

## Submission Data File

General Information	
Form Type*	20-F
Contact Name	Chico Kim
Contact Phone	866-683-5252
Filer Accelerated Status*	Non-Accelerated Filer
Filer File Number	
Filer CIK*	0001607245 [Oasmia Pharmaceutical AB] (Oasmia Pharmaceutical AB)
Filer CCC*	*****
Filer is Shell Company*	N
Filer is Voluntary Filer*	N
Filer is Well Known Seasoned Issuer*	N
Confirming Copy	No
Notify via Website only	No
Return Copy	No
SROS*	NASD
Period*	04-30-2016
(End General Information)	

Document Information	
File Count*	11
Document Name 1*	v447572_20f.htm
Document Type 1*	20-F
Document Description 1	20-F
Document Name 2*	v447572_ex8-1.htm
Document Type 2*	EX-8.1
Document Description 2	EX-8.1
Document Name 3*	v447572_ex12-1.htm
Document Type 3*	EX-12.1
Document Description 3	Exhibit 12.1
Document Name 4*	v447572_ex12-2.htm
Document Type 4*	EX-12.2
Document Description 4	Exhibit 12.2
Document Name 5*	v447572_ex13-1.htm
Document Type 5*	EX-13.1
Document Description 5	Exhibit 13.1
Document Name 6*	v447572_ex13-2.htm
Document Type 6*	EX-13.2
Document Description 6	Exhibit 13.2
(End Document Information)	

Notifications	
Notify via Website only	No
E-mail 1	chico.kim@thevintagegroup.com
(End Notifications)	

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

**FORM 20-F**

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended April 30, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report. Not applicable

Commission file number 001-37604

**Oasmia Pharmaceutical AB**

(Exact name of Registrant as specified in its charter)

**Oasmia Pharmaceutical AB**

(Translation of Registrant's name into English)

**Sweden**

(Jurisdiction of incorporation or organization)

**Vallongatan 1  
SE-752 28 Uppsala  
Sweden**

(Address of principal executive offices)

**Mikael Asp  
Chief Executive Officer  
Oasmia Pharmaceutical AB**

**Vallongatan 1  
SE-752 28 Uppsala  
Sweden**

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Name of each exchange on which registered
American Depositary Shares, each representing three (3) Ordinary Shares, par value SEK 0.10 per share	Nasdaq Capital Market
Ordinary Shares, par value SEK 0.10 per share*	Not Applicable

\* Not for trading, but only in connection with the registration of the American Depositary Shares pursuant to requirements of the Securities and Exchange Commission.

Securities registered or to be registered pursuant to Section 12(g) of the Act.

**Not Applicable**

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

**Ordinary shares: 107 209 310 as per April 30, 2016**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes  No

Note—Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued by the International Accounting Standards Board

Other

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

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## Introduction

This document contains information required for the annual report on Form 20-F for the fiscal year ended April 30, 2016 of Oasmia Pharmaceutical AB (the "Form 20-F"). Unless the context specifically indicates otherwise, references in this Form 20-F to "Oasmia Pharmaceutical AB", "Oasmia Pharmaceutical", "Oasmia", "we", "our", "ours", "us", the "Company" or similar terms refer to Oasmia Pharmaceutical AB.

### Exchange rates

All references in this annual report to "\$" are to U.S. dollars, all references to "SEK" are to Swedish kronor and all references to "TSEK" are to Swedish kronor in thousands. Solely for the convenience of the reader some, but not all, Swedish krona and Euro amounts have been translated into U.S. dollars at the relevant exchange rate posted by the Federal Reserve Bank. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as of that or any other date.

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains estimates and forward-looking statements, principally in "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." Some of the matters discussed concerning our operations and financial performance include estimates and forward-looking statements within the meaning of the Securities Act and the Exchange Act.

These forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause our actual results of operations, financial condition, liquidity, performance, prospects, opportunities, achievements or industry results, as well as those of the markets we serve or intend to serve, to differ materially from those expressed in, or suggested by, these forward-looking statements. These forward-looking statements are based on assumptions regarding our present and future business strategies and the environment in which we expect to operate in the future. Important factors that could cause those differences include, but are not limited to:

- increasing expenses related to clinical studies and development of our product candidates;
  - our ability to obtain funding on acceptable terms or at all;
  - the inherent uncertainty of product development/commercialization of our products;
  - manufacturing and commercialization;
  - patents, including, but not limited to, legal challenges;
  - government regulation and approval, including, but not limited to, the expected regulatory approval dates for Paccal Vet, Paclical, and our other product candidates;
  - current revenue being insufficient to fund operating expenses;
  - future revenue being lower than expected;
  - the level of pricing and reimbursement for our products;
  - increasing competitive pressures in the industry;
  - general economic conditions or conditions affecting demand for the services offered by us in the markets in which it operates, both domestically and internationally, being less favorable than expected;
-

- fluctuations in the price of raw materials and utilities;
- currency fluctuations and hedging risks;
- worldwide economic and business conditions and conditions in the industries in which we operate;
- our relationships with our customers and suppliers;
- increased competition from other companies in the industries in which we operate;
- changing technology;
- serious adverse events or other safety risks related to our products;
- claims for personal injury or death arising from the use of products produced by us;
- the occurrence of accidents or other interruptions to our production processes;
- changes in our business strategy or development plans, and our expected level of capital expenses;
- our ability to attract and retain qualified personnel;
- regulatory, environmental, legislative and judicial developments;
- our ability to expand our pipeline of product candidates;
- our intention to pay dividends; and
- factors that are not known to us at this time.

Additional factors that could cause actual results, financial condition, liquidity, performance, prospects, opportunities, achievements or industry results to differ materially include, but are not limited to, those discussed under "Risk Factors" in this annual report. Additional risks that we may currently deem immaterial or that are not presently known to us could also cause the forward-looking events discussed in this annual report not to occur. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect" and similar words are intended to identify estimates and forward-looking statements. Estimates and forward-looking statements speak only at the date they were made, and we undertake no obligation to update or to review any estimate and/or forward-looking statement because of new information, future events or other factors. Estimates and forward-looking statements involve risks and uncertainties and are not guarantees of future performance. Our future results may differ materially from those expressed in these estimates and forward-looking statements. In light of the risks and uncertainties described above, the estimates and forward-looking statements discussed in this annual report might not occur and our future results and our performance may differ materially from those expressed in these forward-looking statements due to, inclusive of, but not limited to, the factors mentioned above. Because of these uncertainties, you should not make any investment decision based solely on these estimates and forward-looking statements.

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**PART I****ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS**

Not applicable.

**ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE**

Not applicable.

**ITEM 3. KEY INFORMATION****A. Selected financial information**

You should read the following selected financial data in conjunction with our financial statements and the related notes thereto appearing elsewhere in this annual report and in the section of this annual report entitled “Item 5. Operating and financial review.”

The following table summarizes our consolidated financial data as of the dates and for the periods indicated. The selected consolidated financial data for the fiscal years presented have been derived from our consolidated financial statements, which have been prepared in accordance with International Financial Reporting Standards (“IFRS”) issued by the International Accounting Standards Board (“IASB”) and interpretations issued by the International Financial Reporting Interpretations Committee. Furthermore, the recommendation RFR 1, Supplementary accounting regulations for Groups, issued by the Swedish Financial Reporting Board, has been applied. We have prepared the consolidated financial information set forth below on the same basis as our audited consolidated financial statements.

Our consolidated financial statements are prepared and presented in Swedish krona, which is our functional currency. All tables, if not expressly otherwise stated, in this annual report are therefore in Swedish krona.

Our historical results are not necessarily indicative of the results that may be expected in the future. The following summary consolidated financial data should be read in conjunction with the section “Item 5. Operating and financial review” and our consolidated financial statements included elsewhere in this annual report, including our discussions therein regarding the material weakness in our internal control over financial reporting identified by our auditors and the Company’s future financing and going concern.

Key figures are translated into USD as additional information as a service to readers of this annual report in the US. The US Dollar is not the functional currency of Oasmia, which is SEK. The conversion of currency has been made by use of a convenience rate for all figures including those from previous periods. This rate is the closing rate as per August 19, 2016 which was 8.3781 SEK per one USD.

**Consolidated income statement data:**

	2016 (TUSD)	2016 (TSEK)	2015 (TSEK)	2014 (TSEK)	2013 (TSEK) <i>Restated</i>
Net sales	761	6,373	2,070	60	-
Change in inventories of products in progress and finished goods	1,135	9,509	-	-	-
Capitalized development cost	1,997	16,727	16,797	29,464	46,229
Other operating income	0	2	221	4,454	2,524
Raw materials, consumables and goods for resale	(565)	(4,733)	(10,062)	(6,835)	(6,137)
Other external expenses	(11,710)	(98,104)	(60,740)	(75,189)	(62,616)
Employee benefit expenses	(6,882)	(57,661)	(50,530)	(45,101)	(42,408)
Depreciation, amortization and impairment	(573)	(4,804)	(5,190)	(4,941)	(5,089)
Other operating expenses	-	-	(792)	(3)	(86)
Operating income (loss)	(15,838)	(132,691)	(108,225)	(98,091)	(67,583)
Financial income	94	786	210	192	587
Financial expenses	(1,150)	(9,634)	(9,482)	(7,213)	(5,384)
Financial income and expenses - net	(1,056)	(8,848)	(9,272)	(7,021)	(4,798)
Income (loss) before taxes	(16,894)	(141,539)	(117,497)	(105,112)	(72,381)
Income taxes	-	-	-	-	-
Income (loss) for the period	(16,894)	(141,539)	(117,497)	(105,112)	(72,381)
Earnings (loss) per share, before and after dilution, SEK <sup>(1)</sup>	(0.17)	(1.39)	(1.28)	(1.27)	(1.05)
Weighted average number of shares, in thousands before and after dilution <sup>(1)</sup>	101,753	101,753	91,655	82,848	69,082

<sup>(1)</sup> Recalculation of historical figures has been performed with regards to capitalization issue components in the preferential rights share issue carried out in the fiscal quarter ended January 31, 2013 and January 31, 2015.

**Consolidated statement of financial position data:**

	2016 (TUSD)	2016 (TSEK)	2015 (TSEK)	2014 (TSEK)	2013 (TSEK) <i>Restated</i>
Total non-current assets	52,877	443,010	427,879	414,106	383,368
Liquid assets	5,516	46,214	76,990	48,241	62,956
Total current assets	8,662	72,570	86,690	54,276	69,895
Total assets	61,539	515,579	514,569	468,383	453,263
Total equity	38,917	326,053	375,710	281,907	319,153
Total non-current liabilities	0	0	0	891	891
Total current liabilities	22,622	189,527	138,858	185,584	133,219
Total liabilities	22,622	189,527	138,858	186,476	134,110



**Consolidated cash flow statement data:**

	2016 (TUSD)	2016 (TSEK)	2015 (TSEK)	2014 (TSEK)	2013 (TSEK) <i>Restated</i>
Cash flow from operating activities	(15,293)	(128,126)	(107,666)	(86,899)	(71,946)
Cash flow from investing activities	1,201	10,066	(69,755)	(35,682)	(57,388)
Cash flow from financing activities	14,019	117,449	156,017	107,865	190,263

**EXCHANGE RATE INFORMATION**

Fluctuations in the exchange rate between the Swedish krona and the U.S. dollar will affect the U.S. dollar amounts received by owners of the ADSs on conversion of dividends, if any, paid in kronor on the Ordinary Shares and will affect the U.S. dollar price of the ADSs on Nasdaq. The table below shows the period end, average, high and low exchange rates of kronor per U.S. dollar for the periods shown. Average rates are computed by using the noon buying rate of the Federal Reserve Bank of New York for the U.S. dollar on the last business day of each month during the relevant year indicated or each business day during the relevant month indicated. The rates set forth below are provided solely for your convenience and may differ from the actual rates used in the preparation of our consolidated financial statements included in this annual report and other financial data appearing in this annual report

	Period End	Average	High	Low
<b>Year Ended April 30:</b>				
2012	6.7274	6.5990	7.0137	5.9968
2013	6.4817	6.6747	7.2655	6.2880
2014	6.5049	6.5244	6.8171	6.3237
2015	8.3778	7.5000	8.8180	6.4864
2016	8.0267	8.4162	8.7679	8.0267
<b>Month Ended:</b>				
March 2016	8.0962	8.3394	8.6321	8.0962
April 2016	8.0267	8.1110	8.1520	8.0267
May 2016	8.3360	8.2154	8.3599	7.9761
June 2016	8.5028	8.3043	8.5598	8.1102
July 2016	8.5503	8.5722	8.6797	8.4301
August 2016 (through August 19, 2016)	8.3781	8.4787	8.5867	8.3580

**B. Capitalization and indebtedness**

Not applicable

**C. Reason for the Offer and Use of Proceeds**

Not applicable

**D. Risk factors.**

*Our business faces significant risks and uncertainties. You should carefully consider the following risk factors and all other information set forth in this Annual Report on Form 20-F, including our consolidated financial statements, before making an investment decision regarding our securities. The risks and uncertainties described below are those significant risk factors, currently known and specific to us, which we believe are relevant to an investment in our securities. The risk factors are not placed in order of priority and should not be construed as comprehensive. Additional risks and uncertainties not currently known to us or those we now deem immaterial may also harm us and adversely affect your investment in the ADSs. If any of these risks materialize, our business, results of operations, financial condition and future prospects could suffer and the price of the ADSs could decline and you could lose part or all of your investment. In addition to the information disclosed in this annual report, investors should make their own assessment of each risk factor and its potential impact on our future development as well as an assessment of the impact of general conditions, including market conditions and world events.*

## Risks Related to Our Product and Product Candidates

*We are substantially dependent on the success of our product and product candidates, none of which may receive full regulatory approval or be successfully commercialized.*

One of our product candidates has been approved for full commercial distribution, and another one of our product candidates has been conditionally approved. To date, we have invested nearly all of our resources in the research and development of our product candidates, which consist of Paccal Vet-CA1 (“Paccal Vet”) for cancer in dogs, Paclical for ovarian cancer and other cancers in humans, Docecal for breast cancer in humans, Doxophos Vet for lymphoma in dogs, Doxophos for breast cancer and other cancers in humans, and OAS-19 for various cancers in humans. Our near-term prospects, including our ability to finance our company and to enter into strategic collaborations and generate revenue, are directly dependent upon the successful development and commercialization of our product and product candidates, particularly Paccal Vet and Paclical.

