and no representation is made as to the availability of the exemption provided by Rule 144 for resale of any shares,
- the investor will not deposit or cause to be deposited such shares into any depositary receipt facility established or maintained by a depositary bank other than a Rule 144A restricted depositary receipt facility, so long as the shares are "restricted securities" within the meaning of Rule 144(a)(3), and
- Camurus shall not recognise any offer, sale, pledge or other transfer of shares made other than in compliance with the above-stated restrictions.

Each investor who purchases the shares in compliance with Regulation S will be deemed to have represented and agreed that it has received a copy of this offering circular and such other information as it deems necessary to make an informed investment decision and that:

- such investor acknowledges that the shares have not been and will not be registered under the Securities Act, or with any securities regulatory authority of any state of the United States, and are subject to significant transfer restrictions and may not be offered or sold within or into the United States States other than pursuant to available exemption from, or in a transaction not subject to, the registration requirements under the Securities Act, in each case in accordance with any applicable securities laws of any state of the United States,
- such investor and the person, if any, on whose account or benefit the investor is acquiring the shares, was located outside the United States at the time the buy order for the shares originated,
- such investor acknowledges that the shares have not been offered to such investors by means of any "directed selling efforts" as defined in Regulation S,
- such investor is aware of the restrictions on the offer and sale of the shares pursuant to Regulation S described in this document, and

Any offer or sale of shares in Camurus in the United States will be made by broker-dealers registered as such under the U.S. Securities Exchange Act of 1934, as amended. Camurus shall not recognise any offer, sale, pledge or other transfer of shares made other than in compliance with the above-stated restrictions.

NOTICE TO NEW HAMPSHIRE RESIDENTS ONLY NEITHER THE FACT THAT A REGISTRATION STATE-MENT OR AN APPLICATION FOR A LICENSE HAS BEEN FILED UNDER CHAPTER 421-B OF THE NEW HAMPSHIRE REVISED STATUTES ("RSA 421-B") WITH THE STATE OF NEW HAMPSHIRE NOR THE FACT THAT A SECURITY IS EFFECTIVELY REGISTERED OR A PERSON IS LICENSED IN THE STATE OF NEW HAMPSHIRE CONSTITUTES A FIND-ING BY THE SECRETARY OF STATE OF NEW HAMPSHIRE THAT ANY DOCUMENT FILED UNDER RSA 421-B IS TRUE, COMPLETE AND NOT MISLEADING. NEITHER ANY SUCH FACT NOR THE FACT THAT AN EXEMPTION OR EXCEP-TION IS AVAILABLE FOR A SECURITY OR A TRANSACTION MEANS THAT THE SECRETARY OF STATE HAS PASSED IN ANY WAY UPON THE MERITS OR QUALIFICATIONS OF, OR RECOMMENDED OR GIVEN APPROVAL TO, ANY PER-SON, SECURITY OR TRANSACTION. IT IS UNLAWFUL TO MAKE, OR CAUSE TO BE MADE, TO ANY PROSPECTIVE PURCHASER, CUSTOMER OR CLIENT, ANY REPRESENTA-TION INCONSISTENT WITH THE PROVISIONS OF THIS PARAGRAPH.

#### Agreement on confidentiality

Recipients of this document outside of Sweden are hereby informed that this document is provided on a confidential basis and may not, under any circumstances, be reproduced, forwarded or otherwise further distributed, neither in whole nor in part. Furthermore, the recipient is only permitted to use this document for the purpose of considering an acquisition of shares in Camurus and may not disclose the content of this document or use any information herein for any other purpose. This document is personal for every recipient and does not constitute an offering to acquire shares to any person or to the public in any jurisdiction outside Sweden. Recipients of this document will be deemed to have agreed to the above by receiving this document.

#### **Enforcement of service of process**

Camurus is a Swedish limited liability company organised under the laws of Sweden. The majority of the Company's Board members and management are resident outside the United States. All or a substantial portion of Camurus' assets and the assets of such persons' are located outside the United States. As a result, it may not be possible for investors to effect service of a lawsuit against Camurus or such persons, or by a U.S. court enforce a U.S. judgement against Camurus or the management of Camurus. U.S. judgments or enforcement decisions, relating to the civil liability provisions of the federal or state securities legislation of the United States are not directly enforceable in Sweden. The United States and Sweden do not have a treaty providing for reciprocal recognition and enforcement of judgments in civil and commercial matters, other than for arbitration awards. Accordingly, a final judgment for the payment of money rendered by a U.S. court based on civil liability will not be directly enforceable in Sweden. However, if the party in whose favour such final judgment is rendered brings a new lawsuit in a competent court in Sweden, that party may submit the final judgment that has been rendered in the United States to a Swedish court. Even though a judgment by a federal or state court in the United States against the Company or the Group will neither be recognized nor enforced by a Swedish court, such judgment may serve as evidence in a similar action in a Swedish court.

## EEA

No public offering of shares in Camurus is made to any other countries within the European Economic Area (the "EEA") other than Sweden. In other member states of the EEA, which have implemented the Prospectus Directive, such offer may be made only to "qualified investors" in accordance with the definition under article 2.1 e) of the Prospectus Directive or under any other circumstances that do not require Camurus, the Principal Shareholder or the Joint Global Coordinators to announce a prospectus in the relevant member state under article 3 of the Prospectus Directive. Each recipient of this offering circular will be deemed to have committed and guaranteed that they neither have nor will make a public offering in any member state of the EEA.

The expression "an offering to the public" refers to the definition as set forth in article 2.1 d) of the Prospectus Direc-

tive. The expression "Prospectus Directive" refers to Directive 2003/71/ EC of the European Parliament and of the Council and includes any relevant implementing measure in each relevant member state (including implementing measures of Directive 2010/73/ EU of the European Parliament and of the Council amending the Prospectus Directive etc.).

## **United Kingdom**

In the United Kingdom, this document and any other materials in relation to the securities described herein is only being distributed to, and is only directed at, and any investment or investment activity to which this document relates is available only to, and will be engaged in only with, "qualified investors" (as defined in section 86(7) of the Financial Services and Markets Act 2000) and who are (i) persons having professional experience in matters relating to investments who fall within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"); or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). Persons who are not relevant persons should not take any action on the basis of this document and should not act or rely on it.

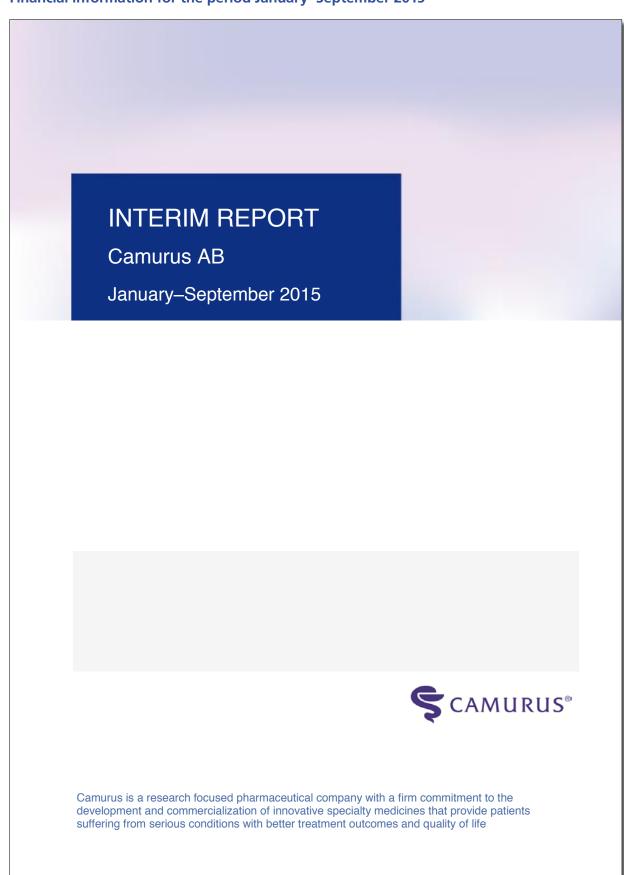
## **Other jurisdiction**

The shares in Camurus have not been registered and will not be registered in Australia, Hong Kong, Japan, Canada or any jurisdiction outside of Sweden and may therefore not be offered or sold in or to any such jurisdiction other than in certain exempt cases where a prospectus would not be required under applicable laws and regulations in such jurisdiction and otherwise would comply with the applicable securities legislation in such jurisdiction.

# Historical financial information

Except for Camurus' audited financial statements for the 2012–2014 financial years and the review of the interim financial report for the period January to September 2015 on p. 107–129 of this offering circular, no information in this offering circular has been reviewed or audited by the Company's auditors.

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## Financial information for the period January–September 2015

## Interim report January–September 2015

Camurus and Braeburn Pharmaceuticals ready to start Phase III trials for CAM2038 for treatment of opioid dependence.

#### Third quarter 2015

- Net sales SEK 37.2 million (34.0).
- Operating profit/loss before items affecting comparability SEK -7.1 million (-1.9).
- Profit/loss after tax SEK -22.7 million (-1.6), including a charge of SEK 17.2 million (0) for a share-related bonus program.
- Earnings per share before and after dilution SEK -3.61 (-0.27).
- Cash flow from operating activities SEK -24.0 million (-24.4).
- Cash and cash equivalents SEK 112.3 million (0.0).
- A development-related milestone payment of USD 2.5 million has been reached in the collaboration with Novartis regarding CAM2029 for treatment of acromegaly and neuroendocrine tumors.
- CAM2038 has been granted Fast Track designation by the US Food and Drug Administration (FDA) for treatment of opioid dependence.
- The FDA has approved the start of two clinical trials, a Phase III and a Phase II trial, forming the basis of the registration of CAM2038 for treatment of opioid dependence.
- Clinical trial applications for a Phase III trial of CAM2038 for treatment of opioid dependence have been submitted to national agencies in the EU and Australia.
- The Board of Camurus has been strengthened with two new members: Kerstin Valinder Strinnholm and Marianne Dicander Alexandersson.
- Preparation for a possible public listing of Camurus on the Nasdaq Stockholm exchange progresses. Costs relating to this have been charged to operating earnings in the amount of SEK 5.1 million.

#### January-September 2015

- Net sales SEK 118.5 million (63.3).
- Operating earnings before items affecting comparability SEK -25.6 million (-34.3), charged with SEK 10.9 million relating to preparation for a possible public listing of Camurus.
- Profit/loss after tax SEK -127.7 million (-26.5), including a charge of SEK 107.7 million (0) for a share based bonus program.
- Earnings per share before and after dilution, SEK -20.26 (-4.55).
- Cash flow from operating activities SEK -45.2 million (-77.2).
- A license and distribution agreement has been entered into with Solasia Pharma regarding the registration and commercialization of episil<sup>®</sup> in Japan and China.
- Two development-related milestone payments amounting to a total of USD 5.0 million have been reached in the collaboration with Novartis regarding CAM2029 for treatment of acromegaly and neuroendocrine tumors.
- Positive results have been reported from two clinical trials comparing CAM2038 (subcutaneous weekly and monthly depots of buprenorphine) against active control (Subutex<sup>®</sup>).
- An End-of-Phase II meeting has been held with the FDA regarding CAM2038 for treatment of opioid dependence.
- GMP manufacturing of CAM2038 (subcutaneous weekly and monthly depots of buprenorphine for treatment of
  opioid dependence) and placebos has been conducted prior to the start of Phase III trials.
- All patients have been enrolled in a Phase II trial of CAM2032 for treatment of prostate cancer.
- Two new research collaborations have been initiated with international pharmaceutical companies, in which Camurus' FluidCrystal<sup>®</sup> injection depots are being evaluated for long-term release of patent protected active ingredients.

2015 July–Sep	2014 July–Sep	2015 Jan–Sep	2014 Jan–Sep	2014 Jan-Dec
37.2	34.0	118.5	63.3	208.2
-7.1	-1.9	-25.6	-34.3	62.3
-29.1	-1.9	-163.7	-34.3	62.3
-22.7	-1.6	-127.7	-26.5	48.3
-24.0	-24.4	-45.2	-77.2	69.4
112.3	0.0	112.3	0.0	0.1
49%	37%	49%	37%	59%
210.2	64.2	210.2	64.2	207.7
	July–Sep 37.2 -7.1 -29.1 -22.7 -24.0 112.3 49%	July-Sep         July-Sep           37.2         34.0           -7.1         -1.9           -29.1         -1.9           -22.7         -1.6           -24.0         -24.4           112.3         0.0           49%         37%	July-Sep         July-Sep         Jan-Sep           37.2         34.0         118.5           -7.1         -1.9         -25.6           -29.1         -1.9         -163.7           -22.7         -1.6         -127.7           -24.0         -24.4         -45.2           112.3         0.0         112.3           49%         37%         49%	July-Sep         July-Sep         Jan-Sep         Jan-Sep           37.2         34.0         118.5         63.3           -7.1         -1.9         -25.6         -34.3           -29.1         -1.9         -163.7         -34.3           -22.7         -1.6         -127.7         -26.5           -24.0         -24.4         -45.2         -77.2           112.3         0.0         112.3         0.0           49%         37%         49%         37%

#### CEO statement on the third quarter

Following a period of intensive planning, preparations and dialogue with the US and European regulatory authorities, we and our partner Braeburn Pharmaceuticals are now ready to start clinical Phase III trials which will form the basis for the registration of CAM2038 (weekly and monthly products). CAM2038 has the potential to transform the treatment of opioid dependence by increasing patient compliance and relieving the burden of having to administer medication daily, while on the same time virtually eliminating the risks of diversion, abuse, misuse, and accidental pediatric exposure associated with current daily medications. Granting fast track to the CAM2038 development program demonstrates the FDA's recognition of the unmet need in this area, and may also contribute to a shorter development time to market approval.

Recruitment of patients to the Phase II and Phase III trials of CAM2038 for treatment of opioid dependence will begin in the US in the fourth quarter. Meanwhile, an additional Phase III trial of CAM2038 for treatment of opioid dependence is being started in Europe and Australia. We are also working with our partner Braeburn Pharmaceuticals on the preparations of clinical trials of CAM2038 for treatment of chronic pain.

Production preparations are under way with Novartis prior to the forthcoming start of Phase III trials of CAM2029 for treatment of acromegaly and neuroendocrine tumors (NET). Alongside this, a Phase II pilot study in two patient groups; acromegaly and NET, is being concluded. In addition, Camurus and Novartis are conducting a dose escalation Phase I trial of another drug candidate, CAM4071, a long-acting peptide (undisclosed ingredient) based on Camurus' FluidCrystal<sup>®</sup> injection depot. A Phase II trial of CAM2032 for treatment of prostate cancer will also be finalized over the next few months. Topline results from this trial will be available at the beginning of 2016.

In addition to the activities and progress in the clinical project portfolio, preclinical evaluations of a number of new drug candidates are being completed. These include both in-house development projects and several project collaborations with international biotech and pharmaceutical companies. Camurus aims at taking one of the product candidates into clinical development during 2016.

In anticipation of a future marketing approval of CAM2038 (weekly and monthly products) in Europe, we have also recently initiated a process to develop and strengthen our commercial organization for launching CAM2038 on selected European markets. The product is deemed to have significant market potential for treatment of opioid dependence and has a concentrated and familiar target group of prescribing physicians.