The development and commercial success of our product and product candidates will depend on a number of factors, including, without limitation, the following:

- timely initiation and successful completion of preclinical studies and clinical trials for our product candidates;
- demonstration to the satisfaction of the United States Food and Drug Administration (“FDA”), the European Medicines Agency (“EMA”) and other applicable regulatory authorities the safety and efficacy of our product and product candidates as well as to obtain regulatory and marketing approval for our product and product candidates in the U.S., Europe and elsewhere;
- continued compliance with all clinical and regulatory requirements applicable to our product and product candidates;
- maintenance of an acceptable safety profile of our products following regulatory approval;
- competition with other treatments;
- creation, maintenance and protection of our intellectual property portfolio, including patents and trade secrets, and regulatory exclusivity for our product and product candidates;
- effectiveness of our and our partners’ marketing, sales and distribution strategy and operations;
- ability of our third-party manufacturers to manufacture supplies of our product and product candidates and to develop, validate and maintain commercially viable manufacturing processes;
- ability to launch commercial sales of our product and product candidates following regulatory approval, whether alone or in collaboration with others;
- acceptance of our animal health product and product candidates by veterinarians, pet owners and the animal health community; and
- acceptance of our human health product candidates from physicians, health care payers, patients and the medical community.

Many of these factors are beyond our control, and we cannot assure you that we will ever be able to generate sufficient revenue or any revenue from the sale of our product and product candidates. Our failure in any of the above factors or in successfully commercializing one or more of our product and product candidates, or any significant delay in doing so, could have a material adverse effect on our business, results of operations and financial condition, and the value of your investment could substantially decline.

***Our product and product candidates may not achieve market acceptance, which could limit our ability to generate revenue from new products.***

Even if we develop our product and product candidates and gain regulatory approvals for our products, unless veterinarians, physicians, and patients accept our products, we may not be able to sell our products and generate significant revenue. We cannot assure you that our current product and product candidates or any other planned products will achieve market acceptance and revenue if and when they obtain the requisite regulatory approvals. Market acceptance of any product depends on a number of factors, including but not limited to:

- the indication and warnings approved by regulatory authorities in the product label;
- continued demonstration of efficacy and safety in commercial use;
- physicians' or veterinarians' willingness to prescribe the product;
- reimbursement from third-party payors such as government health care systems and insurance companies;
- the price of the product, including pet owners' willingness to pay for treatment;
- the nature of any post-approval risk management plans mandated by regulatory authorities;
- competition; and
- the effectiveness of marketing and distribution support.

Any failure by our product and product candidates to achieve market acceptance or commercial success could have a material adverse effect on our business, results of operations and financial condition.

***Problems in our manufacturing process, failure to comply with manufacturing regulations or unexpected increases in our manufacturing costs could harm our business, results of operations and financial condition.***

We are responsible for the manufacture and supply of Paccal Vet, Paical, and our other product candidates for our commercial partners and for use in clinical trials. The manufacturing of our product and product candidates necessitates compliance with US FDA, EU EMA and international current Good Manufacturing Practice ("cGMP") and other international regulatory requirements. Although we contract with third parties such as Baxter Oncology GmbH for a certain amount of the manufacturing of Paccal Vet, Paical and our other product candidates, the market authorization for Paccal Vet and Paical remains with us. As such, even if we could potentially have a claim against one or more third parties, we are legally liable for any noncompliance related to Paccal Vet and Paical and we expect to retain legal responsibility for future product candidates as well.

If we are unable to manufacture, or contract to manufacture, our product and product candidates in accordance with regulatory specifications, or if there are disruptions in the manufacturing process due to damage, loss or failure to pass regulatory inspections of manufacturing facilities, we may not be able to meet the demand for our products or supply sufficient product for use in clinical trials, and this may harm our ability to commercialize Paccal Vet, Paical and our other product candidates on a timely or cost-competitive basis, or preclude us from doing so at all. In addition, we are in the process of expanding and changing parts of our manufacturing facilities in order to meet future demand and FDA requirements, a program which requires significant time and resources. We also expect to expand and upgrade other parts of our manufacturing facilities in the future. These activities may lead to delays, interruptions in supply, or may prove to be more costly than we currently anticipate. Any problems in our manufacturing process could have a material adverse effect on our business, results of operations and financial condition.

In addition, under our license agreements, we expect to generate revenue from the supply of commercial products to our partners at a fixed percentage of our cost of goods sold, and thus any increases in our manufacturing costs could materially and adversely affect our margins and our financial condition.

Before we can begin commercial manufacture of Paccal Vet, Paclical or our other product candidates for sale in the U.S., we must obtain FDA regulatory approval for the product, which requires a successful FDA inspection of our manufacturing facilities, processes and quality systems in addition to other product-related approvals. Although we successfully passed an FDA Pre-Approval Inspection and a FDA routine GMP inspection of our manufacturing facility in Uppsala, Sweden, our pharmaceutical facilities are continuously subject to inspection by the FDA and foreign (EMA) regulatory authorities, even after product approval. Due to the complexity of the processes used to manufacture our product and product candidates, we may be unable to pass federal, state or international regulatory inspections in a cost effective manner, whether initially on at any time thereafter. If we are unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of any approved products, or legal actions such as injunctions or criminal or civil prosecution. These possible sanctions could materially and adversely affect our business, results of operations and financial condition. See also “— Risks Related to Development and Regulatory Approval of Our Product and Product Candidates— The regulatory approval process is uncertain, requires us to utilize significant resources, and may prevent us or our commercial partners from obtaining approvals for the commercialization of some or all of our drug candidates.”

***We expect to face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.***

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product and product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. In addition to existing therapeutic treatments for the indications we are targeting with our product and product candidates, we also face potential competition from other drug candidates in development by other companies. Our potential competitors include large health care companies, such as Celgene, Merck & Co., Inc., Sanofi S.A., Eli Lilly and Company, Roche, Bayer AG, Novartis AG and Boehringer Ingelheim GmbH. Each of these companies also has a presence in animal health. We also know of several smaller early stage companies that are developing products for use in the animal or human health products market. We expect that Paccal Vet and Doxophos Vet will face competition from Palladia, made by Zoetis, Inc., Masivet, made by AB Science S.A., and Blontress and Tactress, made by Aratana Therapeutics, Inc. We may also face competition from generic medicines and products approved for use in humans that are used off-label for pets. Some of the potential competitive compounds referred to above are being developed by large, well-financed and experienced pharmaceutical and biotechnology companies or have been partnered with such companies, which may give them development, regulatory and marketing advantages over our products.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of generic products. Generic products are currently on the market for the indications that we are pursuing. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competing generic products.

Some of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to compete successfully, we may be unable to grow and sustain our revenue, which could materially and adversely affect our business, results of operations and financial condition.

***Generic products may be more cost-effective than our products.***

In addition to the competition that we may face from products produced by other companies in general, we may also face competition from generic alternatives to our products. For example, Paclical is expected to compete with the generic form of Taxol. Generic alternatives are generally less expensive, and competitors who market generic drugs are becoming more aggressive in terms of pricing. Consequently, generic products constitute an increasing percentage of both overall human and animal health sales in certain regions. If human and animal health care customers increase their use of new or existing generic products, or if we are unable to compete with existing generic products, our business, results of operations and financial condition could be materially and adversely affected.

***Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our product and product candidates, or limit the scope of any approved label or market acceptance.***

If any of Paccal Vet, Paclical, or any of our other product candidates, prior to or after any approval for commercial sale, causes serious or unexpected side effects, or become associated with other safety risks such as misuse, abuse or diversion, a number of potentially significant negative consequences could result, including, without limitation:

- regulatory authorities may interrupt, delay or halt clinical trials;
- regulatory authorities may deny regulatory approval of our product candidates;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, or impose restrictions on distribution in the form of a Risk Evaluation and Mitigation Strategy (“REMS”), in connection with approval, if any;
- regulatory authorities may withdraw their approval, require more onerous labeling statements or impose a more restrictive REMS of any product that is approved;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- our relationships with our commercial partners may suffer;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that our product and product candidates are unlikely to receive regulatory approval or are unlikely to be successfully commercialized. In addition, regulatory agencies, an Institutional Review Board (“IRB”), or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, if we elect or are forced to suspend or terminate a clinical trial of Paccal Vet, Paclical or any of our other product candidates, the commercial prospects for that product may be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product and product candidates and materially impair our ability to generate revenue from the commercialization of these products either by us or by our commercial partners and could have a material adverse effect on our reputation, business, results of operations and financial condition.

***If we fail to obtain and sustain an adequate level of reimbursement for our products by third-party payers, sales and profitability will be adversely affected.***

The course of medical treatment for human patients is, and will continue to be, expensive. We expect that most patients and their families will not be capable of paying for our products themselves. Accordingly, it is unlikely that there will be a commercially viable market for Paclical or our other human health care product candidates without reimbursement from third-party payors. Additionally, even if there is a commercially viable market, if the level of third-party reimbursement is insufficient from the patient’s perspective, our revenue and gross margins will be materially and adversely affected.

A current trend in the U.S. health care industry, as well as in other countries around the world, is toward cost containment. Large public and private payers, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Third-party payers, such as government programs, including Medicare in the U.S. and private health care insurers, carefully review and have increasingly been challenging the coverage of, and prices charged for, medical products and services. Many third-party payers limit coverage of or reimbursement for newly-approved health care products. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Cost-control initiatives could decrease the price we or our partners establish for products, which could result in lower product revenue and profitability.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. Our partners may elect to reduce the price of our products in order to increase the likelihood of obtaining reimbursement approvals. In many countries, products cannot be commercially launched until reimbursement is approved and the negotiation process in some countries can exceed 12 months. In addition, pricing and reimbursement decisions in certain countries can be affected by decisions taken in other countries, which can lead to mandatory price reductions and/or additional reimbursement restrictions across a number of other countries, which may thereby adversely affect our sales and profitability. If countries set prices that are not sufficient to allow us or our partners to generate a profit, our partners may refuse to launch the product in such countries or withdraw the product from the market, which would adversely affect our sales and profitability and could materially and adversely affect our business, results of operations and financial condition.

***We may not be successful in our efforts to expand our pipeline of product candidates.***

One element of our strategy is to expand our pipeline of pharmaceuticals based on our XR-17 technology and advance these product candidates through clinical development for the treatment of a variety of indications. Although our research and development efforts to date have resulted in a number of development programs based on XR-17 technology, we may not ultimately be able to develop product candidates that are safe and effective. Even if we are successful in continuing to expand our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. In addition, if we attempt to apply XR-17 technology to develop product candidates for indications outside of cancer, we will need to conduct genotoxicity, carcinogenicity and immunotoxicity trials, in which the results may be uncertain. If we do not successfully develop and commercialize product candidates based upon our technological approach, we will not be able to obtain product revenue in future periods, which would make it unlikely that we would ever achieve profitability.

***The veterinary market we are seeking to enter with Paccal Vet and our other animal health products is untested.***

The market for cancer drugs for dogs is nascent and changing. Consequently, it is difficult to assess to what extent cancer drugs might be accepted by veterinarians, which complicates both the estimate of the market size as well as our share thereof, if any. If a market does not develop, or our share thereof is not meaningful, it could have a material adverse effect on our business, results of operations and financial condition.

***For our animal health products, changes in distribution channels could negatively impact our market share and distribution of our animal health products.***

Since our animal health product and product candidates are designed to be given intravenously by veterinarians, pet owners will not be able to obtain our products over-the-counter or via the internet. Increasingly, pet owners purchase animal health products from sources other than veterinarians, such as internet-based retailers, “big-box” retail stores or other over-the-counter distribution channels. This trend has been demonstrated by the significant shift away from the veterinarian distribution channel in the sale of parasiticides and vaccines in recent years. Pet owners also could decrease their reliance on, and visits to, veterinarians as they rely more on internet-based animal health information. Since we market our animal health products through the veterinarian distribution channel, any decrease in visits to veterinarians by pet owners could reduce our market share for such products and materially and adversely affect our operating results and financial condition.

***Business interruptions could delay us in the process of developing our product and product candidates and could disrupt our product sales.***

Loss of our manufacturing facilities, stored inventory or laboratory facilities through accidents, fire or other causes could have an adverse effect on our ability to meet demand for our products, to continue product development activities and to conduct our business. Failure to supply our partners with commercial products may lead to adverse consequences, including the right of certain partners to take over responsibility for product supply. We have insurance coverage to compensate us for such business interruptions, but should such coverage prove insufficient to fully compensate us for damage to our business resulting from any significant property or casualty loss to our inventory or facilities, it could have a material adverse effect on our business, results of operations and financial condition.

***Product recalls or inventory losses caused by unforeseen events, cold chain interruption and testing difficulties may adversely affect our operating results and financial condition.***

Paccal Vet, Paclical and our other product candidates are manufactured and distributed using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as the strict company and government standards for the manufacture of our products, subjects us to production risks. While product batches released for use in clinical trials or for commercialization undergo sample testing, some defects may only be identified following product release. In addition, process deviations or unanticipated effects of approved process changes may result in these intermediate products not complying with stability requirements or specifications. Most of our products must be stored and transported at temperatures within a certain range, which is known as “strict cold chain” storage and transportation. If these environmental conditions deviate, our products’ remaining shelf lives could be impaired or their efficacy and safety could become adversely affected, making them no longer suitable for use. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches, any of which could have a material adverse effect on our business, results of operations and financial condition.

## Related to Our Financial Position and Capital Needs

***Our independent registered public accounting firm included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited consolidated financial statements included in this Annual report.***

Our audited consolidated financial statements were prepared assuming that we will continue as a going concern. However, the report of our independent registered public accounting firm included elsewhere in this Annual report contains an explanatory paragraph on our consolidated financial statements stating there is substantial doubt about our ability to continue as a going concern, meaning that we may not be able to continue in operation for the foreseeable future or be able to realize assets and discharge liabilities in the ordinary course of operations. Such an opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may also make it more difficult to raise additional funds or operate our business due to concerns about our ability to meet our contractual obligations.

Oasmia has two products approved, but this does not yet create a sufficient cash flow from its business. For this reason, Oasmia continuously works with various financing alternatives. This work includes the fact that the Company is in discussions with potential partners for licensing of distribution and sales rights, negotiations with new and existing investors, financiers and lenders and that the company ensures enough resources to secure that forecasted future revenue streams from regions where the company's products registered, are realized.

Available consolidated liquid assets and unutilized credit facilities as of April 30, 2016 are not sufficient to provide the required capital to pursue the planned activities during the next 12 months. In light of available financing alternatives and the recent developments in the Company, the Board of Directors assesses that the prospects for financing of the Company's operations in the coming year are good. Should funding not be obtained in sufficient quantities there is a risk that the conditions for continued operation do not exist.