In the third quarter, our net sales amounted to SEK 37.2 million (34.0), with an operating profit/loss before items affecting comparability of SEK -7.1 million (-1.9), of which SEK 5.1 million relates to costs incurred for preparations for a possible public listing of the Company. Profit/loss after tax totaled SEK -22.7 million (-1.6), of which SEK 17.2 million represents the cost of a share based bonus program, issued to the employees and Board members of Camurus

In order to realize our strategy and goals of growing and advancing the clinical portfolio and, in parallel, establishing an effective commercial organization for the marketing and sales of CAM2038 in Europe, and other complimentary products, we are now preparing the company for a public listing on the Nasdaq OMX Stockholm exchange.

We look forward to a successful fourth quarter, with considerable opportunities, including the start of our two Phase III trials for CAM2038 to treat opioid dependence together with our US partner Braeburn Pharmaceuticals.



Fredrik Tiberg Chief Executive Officer Camurus AB

## **Activities**

### Product and development portfolio

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. The company's research portfolio contains product candidates for treatment of cancer and the side effects of cancer treatment, endocrine diseases, pain and addiction; see figure below.

By combining its proprietary drug delivery technologies (such as the FluidCrystal® Injection depot) with active

ingredients that have proven efficacy and safety profiles, the Company develops new and patented medicines with improved properties and treatment outcomes. These are developed with significantly lower cost and risk, compared with the development of completely new medicines. Camurus has also developed and launched a medical device with the name episil® on markets in the EU, US and Middle East, where sales are conducted both through Camurus and its partners.

To follow is a summary and status update for Camurus' development projects.



## neuroendocrine tumors (NET)

CAM2029 is a subcutaneous depot of octreotide, which is being developed for treatment of patients with acromegaly or neuroendocrine tumors (NET). CAM2029 is being developed by Novartis, as a new treatment alternative to the current market-leading product Sandostatin<sup>®</sup> LAR<sup>®</sup>, which achieved global sales of USD 1.65 billion in 2014<sup>1</sup>. CAM2029 is provided ready-for-use in prefilled syringe and is administered as a simple subcutaneous injection, whereas Sandostatin<sup>®</sup> LAR<sup>®</sup> has to be prepared from powder in a process consisting of six stages, and then administered by a healthcare professional via an intramuscular injection.

In clinical trials, CAM2029 has demonstrated around 500 percent higher bioavailability of octreotide compared with Sandostatin<sup>®</sup> LAR<sup>®</sup>, which may potentially result in an

<sup>1</sup> Source: Medtrack

improved treatment effect for patients who do not respond satisfactorily to current treatment alternatives.

#### Status Q3

Preparations prior to planned Phase III trials are continuing, while a Phase II pilot study on patients with acromegaly and NET is nearing conclusion.

#### CAM2038 – opioid dependence

CAM2038 includes subcutaneous weekly and monthly depots of buprenorphine, which is being developed by Camurus and its partner Braeburn Pharmaceuticals for treatment of opioid dependence in the form of, for example, painkillers or heroin.

The products are being developed to address a number of shortcomings in currently available medicines, including inadequate patient compliance with frequent relapses, and an extensive diversion, misuse and abuse of current daily buprenorphine medications. To date, CAM2038 has been examined in three clinical studies involving a total 188 individuals, 176 of whom have received doses of CAM2038. In all the studies, the products have displayed a good safety profile, including local tolerance, as well as desirable pharmacokinetic and pharmaco dynamic profiles suitable for weekly and monthly dosing, respectively.

#### Status Q3

CAM2038 has been granted Fast Track designation by the FDA. Fast Track status is assigned to drug candidates that are deemed by the FDA to be capable of satisfying a significant medical need in the treatment of serious or lifethreatening conditions. The FDA has also approved the start of two clinical trials of CAM2038 that will form the basis for the new drug application (NDA); a Phase III efficacy trial and a supporting Phase II trial, which will examine the opioid blocking efficacy of CAM2038. Clinical trial applications for an additional Phase III trial have been submitted to national agencies in Europe and Australia.

#### CAM2038 – chronic pain

In addition to treatment of opioid dependence, CAM2038, weekly and monthly depots, is also being developed for treatment of chronic pain. CAM2038 offers rapid onset, dose-proportional, prolonged exposure to buprenorphine, while avoiding 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 well to the guidelines and recommendations for treatments of chronic pain, i.e. a combination of stable efficacious plasma levels with a reduced risk of misuse, abuse and illicit diversion.

<sup>2</sup> Source: Medtrack

#### Status Q3

Camurus and Braeburn Pharmaceuticals are currently preparing start registration supportive trials of CAM2038 for treatment of chronic pain.

#### 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, which belongs to the class of gonadotropin releasing hormones, with global sales of around USD 4 billion in 2014<sup>2</sup>. CAM2032 is, as the first product in its class, being developed for easy subcutaneous injection, also by patients themselves, in the form of a small volume injections with a duration of one month.

#### Status Q3

CAM2032 is being evaluated in patients with advanced prostate cancer in a repeat dose Phase II trial, which also includes the marketed product Eligard<sup>®</sup> as active control. All patients have been included in the trial and treatment of patients where the last patient will be completing the trial in November 2015. The topline study results from this study are expected to be available in the beginning of 2016.

#### Pre-clinical drug candidates

Camurus has several projects in the pre-clinical phase, during which physical, chemical and pharmacological properties are optimized, while toxicological and preclinical safety studies are carried out in parallel with initial market evaluations. Combining proven active ingredients with Camurus' unique formulation platform FluidCrystal<sup>®</sup> enables the development of new patent protected drugs with improved properties and treatment outcomes for market launch in a shorter period of time, and with a reduced risk compared with traditional drug development.

#### Status Q3

Four drug candidates targeted at different indications, including inflammation and pain, are currently being evaluated in various pre-clinical studies and market analyses. Camurus aims to take one of these candidates into clinical development during 2016.

#### Pre-clinical project collaborations

Camurus is also pursuing collaborative work with various pharmaceutical companies regarding the development of new product candidates based on Camurus' formulation technology and the partner company's patented active

ingredient. These collaborations often involve formulation various pharmacological properties with respect to predetermined technical and market-related product objectives. The project period for these formulation and evaluation projects, or feasibility studies, is usually around 6–12 months. Following evaluation, product development may continue under a license agreement, with opportunities for future development- and sales-related milestone and royalty payments.

#### Status Q3

A number of collaboration projects, based on Camurus' FluidCrystal® formulation technologies are also under early development with different pharmaceutical companies, targeting cancer, obesity, diabetes and viral infection indications.

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

episil<sup>®</sup> is a medical device that is used to treat 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 long-acting 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 local pain relief for up to 8 hours.

#### Status Q3

Camurus' partner Solasia Pharma has initiated work on registering episil<sup>®</sup> in China and Japan. Camurus has also begun marketing episil<sup>®</sup> in Germany, where a new 3 ml product was recently been launched.

## Financial information

## Sales and earnings

#### Revenue

The total revenues in the third quarter amounted to SEK 37.2 million (34.0), an increase of SEK 3.2 million compared with the year-earlier period. The increase is largely attributable to a development-related milestone payment of USD 2.5 million from Novartis, as well as payments for execution of R&D activities relating to clinical trials.

## Expenses and earnings

## Marketing, business development and sales costs

Marketing, business development and sales costs in the third quarter amounted to SEK 5.3 million (2.8). The increase is to SEK 1.5 million due to a retroactive reallocation of costs, mainly between administrative expenses and marketing, business development and sales costs. The remaining increase is attributable to costs incurred for contracted sales representatives for episil® on Camurus' own markets.

#### Administrative expenses

Administrative expenses in the third quarter totaled SEK 0.9 million (5.9). The decrease is mainly explained by a retroactive reallocation of expenses between administrative expenses, marketing and sales costs and research and development costs. Without this reallocation, expenses for the period would have amounted to SEK 11.3 million and the increase relates to higher personnel costs and the ongoing process of preparing the company for a public listing.

#### Research and development costs

Research and development costs in the third quarter 2015 amounted to SEK 38.3 million (25.7) and include depreciation/amortization of tangible and intangible assets. The increase is primarily attributable to a retroactive reallocation between administrative expenses and research and development costs. Prior to the reallocation, costs for the period totaled SEK 29.4 million and the increase is primarily explained by high activity and increased costs for clinical trials.

#### Other operating income and expenses

Other operating income and expenses mainly consists of exchange gains attributable to operational activities. In the third quarter 2015, exchange gains amounted to SEK 0.3 million (-1.6) and have occurred as a result of the fluctuations in the Swedish krona against the euro and the US dollar.

#### Items affecting comparability

Since January 2013, Camurus has had a long-term sharebased incentive program, whereby employees and Board members of Camurus, in the event of a public listing of the company's share, receive shares in the company on the listing date.

At each balance sheet date, Camurus assesses the likelihood of the service and performance conditions being fulfilled in the share bonus program. On 30 June, 2015, Camurus deemed for the first time that an exit event through a public listing was likely. Since the bonus program was allocated to the employees and Board members in a previous accounting period, and is therefore already earned to a certain extent, the result after tax was charged with a cost of SEK 90.5 million on 30 June, 2015. In the third quarter, the result after tax was charged with an additional SEK 17.2 million.

In order to compensate for the social security costs arising net after tax, the company and the principal shareholder Sandberg Development have entered into an agreement (conditional upon a public listing), in which the principal shareholder undertakes to subscribe to newly issued shares in Camurus at total issue proceeds corresponding to 78% of these costs, calculated based on the median of the price range in the offering in connection with the public listing. It is not yet possible to establish the exact number of shares that will be issued.

Since the total cost of the share bonus program is of an unusual nature, non-recurring, and significant in terms of the amount, the item will be recognized as an item affecting comparability in this and future financial reports.

#### Depreciation/amortization

Depreciation and amortization for the third quarter of 2015 amounted to SEK 0.9 million (0.3). The difference compared to the previous year relates to that depreciation/amortization of internally generated intangible assets was initiated in the first quarter of 2015.

#### Net financial items

Net financial items for the period July–September 2015 amounted to SEK 0.0 million (0.1).

#### Profit/loss after tax for the period

The result after tax for the period totaled SEK -22.7 million (-1.6), which corresponds to earnings per share of SEK - 3.61  $\,$ 

(-0.27) before dilution and SEK -3.61 (-0.27) after dilution. Tax for the quarter totaled SEK 6.4 million (0.4) and the difference is mainly attributable to deferred tax for the SEK 22.1 million that was recognized as an expense for the long-term incentive program.

#### **Financial position**

Cash and cash equivalents at 30 September, 2015, totaled SEK 112.3 million (0.0). No loans had been raised as at 30 September, 2015, and none have been raised since.

Cash flow from operating activities in the third quarter was SEK -24.0 million

(-24.4), primarily due to an increase in the working capital requirement.

Cash flow from investing activities amounted to SEK 0.0 million (12.8) in the third quarter, which is a decline of SEK 12.8 million attributable to the company being released from the principal shareholder's intercompany account for cash handling. Cash flow for the period from investing activities relates to acquisitions of tangible assets totaling SEK 0.4 million and payment of a long-term receivable of SEK 0.4 million from the principal shareholder.

Group equity at 30 September, 2015, totaled SEK 103.1 million (23.5). The difference compared to the year-earlier period is mainly related to a greater portion of earnings for 2014 being generated in the fourth quarter, along with that warrants were exercised in the month of December.

#### The Camurus share

At the end of the quarter, the total number of shares in the company amounted to 6,302,140 (5,835,310).

#### Acquisitions

No acquisitions or divestments were made during the third quarter.

## Other disclosures

### Personnel

At the end of the period, Camurus had 48 (39) employees, of whom 35 (28) were within research and development. The average number of employees during the quarter was 49 (37).

#### 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 effect-related 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.

#### Events after the reporting period

Except for the Company's decision to amend its articles of association entailing that the Company has become a public company and the inclusion of a CSD provision, and from the company has decided on a 4:1 share split, no significant changes have occurred to Camurus' financial position or its market position since 30 September, 2015

#### **Parent company**

#### Net sales and earnings development

Net sales for the third quarter 2015 totaled SEK 37.2 million (33.9) and operating result before items affecting comparability amounted to SEK -28.6 million (-2.1), while result after tax was SEK -22.3 million (-1.7).

Parent company equity at 30 September, 2015, totaled SEK 72.9 million (6.5). The difference compared to the year-earlier period is mainly attributable to a greater portion of earnings for 2014 being generated in the fourth quarter, along with that warrants were exercised in the month of December

Total assets at the end of the period amounted to SEK 197.5 million (46.4), and cash and cash equivalents totaled SEK 112.3 million (0.0).

#### Upcoming reporting dates

The year-end report and interim report for the fourth quarter 2015 will be published on 17 February 2016.

The annual report for 2015 will be published during the third week of March 2016.

#### **Further information**

For further information, please contact: Fredrik Tiberg, Chief Executive Officer Tel: +46 46 286 46 92, e-mail: <u>ir@camurus.com.</u>

Lund, 22 October, 2015

Camurus AB

**Board of Directors** 

## Consolidated statement of comprehensive income

SEK thousand Note Net sales 3 Cost of goods sold	2015 July–Sep 37,232	2014 July–Sep 33,992	2015 Jan-Sep	2014 Jan–Sep	2014 Jan-Deo
Net sales 3	July–Sep			Jan–Sep	Jan-Deo
	37,232	33 992			
	37,232	33 992			
Cost of goods sold		00,00L	118,459	63,330	208,20
	-131	88	-132	-523	-65
Gross profit	37,101	34,080	118,327	62,807	207,55
Marketing and distribution costs	-5,255	-2,847	-12,425	-6,555	-11,402
Administrative expenses	-925	-5,891	-18,712	-15,996	-22,16
Research and development costs	-38,263	-25,722	-111,940	-73,062	-114,14
Other operating income	267	10	41	86	2,48
Other operating expenses	-	-1,567	-904	-1,567	
Operating profit/loss before items affecting 7 comparability	-7,074	-1,937	-25,613	-34,287	62,31
Items affecting comparability 7	-22,075		-138,075	-	
Operating profit/loss 6	-29,149	-1,937	-163,688	-34,287	62,31
Finance income	1	4	1	393	39
Finance expenses	-4	-59	-21	-108	-17
Net financial items	-3	-55	-20	285	22
Profit/loss before tax	-29,152	-1,992	-163,708	-34,002	62,54
Income tax 9	6,414	438	36,016	7,480	-14,19

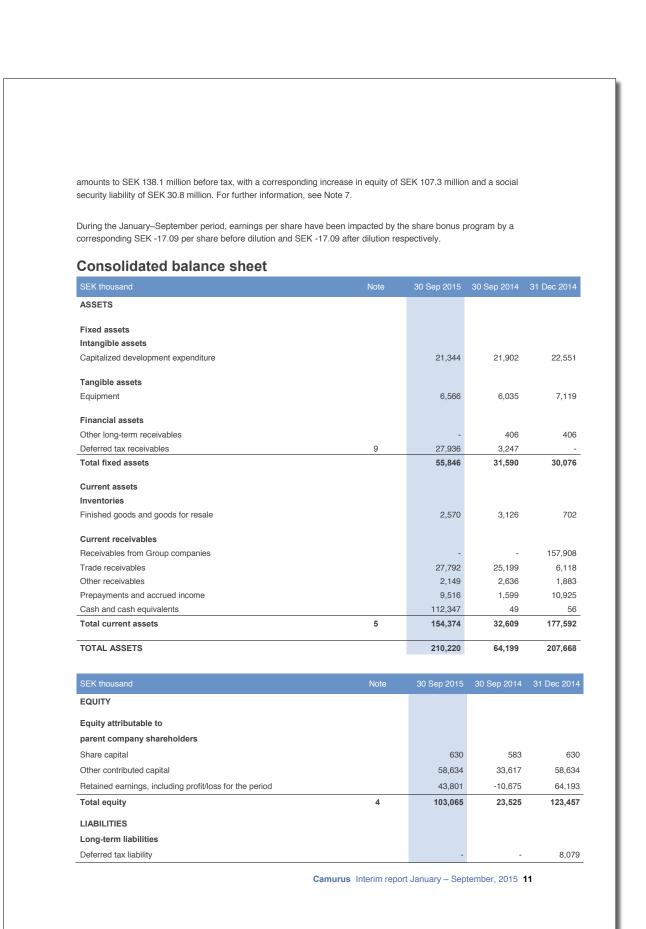
Total comprehensive income is the same as profit/loss for the period, as the consolidated group contains no items that are recognized under other comprehensive income.