***Our independent registered public accounting firm has advised us that it has identified a material weakness in our internal control over financial reporting relating to inadequate financial statement preparation and review procedures.***

In connection with the audit of our financial statements as of and for the fiscal year ended April 30, 2015, 2014 our independent registered public accounting firm reported to our audit committee that it had identified a material weakness in our internal control over financial reporting related to inadequate financial statement preparation and review procedures. During the year ended April 30, 2016, we have performed the remedial activities described below to address the material weakness identified by our independent registered public accounting firm. However there has not yet been a sufficient time period to allow management to assess whether these actions have been implemented successfully, and determine that the newly-designed controls will operate as designed, both routinely and effectively. Accordingly, we cannot yet conclude that the material weakness previously identified has been fully remediated. Under standards established by the Public Company Accounting Oversight Board (United States), a material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. Specifically, our independent registered public accounting firm determined that we did not have adequate procedures and controls to ensure that accurate financial statements could be prepared and reviewed on a timely basis, including:

- sufficient resources and processes in place, including controls in the finance and accounting department, to adequately perform a timely financial statement close process resulting in errors in period-end accruals related to capitalized research and development expenses.
- adequate internal review processes in place over critical accounting areas including timely operation whereby management identifies and resolves significant or complex accounting matters.

As a result of this material weakness, during the financial year ending April 30, 2016 we have implemented the following changes:



- continued to improve necessary procedures to capture all expenses for capitalized research and development expenses;
- further enhanced the internal review processes of critical and significant accounting areas by involving the management group deeper in such judgments and estimates;
- strengthened the finance department by recruitments and organizational change and by hiring additional personnel;
- improved know how of IFRS standards, as adopted by the IASB, through additional education in IFRS standards and also specific SEC reporting in the U.S.;
- Continued to implement and improve formalized written policies and procedures for the timely accrual of capitalized research and development expenses;
- enhanced oversight procedures in an effort to ensure that the accrual process has been performed prior to finalization of the financial statements at each reporting period; and
- formalized accounting evaluation of non-routine judgments and estimations.

We concurred with the findings in the previous fiscal year from our independent registered public accounting firm. We have been working to remediate the material weakness. The actions that we took were subject to ongoing senior management review and audit committee oversight; however, as there has not yet been a sufficient time period to allow management to assess whether these actions have been implemented successfully, and determine that the newly-designed controls will operate as designed, both routinely and effectively, we cannot yet conclude that the material weakness previously identified has been fully remediated. We will continue to strengthen our procedures; however, our initiatives may not prove to be sufficient to avoid any material weakness in the future.

We will be required to disclose changes made in our internal control over financial reporting and procedures on a semi-annual basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We could be an “emerging growth company” for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management’s assessment might not. Additional undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur additional expenses of remediation, and adversely affect our reputation, financial condition and operating results.

***We face litigation risks as a result of the material weakness in our internal control over financial reporting identified by our independent registered public accounting firm.***

In connection with the audit of our financial statements as of and for the fiscal years ended April 30, 2015 and April 30, 2014 our independent registered public accounting firm reported to our audit committee that it had identified a material weakness in internal control over financial reporting related to inadequate financial statement preparation and review procedures. See “— Our independent registered public accounting firm has advised us that it has identified a material weakness in our internal control over financial reporting relating to inadequate financial statement preparation and review procedures.”

As a result of such material weakness and our disclosure thereof, we face the potential for litigation by current or former shareholders based on their purported inability to accurately evaluate our financial performance from reviewing our audited financial statements, based on an alleged material statement or omission contained in our audited financial statements or based on other claims arising from our inadequate financial statement preparation and review procedures. As of the date of this annual report, we have no knowledge of any such shareholder litigation. However, we can provide no assurance that such shareholder litigation will not arise in the future. Any such shareholder litigation, whether successful or not, could have a material adverse effect on our business, results of operations and financial condition.

***Our concentration of ownership could be disadvantageous to shareholders.***

Alceco International S.A. (“Alceco”), as of July 31, 2016, owned approximately 23.82 percent of our shares. Nexttobe AB (“Nexttobe”), as of July 31, 2016, owned approximately 18.28 percent of our shares, and also holds a significant amount of our debt. Alceco and Nexttobe can thus, exercise significant influence over all matters requiring shareholder approval, and may be able to prevent a change in control or take other measures that may benefit Alceco or Nexttobe but could be disadvantageous to other shareholders. Moreover, the sale of a substantial number of our shares by Alceco and/or Nexttobe within a short period of time could cause our share price to decrease, make it more difficult for us to raise funds through future offerings of Ordinary Shares or acquire other businesses using Ordinary Shares as consideration. Additionally, Alceco and Nexttobe may have conflicting interests with us. See “— There are relationships among our directors and our largest shareholders that could pose a conflict of interest.”

***There are relationships among our directors and our largest shareholders that could pose a conflict of interest.***

There are relationships among some of the members of our board of directors with each other and with our largest shareholders that could pose a conflict of interest. Two of our directors, our Executive Chairman Julian Aleksov and Bo Cederstrand are co-owners of Alceco, a holding company based in Luxembourg that conducts no business and exists only for financial management. Alceco owns 25,536,445 of the Ordinary Shares as of July 31, 2016 and is our largest shareholder. In addition to being partners in Alceco, Messrs. Aleksov and Cederstrand also have a familial relationship. Mr. Aleksov is the partner of Mr. Cederstrand’s daughter and the father of his two grandchildren. Alceco has also extended a credit facility of SEK 40 million to us, which as of the date of this annual report has not been drawn upon.

Another director, Alexander Kotsinas, is a partner at Nexttobe, which owned 19,602,173 of our Ordinary Shares as of July 31, 2016 and is our second-largest shareholder. Nexttobe is also our largest creditor, from whom we have a loan of SEK 94.4 million.

These directors may have actual or apparent conflicts of interest with respect to matters involving or affecting us and Alceco and/or Nexttobe. Examples of possible conflicts include:

- the board of directors could have to decide whether to use funds for operating expenses or the repayment of a loan to Nexttobe;
- issues or disputes could arise under the commercial agreements that exist between us and Alceco and Nexttobe;
- under the terms of Alceco’s loan agreements, one or more Alceco creditors could become shareholders and could exercise their voting rights in a manner that could conflict with your interests;
- Nexttobe, a venture capital company, could own or come to own interests in companies that compete with us; and
- given the close relationship between Messrs. Cederstrand and Aleksov, Mr. Cederstrand could be conflicted as to any board decision on the compensation and employment status of Mr. Aleksov.

See also “Related Party Transactions.”

Apart from the conflicts of interest policy contained in our Code of Ethics and Business Conduct, we and Alceco and Nexttobe have not established any formal procedures for us and Alceco and Nexttobe to resolve potential or actual conflicts of interest between us. There can be no assurance that any of the foregoing conflicts will be resolved in a manner that does not adversely affect our business, financial condition or results of operations.

**U.S. investors may have difficulty enforcing civil liabilities against us, our directors or members of senior management and the experts named in this annual report.**

All of our directors and officers named in this annual report are non-residents of the U.S., and all or a substantial portion of the assets of such persons are located outside the U.S. As a result, it may not be possible to serve process on such persons or our company in the U.S. or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the U.S. There is doubt as to whether Swedish courts would enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the U.S. or elsewhere may be unenforceable in Sweden. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Sweden will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The U.S. and Sweden do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters.

***We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.***

Since our inception on April 15, 1988, we have incurred significant operating losses. We incurred net losses of SEK 141.54 million, SEK 117.50 million and SEK 105.11 million for the fiscal years ended April 30, 2016, April 30, 2015 and April 30, 2014. To date, we have financed our operations primarily through private placements of shares in our company, through loans (including convertible debt instruments) and through one-time milestone payments from our commercial partners. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We expect to continue to incur significant expenses and operating losses over the next few years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- initiate and conduct a Phase II program for Paclical for the treatment of metastatic breast cancer;
- initiate and conduct a Phase I/II program for Docecal for the treatment of breast cancer;
- conduct additional efficacy studies in dogs to collect all the necessary efficacy data for full FDA approval of Paccal Vet;
- continue research and development for and commence pre-clinical and clinical trials of Docecal, Doxophos, Doxophos Vet and OAS-19;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products that we choose not to license to a third party and for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, potentially entering into collaboration and license agreements, obtaining regulatory approval for product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or by other regulatory authorities outside of the U.S. to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***We may need substantial additional funding, which may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or our commercialization efforts.***

Our operations have consumed substantial cash since inception. Excluding receipts from milestone fees, our cash flow used for operating activities for the fiscal years ended April 30, 2016, April 30, 2015 and April 30, 2014 was SEK 128.13 million, SEK 107.67 million and SEK 86.90 million, with development costs, which are capitalized, for those years totaling SEK 16.73 million, SEK 16.80 million and SEK 29.46 million. We expect our operating and management and administrative expenses and cash used for operations to continue to be significant and to increase substantially in connection with our planned research, development and continued product commercialization efforts and as we transitioned to a U.S. public company. We may need to raise additional capital to fund our operations and continue to conduct clinical trials to support potential regulatory approval of marketing applications. If we are unable to raise capital when needed or on attractive terms, we could be forced to:

- delay, reduce or eliminate our research and development programs or any future commercialization efforts;
- relinquish or license on unfavorable terms our rights to technologies, our product, or product candidates that we otherwise would seek to develop or commercialize ourselves;
- seek collaborators for our product or one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- cease operations altogether.

We do not expect our existing capital resources to enable us to conduct Phase II development of Paclical for the treatment of metastatic breast cancer, conduct additional efficacy studies in dogs for full FDA approval of Paccal Vet or continue research and development for and commence clinical trials of Docecal, Doxophos Vet, Doxophos and OAS-19. Accordingly, we expect that we will need to raise substantial additional funds in the future. Our future capital requirements will depend on many factors, including:

- the revenue, if any, related to commercial sales of our product and product candidates for which we receive marketing approval;
- the Phase II clinical program for Paclical for the treatment metastatic breast cancer;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates, including those of Docecal, Doxophos Vet, Doxophos and OAS-19;
- our ability to enter into collaborative agreements for the development and commercialization of our product candidates;

- the number and development requirements of other product candidates that we pursue;
- the costs, timing and outcome of regulatory review of our product candidates or any future product candidates, both in the U.S. and outside the U.S.;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for our product or any of our product candidates for which we receive marketing approval;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel; and
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, both in the U.S. and outside the U.S.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product and our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for several months, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

***We do not currently intend to pay dividends on the Ordinary Shares or make any other distribution of earnings to holders of the Ordinary Shares.***

Since our inception, we have not declared or paid any dividends on the Ordinary Shares. We intend to retain any earnings for use in our business and do not currently intend to pay dividends on the Ordinary Shares. The declaration and payment of any future dividends will be at the discretion of our board of directors and will depend upon our results of operations, cash requirements, financial condition, contractual restrictions, restrictions imposed by our indebtedness, any future debt agreements or applicable laws and other factors that our board of directors may deem relevant. This policy may have a material adverse effect on the value of your Ordinary Shares. See “Dividend Policy.”

***The milestone payments we receive are not reliable sources of income and in some cases may be required to be returned at a later date.***

Much of our income has consisted of, and may in the future take the form of, milestone payments, which are contractual one-time payments from our partners as we reach certain targets. There have been cases in which we have not reached the targets and there is no guarantee that we will be able to reach such targets in the future. We may also be required to repay already obtained milestone payments if the agreed upon schedules are not kept or if the required marketing approvals are not obtained. Further, milestone payments often occur irregularly over time, causing fluctuations in our sales and earnings. Milestone payments are not sustainable earnings and any dependence on milestone payments could have a material adverse effect on our business, results of operations and financial condition. See also “Business — Strategic Alliances and Collaborations.”

***Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We commenced active operations in 1999, and our operations thus far have been limited to organizing and staffing our company, business planning, raising capital, identifying potential product candidates, undertaking preclinical studies and conducting clinical trials. To date we have had no commercial operations. All but three of our product candidates are still in preclinical development. We have not yet demonstrated our ability to successfully complete later stage clinical trials, obtain full regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to expand our capabilities to support commercial activities. We may not be successful in adding such capabilities.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any past annual or interim periods as indications of future operating performance.

#### **Risks Related to Development and Regulatory Approval of Our Product and Product Candidates**

##### ***There is a high rate of failure for drug candidates proceeding through clinical trials.***

Generally, there is a high rate of failure for drug candidates proceeding through clinical trials. We may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. Further, even if we view the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with our interpretation of the data. For instance, because a large percentage of subjects in our pivotal trials for Paccal Vet, Paical and our other product candidates in cancer treatment, are being enrolled at sites outside the U.S. (25% of canine subjects and 100% of human patients), differences in efficacy results between U.S. and non-U.S. sites could cause the FDA to require additional trials. In the event that:

- we obtain negative results from the Paccal Vet trials,
- we receive poor clinical results for our other product candidates,
- the FDA places a clinical hold on our Phase III trials due to potential chemistry, manufacturing and controls issues or other hurdles, or
- the FDA does not approve our New Animal Drug Application (“NADA”) for Paccal Vet or our New Drug Application (“NDA”) for Paical or for our other product candidates,

then:

- we may not be able to generate sufficient revenue or obtain financing to continue our operations,
- our ability to execute our current business plan will be materially impaired,
- our reputation in the industry and in the investment community would likely be significantly damaged, and
- the price of the Ordinary Shares would likely decrease significantly.

Any of these results could materially and adversely affect our business, results of operations or financial condition.

***Clinical trials for our product candidates are expensive, time consuming, uncertain and susceptible to change, delay or termination.***

Clinical trials are expensive, time consuming and difficult to design and implement. The result of a clinical trial may be undesirable and can result in a clinical trial cancellation or the need for re-evaluation and supplementation. Even if the results of our clinical trials are favorable, the clinical trials for a number of our product candidates are expected to continue for several years and may even take significantly longer to complete. In addition, we, the FDA, an IRB, or other regulatory authorities, including in the U.S., EU and elsewhere, may suspend, delay or terminate our clinical trials at any time, for various reasons, including:

- lack of effectiveness of any product candidate during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- difficulty in retaining subjects who have initiated a clinical trial but may have withdrawn due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to manufacturing or regulatory constraints;
- inadequacy of or changes in our manufacturing process or product formulation;
- delays in obtaining regulatory authorization to commence a trial, including experiencing “clinical holds” or delays requiring suspension or termination of a trial by a regulatory agency, such as the FDA, before or after a trial is commenced;
- changes in applicable regulatory policies and regulations;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;
- delay or failure to supply product for use in clinical trials which conforms to regulatory specification;
- unfavorable results from ongoing pre-clinical studies and clinical trials;
- failure of our contract research organizations (“CROs”), or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, our CROs or their employees to comply with all applicable FDA or other regulatory requirements relating to the conduct of clinical trials;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols; or
- regulatory concerns with pharmaceutical products generally and the potential for abuse.

Any of the foregoing could have a material adverse effect on our business, results of operations and financial condition.