Total comprehensive income is attributable to parent company shareholders.

## Earnings per share based on earnings attributable to parent company shareholders for the period (in SEK per share)

Key figures	2015 July – Sep	2014 July–Sep	2015 Jan–Sep	2014 Jan–Sep	2014 Jan–Dec
Earnings per share before dilution, SEK	-3.61	-0.27	-20.26	-4.55	8.24
Earnings per share after dilution, SEK	-3.61	-0.27	-20.26	-4.55	7.67

Since 2013, Camurus has had a long-term share-based incentive program aimed at employees and Board members. At each balance sheet date, Camurus assesses the likelihood of conditions in the program being fulfilled. On 30 September, 2015, it was deemed that an exit event through a public listing was likely. Since the bonus program was allocated to the employees during a previous accounting period, and can be regarded as being earned to some extent, a retroactive cost has been charged to earnings in June and in addition a further SEK 22.1 million has been charged to earnings before tax in the third quarter. The total cost of the program charged to earnings at 30 September, 2015,



TOTAL EQUITY AND LIABILITIES		210,220	64,199	207,668
Total short-term liabilities	5	107,155	40,673	76,132
Accrued expenses and deferred income		82,290	20,237	53,152
Other liabilities		1,292	1,595	1,287
ncome taxes		8,936	-	9,600
Deferred tax liability	9	458	344	458
Frade payables		14,177	5,785	9,938
iabilities to Group companies		2	12,712	1,697
Short-term liabilities				
Total long-term liabilities		-	-	8,079

## Consolidated statement of changes in equity

SEK thousand	Note	Share capital	Other contributed capital	Retained earnings, including profit/loss for the period	Total equity
Opening balance at 1 January, 2014		583	33,617	15,847	50,047
Profit/loss for the period and comprehensive income				-26,522	-26,522
Closing balance at 30 September 2014		583	33,617	-10,675	23,525
Opening balance at 1 January, 2014		583	33,617	15,847	50,047
Profit/loss for the period and comprehensive income				48,346	48,346
Transactions with shareholders					
New share issue		47	25,017	-	25,064
Closing balance at 31 December, 2014		630	58,634	64,193	123,457
Opening balance at 1 January, 2015		630	58,634	64,193	123,457
Profit/loss for the period and comprehensive income				-127,692	-127,692
Transactions with shareholders					
Ongoing share bonus program for personnel and Board members	7			107,300	107,300
Closing balance at 30 September 2015		630	58,634	43,801	103,065

## Consolidated statement of cash flow

SEK thousand	Note	2015	2014	2015	2014	2014
		July–Sep	July-Sep	Jan–Sep	Jan–Sep	Jan–Dec
Operating activities						
Operating profit/loss before financial items		-29,149	-1,937	-163,688	-34,287	62,319
Adjustments for non-cash items	8	19,886	333	109,888	914	1,427
Interest received		1	4	1	393	394
Interest paid		-4	-59	-21	-108	-170
Income taxes paid		-212	-184	-664	-552	37
		-9,478	-1,843	-54,484	-33,640	64,007
Increase/decrease in inventories		-870	-116	-1,868	562	2,986
Increase/decrease in trade receivables		-16,381	-16,790	-21,673	-17,408	1,672
Increase/decrease in other current receivables		-491	-374	1,143	1,521	-8,278
Increase/decrease in trade payables		1,821	1,898	4,239	-1,982	2,169
Increase/decrease in other current operating liabilities		1,427	-7,142	27,448	-26,275	6,873
Cash flow from changes in working capital		-14,494	-22,524	9,289	-43,582	5,422
Cash flow from operating activities		-23,972	-24,367	-45,195	-77,222	69,429
Investing activities						
Acquisition of intangible assets		-	-603	-355	-1,179	-1,828
Acquisition of tangible assets		-363	-436	-473	-3,775	-5,370
Divestment/amortization of other financial assets		406	-	406	-	
Increase/decrease in current financial investments		0	13,860	157,908	70,664	-87,244
Cash flow from investing activities		43	12,821	157,486	65,710	-94,442
Financing activities						
Increase/decrease in current financial liabilities		-	11,556	-	11,556	
New share issue		-	-	-	-	25,064
Cash flow from financing activities		-	11,556	-	11,556	25,064
Net cash flow for the period		-23,929	10	112,291	44	51
Cash and cash equivalents at beginning of period		136,276	39	56	5	ţ
Cash and cash equivalents at end of period		112,347	49	112,347	49	56

## **Key figures**

Key figures	2015 July – Sep	2014 July–Sep	2015 Jan–Sep	2014 Jan–Sep	2014 Jan-Dec
Average number of shares, before dilution	6,302,140	5,835,310	6,302,140	5,835,310	5,864,727
Average number of shares, after dilution	6,771,458	6,302,140	6,458,579	6,302,140	6,302,140
Earnings per share before dilution, SEK	-3.61	-0.27	-20.26	-4.55	8.24
Earnings per share after dilution, SEK	-3.61	-0.27	-20.26	-4.55	7.67
Equity per share before dilution, SEK	16.35	4.03	16.35	4.03	19.59
Equity per share after dilution, SEK	15.19	3.73	15.19	3.73	19.59
Number of employees at end of period	48	39	48	39	43
Number of employees in R&D at end of period	35	28	35	28	28
Equity, SEK thousand	103,065	23,525	103,065	23,525	123,457
Equity ratio in Group, %	49%	37%	49%	37%	59%
R&D costs as a percentage of operating expenses	86%	75%	78%	76%	77%

#### Definition of key figures

Equity ratio, %

Average number of shares, before dilution

Average number of shares, after dilution Earnings per share before dilution, SEK

Earnings per share after dilution, SEK Equity per share before dilution Equity per share after dilution R&D costs as a percentage of operating expenses

Equity divided by total capital

Average number of shares before adjustment for the dilution effect of new shares

Average number of shares adjusted for the dilution effect of new shares Profit/loss divided by the average number of shares outstanding before dilution

Profit/loss divided by the average number of shares outstanding after dilution Equity divided by the number of shares at the end of the period before dilution

Equity divided by the number of shares at the end of the period after dilution Research and development costs divided by operating expenses (marketing and distribution costs, administrative expenses and research and development costs).

SEK thousand	Note	2015	2014	2015	2014	2014
	NOLE	July–Sep	July-Sep	Jan–Sep	Jan–Sep	Jan–Dec
Net sales		37,232	33,964	118,459	63,143	207,982
Cost of goods sold		-131	98	-132	-467	-525
Gross profit		37,101	34,062	118,327	62,676	207,457
Marketing and distribution costs		-5,255	2,583	-12,425	-1,125	-11,402
Administrative expenses		-925	-5,870	-18,712	-15,928	-22,087
Research and development costs		-37,741	-31,350	-110,731	-78,564	-114,250
Other operating income		267	10	41	40	2,481
Other operating expenses		-	-1,567	-904	-1,521	-
Operating profit/loss before items affecting comparability		-6,553	-2,132	-24,404	-34,422	62,199
Items affecting comparability	7	-22,075	-	-138,075	-	-
Operating profit/loss		-28,628	-2,132	-162,479	-34,422	62,199
Profit/loss from interests in Group companies					-	-1,697
Interest income and similar items		1	4	1	393	394
Interest expense and similar items		-4	-55	-21	-82	-140
Profit/loss after financial items		-28,631	-2,183	-162,499	-34,111	60,756
Appropriations			-		-	-16,348
Profit/loss before tax		-28,631	-2,183	-162,499	-34,111	44,408
Tax on profit for the period		6,299	480	35,750	7,504	-10,198
Profit/loss for the period		-22,332	-1,703	-126,749	-26,607	34,210

## Income statement – parent company

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.

SEK thousand N	lote	30 Sep 2015	30 Sep 2014	31 Dec 2014
ASSETS				
Fixed assets				
Tangible assets				
Equipment		6,566	6,009	7,119
Financial assets				
Interests in Group companies		573	673	573
Deferred tax assets		35,988	7,703	238
Total fixed assets		43,127	14,385	7,930
Current assets				
Inventories				
Finished goods and goods for resale		2,570	2,595	702
Current receivables				
Receivables from parent company		-	-	157,908
Trade receivables		27,792	25,171	6,118
Other receivables		2,150	2,590	1,884
Prepayments and accrued income		9,516	1,561	10,925
Total current receivables		39,458	29,322	176,83
Cash and bank deposits		112,347	49	5
Total current assets		154,375	31,966	177,593
TOTAL ASSETS		197,502	46,351	185,523

630 11,327 <b>11,957</b> 162,673 25,017 126,749 <b>60,941</b> <b>72,898</b>	583 - 11,327 11,910 21,164 - -26,607 -5,443 6,467	58: 4 11,32 11,95 21,16 25,01 34,21 80,39
11,327 11,957 162,673 25,017 126,749 60,941	- 11,327 <b>11,910</b> 21,164 - -26,607 <b>-5,443</b>	4 11,32 11,95 21,16 25,01 34,21 80,39
11,327 11,957 162,673 25,017 126,749 60,941	- 11,327 11,910 21,164 - -26,607 -5,443	4 11,32 11,95 21,16 25,01 34,21 80,39
11,327 11,957 162,673 25,017 126,749 60,941	- 11,327 11,910 21,164 - -26,607 -5,443	4 11,32 11,95 21,16 25,01 34,21 80,39
11,327 11,957 162,673 25,017 126,749 60,941	- 11,327 11,910 21,164 - -26,607 -5,443	4 11,32 11,95 21,16 25,01 34,21 80,39
<b>11,957</b> 162,673 25,017 126,749 <b>60,941</b>	<b>11,910</b> 21,164 - -26,607 <b>-5,443</b>	11,32 11,95 21,16 25,01 34,21 80,39
<b>11,957</b> 162,673 25,017 126,749 <b>60,941</b>	<b>11,910</b> 21,164 - -26,607 <b>-5,443</b>	11,95 21,16 25,01 34,21 80,39
25,017 126,749 <b>60,941</b>	-26,607 - <b>5,443</b>	25,01 34,21 80,39
25,017 126,749 <b>60,941</b>	-26,607 - <b>5,443</b>	25,01 34,21 80,39
25,017 126,749 <b>60,941</b>	-26,607 - <b>5,443</b>	25,01 34,21 80,39
126,749 60,941	-26,607 <b>-5,443</b>	34,21 <b>80,39</b>
60,941	-5,443	80,39
72,898	6.467	
	5,401	92,34
1,825	986	1,82
15,510	-	15,51
572	166	16
2	11,269	1,69
14,177	5,681	9,93
8,936	-	9,60
1,292	1,595	1,28
82 200	20,187	53,15
02,230	38,732	75,67
	82,290	

#### 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 third quarter 2015 was approved for publication in accordance with a decision from the Board on 22 October, 2015.

All amounts are stated in SEK thousand, 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 "Profit/loss 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

The Group has a share-based bonus plan, in which payments are settled in the form of shares, and where the company receives services from employees as remuneration for the Group's equity instruments (shares). The fair value of the service entitling the employee to allocation is expensed. The total amount that is to be expensed is based on the fair value of the shares allotted, excluding the effect of service conditions and non-market-based vesting conditions.

At the end of each reporting period, the Group reviews its assessments of the number of shares expected to be earned, based on the non-market-based vesting conditions and service conditions. Any deviation from the original assessments brought about by the review is recognized in the income statement and corresponding adjustments are made against equity.

Once the bonus shares have been exercised, the company issues new shares. Payments received, less any directly attributable transaction expenses, are credited to the share capital (quota value) and other contributed capital.

The social security contributions arising on the allocation of the shares are treated as an integral part of the allocation, and the cost is 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:

	2015 July–Sep	2014 July–Sep	2015 Jan–Sep	2014 Jan-Sep
Sales of development-related goods and services	15,825	6,641	67,986	18,870
Milestone payments	21,050	18,025	42,700	18,025
Licensing revenues	180	9,041	7,193	24,030
Other	177	285	580	2,405
Total	37,232	33,992	118,459	63,330

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

	2015 July–Sep	2014 July–Sep	2015 Jan–Sep	2014 Jan–Sep
Europe	26,544	32,179	95,761	59,241
(of which Sweden)	(196)	(11)	(1,906)	(26)
North America	10,666	1,811	15,639	3,910
Other geographical areas	21	2	7,058	179
Total	37,232	33,992	118,459	63,330

Revenue of approximately SEK 26.0 million (32.1) relates to a 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 profit or loss 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.

	2015 July–Sep	2014 July–Sep	2015 Jan–Sep	2014 Jan–Sep
Profit/loss attributable to parent company shareholders	-22,739	-1,554	-127,692	-26,522
Total	-22,739	-1,554	-127,692	-26,522
Weighted average number of ordinary shares outstanding (thousands)	6,302	5,835	6,302	5,835

#### (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.

	2015	2014	2015	2014
	July-Sep	Julv–Sep	Jan–Sen	Jan-Sep
Profit/loss attributable to parent company shareholders	-22,739	-1,554	-127,692	-26,522

Total	-22,739	-1,554	-127,692	-26,522
Weighted average number of ordinary shares outstanding (thousands)	6,302	5,835	6,302	5,835
Adjustments for:				
- Warrants (thousands)	-	467	-	467
<ul> <li>Share bonus program Board of Directors and personnel</li> </ul>	434	-	145	
Weighted average no. of ordinary shares used in calculation of earnings per share after dilution (thousands)	6,736	6,302	6,447	6,302

#### Note 5 Financial instruments - Fair value of financial assets and liabilities 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	30 Sep 2015	30 Sep 2014
Loans and receivables		
Trade receivables	27,792	25,199
Other receivables	0	0
Cash and cash equivalents	112,347	49
Total	140,139	25,248
Other liabilities		
Other liabilities	-	-
Other financial liabilities	-	-
Liabilities to Group companies	-	12,712
Trade payables	14,177	5,785
Total	14,177	18,497

#### Note 6 Related party transactions

Transactions with Sandberg Development AB have occurred regarding IT and HR support services. 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 liability to Sandberg Development AB regarding these services that amounted to SEK

0.0 million (0.3) MSEK. There were no other receivables or liabilities.