*The regulatory approval process is uncertain, requires us to utilize significant resources, and may prevent us or our commercial partners from obtaining approvals for the commercialization of some or all of our drug candidates.*

The research, testing, manufacturing, labeling, approval, sale, marketing and testing of our product and product candidates are subject to extensive regulation by regulatory authorities in the U.S. and Europe, and regulatory requirements applicable to our product and product candidates differ from country to country. Neither we nor any commercial partner is permitted to market any of our current or future product candidates in the U.S. until we receive approval from the FDA of an NADA for our animal health products or an NDA for our human health products. We received conditional approval for Paccal Vet from the FDA in February 2014, which will require additional follow-up efficacy studies for full approval, but have yet to receive any type of approval for any of our other current product candidates. Obtaining approval of either an NADA or an NDA can be an uncertain process that requires us to utilize significant resources. Furthermore, regulatory authorities possess broad discretion regarding processing time and usually request additional information and raise questions which have to be answered. There is considerable uncertainty regarding the times at which products may be approved. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including: warning letters, civil and criminal penalties, injunctions, withdrawal of approved products from the market, product seizure or detention, product recalls, total or partial suspension of production, and refusal to approve pending applications or supplements to approved applications.

The process required by the FDA and most foreign regulatory authorities before human health care pharmaceuticals may be marketed generally involves nonclinical laboratory and animal tests; submission of an Investigational New Drug (“IND”) application, which must become effective before clinical trials may begin; adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses; pre-approval inspection of manufacturing facilities and clinical trial sites; and FDA approval of an NDA, which must occur before a drug can be marketed or sold.

In order to gain approval to market a pet therapeutic for a particular species of pet, we must provide the FDA and foreign regulatory authorities with data from animal safety and effectiveness studies that adequately demonstrate the safety and efficacy of that product in the target animal for the intended indication applied for in the NADA or other regulatory filing. Conditional approval is available under the FDA Minor Use and Minor Species (“MUMS”) designation, which gives the sponsor the right to promote a product before all of the efficacy data necessary for full approval are available. If approved, this provides the sponsor with seven years of market exclusivity. Even for conditional approval, the development of animal health products is a lengthy, expensive and uncertain process, and delay or failure can occur at any stage of any of our development efforts. Success in prior target animal studies or even in the treatment of human beings with a product candidate does not ensure that our studies will be successful and the results of development efforts by other parties may not be indicative of the results of our studies and other development efforts.

Regulatory approval of a NADA or an NDA, or any supplements of either, is not guaranteed, and the approval process requires us to utilize significant resources, could take several years, and is subject to the substantial discretion of the FDA. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or have to repeat or perform additional studies. If our product or any of our current or future product candidates fails to demonstrate safety and efficacy in our studies, or for any other reason does not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

In addition, separate regulatory approvals are required in order to market any product in many jurisdictions, including the U.S., the European Economic Area, which consists of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein, and many others. Approval procedures vary among countries and can involve additional studies and testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may be unable to file for regulatory approvals or to do so on a timely basis and, even if we are able to, we may not receive necessary approvals to commercialize our products in any market. Any of these results could have a material adverse effect on our business, results of operations and financial condition.



***Even if we receive regulatory approval for any of our current or future product candidates, we will be subject to ongoing FDA and other regulatory body obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product and any product candidates, if approved, will be subject to labeling and manufacturing requirements and could be subject to other restrictions. Failure to comply with these regulatory requirements or the occurrence of unanticipated problems with our products could result in significant penalties.***

Any regulatory approvals that we or any of our collaborators receive for any of our current or future product candidates may be subject to conditions of approval or limitations on the approved indicated uses for which the product may be marketed, or may contain requirements for potentially costly surveillance to monitor the safety and efficacy of the product candidate. In addition, our product and any of our current or future product candidates, if approved by the FDA or other regulatory bodies, will be subject to extensive and ongoing regulatory requirements regarding the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping. These requirements will include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP, Good Laboratory Practice and Good Clinical Practice for any studies that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on target studies;
- refusal by the FDA or other applicable regulatory body to approve pending applications or supplements to approved applications filed by us or our strategic collaborators, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties

The policies of the FDA and other regulatory bodies may change, and additional government regulations may be promulgated that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or elsewhere. If we are slow or unable to adapt to changes in or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would materially and adversely affect our business, results of operations and financial condition.

***Our product and any of our current or future product candidates, if approved, may cause or contribute to adverse medical events that we are required to report to the FDA and regulatory authorities in other countries and, if we fail to do so, we could be subject to sanctions that would materially harm our business.***

If we are successful in commercializing our product and any of our current or future product candidates, regulations of the FDA and of the regulatory authorities in other countries require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA and regulatory authorities in other countries could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products, which could have a material adverse effect on our business, results of operations and financial condition.

***Legislative or regulatory reforms with respect to human or animal health products may make it more difficult and costly for us to obtain regulatory clearance or approval of any of our current or future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.***

From time to time, legislation is drafted and introduced in the U.S. Congress and lawmaking bodies in other countries that could significantly change the statutory provisions governing the testing, regulatory clearance or approval, manufacture, and marketing of regulated products. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Similar changes in laws or regulations can occur in other countries. Any new regulations or revisions or reinterpretations of existing regulations in the U.S. or in other countries may impose additional costs or lengthen review times of our product and any of our current or future product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- requests for additional endpoints or studies;
- changes to manufacturing methods;
- recall, replacement, or discontinuance of certain products; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could have a material adverse effect on our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products could materially and adversely affect our business, results of operations and financial condition.

***Our ability to market our product and product candidates in the U.S., if approved, will be limited to use for the treatment of the indications for which they are approved, and if we want to expand the indications for which we may market our product and product candidates, we will need to obtain additional FDA approvals, which may not be granted.***

We plan to seek full FDA approval in the U.S. for Paccal Vet for mammary carcinoma and squamous-cell carcinoma in dogs, Paclical for ovarian cancer in humans, Docecal for breast cancer in humans, Doxophos Vet for lymphoma in dogs, Doxophos for breast cancer in humans, and OAS-19 for various cancers in humans. If our product candidates are approved, the FDA will restrict our ability to market or advertise them for anything other than the indications for which they are approved, which could limit their use. If we decide to attempt to develop, promote and commercialize new treatment indications and protocols for our product and product candidates in the future, we could not predict when, or if, we would ever receive the approvals required to do so. We would be required to conduct additional studies to support such applications for additional use, which would consume additional resources and may produce results that do not result in FDA approvals. If we do not obtain additional FDA approvals, our ability to expand our business in the U.S. would be adversely affected, which could materially and adversely affect our business, results of operations and financial condition.

***The anticipated development of a REMS for Paclical and our other human health product candidates could cause delays in the approval process and would add additional layers of regulatory requirements that could impact our ability to commercialize our human health product candidates in the U.S. and reduce their market potential.***

As a condition of approval of an NDA, the FDA may require a REMS to ensure that the benefits of the drug outweigh the potential risks. REMS elements can include medication guides, communication plans for health care professionals, and elements to assure safe use (“ETASU”). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug’s safety or efficacy. We may be required to adopt a REMS for Paclical and our other human health product candidates to ensure that the benefits outweigh the risks of abuse, misuse, diversion and other potential safety concerns. Even if the risk of abuse, misuse or diversion are not as high as for some other products, there can be no assurance that the FDA will approve a manageable REMS for Paclical and our other human health product candidates, which could create material and significant limits on our ability to successfully commercialize our human health product candidates in the U.S. Delays in the REMS approval process could result in delays in the NDA approval process. In addition, as part of the REMS, the FDA could require significant restrictions, such as restrictions on the prescription, distribution and patient use of the product, which could significantly impact our ability to effectively commercialize Paclical and our other human health candidates, and dramatically reduce their market potential thereby adversely impacting our business, financial condition and results of operations. Even if initial REMS are not highly restrictive, if, after launch, Paclical or our other human health product candidates were to be subject to significant abuse/non-medical use or diversion from licit channels, this could lead to negative regulatory consequences, including a more restrictive REMS, which could materially and adversely affect our business, results of operations and financial condition.

***If we are found in violation of “fraud and abuse” laws, we may be required to pay a penalty and/or be suspended from participation in government-run health care programs, which may adversely affect our business, financial condition and results of operations.***

If we are successful in obtaining marketing approval for our products in the U.S. and elsewhere, we will be subject to various health care “fraud and abuse” laws, including anti-kickback laws, false claims laws and other laws intended to reduce fraud and abuse in government-run health care programs, which could affect us, particularly upon successful commercialization of our products in the U.S. For example, the Medicare and Medicaid Patient Protection Act of 1987 (otherwise known as the federal “Anti-Kickback Statute”) makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug for which payment may be made under a U.S. health care program such as Medicare or Medicaid. Under U.S. federal government regulations, some arrangements, known as safe harbors, are deemed not to violate the Anti-Kickback Statute. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the Anti-Kickback Statute and similar laws in other jurisdictions. False claims laws prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third-party payers, including government payers, reimbursement claims for drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the payment of kickbacks to pharmaceutical providers has resulted in the submission of false claims to governmental health care programs. Under laws such as the Health Insurance Portability and Accountability Act of 1996 in the U.S., we are prohibited from knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and/or exemption or suspension from government-run health care programs such as Medicare and Medicaid and debarment from contracting with the U.S. and other governments. In addition, in the U.S. individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under state false claims laws.

Many states in the U.S. have adopted laws similar to the Anti-Kickback Statute, some of which apply to the referral of patients for health care services reimbursed by any source, not just governmental payers. In addition, California and a few other states in the U.S. have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals. In addition, several states impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.

We have yet to receive definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. While we believe we have structured our business arrangements to comply with these laws, it is possible that the government could allege violations of, or convict us of violating, these laws. If we are found in violation of one of these laws, we could be required to pay a penalty and could be suspended or excluded from participation in certain government-run health care programs, and our business, results of operations and financial condition may be materially and adversely affected.

#### **Risks Related to Our Business and Industry**

***If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our product or our current or future product candidates, conduct our in-licensing and development efforts or commercialize our product or any of our current or future product candidates.***

Our future growth and success depends in part on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We are highly dependent upon our senior management, particularly Julian Aleksov, our Executive Chairman, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our current or future product pipeline, completion of our planned development efforts or the commercialization of our product and product candidates. Although we have entered into an employment agreement with Julian Aleksov, the agreement does not provide for a fixed term of service, and does not contain any competition or non-solicitation clauses after the termination of employment. It is possible that current or former employees of Oasmia could put forward claims for an alleged right to our patents and demand compensation therefor. However, all our employees have signed an agreement where they assign all their inventions and intellectual property rights generated by them in their work to us. In addition, there is a law in Sweden that regulates the right to patentable inventions made by employees which gives the employer the rights to the inventions if they are invented in the course of the employees work. If one or more of the key personnel were to leave us and engage in competing operations, our business, results of operations and financial condition could be materially and adversely affected. To date, none of our key personnel has left us or, to our knowledge, engaged in competing operations, nor has any departure of key personnel had any material effect on Oasmia.

***We may have trouble hiring additional qualified personnel.***

As we expand our development and commercial activities, we will need to hire additional personnel and could experience difficulties attracting and retaining qualified employees. Competition for qualified personnel in the biopharmaceutical field is intense due to the limited number of individuals who possess the skills and experience required by that industry. We may not be able to attract and retain quality personnel on favorable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that such personnel have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. Any of these difficulties could have a material adverse effect on our business, results of operations and financial condition.

***We are subject to risks relating to legal proceedings.***

We are subject to various claims and legal actions arising in the ordinary course of its business. Any such litigation could be very costly and could distract our management from focusing on operating our business. The existence of any such litigation could harm our business, results of operations and financial condition. Results of actual and potential litigation are inherently uncertain. Additionally, in the past we have been subject to fines by a foreign exchange relating to our disclosures. See "Business — Foreign Exchanges." An unfavorable result in a legal proceeding could adversely affect our reputation, financial condition and operating results.

***If product liability lawsuits are successfully brought against us, we will incur substantial liabilities and may be required to limit the commercialization of Paccal Vet, Paclical and our other product candidates.***

We and our partners face potential product liability exposure related to the testing of our product and product candidates in human and animal clinical trials. We will face exposure to claims by an even greater number of persons if we begin to market and distribute our products commercially in the U.S. and elsewhere, including those relating to misuse of Paccal Vet, Paclical and our other product candidates. Now, and in the future, an individual may bring a liability claim against us alleging that our product or one of our product candidates caused an injury. While we continue to take, what we believe to be appropriate precautions (including SEK 20 million, approximately \$2.39 million, in product liability insurance coverage as of the date of this annual report), we may be unable to avoid significant liability if any product liability lawsuit is brought against us. It should be noted that the amount of the product liability insurance is revised continuously of the insurance broker. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for Paccal Vet, Paclical and our other product candidates, if such product candidates are approved;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients, pet owners and others;
- increased cost of liability insurance;
- loss of revenue; and
- our inability to successfully commercialize our products.

Furthermore, in the future there may be a need to expand the scope of our insurance coverage, which could result in significantly increased costs or the inability to obtain sufficient insurance coverage. Any of these occurrences could have a material adverse effect on our business, results of operations and financial condition.

***Failure of our information technology systems could significantly disrupt the operation of our business.***

Our ability to execute our business plan and to comply with regulatory requirements with respect to data control and data integrity depends, in part, on the continued and uninterrupted performance of our information technology systems ("IT systems"). These systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, there are no assurances that electronic break-ins, computer viruses and similar disruptive problems, and/or sustained or repeated system failures or problems arising during the upgrade of any of our IT systems that interrupt our ability to generate and maintain data will not occur. The occurrence of any of the foregoing with respect to our IT systems could have a material adverse effect on our business, results of operations or financial condition.

***We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations and financial condition.***

Our operations are subject to certain anti-corruption laws, including the U.S. Foreign Corrupt Practices Act (“FCPA”), and other anti-corruption laws that apply in countries where we do business. The FCPA and other anti-corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential FCPA violations and we participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered in the U.S. and in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations (collectively, “Trade Control Laws”).

There can be no assurance that we will be completely effective in ensuring our compliance with all applicable anticorruption laws, including the FCPA or other legal requirements, such as Trade Control Laws. Any investigation of potential violations of the FCPA, other anti-corruption laws or Trade Control Laws by U.S., EU or other authorities could have an adverse impact on our reputation, our business, results of operations and financial condition. Furthermore, should we be found not to be in compliance with the FCPA, other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, as well as the accompanying legal expenses, any of which could have a material adverse effect on our reputation and liquidity, as well as on our business, results of operations and financial condition.