#### Note 7 Items affecting comparability

Camurus has a share-based bonus program whereby employees and Board members of Camurus, in the event of a public listing of the company's share, receive shares in the company on the listing date The shares are received on payment of the share's quota value, i.e. essentially free of charge. Should an exit event occur involving the transfer of more than 90% of all shares in Camurus, employees and Board members are entitled to receive cash.

Up until 12 June 2015, when the bonus program was modified, the share bonus program was a cash bonus program in which settlement would be made in cash. Up until the point the program was modified, Camurus did not consider it likely that an exit event would occur, which is why no cost or liability regarding the bonus program was recognized from previously.

At each balance sheet date, Camurus assesses the likelihood of service and performance conditions being fulfilled. On 30 June 2015, Camurus deemed it likely for the first time that an exit event would occur via a public listing, which means that employees and members of the Board of Camurus will receive a share bonus in the form of shares in the company

on the listing date. Since the bonus program was allocated to the employees in a previous accounting period, and is therefore already earned to a certain extent, earnings on 30 June 2015 have been charged with a retroactive cost of SEK 116.0 million, including social security contributions before tax, with a corresponding increase in equity of SEK 88.3 million and a social security liability of SEK 27.7 million. In the third quarter, earnings have been charged with a cost of SEK 22.1 million, including social security contributions before tax, with a corresponding increase in equity of SEK 19.0 million and a social security liability of SEK 3.1 million. The total cost of the bonus program charged to earnings at 30 September, 2015, amounts to SEK 107.7 million after tax.

In order to compensate for the social security costs arising net after tax, the company and principal shareholder Sandberg Development have entered into an agreement (conditional upon a public listing), in accordance with which the principal shareholder undertakes to subscribe to newly issued shares in Camurus at total issue proceeds corresponding to 78% of these costs, calculated based on the median of the price range in the offering submitted in connection with the public listing. Since the agreement is conditional upon a public listing, this undertaking on the part of the principal shareholder has not, in accordance with generally accepted accounting practices, been recognized as a receivable as of 30 September 2015.

Since the total cost is of an unusual nature, non-recurring, and significant in terms of the amount, the item will be recognized as an item affecting comparability in future financial reports.

To follow below is the consolidated income statement as it would have looked had the cost not been separated out. A reallocation of costs in the current period, primarily from administrative expenses to marketing and sales costs as well as research and development costs, means that the outcome in the third quarter and comparisons to previous periods will be misleading. If the outcome is adjusted for this reallocation, costs for the period (both for the third quarter and for the January–September period) for marketing and sales would have been SEK 1.2 million higher. If administrative expenses are adjusted correspondingly, these costs would have been SEK 25.6 million higher and research and development costs SEK 26.8 million lower.

SEK thousand	Note	2015 July–Sep	2014 July–Sep	2015 Jan-Sep	2014 Jan-Sep	2014 Jan–Dec
Net sales	3	37,232	33,992	118,459	63,330	208,207
Cost of goods sold		-131	88	-132	-523	-656
Gross profit		37,101	34,080	118,327	62,807	207,551
Marketing and distribution costs		-4,701	-2,847	-23,471	-6,555	-11,402
Administrative expenses		7,862	-5,891	-43,565	-15,996	-22,165
Research and development costs		-69,679	-25,722	-214,116	-73,062	-114,146
Other operating income		267	10	41	86	2,481
Other operating expenses		-	-1,567	-904	-1,567	-
Operating profit/loss	6	-29,149	-1,937	-163,688	-34,287	62,319
Finance income		1	4	1	393	394
Finance expenses		-4	-59	-21	-108	-170
Net financial items		-3	-55	-20	285	224
Profit/loss before tax		-29,152	-1,992	-163,708	-34,002	62,543
Income tax	9	6,414	438	36,016	7,480	-14,197
Profit/loss for the period		-22,739	-1,554	-127,692	-26,522	48,346

#### Note 8 Cash flow

Adjustment for non-cash items:

Adjustments for non-cash items	2015 July – Sep	2014 July–Sep	2015 Jan–Sep	2014 Jan-Sep	2014 Jan–Dec
Depreciation/amortization	886	333	2,588	914	1,427
Estimated costs of share bonus program	19,000	-	107,300	-	-
Total	19,886	333	109,888	914	1,427

#### Note 9 Deferred tax

Tax for the period amounted to SEK 6.4 million (0.4), an increase of SEK 6.0 million, primarily attributable to the cost of the ongoing bonus program, which in the third quarter 2015 impacted on earnings in the amount of SEK 22.1 million before tax.

## **Report of Review of Interim Financial Information**

Auditors' report of review of the condensed interim financial information (interim report) prepared accordance with IAS 34 and Chapter 9 of the Swedish Annual Accounts Act

#### Introduction

We have reviewed the condensed interim financial information (interim report) of Camurus AB (publ) as of 30 September 2015 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

#### Scope of review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, *Review of Interim Report Performed by the Independent Auditor of the Entity.* A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

#### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Lund, 22 October 2015

Mazars SET Revisionsbyrå AB Gunilla Malmsten Auditor in charge Authorized public accountant PricewaterhouseCoopers AB Ola Bjärehäll Auditor in charge Authorized public accountant

## Financial information for financial years 2012–2014

### **Consolidated income statement**

		Fir		
SEK thousand	Note	2014	2013	2012
Net sales	4	208,207	197,716	95,204
Cost of goods sold	5	-656	-1,575	-3,321
Gross profit		207,551	196,141	91,883
Operating expenses				
Marketing and distribution costs	5	-11,402	-3,821	-2,385
Administrative expenses	5,7	-22,165	-17,775	-14,505
Research and development costs	5	-114,146	-52,675	-54,818
Other income	6, 12	2,481	5,446	114
Other expenses	12	-	-	-1,527
Operating profit/loss before items affecting comparability	8, 25, 27	62,319	127,316	18,761
Items affecting comparability		-	-	-
Operating profit/loss		62,319	127,316	18,761
Profit/loss from financial items				
Finance income	9	394	73	1
Finance expenses	9	-170	-121	-902
Net financial items		224	-48	-901
Profit/loss before tax		62,543	127,268	17,860
Income tax	10	-14,197	-28,032	-4,543
Profit/loss for the year		48,346	99,235	13,317

Comprehensive income is the same as profit/loss for the year, as the consolidated group contains no items that are recognized under other comprehensive income.

Earnings per share based on earnings attributable to parent company shareholders for the year (in SEK per share)						
Earnings per share before dilution	11	8.24	17.01	2.28		
Earnings per share after dilution	11	7.67	15.75	2.11		

## **Consolidated balance sheet**

SEK thousand	Note	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
ASSETS	2				
Fixed assets					
Intangible assets					
Capitalized development expenditure	13	22,551	20,723	7,421	3,566
Tangible assets					
Equipment	14	7,119	3,176	2,461	1,896
Financial assets					
Long-term receivables from Group companies		406	406	406	406
Deferred tax receivables	15	-	-	-	8,260
Total fixed assets		30,076	24,305	10,288	14,128
Current assets					
Inventories					
Finished goods and goods for resale		702	3,688	2,270	858
Current receivables					
Receivables from Group companies	17, 18	157,908	70,664	37,049	-
Trade receivables	17, 19	6,118	7,790	4,408	70,227
Other receivables	17	1,883	2,305	2,282	1,554
Prepayments and accrued income	20	10,925	2,899	1,105	1,078
Cash and cash equivalents	17, 21	56	5	3	2
Total current assets		177,592	87,351	47,117	73,719
TOTAL ASSETS		207,668	111,656	57,405	87,847

## Consolidated balance sheet, cont.

SEK thousand	Note	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
EQUITY					
Equity attributable to parent company shareholders	22				
Share capital		630	583	583	583
Other contributed capital		58,634	33,617	33,617	33,617
Retained earnings, including profit/loss for the year		64,193	15,847	6,010	-22,655
Total equity		123,457	50,047	40,210	11,545
LIABILITIES	2				
Long-term liabilities					
Deferred tax liability	15	8,079	4,577	1,762	-
Total long-term liabilities		8,079	4,577	1,762	-
Short-term liabilities					
Liabilities to Group companies	17, 18	1,697	508	382	3,585
Trade payables	17	9,938	7,769	6,288	2,716
Deffered tax	15	458	-	-	-
Income taxes		9,600	-	-	-
Other liabilities	17	1,287	1,172	1,031	983
Accrued expenses and deferred income	24	53,152	47,583	7,733	69,018
Total short-term liabilities		75,674	57,032	15,434	76,302
TOTAL EQUITY AND LIABILITIES		207,668	111,656	57,405	87,847

### Consolidated statement of changes in equity

SEK thousand	Share capital	Other contributed capital	Retained earnings, including profit/loss for the year	Total equity
Opening balance at 1 January, 2012	583	33,617	-22,655	11,545
Profit/loss for the year and comprehensive income			13,317	13,317
Transactions with shareholders				
Group contribution received			15,348	15,348
Closing balance at 31 December, 2012	583	33,617	6,010	40,210
Opening balance at 1 January, 2013	583	33,617	6,010	40,210
Profit/loss for the year and comprehensive income			99,235	99,235
Transactions with shareholders				
Group contribution paid			-89,398	-89,398
Closing balance at 31 December, 2013	583	33,617	15,847	50,047
Opening balance at 1 January, 2014	583	33,617	15,847	50,047
Profit/loss for the year and comprehensive income			48,346	48,346
Transactions with shareholders				
Exercise of warrants/new shares	47 <sup>1</sup>	25,017		25,064
Closing balance at 31 December, 2014	630	58,634	64,193	123,457

<sup>1</sup> On 9 December 2014, 466,830 outstanding warrants were exercised, corresponding to 466,830 new shares and 46,683 SEK increase in share capital. The subscription price was SEK 53.69 per new share, corresponding to a total of SEK 25,064,103, of which SEK 25,017,420 has been transferred to other contributed capital. The new shares were registered on 9 January, 2015.

## Consolidated statement of cash flow

		Financial year		
SEK thousand	Note	2014	2013	2012
Operating activities				
Operating profit/loss before financial items		62,319	127,316	18,761
Adjustments for non-cash items	26	1,427	814	699
Interest received		394	73	1
Interest paid		-170	-121	-902
Income taxes paid		37	0	-20
		64,007	128,082	18,539
Increase/decrease in inventories		2,986	-1,418	-1,412
Increase/decrease in trade receivables		1,672	-3,382	65,819
Increase/decrease in other current receivables		-8,278	-1,817	-735
Increase/decrease in trade payables		2,169	1,482	3,571
Increase/decrease in other current operating liabilities		6,873	40,117	-61,047
Cash flow from changes in working capital		5,422	34,982	6,196
Cash flow from operating activities		69,429	163,064	24,735
Investing activities				
Aquisition of intangible assets	13	-1,828	-13,302	-3,855
Aquisition of tangible assets	14	-5,370	-1,529	-1,261
Increase/decrease in current financial investments (intercompany account for cash handling)		-87,244	-33,615	-37,049
Cash flow from investing activities		-94,442	-48,446	-42,165
Financing activities				
Increase/decrease in current financial liabilities (intercompany account for cash handling)		-	-	-3,393
Exercise of warrants/new shares		25,064	-	-
Group contributions received/paid		-	-114,616	20,824
Cash flow from financing activities		25,064	-114,616	17,431
Net cash flow for the year		51	2	1
Cash and cash equivalents at beginning of year	21	5	3	2
Cash and cash equivalents at year-end	21	56	5	3

#### The Group's notes

Camurus AB, Reg. 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 Sölvegatan 41A, 223 62 Lund.

#### Note 1 – Summary of key accounting policies

The most important accounting policies applied in these consolidated financial statements are set out below. Unless otherwise stated, these policies have been applied consistently for all presented periods.

## 1.1 Principles for the preparation of the financial statements

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 financial report is Camurus' first set of consolidated financial statements and first financial report prepared in accordance with IFRS. Since the consolidated financial statements have not previously been prepared, there is no transition information for the Group from previously applied accounting policies.

Preparing financial statements to conform to IFRS requires use of certain critical accounting estimates. It also requires management to make certain judgments when applying the Group's accounting policies, see note 3.

#### 1.1.1 Changes to accounting policies and disclosures Standards, amendments and interpretations of existing standards that are not yet in force and that have not been adopted in advance by the Group

A number of new standards and interpretations enter into force for the financial year starting 1 January, 2014, and have not been applied when preparing this financial report. Below are the standards that are deemed to be of relevance to the Group:

IFRS 9 Financial Instruments addresses classification, valuation and recognition of financial assets and liabilities. The complete version of IFRS 9 was published in July 2014. It replaces parts of IAS 39, which addresses classification and valuation of financial instruments. IFRS 9 maintains a mixed valuation approach but simplifies this approach in some respects. There will be three valuation categories for financial assets, amortized cost, fair value over other comprehensive income and fair value over profit/loss. The way in which an instrument is classified depends on the company's business model and the instrument's characteristics. Investments in equity instruments are recognized at fair value over profit/loss, but there is also an opportunity on initial recognition to recognize the instrument at fair value over other comprehensive income, in which case the instrument will not be reclassified to the income statement on disposal. IFRS 9 is also introducing a new model for calculating credit loss reserves, based on anticipated credit losses. The classification will not change for financial liabilities except for in cases where a liability is recognized at fair value over profit/loss, based on the fair value alternative. Changes in value attributable to changes in own credit risk should then be recognized in other comprehensive income. IFRS 9 reduces requirements for the application of hedge accounting by the 80-125 percent criterion being replaced with the requirement that there be an economic relationship between the hedging instrument and the hedged item, and that the hedge ratio should be the same as that used in risk management. Hedging documentation is also changing slightly compared with IAS 39. The Group intends to apply the new standard no later than for the financial year

commencing 1 January, 2018, and has not yet evaluated the effects. This standard has not yet been adopted by the EU.

IFRS 15 Revenue from Contracts with Customers was published in May 2014. IFRS 15 replaces all previously published standards and interpretations relating to revenue recognition (i.e. IAS 11 Construction Contracts and IAS 18 Revenue, IFRIC 13 Customer Loyalty Programs, IFRIC 15 Agreements for the Construction of Real Estate, IFRIC 18 Transfers of Assets from Customers, SIC 31 Barter Transactions Involving Advertising Services). IFRS 15 comes into effect on 1 January, 2018. The standard will be applied retroactively. The Group intends to apply the new standard no later than for the financial year commencing 1 January, 2018, and has not yet evaluated the effects.

None of the other IFRS or IFRIC interpretations that have yet to enter into force are expected to be of relevance to, or have any material impact on the Group.

#### **1.2 Consolidated financial statements** Subsidiaries

Subsidiaries are all companies (including structured entities) over which the Group has a controlling interest. The Group controls a company when it is exposed or entitled to variable returns from its holding in the company and has the opportunity to influence the return through its interest in the company. Subsidiaries are consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

The Group uses the acquisition method to recognize the Group's business combinations. The purchase price for the acquisition of a subsidiary comprises the fair value of transferred assets, liabilities incurred by the Group to former owners of the acquired company and the shares issued by the Group. The purchase price also includes the fair value of all liabilities resulting from a contingent consideration arrangement. Identifiable acquired assets and liabilities assumed in a business combination are measured initially at their fair values on the acquisition date.