***We are exposed to risks related to currency exchange rates.***

Currency risks arise when future commercial transactions or reported assets or liabilities are denominated in a currency other than our functional currency, the Swedish krona. Our primary contract manufacturer and all of our clinical trials are located outside of Sweden. Because our financial statements are presented in kronor, changes in currency exchange rates have had and could continue to have a significant effect on our operating results. Exchange rate fluctuations between local currencies and the krona create risk in several ways, including the following:

- weakening of the krona may increase the krona cost of overseas research and development expenses and the cost of sourced product components outside Sweden;
- strengthening of the krona may decrease the value of our revenues denominated in other currencies;
- the exchange rates on non-kronor transactions and cash deposits can distort our financial results; and
- the pricing and profit margins of Paccal Vet, Paclical and our other product candidates may be affected by currency fluctuations.

In addition, to the extent our need for contract manufacturing increases once our products reach the commercial market, our exposure to currency risks will increase proportionally. We do not engage in regular hedging transactions, since to date our currency exposure has been mostly related to purchased services for product development, which has been irregular and difficult to anticipate. It is possible that fluctuations in currency exchange rates could have a material adverse effect on our business, results of operations and financial condition.

***If we are unable to use our net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments or benefit from favorable tax legislation, our business, results of operations and financial condition may be adversely affected.***

As a Swedish resident trading entity, we are subject to Swedish corporate taxation. As of April 30, 2016, we had cumulative carry forward tax losses of SEK 723.23 million, as of April 30, 2015, we had cumulative carry forward tax losses of SEK 521.39 million and as of April 30, 2014 we had cumulative carry forward tax losses of SEK 404.26 million. These losses are available to carry forward and offset against future operating profits, unlimited in time. If, however, there are unexpected adverse changes to the Swedish tax law, our business, results of operations and financial condition may be adversely affected.

#### **Risks Related to Our Reliance upon Third Parties**

***We depend substantially on the commercial expertise of our commercial partners.***

We do not have a sales and marketing operation and expect to rely, in certain geographical areas such as Japan and the CIS, on the expertise and commercial skills of our commercial partners to sell Paccal Vet, Paclical, Doxophos Vet, and our other product candidates in selected territories. We have entered into agreements for the commercialization of Paccal Vet in Japan, where Paccal Vet is licensed to Nippon Zenyaku Kogyo, and Russia and the CIS, where we retain commercialization rights. We have entered into agreements for the commercialization of Paclical with Medison Pharma in Israel and Turkey and with Pharmasintez in Russia and the CIS, as well as Ukraine, Georgia and Turkmenistan. The commercial success of Paclical and many of our other product candidates in each of these markets will depend entirely on the expertise and commercial skills of our commercial partners, whereas we will be responsible for the distribution and sales of Paccal Vet and Doxophos Vet. In addition, it is customary that in these types of commercial agreements our partners are entitled to price our products, which means that much of our financial performance will be dependent on our partners. Our partners also have the right, under certain circumstances, to terminate their agreements with us. See "Business — Strategic Alliances and Collaborations" for descriptions of the agreements with our commercial partners. A failure by our partners to successfully market Paccal Vet, Paclical, Doxophos Vet and our other product candidates, or the termination of agreements with our partners, would have a material adverse effect on our business, results of operations and financial condition.

As referred to elsewhere herein, we have entered into various licensing and distribution agreements with established pharmaceutical companies to sell Paccal Vet. Specifically, we had entered into an agreement for the global commercialization of Paccal Vet with Abbott Animal Health, the assets of which were acquired by Zoetis on February 10, 2015. In connection with Zoetis' purchase of Abbott Animal Health, Zoetis terminated the distribution arrangement effective September 30, 2015.

***We depend on the financial ability of our commercial partners.***

94 percent of our sales revenue in the financial year ending April 30, 2016 emanate from one single transaction. The largest part of that revenue was on April 30, 2016 still unpaid by the customer. If the customer fails to pay his liability to us we will have to book a credit loss in our income statement.

Based on forecasts from the same customer we have to build up our inventory. If the customer fail to purchase according to his forecast there is a risk that we will not be able to sell these products to other customers before they expire or before the expiry date is so close that the products are unattractive for a customer. In that case we might have to write down the inventory value over the income statement.

***We currently have no sales and marketing organization for the distribution of Paccal Vet or Doxophos Vet as a result of the pending termination of the Distribution Agreement with Zoetis. If we are unable to establish a direct sales force in the U.S. to promote our products, the commercial opportunity for our products may be diminished.***

We currently have no sales and marketing organization for the distribution of Paccal Vet or Doxophos Vet as a result of the pending termination of the Distribution Agreement with Zoetis, which covered the entire world except for Japan and the CIS. While we have established an entity through which Oasmia intends to distribute these products in the United States, the Company currently has no sales and marketing organization for these products. The Company will incur significant additional expenses and commit significant additional management resources to establish our sales force. The Company may not be able to establish these capabilities despite these additional expenditures. The Company will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel.

If the Company elects to rely on third parties to sell these products in the U.S., it may receive less revenue than the Company we sold our products directly. In addition, while the Company anticipates using due diligence in monitoring their activities, it may have little or no control over the sales efforts of those third parties. In the event the Company is unable to develop its own sales force or collaborate with a third party to sell these products, the Company may not be able to commercialize these products which would negatively impact its ability to generate revenue.

***We rely on contract manufacturers for the production of our products, which can create production uncertainties.***

Our own production facility has the technical capacity for production of our finished products up to a limited commercial scale. We produced the launch supply of Paccal Vet, but we do not have adequate capacity to supply the product in the long term. As such, full-scale production of our products for commercial use will be carried out by contract manufacturers. Production at our primary contract manufacturer is expected to commence shortly. If it proves difficult for contract manufacturers to scale-up production, full-scale production may be delayed, which could then delay the product launch schedule.

We will also be required to validate full-scale production and submit documentation to the relevant health authorities in connection with the scaling-up of the production to full-scale production. These agencies must approve the production at the manufacturers we select. We will be relying upon the contract manufacturers to provide us with the appropriate information for the regulators, and if the documentation is incomplete or incorrect there is a risk that the product launch will be delayed, which may have a material adverse effect on our financial position and performance.

***We depend on a limited number of suppliers for materials and components required to manufacture Paccal Vet, Paclical and our other product candidates. The loss of these suppliers, or their failure to supply us on a timely basis, could cause delays in our current and future capacity and adversely affect our business.***

The majority of the raw materials used in the production of our pharmaceuticals are purchased from a limited number of suppliers. As a result, we may not be able to obtain sufficient quantities of critical materials and components in the future. A delay or interruption by our suppliers may harm our business, results of operations and financial condition. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify for and, in some cases, obtain regulatory approval for a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Our dependence on a limited number of suppliers exposes us to numerous risks, including:

- our suppliers could cease or reduce production or deliveries, raise prices or renegotiate terms;
- we may be unable to locate a suitable replacement suppliers on acceptable terms or on a timely basis, or at all; and
- delays caused by supply issues may harm our reputation, frustrate our customers and cause them to turn to our competitors for future needs.

Any one of these occurrences could have a material adverse effect on our business, results of operations and financial condition.



## Risks Related to Our Intellectual Property

### *We may be forced to litigate to enforce or defend our intellectual property rights, or the intellectual property rights of our licensors.*

We may be forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors. In so doing, we may place our intellectual property at risk of being invalidated, held unenforceable, or narrowed in scope. Further, an adverse result in any litigation or defense proceedings may place pending applications at risk of non-issuance. In addition, if any licensor fails to enforce or defend its intellectual property rights, this may adversely affect our ability to develop and commercialize our product and product candidates as well as our ability to prevent competitors from making, using, and selling competing products. Any such litigation could be very costly and could distract our management from focusing on operating our business. The existence or outcome of any such litigation could harm our business, results of operations and financial condition.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of the Ordinary Shares.

### *We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.*

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection or failure to adequately protect our intellectual property could enable competitors to develop generic products or use our proprietary information to develop other products that compete with our products or cause additional, material adverse effects upon our business, results of operations and financial condition.

The transfer of technology and knowledge to contract manufacturers pursuant to the production of our products also creates a risk of uncontrolled distribution and copying of concepts, methods and processes relating to our products. Such uncontrolled distribution and copying could have a material adverse effect on the value of our products if used for the production of competing drugs or otherwise used commercially without our obtaining financial compensation.

### *We may become subject to third parties' claims alleging infringement of patents and proprietary rights or seeking to invalidate our patents or proprietary rights, which would be costly, time-consuming and, if successfully asserted against us, delay or prevent the development and commercialization of our product and our current or future product candidates.*

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry, as well as patent challenge proceedings, including interference and administrative law proceedings before the U.S. Patent and Trademark Office ("U.S. PTO") and the European Patent Office ("EPO"), and oppositions and other comparable proceedings in other jurisdictions. Recently, under U.S. patent reform laws, new procedures including *inter partes* review and post grant review have been implemented. As stated below, the novel implementation of such reform laws presents uncertainty regarding the outcome of challenges to our patents in the future.

We cannot assure you that our product or any of our current or future product candidates will not infringe existing or future patents. We may be unaware of patents that have already issued that a third party might assert are infringed by our product or one of our current or future product candidates. Because patent applications can take many years to issue and may be confidential for eighteen months or more after filing, there may be applications now pending of which we are unaware and which may later result in issued patents that we may infringe by commercializing our product or any of our current or future product candidates. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may face claims from non-practicing entities (commonly referred to as "patent trolls"), which have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect.

We may be subject to third-party claims in the future against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents. If a patent infringement suit were brought against us or our collaborators, we or our collaborators could be forced to stop or delay research, development, manufacturing or sales of the product candidate that is the subject of the suit. As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. Even if we are successful in defending such claims, infringement and other intellectual property litigation can be expensive and time-consuming to litigate and divert management's attention from our core business. Any of these events could harm our business significantly.

In addition to infringement claims against us, if third parties have prepared and filed patent applications in the U.S. that also claim technology to which we have rights, we may have to participate in interference proceedings in the U.S. PTO to determine the priority of invention. Third parties may also attempt to initiate reexamination, post grant review or *inter partes* review of our patents in the U.S. PTO. We may also become involved in similar opposition proceedings in the EPO or comparable offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Any of these claims could have a material adverse effect on our business, results of operations and financial condition.

***If our efforts to protect the proprietary nature of the intellectual property related to our product or any of our current or future product candidates are not adequate, we may not be able to compete effectively in our market.***

We rely upon a combination of patents, trade secret protection as well as confidentiality and license agreements to protect the intellectual property related to our product and our current product candidates and our development programs.

Composition-of-matter patents on an active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any particular method of use or manufacture. We cannot be certain that the claims in our patent application covering composition-of-matter of our product and our product candidates will be considered patentable by the U.S. PTO and courts in the U.S., or by the patent offices and courts in foreign countries. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, for our animal health products particularly, even if competitors do not actively promote their products for our targeted indications, veterinarians may recommend that pet owners use these products off label, or pet owners may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, we believe the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the field of human and animal health products involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the U.S. or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we own, in-license or pursue with respect to our product or any of our current or future product candidates is threatened, it could threaten our ability to commercialize our product or any of our current or future product candidates. Further, if we encounter delays in our development efforts, the period of time during which we could market our product or any of our current or future product candidates under patent protection would be reduced. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product and product candidates. Furthermore, for patent applications in which claims are entitled to a priority date before March 16, 2013, an interference proceeding can be initiated by a third party or instituted by the U.S. PTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For patent applications containing a claim not entitled to a priority date before March 16, 2013, there is a greater level of uncertainty in the patent law with the passage of the America Invents Act, some provisions of which went into effect on that date whereas the America Invents Act itself first went into effect on September 16, 2011 and brought about significant changes to the U.S. patent laws that have yet to be well defined, and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is creating a "first to file" system in the U.S., which requires us to minimize the time from invention to filing of a patent application.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios than we have.

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we endeavor to execute confidentiality agreements with all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or had access to our proprietary information, nor that our agreements will not be breached. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the EU or the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and elsewhere. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially and adversely affect our business, results of operations and financial condition.

Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in other situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. PTO, the laws and regulations governing patents could change in ways that would weaken our ability to obtain new patents or to enforce our existing licensed patents and patents that we might obtain in the future. Similarly, changes in EU patent law and elsewhere could negatively affect the value of our patents registered outside of the U.S.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with any of these requirements.***

The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case, which could have a material adverse effect on our business, results of operations and financial condition.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on product and product candidates throughout the world is prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

**Risks related to the ADSs and the Warrants**

***A trading market for the ADSs was only recently established.***

In connection with our initial public offering, we listed the ADSs on the NASDAQ Capital Market (“Nasdaq”) and trading commenced on October 23, 2015. No public market for the ADSs existed prior to that offering.

However, there can be no assurance that an active trading market for the ADSs will develop or be sustained in the future. The initial offering price was determined by negotiations among the lead underwriters and us. Among the factors considered in determining the initial offering price were our future prospects and the prospects of our industry in general, our revenue, net income and certain other financial and operating information in recent periods, and the financial ratios, market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. However, there can be no assurance that the ADSs will ever trade at a price equal to or greater than the offering price.

In addition, the market price of the ADSs may be volatile. Many factors may have a material adverse effect on the market price of the ADSs, including, but not limited to:

- announcements of the failure to obtain regulatory approvals or receipt of a “complete response letter” from the FDA;
- announcements of restricted label indications or patient populations, or changes or delays in regulatory review processes;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to Paccal Vet, Paclical, or our other product candidates;

- the failure of our testing and clinical trials;
- product liability claims, other litigation or public concern about the safety of our product, product candidates or future products;
- any adverse changes to our relationship with licensors, manufacturers or suppliers;
- the loss of any of our key scientific or management personnel;
- any major changes in our board of directors or management;
- the failure to retain our existing, or obtain new, commercial partners;
- announcements concerning our competitors or the pharmaceutical industry in general;
- the achievement of expected product sales and profitability;
- the failure to obtain reimbursements for our products or price reductions;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our cash position or operating results;
- manufacturing and supply issues related to our product or our current or future product candidates for our development programs and commercialization;
- changes in financial estimates or recommendations by securities analysts;
- the termination of any of our existing license agreements;
- announcements relating to future licensing or development agreements;
- potential acquisitions;
- the trading volume of ADSs on Nasdaq and of the Ordinary Shares on NASDAQ Stockholm and the Frankfurt Stock Exchange;
- sales of the ADSs or Ordinary Shares by us, our executive officers or directors or our shareholders;
- fluctuations in the U.S. equity markets;
- changes in accounting principles;
- market conditions in the human and animal health sectors; and
- general economic conditions in the U.S. and elsewhere.

In addition, the stock market in general, and Nasdaq in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of the ADSs, regardless of our actual operating performance.