Acquisition-related costs are expensed as they arise.

Inter-company transactions, balance sheet items, income and expenditure on transactions between Group companies are eliminated. Profit and losses resulting from inter-company transactions and that are recognized in assets are also eliminated. The accounting policies for subsidiaries have been amended, where applicable, to ensure consistent application of the Group's policies.

The items 'Receivables from Group companies' and 'Liabilities to Group companies' in the consolidated balance sheet concern receivables and liabilities to the parent company Sandberg Development AB.

#### 1.3 Functional currency and presentation currency

The functional currency of the parent company is the Swedish krona (SEK), which is also the presentation currency of the Group. This means that the financial statements are presented in SEK. Unless otherwise stated, all amounts are given and rounded to the nearest SEK thousand.

#### **1.4 Foreign currency translation** Transactions and balance sheet items

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing on the transaction date. Exchange gains and losses arising on payment of such transactions and on translation of monetary assets and liabilities denominated in foreign currencies at the exchange rate on the balance sheet date are recognized in operating profit in the income statement.

#### Translation of foreign Group companies

The earnings and financial position of all Group companies with a

functional currency that differs from the presentation currency are translated into the Group's presentation currency. Assets and liabilities for each balance sheet are translated from the foreign operation's functional currency into the Group's presentation currency, SEK, at the exchange rate on the balance sheet date. Income and expenditure for each income statement are translated into SEK at the average exchange rate prevailing at the point of each transaction. Translation differences arising when translating the data of foreign operations are recognized in other comprehensive income.

#### 1.5 Segment reporting

Operating segments are reported in the same way as internal reporting, which is submitted to the highest executive decision maker. 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, who makes strategic decisions in consultation with the Board.

#### 1.6 Intangible assets Capitalized development costs

The Group conducts research and development relating to new products. The overall level of risk associated with current development projects is high. The risk comprises technical and manufacturing-related risks, safety and effect-related risks that can arise in clinical studies, regulatory risks relating to applications for approval of clinical studies and market approval, as well as IP risks relating to approval of patent applications and patent protection. All development work is therefore treated as research (since the work does not meet the criteria listed below), until the point at which the product has been granted market approval. Research expenditure is expensed as it occurs.

Expenses directly attributable to development and testing of identifiable and unique products controlled by the Group are recognized as intangible assets once the following criteria have been satisfied:

- it is technically possible to complete the product so that it can be used,
- · the company intends to complete the product and use or sell it,
- · the conditions are in place to use or sell the product,
- it can be shown that the product will generate probable future economic benefits,
- adequate technical, financial and other resources to complete the development and to use or sell the product are available, and
- expenses attributable to the product during its development can be reliably calculated.

Capitalized assets that have satisfied the capitalization criteria above have a limited useful life and are carried at cost less accumulated amortization. Amortization is initiated once the asset is ready for use. Amortization is conducted on a straight-line basis to distribute the cost of the proprietary intangible assets over their estimated useful life, which coincides with the product's remaining patent period.

Directly attributable costs that are capitalized include development expenditure, as well as personnel costs and a reasonable proportion of indirect costs. Other development expenditure that does not satisfy the above criteria is expensed as it arises. Development expenses that have been previously expensed are not recognized as assets in the subsequent period.

#### 1.7 Property, plant, and equipment

Property, plant and equipment are recognized at cost less depreciation. The cost of acquisition includes expenditures that can be related directly to the acquisition of the asset.

Additional expenses are added to the asset's carrying amount or recognized as a separate asset, depending on which is appropriate,

only when it is likely that the future economic benefits associated with the asset will be of use to the Group, and the cost of the asset can be reliably measured. The carrying amount of a replaced part is derecognized from the balance sheet. All other forms of repair and maintenance are recognized as costs in the income statement in the period in which they arise.

Depreciation is carried out on a straight-line basis as follows: Equipment 4–8 years

The assets' residual values and useful lives are reviewed at the end of each reporting period and adjusted if required. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposal of property, plant or equipment are determined by comparing sales proceeds with the carrying amount and are recognized in other operating income or other operating expenses in the income statement.

#### 1.8 Impairment of non-financial non-current assets

Intangible assets that have an indeterminable useful life or intangible assets that are not ready for use are not subject to amortization but are tested annually for impairment. Assets subject to amortization are reviewed for impairment in value whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized at the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of the asset's fair value less distribution costs and its value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). For assets previously impaired, a review is conducted every balance sheet date as to whether a reversal should be carried out.

#### **1.9 Inventories**

Inventories are carried at the lower of cost and net realizable value. Cost is established via the First In First Out method, (FIFO). The net realizable value is the estimated selling price in the ordinary course of business less applicable variable distribution costs.

#### **1.10 Financial instruments** *1.10.1 Classification*

The Group classifies its financial assets and liabilities into the following categories: loans and trade receivables, and other financial liabilities. The classification depends on the purpose for which the financial asset or liability is acquired.

#### (a) Loans and receivables

Loans and receivables are non-derivative financial assets, with fixed or determinable payments, that are not quoted in an active market. They are included in current assets, with the exception of items with maturities extending 12 months beyond the balance sheet date; these are classified as fixed assets. The Group's loans and receivables comprise trade receivables, cash and cash equivalents and the financial instruments that are reported in other receivables.

#### (b) Other financial liabilities

Liabilities to Group companies, trade payables and the part of other current liabilities that concerns financial instruments are classified as other financial liabilities.

#### 1.10.2 Recognition and measurement

The Group's financial instruments are initially measured at fair value plus transaction costs. Financial assets are removed from the balance sheet when the right to receive cash flows from the instrument expires or is transferred and the Group has transferred virtually all risks and rewards of ownership. Financial liabilities are removed from the balance sheet when the obligation in the agreement has been completed or in some other way eliminated.

Loans and receivables and other financial liabilities are recognized after the date of acquisition at amortized cost using the effective interest method.

#### 1.10.3 Offsetting of financial instruments

Financial assets and liabilities are offset and recognized in the balance sheet at a net amount, only when a legal right exists to offset the recognized amounts and there is an intention to settle them at a net amount, or to realize the asset and settle the liability at the same time.

## 1.10.4 Impairment of financial instruments Assets measured at amortized cost

The Group performs an assessment at the end of each reporting period of whether there is objective evidence that a financial asset or group of financial assets is impaired. A financial asset or group of financial assets is impaired only if there is objective evidence of an impairment need due to one or more events occurring after the point at which the asset was initially recognized, and this event/these events has an impact on the estimated future cash flows for the financial asset or group of financial assets that can be reliably estimated.

The impairment is calculated as the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted to the financial asset's original effective interest rate. The asset's carrying amount is impaired and the impairment amount is recognized in the consolidated income statement within operating profit or within net financial income/expense, depending on the kind of financial asset that is being impaired. If the impairment requirement decreases in a subsequent period and the decrease can be objectively attributed to an event that occurred after the impairment was recognized, the reversal of the previously recognized impairment is recognized in the consolidated income statement within operating profit or within net financial income/expense, depending on the kind of financial asset that is being impaired.

#### 1.11 Trade receivables

Trade receivables are financial instruments comprising amounts that are due to be paid by customers for goods and services sold in the ordinary course of business. Payments expected within one year or less are classified as current assets. Otherwise they are recognized as fixed assets.

Trade receivables are initially recognized at fair value and thereafter at amortized cost using the effective interest method, less any provision for decrease in value.

#### 1.12 Cash and cash equivalents

Cash and cash equivalents are financial instruments and comprise cash and bank balances.

#### 1.13 Equity

Ordinary shares are classified as equity. Transaction costs directly attributable to the issue of new ordinary shares or warrants are recognized, net after tax, in equity as deductions from the issue proceeds.

When the warrants are exercised, the company issues new shares. Payments received are credited to the share capital (quota value) and other contributed capital.

Group contributions paid or received are recognized directly in equity in the item retained earnings including profit/loss for the year.

#### 1.14 Trade payables

Trade payables are financial instruments and relate to obligations to pay for goods and services that have been acquired in the ordinary course of business. Trade payables are classified as current liabilities if they are payable within one year. Otherwise they are recognized as long-term liabilities.

Trade payables are initially recognized at fair value, and thereafter at amortized cost using the effective interest method.

#### 1.15 Current and deferred tax

Tax expense for the period includes current income tax and deferred tax. The current income tax expense is calculated on the basis of the tax regulations that are enacted or substantively enacted on the balance sheet date in countries where the parent company and its subsidiaries operate and generate taxable revenue.

Deferred tax is recognized using the balance sheet method, on all temporary differences arising between the tax base of assets and liabilities and their carrying amounts in the consolidated accounts. Deferred income tax is determined using the tax rates enacted or announced by the balance sheet date and that are expected to apply when the related deferred tax asset is realized or the deferred tax liability is settled.

Deferred tax assets on loss carryforwards are recognized to the extent that it is likely future taxable surpluses will be available, against which the losses can be utilized.

Deferred tax assets and tax liabilities are offset when a legally enforceable right to offset exists for current tax assets and liabilities, the deferred tax assets and liabilities refer to taxes charged by one and the same tax authority and relate either to the same taxable entity or different taxable entities and there is an intention to settle the balances using net payments.

#### **1.16 Employee benefits** Pension obligations

The Group has defined contribution pension schemes, as well as defined benefit Alecta plans. All plans are recognized as defined contribution plans. The plan extends to all employees, including the Group CEO and senior executives.

A defined contribution plan is a pension plan under which the Group pays fixed contributions into a separate legal entity. The Group does not have any legal or informal obligation to pay additional contributions if this legal entity does not have sufficient assets to pay all benefits to employees attached to the employees' service during the current or previous periods.

For defined contribution plans, the Group pays contributions to public or privately administered pension insurance plans on a mandatory, contractual or voluntary basis. The Group has no additional payment obligations once the contributions have been paid. The contributions are recognized as personnel costs when they fall due for payment. Prepaid contributions are recognized as an asset to the extent that cash repayment or reduction of future payments may benefit the Group.

For salaried employees in Sweden, the ITP 2 plan's defined benefit pension obligations for retirement pension and family pension are secured through insurance held at Alecta. A defined benefit plan is a pension plan that is not a defined contribution plan. Defined benefit plans differ in that they define an amount of pension benefit that an employee will receive on retirement, usually dependent on one or more factors such as age, years of service and salary.

As per UFR 3 Classification of ITP plans financed by insurance in Alecta (a statement issued by the Swedish Financial Reporting Board), this is a multi-employer defined benefit plan. The Company has not had access to information for the period in order to report its proportional share of the plan's commitments, plan assets and costs, which has meant that it has not been possible to recognize the plan as a defined benefit plan. The ITP 2 pension plan, secured through insurance held at Alecta, is thus recognized as a defined contribution plan. The premium for the defined benefit retirement and family pension is calculated individually and depends on such factors as salary, previously earned pension and expected remaining period of service. Anticipated contributions the next reporting period for ITP 2 insurance with Alecta amount to SEK 1.0 million (2013: SEK 1.0 million, 2012: SEK 0.7 million). The Group's share of the total contributions to the plan is not significant.

The collective consolidation level comprises the market value of Alecta's assets as a percentage of the insurance obligations, calculated in accordance with Alecta's actuarial methods and assumptions, which does not correspond with IAS 19. The collective consolidation level is normally allowed to vary between 125 and 155 percent. If Alecta's collective consolidation level falls short of 125 percent or exceeds 155 percent, measures will be taken to create conditions to restore the consolidation level to the normal interval. In the event of low consolidation, a possible measure might be to raise the agreed price of new subscription and extension of existing benefits. In the event of high consolidation, a possible measure might be to introduce premium reductions. At the end of 2014, Alecta's surplus (in the form of the collective consolidation level) was 143 percent (2013: 148 percent, 2012: 129 percent).

#### 1.17 Revenue recognition

Revenue is measured at the fair value of what has been received or will be received, and corresponds to the amounts received for sold goods and services, less deductions for discounts and value added tax.

The Group recognizes revenue when its amount can be reliably measured, it is probable that the future economic benefits associated with the transaction will flow to the company, and certain criteria have been satisfied for each of the Group's operations as described below.

#### License and collaboration agreements

Revenue from agreements that are made with customers in research projects is recognized based on the financial implications of the agreement. Revenue from license and collaboration agreements may consist of one-off payments, license, royalty and milestone payments and remuneration for research services. In addition, under the agreements Camurus may also be entitled to compensation for costs incurred. Revenue recognition reflects earnings in accordance with the specific contractual terms.

Camurus applies the criteria for revenue recognition on each individual transaction. However, in some situations it is necessary to apply the criteria to those parts of a transaction that can be separately identified, so that the financial implications of the transaction can be reflected in the financial statements. This means, for example, that the various transactions in the agreements are divided up and that identifiable parts are recognized separately. If the total value of the agreement falls short of the fair value of the transactions' separate parts, the difference ('discount') is allocated among the separate parts based on their relative fair values in the transaction.

The principles for revenue recognition of different parts (and for corresponding separate transactions) in license and collaboration agreements are described below:

#### Licensing rights to Camurus' intangible assets

An assessment is made as to whether the license acquired by the counterparty in the agreement means that the intangible asset has been divested from an accounting perspective (i.e. as a sold license, where the counterparty appropriates the asset), or whether it gives the counterparty a right to utilize the intangible asset.

The assessment is made based on the financial implications of the

agreement. An assignment of licensing rights for a fixed fee under a non-cancellable agreement allowing the licensee to freely utilize Camurus' rights, and where Camurus does not have any remaining obligations to perform, is essentially regarded as a sale. If the agreement means that the intangible asset has been divested and satisfies the criteria for revenue recognition of a good, revenue recognition is carried out in accordance with the principles for goods sold (see 'Sale of goods' below). If the agreement does not constitute a divestment of the intangible asset, the customer has right of use and remuneration is normally allocated on a straight-line basis over the term of the agreement.

#### Sale of goods

Revenue from the sale of goods is recognized when significant risks and benefits associated with ownership of the goods has been transferred and Camurus no longer has any commitment in the ongoing management of business operations that is normally associated with ownership, and neither does the company exercise any real control over the sold goods. Furthermore, it must be possible to calculate the revenue in a reliable way, it should be likely that the economic benefits associated with the transaction will accrue to the company and the expenses that have arisen, or that are expected to arise as a result of the transaction, can be reliably calculated. In Camurus' case this usually means that goods are recognized as income on delivery to the customer.

#### **Research services**

Regular remuneration is received for research services, often in advance as a fixed amount. Research remuneration received is recognized in the period in which the services are carried out. Revenue is calculated by establishing the degree of completion for the transaction in question based on the proportion the services rendered represent of the total services to be performed. Research services performed on an open account basis are recognized as income as the services are carried out.

#### Royalties

Remuneration in the form of royalties is recognized as revenue when it is likely that the economic benefits associated with the transaction will accrue to Camurus and the revenue can be reliably calculated. Royalties are accrued as per the relevant agreement's financial implications. In some cases the royalties received are dependent upon a future event, for example future sales. In such cases, revenue from royalties is recognized when it is likely that the royalty remuneration will be received, usually in connection with the future sale.

#### Milestone payments

Remuneration received when milestones are achieved is recognized as revenue when it is likely that the economic benefits associated with the transaction will accrue to Camurus and the revenue can be reliably calculated. Payments for milestones are received when a certain result has been achieved, or a particular event has occurred in accordance with definitions in the respective collaboration agreement. Revenue for milestones is recognized when all terms for the right to remuneration in accordance with the agreement have been met, usually in connection with the contractually agreed milestone being achieved, and Camurus has satisfied all conditions for the milestone in accordance with the collaboration agreement.

#### Compensation for costs incurred

Compensation for costs incurred, i.e. costs that are forwarded onto the customer, is recognized in accordance with the guidance under IAS 18 for determining whether an entity is acting as a principal or as an agent. This means that Camurus analyses whether the Company is acting as a principal in the transaction, i.e. that Camurus is exposed to the significant risks and benefits on the sale of a good or service. If Camurus is a principal in the transaction, the amount received from the counterparty is recognized as revenue. If Camurus is acting as an agent, the revenue instead comprises commission received.

#### 1.18 Interest income

Interest income is recognized as revenue using the effective interest method. When the value of a claim in the category 'Loans and receivables' has fallen, the Group reduces the carrying amount to the recoverable value, which comprises estimated future cash flow, discounted with the original effective interest rate for the instrument, and continues to dilute the discounting effect as interest income. Interest income on impaired loans and receivables is recognized at the original effective interest rate.

#### 1.19 Share-based payment

The Group has a share-based bonus plan in which payments are settled in cash. The fair value of the service entitling the employee to a bonus is expensed with a corresponding increase in liabilities. The cost of the bonus is based on the fair value of the allotted share-based payment, which is established on each closing date up until the final settlement. At the end of each reporting period, the Group reviews its assessments of whether the share-related payment is expected to be earned based on service and performance conditions. Performance conditions are related to an exit event (see note 3 Important estimates and assessments; IFRS 2 Share-based Payment). Any deviation from the original assessments brought about by the review is recognized in the income statement and corresponding adjustments are made against the liability.

The social security contributions arising on the allocation of the share-based payment are treated as an integral part of the allocation, and the cost is treated as a cash-settled, share-based payment that is re-measured every year-end up until settlement occurs.

#### 1.20 Leasing

The Group only recognizes operating leases relating to premises, cars, machinery and equipment. Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made during the lease term are expensed in the income statement on a straight-line basis over the lease term.

#### 1.21 Cash flow statement

The cash flow statement has been prepared in accordance with the indirect method. This means that the operating profit is adjusted for transactions that have not involved incoming payments or disbursements during the period, and for any revenue and expenses relating to the cash flows of investing or financing activities. The Group-wide account for cash management (cash pool) is not included in cash and cash equivalents but is instead recognized in the balance sheet in transactions with the principal shareholder Sandberg Development AB, and the change in the item is reflected in the cash flow statement as investing or financing activity (depending on whether it is a claim or a liability).

## Not 2 – Financial risk management

#### 2.1 Financial risk factors

As a result of its business, the Group is exposed to a number of different risks: market risk (including foreign exchange risk), credit risk and liquidity risk. The Group has decided not to actively manage its risks through the use of derivatives, for example.

#### a) Market risk

The most significant market risk for the Group is the foreign exchange risk, which is described in a separate section below. The interest rate risk is limited within the Group, as there is no long-term borrowing or long-term interest-bearing investment.

#### Foreign exchange risk

The Group operates internationally and is exposed to foreign exchange risks arising from various currency exposures, primarily relating to the US dollar (USD) and euro (EUR). The foreign exchange risk arises through future finance transactions, recognized assets and liabilities. Foreign exchange risks arise when future finance transactions or recognized assets or liabilities are expressed in a currency that is not the functional currency of the entity.

The Group has the following balance sheet exposure for assets, which include trade receivables and cash and cash equivalents:

	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
USD	5,296	7,139	3,584	69,001
EUR	779	600	798	1,220
Other currencies	89	42	9	-
Total	6,164	7,781	4,391	70,221

The balance sheet exposure for trade payables is as follows:

	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
USD	-4,964	-849	-1,467	-512
EUR	-1,855	-1,830	-1,508	-275
GBP	-313	-1,815	-690	-751
Other currencies	-	-17	-169	-
Total	-7,132	-4,511	-3,834	-1,538

Had the Swedish krona weakened/strengthened by 5 percent in relation to the US dollar, with all other variables remaining constant, the recalculated profit/loss for the year and equity at 31 December 2014, would have been SEK 17 thousand (31 December 2013: SEK 315 thousand, 31 December 2012: SEK 106 thousand, 1 January 2012: SEK 3,424 thousand) higher/lower. On 1 January, 2012, gains/losses on translation of trade receivables in USD had had a major impact, as they were temporarily high. Changes to SEK in relation to EUR and GBP are not deemed to have any material impact on profit/loss for the year.

#### (b) Credit risk

Credit risk exists through cash and cash equivalents and cash balances with banks and financial institutions, and credit exposures to customers, wholesalers and retailers, including outstanding receivables and committed transactions. Only banks and financial institutions that are among the four largest Swedish banks according to Standard & Poor's rating list are accepted.

Before an agreement is entered into, the Group's customers are subjected to a credit assessment, whereupon information about the customer's financial position is accessed from various credit assessment companies. The overall assessment also considers other factors. The customer's financial position is also followed up and continually monitored. Trade receivables are continually followed up with checks on overdue invoices. Management does not expect any losses resulting from non-payment as the Group's counterparties mainly comprise major companies, which is why the credit risk is currently deemed to be low.

#### (c) Liquidity risk

The Group closely monitors rolling forecasts for its liquidity reserve to ensure that the Group has sufficient cash funds to meet requirements in the ordinary course of business.

The table below analyses the Group's non-derivative financial liabilities classified by the time that, on the balance sheet date, remained until the contractually agreed maturity date. The amounts given in the table are the contractually agreed undiscounted cash flows.

Group, 31 December, 2014	Up to one month	1–3 months	3 months– 1 year	1–5 years
Liabilities to Group companies	1,697			
Trade payables	9,938			
Other short-term liabilities	191			
Total	11,826	-	-	-
Group, 31	Up to one	1–3	3 months-	1–5
December, 2013	month	months	1 year	years
Liabilities to Group companies			508	
Trade payables	7,769			
Other short-term liabilities	191			
Total	7,960	-	508	-
Group,	Up to one	1–3	3 months-	1–5
31 December, 2012	month	months	1 year	years
Liabilities to Group companies			382	
Trade payables	6,288			
Other short-term				

Group, 1 January, 2012	Up to one month	1–3 months	3 months– 1 year	1–5 years
Liabilities to Group companies			3,393	
Trade payables	2,716			
Other short-term liabilities	191			
Total	2,907	-	3,393	-

192

382

6,480

#### 2.2 Management of capital

liabilities

Total

The aim of the Group regarding capital structure is to ensure the Group's ability to continue its operations so that it can continue to generate a return for shareholders and benefit for other stakeholders,

as well as maintaining an optimal capital structure to keep costs of capital down.

To maintain or adjust the capital structure, the Group can issue new shares or sell assets to reduce debt.

The Group is mainly engaged in research and development activities. Operations have been financed through capital contributions from the parent company Sandberg Development AB, as well as through earnings generated from successful research and development projects. Equity is therefore viewed as the Group's capital.

#### 2.3 Fair value estimation

The Group does not hold any instruments that are measured at fair value. The fair value of current receivables and liabilities corresponds to their carrying amounts, since discounting effects are minimal.

#### Not 3 – Important estimates and assessments

Estimates and assessments are evaluated continually and are based on historic experience and other factors, including expectations of future events that are judged reasonable under prevailing conditions.

# Important estimates and assessments for accounting purposes

Group management makes estimates and assumptions cconcerning the future. There is a risk that the estimates made for accounting purposes do not corresponding to the actual result. The estimates and assumptions that involve a significant risk of material adjustments to carrying value of assets and liabilities within the next coming financial year, are outlined in brief below.

#### Revenue recognition

Camurus has complex customer agreements and the management must make assessments and estimates when applying revenue recognition principles. The section entitled 'Accounting policies' regarding revenue details the areas for which assessments and estimates need to be carried out. Key areas in the assessment include the division of agreements in various sub-transactions, how the price of these transactions should be allocated, the point in time at which transactions should be recognized and the way in which the transaction should be recognized (on a single occasion or over a period of time). Camurus also needs to decide whether an agreement that includes a license to utilize Camurus' intellectual property constitutes a sale of the license in the form of a good that is recognized as revenue on delivery, or whether the agreement constitutes right of use, which is recognized as revenue over time. The assessments made by management affect the period in which, and amount at which the revenue is recognized.

#### IFRS 2 Share-based Payment

Camurus has a cash-settled share-based bonus program aimed at specific employees and all Board members (apart from Per Sandberg) at Camurus, in which the right to receive a bonus in relation to bonus shares issued begins with an exit event, which means a transfer of more than 90 percent of all shares in Camurus or a public listing of Camurus' shares within the period prescribed in the program. The bonus amount is a certain percentage of the agreed purchase price on transfer of the shares in Camurus, or the equivalent percentage of the enterprise value on a public listing of Camurus' shares. The cash bonus program is classified in accordance with IFRS 2 Share-based Payment as a cash-settled share-based payment, where Camurus receives services from its employees by undertaking a commitment to transfer cash to the employees in exchange for an amount based on the price or value of Camurus' Shares. The fair value of the cash bonus program is expensed with a corresponding increase in liabilities. At each balance sheet date, Camurus assesses the likelihood of service and performance conditions being fulfilled. During the reporting period, Camurus has concluded that it is not likely that an exit event will occur within the period prescribed in the program and therefore no cost or liability regarding the cash bonus program has been recognized as per 31 December 2014.

In 2015, the bonus program was converted into a share bonus program, see note 28.

#### Capitalized product development expenditure

The Group capitalizes costs attributable to product development projects to the extent that they are deemed to satisfy the criteria in accordance with IAS 38 p. 57 (see note 1.6 Intangible assets).

Intangible assets that are not ready for use are not subject to amortization but are tested annually for impairment. Impairment testing for capitalized development costs has therefore been carried out to ensure that the carrying amount does not exceed the recoverable amount. The material assumptions used for calculations of value in use include:

- Market size
- Anticipated market share
- Anticipated economic benefits
- Discount rate
- Anticipated growth rate

#### Not 4 – 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

Below a breakdown of revenue from all products and services:

	2014	2013	2012
Sales of development-related goods and services	33,674	18,708	6,529
Milestone payments	18,025	0	0
Licensing revenues	153,687	174,857	76,431
Other	2,821	4,151	12,244
Total	208,207	197,716	95,204

Revenue from external customers is allocated by geographical area, based on where the customers are located:

Total	208,207	197,716	95,204
Other geographical areas	177	964	325
North America	5,697	2,294	27,737
(of which Sweden)	(47)	(44)	(99)
Europe	202,333	194,458	67,142
	2014	2013	2012

Revenue of approximately SEK 128.8 million for 2014, SEK 192.4 million for 2013 and SEK 62.3 million for 2012 relates to a single external customer.

All fixed assets are located in Sweden.

#### Not 5 – Expenses divided by type of

Operating expenses are presented in the statement of comprehensive income with a classification based on the functions 'Cost of sales', 'Marketing and distribution costs', 'Administrative expenses' and 'Research and development costs'. The total costs by function were allocated according to the following cost items.

Allocation by cost item	2014	2013	2012
Changes in stock of finished goods and work in progress	2,383	-1,389	-838
Raw materials and consumable supplies	427	2,964	4,159
Other external expenses <sup>1, 2</sup>	90,278	28,162	36,110
Costs of premises, including laboratory costs	13,520	11,279	9,277
Costs relating to employee benefits (note 8) <sup>2</sup>	40,332	34,016	25,628
Depreciation, amortization and impairment losses (notes 13 and 14)	1,429	814	693
Total cost of sales, research and development, sales and administration	148,369	75,846	75,029

<sup>1</sup> This item includes costs that form the basis for research and development projects.

<sup>2</sup> Costs incurred for partner-financed activities within research and development during the period have most essentially matched the size of the revenue. See also note 4 Segment information and the item 'Sales of development-related goods and services'.

# Not 6 – Other operating income

Other operating income	2014	2013	2012
Exchange gains	2,423	5,345	67
Other items	58	101	47
Total other operating income	2,481	5,446	114

# Not 7 – Audit fees

Auditing assignments include auditing of the annual financial statements and accounting, as well as the management by the Board and the Chief Executive Officer, other duties incumbent upon the company's auditors to perform, along with advice or other assistance required as a result of observations during such audit or the performance of such other duties. Everything else is regarded as other assignments.

Group	2014	2013	2012
Mazars SET Revisionsbyrå AB			
Auditing assignment	282	193	124
Total	282	193	124

# Not 8 – Expenses for employee compensations.

	2014	2013	2012
Salaries and other compensation	26,834	21,292	16,295
Social security	8,236	8,287	5,763
Pension expenses – defined contribution plans	4,332	3,189	2,695
Total	39,402	32,768	24,753

Salaries and other remuneration			
(of which bonus)	2014	2013	2012
Board members, CEO and	6,626	5,069	4,647
other senior management	(1,732)	(1,450)	(851)
Other employees	20,208	16,223	11,648
Total	26,834	21,292	16,295
Pension expenses	2014	2013	2012
Board members, CEO and			
other senior management	1,583	1,163	1,316
Other employees	2,749	2,026	1,379
Total	4,332	3,189	2,695

	2014	2013	2012
Gender distribution in the			
Group (incl. subsidiaries)			
for Board members and	Number	on balance s	heet date
other senior management	(of	which wom	nen)
Board members	7	7	6
CEO and other senior			
management	5 (2)	4 (1)	4 (1)
Total	12	11	10
	2014	2013	2012
	(of which	(of which	(of which
Average no. of employees	women)	women)	women)
Sweden	38 (24)	35 (22)	27 (16)

For remuneration and other benefits to the Board and senio management , see note 27 Related party transactions. See also note 23 Sharebased Payment.  $\mathsf{v}$ 

# Not 9 – Finance income and expenses

Finance income	2014	2013	2012
Interest income, cash pool	394	72	-
Interest income, other	-	1	1
Finance income	394	73	1
Finance expenses	2014	2013	2012
Interest expenses, cash pool	-168	-119	-902
Interest expenses, other	-2	-2	-
Finance expenses	-170	-121	-902
Total financial items – net	224	-48	-901

# Not 10 – Income tax

	2014	2013	2012
Income tax:			
Income tax on profit for the year	-10,237	-	-
Tax on Group contributions	-	-25,217	5,479
Total current tax:	-10,237	-25,217	5,479
Deferred tax (see note 15)	-3,960	-2,815	-10,022
Total deferred tax	-3,960	-2,815	-10,022
Income tax	-14,197	-28,032	-4,543

The income tax on profit differs from the theoretical amount that would have resulted from the use of a weighted average tax rate for earnings in the consolidated companies in accordance with the following:

	2014	2013	2012
Profit/loss before tax	62,543	127,268	17,860
Income tax is calculated in accordance with the national tax rates in force prior to the results in			
each country	-13,759	-27,999	-4,697
Tax effects of:			
- Non-taxable revenue	0	0	0
- Non-deductible expenses	-56	-33	-40
- Tax loss for which no deferred tax asset has been recognized	-382	-	-
- Difference in tax rate between current tax (26.3%) and deferred tax (22%)	-	-	194
Tax expense	-14,197	-28,032	-4,543

Weighted average tax rate for the Group is 22.7 percent (2013: 22.0 percent, 2012: 25.4 percent). The main change relates to reduced national tax rates as of 2013.