***The multiple listing of the Ordinary Shares and the ADSs may adversely affect the liquidity and value of the ADSs.***

The Ordinary Shares will continue to be listed on NASDAQ Stockholm and the Frankfurt Stock Exchange, and the ADSs trade on the NASDAQ Capital Market. We cannot predict the effect of this multiple listing on the value of the Ordinary Shares and the ADSs. However, it is possible the multiple listing of the Ordinary Shares and ADSs may dilute the liquidity of these securities in one or all three markets and may adversely affect the development of an active trading market for the ADSs in the U.S. The price of the ADSs could also be adversely affected by trading in the Ordinary Shares on NASDAQ Stockholm and the Frankfurt Stock Exchange. Although currently we have no plans to do so, we may decide to delist the Ordinary Shares from either exchange in the future. We cannot predict the effect such delisting of the Ordinary Shares would have on the market price of the ADSs on Nasdaq.

***If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding the ADSs or the Ordinary Shares, the price of these securities and their trading volume could decline.***

The trading market for the ADSs and the Ordinary Shares will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If we do not obtain adequate securities or industry analyst coverage, the trading price for the ADSs and the Ordinary Shares may be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our products, our intellectual property or the ADSs or our ordinary share performance, or if our target studies and operating results fail to meet the expectations of analysts, the prices of the ADSs and the Ordinary Shares may decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause the prices of the ADSs and the Ordinary Shares, as well as their respective trading volume to decline.

***Substantial future sales of the Ordinary Shares or the ADSs in the public market, or the perception that these sales could occur, could cause the price of the ADSs to decline.***

Additional sales of the Ordinary Shares in the public market, or the perception that such sales could occur, could cause the market price of the Ordinary Shares to decline. As of the date of this annual report, we had 107,209,310 Ordinary Shares issued and outstanding, including those underlying presently issued and outstanding ADS but excluding all such Ordinary Shares underlying the ADSs issuable upon exercise of the Warrants and excluding any exercise by the underwriters of the option to purchase Ordinary Shares. All ADSs are freely transferable without restriction or additional registration under the Securities Act. The Ordinary Shares held by our directors, officers, and large institutional shareholders are available for sale since the expiration of the lock-up period has occurred. The remaining Ordinary Shares are also available for sale since they are not subject to contractual and legal restrictions on resale. To the extent shares are sold into the market, the market price of the ADSs could decline.

***There is presently no public market for the Warrants to purchase ADSs and none is expected to develop.***

There is presently no established public trading market for the Warrants and we do not expect a market to develop. Without an active market, the liquidity of the Warrants will be limited. Further, the existence of the Warrants may act to reduce both the trading volume and the trading price of our common stock.

***Speculative nature of Warrants.***

The Warrants do not confer any rights of ownership of ADSs on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire ADSs at a fixed price for a limited period of time. Specifically, holders of the Warrants may exercise their right to acquire ADSs and pay an initial exercise price of \$4.06, subject to adjustment, prior to ten (10) years from the date of issuance, after which date any unexercised Warrants will expire and have no further value. There can be no assurance that the market price of the ADSs will ever equal or exceed the exercise price of the Warrants, and consequently, whether it will ever be profitable for holders of the Warrants to exercise them.

***You may not have the same voting rights as the holders of the Ordinary Shares and may not receive voting materials in time to be able to exercise your right to vote.***

Holders of ADSs are not shareholders of our company and therefore do not have direct voting rights or the right to attend shareholders' meetings. ADS holders do have the right to instruct the depositary how to vote the Ordinary Shares underlying their ADSs, but the depositary will only send voting materials to ADS holders if we ask it to. Therefore, you may not receive voting materials or you may not receive voting materials in time to instruct the depositary to vote, and it is possible that you, or persons who hold their ADSs through brokers or other securities intermediaries, will not have the opportunity to exercise a right to vote. The Warrants confer no equity ownership in our company, nor do they provide voting rights until exercised and the underlying ADSs are issued.

***You may not receive distributions on the Ordinary Shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs.***

The depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on the Ordinary Shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of the Ordinary Shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of the ADSs, Ordinary Shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on the Ordinary Shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have a material adverse effect on the value of your ADSs.

***As a foreign private issuer, we are exempt from a number of U.S. securities laws and rules promulgated thereunder and are permitted to file less information with the SEC than U.S. companies must. This will limit the information available to holders of the ADSs.***

We currently qualify as a "foreign private issuer," as defined in the SEC's rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to companies organized within the U.S. For example, we are exempt from certain rules under the U.S. Securities Exchange Act of 1934, as amended (the "Exchange Act"), that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. We are also not subject to Regulation FD under the Exchange Act, which would prohibit us from selectively disclosing material nonpublic information to certain persons without concurrently making a widespread public disclosure of such information. Accordingly, there may be less publicly available information concerning our company than there is for U.S. public companies.

As a foreign private issuer, we will file an annual report on Form 20-F within four months of the close of each fiscal year ended April 30 and reports on Form 6-K relating to certain material events promptly after we publicly announce these events. However, because of the above exemptions for foreign private issuers, our shareholders will not be afforded the same protections or information generally available to investors holding shares in public companies organized in the U.S.

***As a foreign private issuer, we are not subject to certain Nasdaq corporate governance rules applicable to U.S. listed companies.***

We rely on a provision in Nasdaq's Listed Company Manual that allows us to follow Swedish corporate law and the Swedish Companies Act (SFS 2005:551) (the "Swedish Companies Act") with regard to certain aspects of corporate governance. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on Nasdaq.

For example, we are exempt from Nasdaq regulations that require a listed U.S. company to:

- have a majority of the board of directors consist of independent directors;
- require non-executive directors to meet on a regular basis without management present;
- promptly disclose any waivers of the code of ethics for directors or executive officers that should address certain specified items;
- have an independent nominating committee;
- solicit proxies and provide proxy statements for all shareholder meetings; and
- seek shareholder approval for the implementation of certain equity compensation plans and issuances of Ordinary Shares.

As a foreign private issuer, we are permitted to, and we will, follow home country practice in lieu of the above requirements. The determination of foreign private issuer is made annually on the last business day of an issuer's most recently completed second fiscal quarter, and, accordingly, the next determination will be made with respect to us as of the end of our second quarter of the current fiscal year. If we do not meet the SEC's requirements for foreign private issuer, we will be subject to a number of additional rules and regulations, including those identified above, and as a result we may incur significant regulatory compliance costs.

In accordance with our Nasdaq listing, our audit committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act, and Rule 10A-3 of the Exchange Act, both of which are also applicable to Nasdaq-listed U.S. companies. Because we are a foreign private issuer, however, our audit committee is not subject to additional Nasdaq requirements applicable to listed U.S. companies, including an affirmative determination that all members of the audit committee are "independent," using more stringent criteria than those applicable to us as a foreign private issuer.

***We are an "emerging growth company," as defined in the JOBS Act, and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, the ADS and Ordinary Shares may be less attractive to investors.***

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We cannot predict if investors will find the ADSs or the Ordinary Shares less attractive because we will rely on these exemptions. If some investors find the ADSs or the Ordinary Shares less attractive as a result, there may be a less active trading market for the ADSs or the Ordinary Shares and the price of the ADSs may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year: (a) following the fifth anniversary of the completion of the initial public offering, (b) in which we have total annual gross revenue of at least USD\$1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of the Ordinary Shares that is held by non-affiliates exceeds USD\$700 million as of the prior October 31; and (2) the date on which we have issued more than USD\$1.0 billion in non-convertible debt during the prior three-year period.



***If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.***

Section 404(a) of the Sarbanes-Oxley Act requires that beginning with our annual report for the year ending April 30, 2017, management shall assess and report annually on the effectiveness of our internal control over financial reporting and identify any material weaknesses in our internal controls over financial reporting. Although Section 404(b) of the Sarbanes-Oxley Act requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) of the Sarbanes-Oxley Act until such time as we are no longer an emerging growth company.

Our first Section 404(a) assessment will take place beginning with our annual report for the year ending April 30, 2017. Although remedial activities to address the material weakness identified by our independent registered public accounting firm have been carried out, the presence of a material weakness in previous year could result in financial statement errors which, in turn, could lead to errors in our financial reports or delays in our financial reporting, and could require us to restate our operating results or require our auditors to issue a qualified audit report. For the fiscal years ended April 30, 2015 and April 30, 2014, our independent registered public accounting firm reported to our audit committee that it had identified a material weakness in internal control over financial reporting related to inadequate financial statement preparation and review procedures. See "Our independent registered public accounting firm has advised us that it has identified a material weakness in our internal control over financial reporting relating to inadequate financial statement preparation and review procedures." In order to maintain and improve the effectiveness of our disclosure controls and procedures and our internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal controls.

If we are unable to conclude that we have effective internal control over financial reporting or, at the appropriate time, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal control over financial reporting as required by Section 404(b) of the Sarbanes-Oxley Act, investors may lose confidence in our operating results, the price of the Ordinary Shares could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, we may not be able to remain listed on Nasdaq.

***We will incur significant increased costs as a result of operating as a company whose ADSs are publicly traded in the U.S., and our management will be required to devote substantial time to new compliance initiatives.***

As a company with publicly traded ADSs in the U.S., we will incur significant legal, accounting, insurance and other expenses that we have not previously incurred. In addition, the Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform Act, Consumer Protection Act and related rules implemented by the SEC and Nasdaq have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We estimate that our annual compliance expenses will be approximately SEK 3 million in each of the next two fiscal years. Among other matters, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. These laws and regulations could also make it more difficult and expensive for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of the ADSs, fines, sanctions and other regulatory action and potentially civil litigation.

***The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.***

We are incorporated under Swedish law. The rights of holders of Ordinary Shares and, therefore, certain of the rights of holders of ADSs, are governed by Swedish law, including the provisions of the Swedish Companies Act, and by our Articles of Association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations.

*We may be or may become a passive foreign investment company (“PFIC”) for U.S. federal income tax purposes.*

Whether we are or may be a PFIC is a complex determination based on the classification of various assets and income under the PFIC rules. Further, a determination as to whether or not we are a PFIC must be made annually and our circumstances may change in any given year. We do not intend to make decisions regarding our business operations with the specific purpose of reducing the likelihood of our becoming a PFIC. Accordingly, our business plan may result in our engaging in activities that could cause us to become a PFIC. If we are or become a PFIC, U.S. Holders may be subject to increased U.S. federal income taxes on a sale or other disposition of our ADSs and on the receipt of certain distributions and will be subject to increased U.S. federal income tax reporting requirements. Moreover, we may not decide to provide the information that would enable U.S. Holders to make an election to treat us as a “qualified electing fund” (a “QEF”), which election could mitigate the adverse U.S. federal income tax consequences of us being classified as a PFIC if we were so classified. See “Taxation — Passive Foreign Investment Company Status” for a more detailed discussion of the consequences if we are treated as a PFIC.

#### **ITEM 4. INFORMATION ON THE COMPANY**

##### **A. History and Development of the Company**

Oasmia Pharmaceutical AB is a pharmaceutical company which develops, manufactures, markets and sells a new generation of drugs within human and veterinary oncology. The product development aims to manufacture novel formulations based on well-established cytostatic which, in comparison with current alternatives, show improved properties, a reduced side-effect profile and an expanded therapeutic area. The product development is based on in-house research within nanotechnology and company patents. The Company’s shares are listed at NASDAQ Stockholm, NASDAQ Capital Markets and the Frankfurt Stock Exchange.

We are a Swedish public company. Our principal executive offices are located in Uppsala, Sweden.

##### **Company information**

Company name: OASMIA PHARMACEUTICAL AB

Address: Vallongatan 1, 752 28 Uppsala, Sweden

Contact information: +46 18 50 54 40

Fax: +46 18 51 08 73

Email address: info@oasmia.com

Website: www.oasmia.com

##### **B. Business overview.**

We are a pharmaceutical company focused on innovative treatments within human and animal oncology. Our product and product candidates utilize a proprietary, nanoparticle formulation technology that is designed to facilitate the administration of intravenously-delivered active pharmaceutical ingredients, without the addition of toxic solvents. We believe our formulation may result in improved safety, efficacy and ease of administration over existing drugs. Our initial development and commercialization efforts are focused on creating novel formulations of well-established chemotherapeutic drugs that can be used for the treatment of cancer in both humans and companion animals. We have four human oncology product candidates in pre-clinical and/or clinical development, and two veterinary oncology product candidates. We disclosed top line Phase III data for our lead human oncology product candidate in the fourth quarter of 2014 and positive overall survival data in April 2016. In February 2014, we received conditional approval by the United States Food and Drug Administration (“FDA”) for our initial veterinary oncology product, which made us eligible for royalties and potential milestone payments from Abbott Animal Health, the animal health division of Abbott Laboratories. Our lead products utilize paclitaxel, the active ingredient of Taxol and Abraxane, two widely used cancer drugs marketed by Bristol-Myers Squibb and Celgene, respectively. Based on the potential benefits of our proprietary formulation technology, we are pursuing a strategy to replace the use of existing paclitaxel-based products in multiple cancers with our novel formulations. Our formulation is currently called Paclical or Apealea, depending on market, for human indications, and is marketed under the name Paccal Vet-CA1 (“Paccal Vet”) for veterinary indications. We own the global commercial rights to Paclical, excluding Israel, Turkey, Russia, the Commonwealth of Independent States (“CIS”), Ukraine, Georgia and Turkmenistan. We own the global commercial rights of Paccal Vet, excluding Japan.

A phase III study with our lead human oncology product candidate, Paclical, for the treatment of epithelial ovarian cancer has been completed. We have received orphan designation for Paclical in the EU and the U.S. Results regarding progression free survival are available and we filed an MAA in the EU based upon these results in February 2016. We obtained overall survival, OS, data in April 2016 and we will file to the FDA late 2016 or 2017. We previously submitted an application to market Paclical in Russia, and we received market authorization in April 2015 and were entered into the Russian reimbursement system in January 2016. We are also conducting and planning additional clinical trials to evaluate Paclical in other cancer types, initially breast cancer.

Paccal Vet is the first injectable chemotherapeutic agent authorized for marketing for the treatment of squamous cell carcinoma and mammary carcinoma in dogs. We obtained conditional approval by the FDA for Paccal Vet for the treatment of mammary carcinoma and squamous cell carcinoma under the Minor Use and Minor Species (“MUMS”) designation in the U.S. MUMS designation is a status similar to orphan designation for human drugs, making the sponsor eligible for incentives to support the approval or conditional approval of the designated drug, including seven years of market exclusivity in the U.S, during which period a different drug company cannot pursue full or conditional approval of a generic version or another brand name version of the drug in the same form for the same intended use.

In order to receive the MUMS designation in the U.S. for Paccal Vet, we were required to show that squamous cell carcinoma and mammary carcinoma, the drug’s two indications, occur infrequently and in less than 70,000 dogs in the U.S. each year. To receive conditional approval pursuant to the MUMS designation, we were also required to show (i) that our manufacturing process for Paccal Vet satisfied certain criteria, including purity and stability (see “Government Regulation — Requirements for Approval of Veterinary Pharmaceuticals for Pets — Defined Manufacturing Process”); (ii) that the production and use of Paccal Vet satisfied certain human and environmental safety criteria (see “Government Regulation — Requirements for Approval of Veterinary Pharmaceuticals for Pets — Safe for Humans and the Environment”); and (iii) a reasonable expectation of effectiveness in treating mammary carcinoma and squamous cell carcinoma. To receive full approval, we will need to show that the manufacturing and safety criteria described above remain satisfied, and that Paccal Vet is completely effective in treating mammary carcinoma and squamous cell carcinoma. Accordingly, upon our receipt of conditional approval pursuant to the MUMS designation, sales of Paccal Vet could be made in the U.S. We believe Paccal Vet can be on the market for up to five years, through annual renewals, while we collect remaining required effectiveness data for full approval. We are currently conducting additional studies in dogs to collect all the necessary efficacy data for full U.S. approval of Paccal Vet for mammary carcinoma and squamous cell carcinoma.

“[The] FDA’s Center for Veterinary Medicine determined that the drug’s two indications fit the ‘minor use in a major species’ category. Both mammary carcinoma and squamous cell carcinoma — within the limitations described on the label — occur infrequently and in a small number of dogs each year (fewer than 70,000 dogs in the U.S. in one year).”

Reference: FDA

<http://www.fda.gov/animalveterinary/resourcesforyou/ucm402476.htm>

“[The] FDA’s Center for Veterinary Medicine granted Oasmia Pharmaceutical AB’s request to declare the drug a “designated” animal drug for its two label indications. This designation status qualifies the company to receive financial incentives. First, it gives Oasmia Pharmaceutical AB seven years of exclusive marketing rights, beginning on February 27, 2014, the date that FDA conditionally approved PACCAL VET-CA1. During this 7-year period, a different drug company cannot pursue approval or conditional approval of a generic copy or another pioneer (brand name) version of the same drug in the same form for the same intended use.”

Reference to FDA (quotes): <http://www.fda.gov/animalveterinary/resourcesforyou/ucm402476.htm>

In Europe, we intend to submit a Marketing Authorization Application (“MAA”) to the European Medicines Agency (“EMA”) for Paccal Vet for the treatment of squamous cell carcinoma, mammary carcinoma and mast cell tumors (mast cells develop in bone marrow and are found in connective tissue throughout the body. Mast cells are, among other items, involved in the defense against parasitic infestations and infections. They contain histamine and are associated with allergic reactions based on data from the ongoing phase III studies.

In addition to Paccal Vet and Paclical, we have four additional product candidates:

- Docecal is a proprietary, patented formulation of docetaxel. Docetaxel is the active ingredient in Taxotere, a product marketed by Sanofi. Taxotere, one of the most commercially-successful and widely used chemotherapeutic medications, generated annual worldwide sales of more than \$2.8 billion in 2010, the year its patent expired. We have completed a number of pre-clinical studies and have initiated human clinical trials with Docecal for the treatment of metastatic breast cancer in 2015. We retain global rights to Docecal.
- Doxophos Vet and Doxophos are a proprietary, patented formulation of doxorubicin, one of the most effective and commonly used substances for the treatment of cancer. Doxorubicin is the active ingredient in Doxil and Adriamycin. Our product candidate is called Doxophos Vet for veterinary indications and Doxophos for human indications. Doxophos Vet is being developed for the treatment of lymphoma, one of the most common cancers in dogs. A Phase I dose-finding clinical trial with Doxophos Vet was completed during the fourth quarter of 2014 and the study report was completed in June of 2015. We have completed a number of pre-clinical studies and we are currently planning to initiate a clinical trial of Doxophos in humans to explore its pharmacokinetics compared to generic Adriamycin and to Doxil. In December 2015 we submitted a request for market authorization of Doxophos in Russia.
- OAS-19 is a proprietary combination of two widely used chemotherapeutic agents in a single formulation that can be administered in a single dose. In the past, cancers were often treated with a single chemotherapeutic agent but combination therapies have become more prevalent in clinical practice, including the combined use of multiple traditional chemotherapeutic agents and the combined use of newer cancer therapies in conjunction with traditional chemotherapeutic agents, which often require multiple infusions that can be time consuming and costly. By combining two chemotherapeutic agents in a single formulation, we believe that OAS-19 could offer physicians the ability to dose chemotherapy in a single infusion instead of two sequential infusions, which we believe decreases infusion times, the number of clinical visits, and associated treatment costs. We are currently evaluating OAS-19 in preclinical studies. We retain global rights to OAS-19.

We believe that our strategy of applying our formulation technology to existing chemotherapeutic drugs will allow us to use the 505(b)(2) regulatory pathway in the United States to obtain regulatory approval for our human product candidates. The 505(b)(2) regulatory pathway permits the filing of a New Drug Application (“NDA”) where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. We believe this pathway is attractive as it has the potential to prevent the need for costly and time consuming clinical trials. We believe we will first be able to apply this to Paclical in the United States referencing Taxol.

## Our Product and Product Candidates

The following tables summarize key information about our product and our most advanced product candidates:

Product Candidate	Commercial Rights	Stage of Development & Anticipated Milestones
<i>Paclitaxel</i> <b>Paclical</b>	<b>Oasmia:</b> Global (excluding Israel, Turkey, Russia/CIS, Ukraine, Georgia and Turkmenistan) <b>Medison Pharma:</b> Israel and Turkey <b>Pharmasyntez:</b> Russia/CIS, Ukraine, Georgia and Turkmenistan	<ul style="list-style-type: none"> <li>Final results, overall survival data, from Phase III trial vs. Taxol was disclosed in April 2016</li> <li>Applied for marketing authorization in EU in February 2016 and aim to apply in the U.S. in late 2016 or early 2017</li> <li>Received for marketing authorization in Russia in April of 2015</li> </ul>
<b>Paccal Vet</b>	<b>Oasmia:</b> Global (excluding Japan, Russia/CIS) <b>Nippon Zenyaku Kogyo:</b> Japan <b>Oasmia:</b> Russia/CIS	<ul style="list-style-type: none"> <li>Conditional U.S. approval received in February 2014</li> <li>Conducting additional efficacy studies in dogs to support EMA approval, full U.S. approval and additional cancer indications</li> <li>Apply for marketing authorization with the EMA</li> </ul>
<i>Docetaxel</i> <b>Docecal</b>	<b>Oasmia:</b> Global	<ul style="list-style-type: none"> <li>Pre-clinical studies ongoing</li> <li>Initiated Phase I pharmacokinetic clinical trial in metastatic breast cancer in the first half of 2016</li> </ul>
<i>Doxorubicin</i> <b>Doxophos Vet</b>	<b>Oasmia:</b> Global (excluding Russia/CIS) <b>Oasmia:</b> Russia/CIS	<ul style="list-style-type: none"> <li>Dose-finding clinical trial completed</li> <li>Proof of Concept study is ongoing</li> </ul>
<b>Doxophos</b>	<b>Oasmia:</b> Global	<ul style="list-style-type: none"> <li>Pre-clinical studies ongoing</li> <li>Initiate Phase I pharmacokinetic clinical trial in metastatic breast cancer in 2017</li> <li>Submitted for MAA in Russia December 2015</li> </ul>
<i>Combination</i> <b>OAS-19</b>	<b>Oasmia:</b> Global	<ul style="list-style-type: none"> <li>Currently in pre-clinical development</li> <li>Initiate a Phase I dose-finding clinical trial</li> </ul>

## Definitions

The following definitions are used throughout this document;

- Phase I: The first study initiated with a compound. This can be either a dose-finding study or a PK-study.
- Phase II: A study to assess safety and efficacy in a smaller study in the intended indication.
- Phase III: A study to show efficacy and safety and to be used as a basis for an application to obtain marketing authorization.

The label phase I is also used for veterinary studies although the nomenclature of the Center for Veterinary Medicine at the FDA (“CVM”) is “Dose characterization study” for phase I. Phase II is referred to herein as “Dose confirmation study” and phase III “field study”.

HUMAN HEALTH							
Candidate	Indication	Pre-clinical	Phase I	Phase II	Phase III	Reg/Approval	Geography Rights
Paclical/Apealea (paclitaxel)	Ovarian cancer					Preparing submission	USA
	Ovarian cancer					Application submitted*	EU
	Ovarian cancer					Approved**	RUS/CIS
	Metastatic breast cancer		On-going				Global
Doxophos (doxorubicin)	Breast cancer		Hybrid application			Application submitted RUS	Global
Docecal (docetaxel)	Breast cancer	On-going	On going				Global
OAS-19 (Combination)	Various cancers	On-going					

\*EU EMA

\*\*Russia and the CIS Countries

ANIMAL HEALTH							
Candidate	Indication	Pre-clinical	Phase I	Phase II	Phase III	Reg/Approval	Geography Rights
Paccal Vet*/Paccal Vet* - CA1 (paclitaxel)	Mammary				Ongoing for full approval	Conditionally Approved US	Global (ex-JAP)
	Squamous cell				Planned for full approval	Conditionally Approved US	Global (ex-JAP)
	Mast cell				On-going		Global (ex-JAP)
Doxophos Vet (doxorubicin)	Lymphoma			On-going			Global

## Paclical, Our Lead Human Oncology Candidate

### Paclical Overview

Paclical is our XR-17 formulation of paclitaxel for human use. Our XR-17 technology increases the solubility of paclitaxel without the use of toxic solvents, which we believe facilitates the ease of administration and allows for higher doses than some of the other existing products on the market (250 mg/m<sup>2</sup> compared to 175 mg/m<sup>2</sup>).

Based on the potential benefits of XR-17, we are pursuing a strategy to replace the use of existing paclitaxel-based products in treating multiple types of cancer. Our initial focus is to obtain regulatory approval for the treatment of ovarian cancer and expand use through additional regulatory approvals, starting with breast cancer. Since we are not conducting any human clinical studies in the U.S. we are not required to file an IND.

We have obtained orphan designation for epithelial ovarian cancer in the EU and in the U.S. based on the hypothesis that Paclical provides potential benefits to safety and tolerability compared to Taxol, which is currently used as a treatment for epithelial ovarian cancer. Both Paclical and Taxol are being administered in combination with carboplatin, a platinum-based chemotherapeutic that is the current standard of care for ovarian cancer. Carboplatin has historically been given as a monotherapy for the treatment of ovarian cancer, an incremental survival benefit by adding Taxol. On June 16, 2014, Oasmia announced that the primary endpoint for the Phase III study with Paclical for treatment of ovarian cancer had been met. The endpoint was to demonstrate that Paclical and Taxol, both in combination with carboplatin, have the same progression-free survival time. Further, we disclosed final results which showed a positive risk/benefit profile in the fourth quarter of 2014. This data served as the basis of an MAA to the EMA, which we submitted in February 2016. We continued to follow patients from the Phase III clinical trial to measure overall survival and received final data in April 2016. We expect to be able to utilize the Section 505(b)(2) regulatory pathway for Paclical in the United States. We do not currently plan to conduct any other pivotal study of Paclical for epithelial ovarian cancer at this time since only one study is needed for submission to the FDA and EMA, although we intend to include other supportive studies in our Section 505(b)(2) application.

In addition to the development of Paclical in ovarian cancer, we intend to enhance the commercial potential of Paclical by demonstrating the potential safety, efficacy, and convenience advantages of Paclical over other paclitaxel-based therapies in additional clinical trials. For example, we have recently completed a pharmacokinetic study to compare Paclical with Abraxane. In addition, this data can be used in our discussions with payor organizations and physicians to help drive market acceptance of Paclical.

In addition to our efforts in the EU and the U.S., we submitted an application for marketing authorization for Paclical in Russia in September 2012 and received approval in April of 2015 and was approved for their reimbursement system in January 2016.

### ***Paclical Market***

The two leading paclitaxel-based products on the market are Taxol and Abraxane, two widely used cancer drugs. Taxol generated \$1.6 billion in sales in 2000 alone, prior to losing its patent protection in 2001. In 2013, Taxol generated \$92 million in post-patent sales. Abraxane, which received FDA approval in 2005 for metastatic breast cancer, followed by approvals for lung (in 2012) and pancreatic cancer (in 2013), generated \$649 million in worldwide annual sales in 2013 and generated \$848 million in 2014. In order to deliver paclitaxel, Taxol contains the solvent Cremophor EL. The toxicity of Cremophor EL limits the dose of Taxol that can be administered during a reasonable time, potentially limiting the efficacy of the drug. In addition, patients receiving Taxol require pre-medication with steroids and antihistamines to prevent the toxic side effects associated with the combination of paclitaxel and Cremophor EL. Abraxane was developed as a Cremophor-free product containing paclitaxel suspended in human albumin. Because Abraxane contains no Cremophor solvent, Abraxane's recommended dosing enables the delivery of 50% more paclitaxel while maintaining a similar safety profile, and requires no routine pre-medication to prevent hypersensitivity reactions or the immediate allergic effects that often prevent or limit treatment. Like Abraxane, Paclical is free of Cremophor EL, but unlike Abraxane, Paclical does not contain human albumin.

Our initial indication for Paclical is epithelial ovarian cancer, which is the fifth leading cause of cancer death among American women, and an indication for which Abraxane has no approval. There are clinical studies and case reports that indicate that Abraxane is used off-label by oncologists to treat certain types of epithelial ovarian cancer, but we cannot estimate how frequently they do so or whether Abraxane is used off-label to treat second line epithelial ovarian cancer. It is easier to find publications on platinum resistant epithelial ovarian cancer and first line epithelial ovarian cancer than on second line epithelial ovarian cancer (Paclical's intended indication), but it is not possible to say if that reflects the usage. Epithelial ovarian cancers account for about 85% to 90% of ovarian cancers, and are the most aggressive and dangerous sub-type. According to the National Cancer Institute, in 2011, the most recent year in which data are available, there were over 185,000 women living with ovarian cancer in the U.S. The five year survival rate for ovarian cancer from 2004 to 2010 was 44.6%, and it is estimated that 21,980 women will develop and 14,270 women will die from ovarian cancer in 2014. In the EU, the five year survival rate for ovarian cancer was 37.6% from 2000 – 2007 according to a study published in *The Lancet*. In 2012, there were 44,149 diagnosed cases of ovarian cancer in the EU, according to the European Cancer Observatory/International Agency for Research on Cancer, while 29,758 women died of ovarian cancer. In the U.S., 51% of women with ovarian cancer are diagnosed with stage III cancer, characterized by microscopically confirmed peritoneal metastasis outside the pelvis and/or regional lymph node metastasis. Common chemotherapy drugs used for the treatment for ovarian cancer include cisplatin or carboplatin, and paclitaxel or docetaxel, which are most often given in combination.

Our second indication, breast cancer, will be targeted with weekly administration of Paclical. Breast cancer is by far the most frequent cancer among women. The WHO estimates that 1.38 million women worldwide are diagnosed with breast cancer each year. Roughly 458,000 women worldwide die from the disease annually.