# Not 11 – Earnings per share

#### (a) Basic

Basic earnings per share is calculated by dividing the profit or loss 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.

	2014	2013	2012
Profit/loss attributable to parent company shareholders	48,346	99,235	13,317
Weighted average number of outstanding ordinary shares (thousands)	5,865	5,835	5,835

## (b) Diluted

In order to calculate diluted earnings per share, the weighted average number of outstanding ordinary shares is adjusted to take into account the effect of diluting all potential ordinary shares. The parent company has one category of potential ordinary shares with dilution effect: 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 with the number of shares that would have been issued assuming the warrants are exercised. For further information regarding the warrant program, see note 27 Related party transactions.

	2014	2013	2012
Profit/loss attributable to parent company shareholders	48,346	99,235	13,317
Weighted average number of outstanding ordinary shares (thousands)	5,865	5,835	5,835
Adjustments for:			
- warrants (thousands)	437	467	467
Weighted average no. of ordinary shares in calculation of diluted earnings per share (thousands)	6,302	6,302	6,302

# Not 12 – Exchange rate differences

Exchange rate differences have been recognized in the income statement as follows:

	2014	2013	2012
Other operating income (note 6)	2,423	5,345	67
Other operating expenses	-	-	-1,524
Total exchange rate differences in income			
statement	2,423	5,345	-1,457

# Not 13 – Intangible assets

	Capitalized development expenditure
On 1 January, 2012	
Acquisitions	3,566
Opening balance	3,566
2012 financial year	
Opening balance	3,566
Capitalized expenses	3,855
Closing balance	7,421
On 31 December, 2012	
Cost	7,421
Opening balance	7,421
2013 financial year	
Opening balance	7,421
Capitalized expenses	13,302
Closing balance	20,723
On 31 December, 2013	
Cost	20,723
Carrying amount	20,723
2014 financial year	
Opening balance	20,723
Capitalized expenses	1,828
Closing carrying amount	22,551
On 31 December, 2014	
Capitalized expense	22,551
Closing balance	22,551

Impairment testing has been carried out for the above carrying amounts as they relate to intangible assets that are not yet ready for use, with the conclusion that an impairment requirement does not exist. The impairment testing comprises the recoverable amount of the cash-generating unit's estimated value in use.

# Not 14 – Property, plant, and equipment

	Equipment
On 1 January, 2012	
Investments	5,447
Accumulated depreciation	-3,552
Closing balance	1,896
2012 financial year	
Opening balance	1,896
Investments	1,261
Sales and disposals	-3
Depreciation	-693
Closing balance	2,461
On 31 December, 2012	
Investments	6,583
Accumulated depreciation	-4,122
Closing balance	2,461
2013 financial year	
Opening balance	2,461
Investments	1,529
Sales and disposals	0
Depreciation	-814
Closing balance	3,176
On 31 December, 2013	
Investments	8,103
Accumulated depreciation	-4,927
Closing balance	3,176
2014 financial year	
Opening balance	3,176
Investments	5,419
Sales and disposals	-47
Depreciation	-1,429
Closing balance	7,119
On 31 December, 2014	
Investments	12,742
Accumulated depreciation	-5,623
Closing balance	7,119

Depreciation expenses of SEK 1,429 thousand (2013: SEK 814 thousand, 2012: SEK 693 thousand) are included in their entirety among administrative expenses.

# Not 15 – Deferred tax

Deferred tax assets and tax liabilities are distributed as follows:

	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
Deferred tax assets				
Deferred tax assets to be used after 12 months	238	199	114	156
Deferred tax assets to be used within 12 months	-	-	-	9,159
Total deferred tax assets	238	199	114	9,315
Deferred tax liabilities				
Deferred tax liabilities to be used after 12 months	-8,317	-4,776	-1,876	-1,055
Deferred tax liabilities to be used within 12 months	-458	-	-	-
Total deferred tax liabilities	-8,775	-4,776	-1,876	-1,055
Deferred tax liabilities/assets (net)	-8,537	-4,577	-1,762	8,260
Gross change regarding deferred taxes:				
		2014	2013	2012
Opening balance		-4,577	-1,762	8,260
Recognition in income statement (note 10)		-3,960	-2,815	-10,022
Closing balance		-8,537	-4,577	-1,762

Details of changes in deferred tax assets and tax liabilities during the year that have not been recognized in the income statement, excluding offsetting that has been carried out within the same tax jurisdiction, are given below:

	Untaxed	Intangible	
Deferred tax liabilities	reserves	assets	Total
On 1 January, 2012	-271	-784	-1,055
Recognized in income statement	28	-849	-821
On 31 December, 2012	-243	-1,633	-1,876
Recognized in income statement	26	-2,926	-2,900
On 31 December, 2013	-217	-4,559	-4,776
Recognized in income statement	-3,597	-402	-3,999
On 31 December, 2014	-3,814	-4,961	-8,775
	Reserved	Accrued	
Deferred tax assets	pension costs	revenue	Total
On 1 January, 2012	156	9,159	9,315
Recognized in income statement	-42	-9,159	-9,201
On 31 December, 2012	114	-	114
Recognized in income statement	85	-	85
On 31 December, 2013	199	-	199
Recognized in income statement	39	-	39
On 31 December, 2014	238	-	238

# Not 16 – Interests in Group companies

The Group has shares in the following subsidiaries:

		Country of registration and	Share of	Number of
Name	Corp. ID No.	operation	equity	shares
Camurus Inc	43-1648843	USA	100 %	1,000
Cubosome Inc	43-1648841	USA	100 %	1,000
Camurus Development AB	556421-1208	Sweden	100 %	3,591,143
Bioimplant Scandinavia AB	556372-5885	Sweden	-/(100 %)	-/(1,000)
Total				

The share of voting rights corresponds to the share of equity

On 3 July, 2012, the shares in Bioimplant Scandinavia AB were acquired from the parent company Sandberg Development AB. The transaction is what is known as a 'transaction between companies under common control'. IFRS 3 Business Combinations excludes transactions involving companies under common control. Under IFRS it is possible to argue that both the acquisition method in accordance with IFRS 3 (fair value) and historical carrying amounts can be used for transactions between companies under common control. Company management has opted to use historical values and will apply the chosen principle consistently. The purchase price amounted to SEK 100 thousand.

On 31 December 2014, the shares in Bioimplant Scandinavia AB were sold to the parent company Sandberg Development AB. The purchase price amounted to SEK 100 thousand.

## Not 17 – Financial instruments by category

Loans and receivables 157,908 6,118 0 56 164,082 70,664 7,790 2 5 78,461
6,118 0 56 <b>164,082</b> 70,664 7,790 2 5
6,118 0 56 <b>164,082</b> 70,664 7,790 2 5
0 56 <b>164,082</b> 70,664 7,790 2 5
56 <b>164,082</b> 70,664 7,790 2 5
<b>164,082</b> 70,664 7,790 2 5
70,664 7,790 2 5
7,790 2 5
7,790 2 5
7,790 2 5
2
5
78,461
37,049
4,408
1
3
41,461
70,227
0
2

Liabilities in the balance sheet	Other financial liabilities
31 December, 2014	
Liabilities to Group companies	1,697
Trade payables	9,938
Other current liabilities	191
Total	11,826
21 December 2012	
31 December, 2013	
Liabilities to Group companies	508
Trade payables	7,769
Other current liabilities	191
Total	8,468

31 December, 2012	
Liabilities to Group companies	382
Trade payables	6,288
Other current liabilities	192
Total	6,862
1 January, 2012	
Liabilities to Group companies	3,393
Trade payables	2,716
Other current liabilities	191
Total	6,300

Namn	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
Cash pool	157,986	187,702	18,826	-24,719
Group contributions received/paid	-	-116,922	18,442	25,278
Other settlement	100	120	-9	-3,952
Accrued expenses	-178	-236	-210	-192
Total	157,908	70,664	37,049	-3,585

# Not 18 - Parent company's transactions with principal shareholder

The summary gives details of the transactions that the parent company Camurus AB has with principal shareholder Sandberg Development AB.

# Not 19 – Trade receivables

	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
Trade receivables	6,118	7,790	4,408	70,227
Deduction: Provision for bad debts	-	-	-	-
Trade receivables – net	6,118	7,790	4,408	70,227

Sound receivables on 31 December 2014, totaled SEK 6,118 thousand (31 December 2013: SEK 7,790 thousand, 31 December 2012: SEK 4,408 thousand, 1 January 2012: SEK 70,227 thousand) for the Group.

On 31 December 2014, overdue trade receivables stood at SEK 1,551 thousand (31 December 2013: SEK 2,079 thousand, 31 December 2012: SEK 277 thousand, 1 January 2012: SEK 166 thousand), but without any impairment requirement deemed to exist for the Group. The overdue receivables relate to a number of customers who have not previously had any payment difficulties.

Their aging analysis is as follows:

Reported amount, by currency, for trade receivables are as follows:

2014         2013         2012         2011           1-30 days         1,482         1,808         16         16           31-60 days         0         219         0         261           > 61 days         69         52         261         261           Total overdue					
31-60 days         0         219         0           > 61 days         69         52         261           Total overdue         2         2         2					01 Jan. 2012
> 61 days 69 52 261 Total overdue	1–30 days	1,482	1,808	16	166
Total overdue	31–60 days	0	219	0	0
	> 61 days	69	52	261	0
		1,551	2,079	277	166

	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
SEK	8	3	0	5
EUR	779	640	798	1,220
USD	5,296	7,108	3,601	69,001
Other currencies	35	39	9	-
Total trade receivables	6,118	7,790	4,408	70,227

The Group has not had any trade receivables with an impairment requirement.

# Not 20 – Prepayments and accrued income

	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
Prepayments	2,105	1,779	1,105	1,078
Accrued income relating to unbilled costs	7,796	374	-	-
Accrued income, other	1,024	746	-	-
Total	10,925	2,899	1,105	1,078

## Not 21 – Cash and cash equivalents

The following is included in cash and cash equivalents in the balance sheet and cash flow statement:

	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
Cash and bank deposits	54	3	0	0
Petty cash	2	2	3	2
Total	56	5	3	2

	Number		Other	
	of shares		contributed	
	(thousands)	Share capital	capital	Total
On 1 January, 2012	5,835	583	33,617	34,200
On 31 December, 2012	5,835	583	33,617	34,200
On 31 December, 2013	5,835	583	33,617	34,200
Exercise of warrants/new shares	467	47	25,017	25,064
On 31 December, 2014	6,302	630	58,634	59,264

# Not 22 – Share capital and other contributed capital

Share capital consists of 6,302,140 shares with a quota value of SEK 0.10. The shares carry a voting right of one (1) vote per share. All shares issued by the parent company are fully paid up.

On 9 December 2014, 466,830 outstanding warrants were exercised, corresponding to 466,830 new shares and an increase in the share capital of SEK 46,683. The subscription price was SEK 53.69 per new share, corresponding to a total of SEK 25,064,103, of which SEK 25,017,420 has been transferred to other contributed capital. The new shares were registered on 9 January, 2015.

# Not 23 – Share-based Payment

Camurus has a cash-settled share-based bonus program aimed at specific employees and all Board members (apart from Per Sandberg) at Camurus, in which the right to receive a bonus in relation to bonus shares issued begins with an exit event, which means a transfer of more than 90 percent of all shares in Camurus or a public listing of Camurus' shares within the period prescribed in the program. The bonus amount is a certain percentage of the agreed purchase price on transfer of the shares in Camurus, or the equivalent percentage of the enterprise value on a public listing of Camurus' shares. The cash bonus program is classified in accordance with IFRS 2 Share-based Payment as a cash-settled share-based payment, where Camurus receives services from its employees by undertaking a commitment to transfer cash to the employees in exchange for an amount based on the price or value of Camurus' Shares. The fair value of the cash bonus program is expensed with a corresponding increase in liabilities. At each balance sheet date, Camurus assesses the likelihood of service and performance conditions being fulfilled. During the reporting period, Camurus has concluded that it is not likely that an exit event will occur within the period prescribed in the program and therefore no cost or liability regarding the cash bonus program has been recognized as at 31 December 2014.

In 2015, the bonus program was converted into a share bonus program, see note 28.

# Not 24 – Accruals and deferred income

	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
Accrued holiday pay and other items	6,887	5,775	3,302	3,477
Accrued social security contributions	5,000	4,104	2,485	2,692
Accrued expenses relating to clinical studies	14,143	4,601	1,389	-
Accrued expenses, other	894	1,415	557	607
Accrued licensing revenues	26,228	31,688	-	62,242
Total	53,152	47,583	7,733	69,018

# Not 25 – Leases

**Operating leases** 

The Group only has operating leases relating to premises, cars and machinery.

Future minimum lease payments in accordance with non-cancellable operating leases valid at the end of the reporting period are due for payment as follows:

	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
0–1 year	5,407	5,242	3,217	3,055
1–5 years	13,224	18,309	6,020	224
> 5 years	-	-	-	-
Group total	18,631	23,551	9,237	3,279

Costs for operating leases in the Group during the financial year have amounted to SEK 5,279 thousand (2013: SEK 3,892 thousand, 2012: SEK 3,139 thousand).

#### Not 26 – Other non-cash items

	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012
Depreciation	1,427	814	693
Other	-	-	6
Total	1,427	814	699

#### Not 27 – Related party transactions

Sandberg Development AB owns 85.5 percent of the shares in Camurus AB and therefore has a controlling interest in the Group. The remaining 14.5 percent is owned by the CEO, other private individuals and a foundation. Sandberg Development AB is in turn 100-percent owned by PGS Group AB, which is in turn 100-percent owned by Per Sandberg. Other related parties are all subsidiaries in the Group, along with key management personnel in the Group, i.e. the Board and company management, as well as their family members.

The following transactions have occurred with related parties:

#### (a) Purchase of services

	2014	2013	2012
Purchase of services:			
- Parent company (primarily IT and administrative services)	2,789	2,790	2,604
Summa	2,789	2,790	2,604

Goods and services are purchased and sold on normal commercial terms.

Transactions with Sandberg Development AB occur regarding IT and HR support services supplied. Pricing is done in accordance with allocation of costs in relation to utilization rate and on commercial terms.

#### (b) Remuneration for executive management

Executive management have received the following remuneration:	2014	2013	2012
Salaries and other short-term benefits	6,276	4,750	4,397
Termination benefits	-	-	-
Post-employment benefits	-	-	-
Other long-term benefits	1,583	1,163	1,316
Share-based payment	-	-	-
Total	7,859	5,913	5,713

#### Guidelines

Fees are paid to the Chairman of the Board, Board members and for committee work in accordance with decisions made by the AGM.

The AGM has decided on the following guidelines regarding remuneration to management. Remuneration to the Chief Executive Officer and other key management personnel comprises basic salary, variable pay, other benefits and financial instruments, etc. Other key management personnel includes those individuals who together with the CEO form Group management. For the current composition of Group management, see p.80-81.

The division between basic salary and variable pay must be in pro-

portion to the executive's level of responsibility and authority. For the CEO, variable pay in 2014 was set at a maximum of SEK 0.8 million, and in 2012–2013 it was set at SEK 1 million. For other key management personnel, variable pay was set at a maximum of 33 percent of basic salary in 2014, and in 2012–2013 a maximum of 42 percent. Variable pay is based on the outcome of established business targets.

Other benefits to the CEO and other key management personnel are paid as part of total remuneration. Pension cost includes expenses for pensions payable according to agreements.

# Remuneration and other benefits 2014

	Basic salary/ Board fee	Variable remuneration	Other benefits	Pension expenses	Other remuneration	Total
Board of Directors						
Björn Olsson, chair	170	-	-	-	-	170
Per-Olof Wallström	60 <sup>1</sup>	-	-	-	-	60
Svein Mathisen	60	-	-	-	-	60
Martin Jonsson	-	-	-	-	-	-
Fredrik Tiberg	-	-	-	-	-	-
Per-Anders Abrahamsson	60 <sup>1</sup>	-	-	-	0	60
Per Sandberg	-	-	-	-	-	-
Group management						
Fredrik Tiberg, CEO	1,754	800	76	646	-	3,276
Other executive management (4 individuals)	2,790	932	187	937	-	4,846
Total	4,894	1,732	263	1,583	-	8,472

<sup>1</sup> Remuneration invoiced via company

#### Remuneration and other benefits 2013

	Basic salary/ Board fee	Variable remuneration	Other benefits	Pension expenses	Other remuneration	Total
Board of Directors						
Björn Olsson, chair	110	-	-	-	-	110
Per-Olof Wallström	60 <sup>1</sup>	-	-	-	-	60
Svein Mathisen	50	-	-	-	-	50
Martin Jonsson	-	-	-	-	-	-
Fredrik Tiberg	-	-	-	-	-	-
Per-Anders Abrahamsson	O <sup>1</sup>	-	-	-	100 <sup>1</sup>	100
Per Sandberg	-	-	-	-	-	-
Group management						
Fredrik Tiberg, CEO	1,572	836	72	573	-	3,053
Other executive management (3 individuals)	1,727	615	127	590	-	3,059
Total	3,519	1,451	199	1,163	100	6,432

<sup>1</sup> Remuneration invoiced via company.

#### Remuneration and other benefits 2012

	Basic salary/ Board fee	Variable remuneration	Other benefits	Pension expenses	Other remuneration	Total
Board of Directors						
Per Sandberg, Chairman	-	-	-	-	-	-
Björn Olsson	50	-	-	-	-	50
Svein Mathisen	50	-	-	-	-	50
Fredrik Tiberg	-	-	-	-	-	-
Per-Anders Abrahamsson	O <sup>1</sup>	-	-	-	100 <sup>1</sup>	100
Per-Olof Wallström		-	-	-	50 <sup>1</sup>	50
Group management						
Fredrik Tiberg, CEO	1,439	500	76	512	-	2,527
Other executive management (3 individuals)	2,107	351	121	804	-	3,383
Total	3,646	851	197	1,316	150	6,160

<sup>1</sup> Arvode fakturerat genom bolag.

#### **Financial instruments**

#### Warrants

On 7 December 2010, at the company's AGM, 466,830 warrants were issued with a right to subscribe to the equivalent number of shares in the Company during the period 1 December 2014 – 31 December 2014. The warrants were subscribed by the CEO at a subscription price corresponding to the fair value of the warrants, which is why no cost is recognized in the income statement regarding this program. The subscription price was recognized as other contributed capital. In December 2014, the CEO sold 105,000 warrants to Sandberg Development AB and exercised the other 361,830 warrants for subscription of the equivalent number of shares in the Company at a subscription price of SEK 53.69 per share (according to terms of issue). Sandberg Development AB exercised 105,000 warrants for subscription of the equivalent number of shares in the Company at a subscription price of SEK 53.69 per share (according to terms of issue). Sandberg Development AB exercised 105,000 warrants for subscription of the equivalent number of shares in the Company at a subscription price of SEK 53.69 per share.

#### Share-based payment

See note 23 Share-based Payment.

#### Pensions

The pensionable age for the Chief Executive Officer and key management personnel is 65 years.

#### **Termination benefits**

The notice period between the Company and CEO is 12 months from the Company, and 6 months from the CEO. If the CEO's employment at the Company ceases as a result of, or in connection with the Company being transferred to a new owner, a notice period of 24 months from the Company applies. During the notice period a fixed monthly salary is paid, along with other remuneration in accordance with the applicable employment agreement. Remuneration from the Company will not in this case be reduced by any other possible remuneration that the CEO may receive during the notice period. No severance pay is payable in the event of notice being given by the CEO.

A mutual notice period of 3–6 months applies between the company and other key management personnel.

#### (c) Receivables and liabilities at year-end resulting from purchase of services and cash pool arrangement

Receivables from related parties	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
Sandberg Development AB	157,908	70,664	37,049	-
Total	157,908	70,664	37,049	-

Receivables from related parties are essentially derived from a joint cash pool plus Group contributions paid/received. The Group has not made any provisions for bad debts from related parties.

Liabilities to related parties	31 Dec. 2014	31 Dec. 2013	31 Dec. 2012	01 Jan. 2012
Sandberg Development AB	-	508	382	3,585
Bioimplant Scandinavia AB	1,697	-	-	-
Total	1,697	508	382	3,585

The liability as per Jan 1, 2012, essentially related to the cash pool balance less Group contributions received. On 31 December 2012 and 2013, the liability related to the cash pool in Bioimplant Scandinavia AB. The liability as per 31 December 2014, concerns shareholder contributions to Bioimplant Scandinavia AB.

# (d) Acquisition and sales of shares in Bioimplant

Scandinavia AB

See note 16 Interests in Group companies.

#### Not 28 – Events after the balance sheet date

On 12 June, 2015, a modification was made to the cash-settled sharebased bonus program, in that on the share listing date, employees and Board members of Camurus will receive a share bonus in the form of shares in Camurus instead of cash. The share bonus comprises 1,909,483 newly issued shares, which are divided between employees and Board members in accordance with the bonus agreement entered into. The shares are received in exchange for payment of the share's quotient value of SEK 0.025 per share, i.e. essentially free of charge. The issue, which was decided on 18 November 2015, is conditional on the implementation of the Offering.

Up until the point the program was modified, Camurus did not consider it likely that an exit event would occur, which is why no cost or liability regarding the bonus program was recognized from previously.

At each balance sheet date, Camurus assesses the likelihood of service and performance conditions being fulfilled. On 30 June, 2015, Camurus deemed that an exit event through a public listing was likely. Since the bonus program was allocated to the employees during a previous accounting period, and has therefore already been partly earned, costs for this program have impacted on earnings in June 2015 up to and including the intended date for allocation, which it is assumed will coincide with the public listing. The total cost of the bonus program is expected to amount to SEK 125.3–149.9 million, including social security contributions before tax, with a corresponding increase in equity of SEK 97.4–116.5 million and liability regarding social security contributions of SEK 27.9–33.4 million. Since the total cost is of an unusual nature and significant, the item ise recognized as an item affecting comparability in this and future financial reports.

The principal shareholder Sandberg Development AB will subscribe for 426,601 newly issued shares in a directed new share issue in order to cover the corresponding of approximately 78 percent of the portion that affects the Company's earnings with respect to social security contributions related to the program.

# Audit report regarding reworked financial reports on historical financial information

#### To the Board of Directors of Camurus AB, corporate identity no. 556667-9105

#### Auditors' report on revised financial statements containing historical financial information

We have audited the financial statements for Camurus AB and its subsidiaries ("the Group") on pages 131-153, which comprise the balance sheets as of 31 December 2014, 31 December 2013 and 31 December 2012 and the income statements, cash flow statements and statements of changes in equity for the years then ended, and a summary of significant accounting policies and other explanatory notes.

#### The Board of Director's and the Managing Director's responsibility for the financial statements

The Board of Directors and the Managing Director are responsible for the preparation of the financial statements and for ensuring that these financial statements provide a true and fair view of the financial position, financial performance, changes in equity and cash flows in accordance with International Financial Reporting Standards as adopted by the EU, and according to the Annual Accounts Act and all applicable supplementary standards. This responsibility includes designing, implementing and maintaining the internal control relevant to prepare and appropriately present the financial statements free from material misstatement, whether due to fraud or error. The Board of Directors is also responsible for the preparation of the financial statements and for ensuring that these financial statements are presented according to the requirements of the Prospectus Directive implementing Regulation 809/2004/EC.

#### The auditors' responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with FAR SRS's Recommendation RevR 5 Examination of Prospectuses. This recommendation requires that we have complied with ethical guidelines and that we have planned and performed the audit to obtain reasonable assurance that the financial statements are free from material misstatement.

An audit conducted in accordance with FAR SRS's Recommendation RevR 5 Examination of Prospectuses involves performing procedures to obtain audit evidence corroborating the amounts and disclosures in the financial statements. The audit procedures selected depend on our assessment of the risks of material misstatement in the financial statements, whether due to fraud or error. In making these risk assessments, we consider internal control relevant to the Company's preparation and presentation of the financial statements as a basis for designing audit procedures that are applicable under those circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. An audit also involves evaluating the accounting policies applied and the reasonableness of the significant accounting estimates made by the Board of Directors and the Managing Director, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence obtained comprises sufficient and appropriate supporting documentation for our opinion.

#### Opinion

In our opinion, the financial statements give a true and fair view of the financial position, financial results, changes in equity and cash flows of Camurus AB (publ) AB as of 31 December 2014, 31 December 2013 and 31 December 2012, in accordance with the International Financial Reporting Standards adopted by the EU and in accordance with Annual Accounts Act and all applicable supplementary standards.

Lund, 18 November 2015

Mazars SET Revisionsbyrå AB Gunilla Malmsten Auditor-in-Charge Authorised Public Accountant PricewaterhouseCoopers AB Ola Bjärehäll Auditor-in-Charge Authorised Public Accountant

# Glossary

Acromegaly	A disorder caused by overproduction of growth hormones resulting in abnormal body growth
Agonist	A drug or other substance that binds to and blocks a receptor and thereby stimulates the activ-
	ity of the receptor
Analogue	Similar molecular structure
Androgen	Male sexual hormone
Antagonist	A drug or other substance that binds to and blocks a receptor without stimulating the activity of the receptor
Bioadhesive	
	A substance that is adhesive to biological surfaces
Bioavailability	The degree and rate at which a substance (as a drug) is absorbed by the body
Buprenorphine	Active ingredient that is strongly analgesic and that may be used for treatment of opioid depend- ence
CAGR	Compounded Annual Growth Rate, average an- nual growth
Cash pool	Cash management technique employed by companies
CE marking	CE marking of a product is used within the EU/ EEA to show that the manufacturer or importer has followed the essential requirements regarding safety, health, performance etc. that are outlined in the applicable EU directives
СНМР	Committee for Medicinal Products for Human Use, the committee at EMA that is responsible for preparing opinions on questions concerning medicines for human use
Clinical trials	Investigations performed in humans in order to study the properties of an investigational product
COWS	Clinical Opiate Withdrawal Scale, a scale used for clinical evaluation of withdrawal symptoms caused by opiates
CSA	US Controlled Substances Act of 1970
DATA 2000	US Drug Addiction Treatment Act of 2000
DEA	US Drug Enforcement Administration
Dispersion	Dissemination or distribution of a substance
EEA	European Economic Area
EMA	European Medicines Agency, a decentralized agency of the EU, responsible for the scientific evaluation of medicines developed by pharmaceu- tical companies for use in the EU
Endocrine diseases	Diseases affecting the endocrine system, i.e. the body's production, secretion and response to hormones
Endometriosis	A disease in which tissue that normally grows inside the uterus (endometrium) grows outside the uterus
EU5	France, Germany, Italy, the United Kingdom and Spain
EudraCT	European Union Drug Regulating Authorities Clinical Trials, the EU database for clinical trials
FDA	Food and Drug Administration, the US food and drug authority
FDCA	Federal Food, Drug and Cosmetic Act
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Gauge	The dimension of the outer diameter of an injec- tion needle. The gauge value decreases when the	
C C D	outer diameter increases	
GCP	Good Clinical Practice	
Generic drug	A drug that has the same active ingredient as a brand name drug	
GMP	Good Manufacturing Practice	
GnRH	Gonadotropin-Releasing Hormone	
IFRS	International Financial Reporting Standards	
IGF-1	Insulin-like Growth Factor 1	
In situ	On site, in position	
In vitro	Biological process that takes place outside a living cell or organism	
In vivo	Biological process that takes place in living cells and tissues in an organism	
Incidence	Number of new cases per population at risk	
IND	Investigational New Drug, classification that is required for development of a new drug in the US	
Intramuscular injection	Injection of a drug in a muscle, e.g. the gluteal muscle	
Intravenous injection	Injection of a drug into a vein	
Leuprolide	Active ingredient used for treatment of e.g. prostate cancer	
Lipids	Group of compounds consisting of fat or fat-like substances	
MAA	Marketing Authorisation Application, application for marketing authorisation of a drug within the EU/EAA	
Milestone payment	Economic compensation obtained within a frame work of a partner program when a specific goal has been achieved	
Morbidity	The incidence of a disease within a population	
Mortality	The incidence of death or number of deaths within a population	
Naloxone	Active ingredient used as an antidote to reverse respiratory depression after opioid or opiate overdoses	
Nanoparticle	Microscopic particle that behaves as a whole unit	
NDA	New Drug Application, application for approval from the FDA to commercialise a new drug in the US	
NET	Neuroendocrine tumours, a group of different kinds of hormone producing tumours	
Octreotide	Active ingredient used for treatment of e.g. cancer	
Oral mucositis	Inflammation of the oral mucosa that leads to ulcers and pain in the oral cavity	
Orphan drugs	Drugs intended to treat serious or life-threatening diseases that are so rare that pharmaceutical companies are reluctant to develop them for economic reasons	
Peptide	Molecule consisting of a chain of amino acids	
Pharmacodynamics	The biochemical and physiological effects of a drug on the body	

Pharmacokinetics	The fate of a drug within the body (i.e. the ab- sorption, distribution, metabolism and excretion)	
Pharmacovigilance	System for detection, assessment, understanding and prevention of adverse effects and other drug- related problems	
Pre-clinical studies	Studies performed in model systems, i.e. not in humans	
Prevalence	The proportion of a population that is affected with a particular disease or condition	
Reconstitution	Preparation of a drug before administration, often addition of a diluent to a powder	
SOWS	Subjective Opiate Withdrawal Scale, a scale used for subjective evaluation of withdrawal symptoms caused by opiates	
SSA	Somatostatin Anologues, the standard for safe and effective medical therapy for acromegaly and symptom control in NETs	
Subcutaneous injection	Injection of a drug under the skin	
Sublingual	Under the tongue	
the Directive	Directive 2001/83/EC of the European Parliament and of the Council of 06 November 2001 on the Community code relating to medicinal products for human use	
Toxicity	The degree to which a substance is toxic	
Transdermal	A route of administration wherein active ingre- dients are delivered across the skin for systemic distribution, e.g. via patches or ointments	
Viscosity	A measure of how viscous or thick a fluid is	
WHO	World Health Organization	

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