Although we may choose to license Paclical to a commercial partner, we also believe we could successfully market and sell the product ourselves. There have been numerous examples of successful oncology drugs, including Abraxane, launched by small companies.

### ***Paclical Phase III Clinical Trial***

We have completed a Phase III open, randomized, multi-center trial in patients with recurrent epithelial ovarian cancer, primary peritoneal cancer or fallopian tube cancer to compare the efficacy and safety of Paclical to Taxol, both in combination with carboplatin. Carboplatin was historically given as a monotherapy for the treatment of ovarian cancer but some studies have demonstrated an incremental survival benefit from adding Taxol, which has increased the use of the two drugs in combination. Top-line progression free survival results were disclosed in the second quarter of 2014. Since there are no human clinical studies in the U.S. we are not required to file an IND.

The study was designed to achieve the following primary objectives:

- For progression free survival, to show non-inferiority of Paclical (250 mg/m<sup>2</sup>) versus Taxol (175 mg/m<sup>2</sup>) using computed tomography (“CT”) scans, as assessed according to RECIST by central review.
- For overall survival, to show non-inferiority of Paclical (250 mg/m<sup>2</sup>) versus Taxol (175 mg/m<sup>2</sup>).

Inclusion criteria included patients, in total 789 patients, who relapsed at least six months after ending the first line or second line treatment including platinum based therapy. Paclical was administered as a one-hour intravenous infusion at its recommended dose of 250 mg/m<sup>2</sup> to 391 patients. Taxol was administered as a three-hour intravenous infusion at its recommended dose of 175 mg/m<sup>2</sup> to 391 patients. Both drugs were dosed in six three-week cycles, which is consistent with clinical practice. After completing the treatment cycles, patients were managed by their respective physicians and tracked for certain measures, including progression free survival and overall survival.

Tumor response was evaluated with a biomarker, CA 125, and through CT scans. CA 125 is used in clinical practice to assess when to re-treat a patient, as it is generally accepted as a sign of disease progression. We received guidance from Russian regulators that CA 125 would be an acceptable endpoint for regulatory submission. In an interim analysis we assessed the response to Paclical and to Taxol with regard to concentration average of CA 125 during the treatment period. The objective to show non-inferiority of the two treatments was met. The results of the interim analysis were used in a submission for marketing authorization to Russian authorities. Beyond the Russian market, we believe the use of both CA 125 and CT scan data in one study will give us the opportunity to include a comparison of progression free survival based on CA 125 and based on CT evaluation in the final analysis.

On June 16, 2014, we announced the results of this trial. The primary end-point has been analyzed and it shows a progression free survival of 10.3 months in the Paclical + carboplatin group and 10.1 months in the control group (Taxol + carboplatin). The protocol objective to show non-inferiority (or similar efficacy) was thus met (p-value of 0.09).

A protocol amendment increased the frequency of CT scans to be performed every three months after end of treatment. An analysis of the Progression Free Survival rate (“PFS”) in this subset of patients showed a PFS for Paclical of 12.2 month and 10.2 months for Taxol. The non-inferiority criteria were met also regarding the secondary efficacy variables. Even though the data on efficacy were not significantly different, PFS tended to be better in the Paclical group regardless of patient population; more frequent CTs showed the most pronounced differences.

The safety profile of Paclical active substance dose of 250 mg/m<sup>2</sup>, is rather similar to the safety profile of Taxol, active substance of 175 mg/m<sup>2</sup>. The number of patients with serious myelosuppression is substantial, but many of them were detected in the hematology analyses and were without clinical signs. Further, when needed, myelosuppression is easily managed in the clinic.

Considering both efficacy and safety of Paclical, including a comparatively short infusion time and less frequent use of pre-medications, we believe that the benefits of Paclical outweigh the potential risks of the treatment.

### ***Paclical Phase I and Phase I/II Clinical Trials***



### *Paclical Phase I/II Dose Escalation Trial*

We evaluated Paclical in a dose escalating Phase I/II trial to define the maximum tolerated dose and desired dose to use in clinical trials of Paclical. Thirty-four patients with different kinds of cancers were included in the trial. Patients received escalating doses (90 – 275 mg/m<sup>2</sup>) of Paclical, until the dose-limiting toxicity was noted. Dose-limiting toxicity (“DLT”) is the emergence of side effects during treatment that are severe enough to prevent further increases in dosage of the treatment. Paclical was given as a one-hour intravenous infusion every 21 days for three cycles. No premedication was administered prior to Paclical administration.

Eight patients experienced at least one adverse event classified as DLT. The first occurred at 225 mg/m<sup>2</sup> and consisted of fatigue, skin reaction, and stomatitis. The following 4 incidences of DLT occurred at 250 mg/m<sup>2</sup> where one patient experienced myalgia, arthralgia and leukopenia classified as DLT during both first and second treatment cycle, and another three patients experienced mucositis, peripheral neuropathy and neuropathy, respectively. Three patients also experiences DLTs at the 275 mg/m<sup>2</sup> dose level; all three experienced fatigue, one in combination with small intestinal obstruction and one in combination with peripheral sensory neuropathy.

Stomatitis (at 250 mg/m<sup>2</sup>), myalgia, arthralgia (at 250 mg/m<sup>2</sup>), and small intestinal obstruction (at 250 mg/m<sup>2</sup>) fulfilled the criteria of serious adverse event. Other serious adverse events considered related to Paclical were pyrexia (2 patients) and hemoglobin decrease (2 patients).

The maximum tolerated dose was established at 250 mg/m<sup>2</sup>, which is 75 mg/m<sup>2</sup> greater than the recommended dose for Taxol of 175 mg/m<sup>2</sup> and similar to the recommended dose for Abraxane of 260 mg/m<sup>2</sup>. No hypersensitivity reactions were reported despite the fact that no premedication was given before the administration of Paclical. In addition to the foregoing results, this trial indicated that Paclical was effective when administered with a one hour infusion period, while Taxol requires three hours.

The patient population consisted of terminally ill patients for whom no further treatment was available. Further, no patient received more than 3 cycles. Considering these circumstances, we consider the efficacy results, 10 patients with stable disease to be promising.

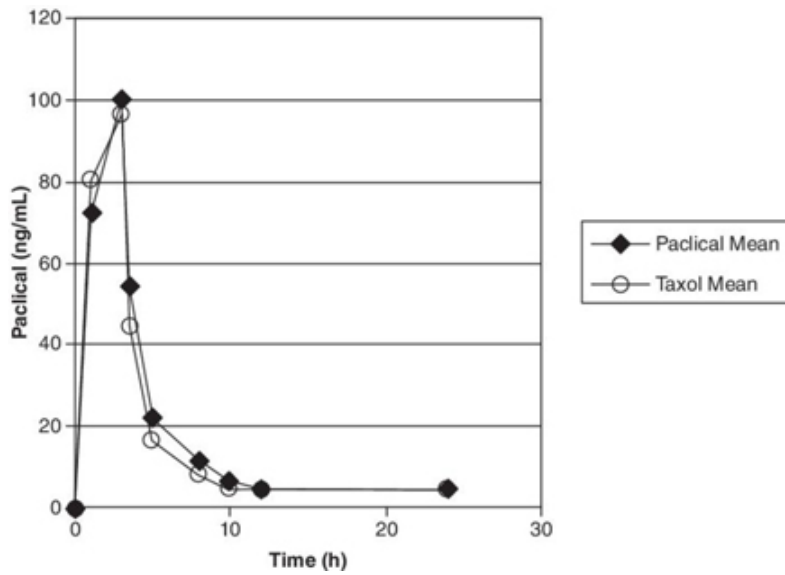
The most important result from these trials, in our view, was that Paclical can be given without pre-treatment, the maximum tolerated dose is 250 mg/m<sup>2</sup> and the infusion period is one hour. This demonstrates that there are benefits associated with Paclical compared to Taxol since Taxol requires pre-treatment, the maximum tolerated dose is 175 mg/m<sup>2</sup> and the infusion for Taxol is three hours.

### *Pharmacokinetic Comparison with Taxol*

The pharmacokinetic properties of paclitaxel following an intravenous infusion of Paclical at a dose of 175 mg/m<sup>2</sup> were evaluated in a Phase I crossover pharmacokinetic study comparing the pharmacokinetics of Paclical and Taxol in humans. The mean unbound plasma concentrations, which indicate the levels of paclitaxel in the bloodstream that are not bound to common blood proteins and therefore can readily cross cell membranes, were similar for the two formulations (see Figure 2). We believe that this supports the thesis that the paclitaxel-related effects for Paclical and Taxol when given at the same dose and during the same infusion time should be comparable and should have the same temporal course of action. We believe that this trial supports the pursuit of the 505(b)(2) regulatory path in the U.S.

Figure 2: Mean curves of unbound plasma concentration of paclitaxel after identical doses of Paclical and Taxol, 175 mg/m<sup>2</sup> over 3 hours.

**Paclitaxel Mean Cu after Paclical and Taxol**



*Pharmacokinetic Comparison with Abraxane*

The pharmacokinetic properties of paclitaxel have also been evaluated following an intravenous infusion of Paclical or Abraxane at a dose of 260 mg/m<sup>2</sup> in order to compare the pharmacokinetics of Paclical and Abraxane in humans. The study was a cross-over study and both the mean total plasma concentrations and the mean unbound plasma concentrations were compared, and both were similar for the two formulations (see Figure X and Y). We interpret these findings as an indication of similar efficacy of the two compounds.

Figure X Mean ( $\pm$ SD) Total Plasma Paclitaxel Concentrations Following IV Administration of Paclical or Abraxane — All Patients

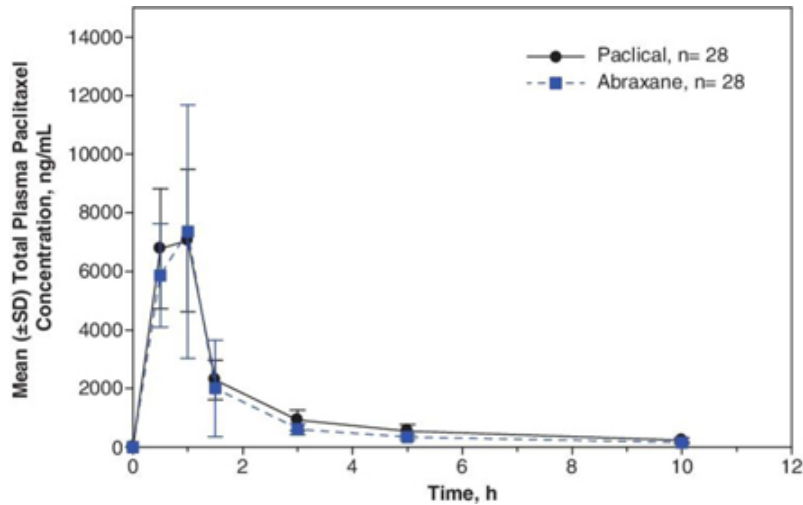
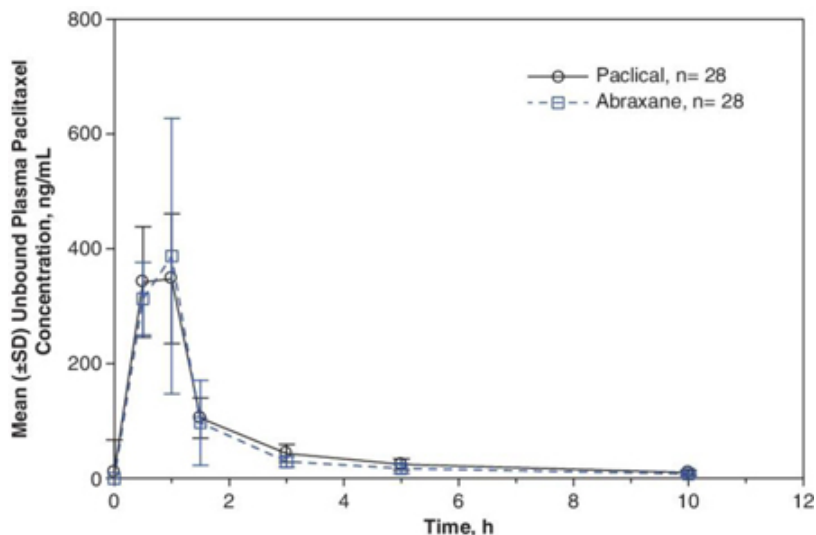


Figure Y Mean ( $\pm$ SD) Unbound Plasma Paclitaxel Concentrations Following IV Administration of Paclical or Abraxane — All Patients



### ***Paclical/Abraxane Head to Head Study***

On August 4, 2015, we announced the results of a preliminary study of a head-to-head pharmacokinetic comparison between Paclical and Abraxane, which found that the concentration of both total and unbound paclitaxel in plasma was similar.

Our formulation is currently called Paclical for human indications, and is marketed under the name Paccal Vet-CA1 (“Paccal Vet”) for veterinary indications. We own the global commercial rights to Paclical, excluding Israel, Turkey, Russia, the Commonwealth of Independent States (“CIS”), Ukraine, Georgia and Turkmenistan. We have licensed the global commercial rights to Paccal Vet for sale in Japan, Russia and the CIS. Paclical received marketing approval in Russia and the CIS in April 2015.

### **Paclical Vet, Our Initial Animal Health Product**

#### ***Paclical Vet Overview***

Paccal Vet is a novel XR-17 based formulation of paclitaxel. Paclitaxel is a well-established, widely used chemotherapeutic that on its own is practically insoluble in water. Paccal Vet is our initial product in veterinary oncology. Our former commercial partner, Abbott Animal Health, a leading animal health company, launched the product in mid-2014, at which time we were eligible to receive royalties that start at a minimum approximately one third of net sales. The Investigative New Animal Drug (“INAD”) number for Paccal Vet is 011609, which we requested on March 20, 2007.

In February 2014, we received conditional approval from the FDA for Paccal Vet for the treatment of nonresectable stage III, IV or V mammary carcinoma and resectable and nonresectable squamous-cell carcinoma, both for dogs that have not received previous chemotherapy or radiotherapy.

To receive conditional approval pursuant to the MUMS designation, we were also required to (i) show that our manufacturing process for Paccal Vet satisfied certain criteria, including purity and stability (see “Government Regulation — Requirements for Approval of Veterinary Pharmaceuticals for Pets — Defined Manufacturing Process”); (ii) show that the production and use of Paccal Vet satisfied certain human and environmental safety criteria (see “Government Regulation — Requirements for Approval of Veterinary Pharmaceuticals for Pets — Safe for Humans and the Environment”); and (iii) provide a reasonable expectation of effectiveness in treating mammary carcinoma and squamous cell carcinoma. To receive full approval, we will need to show that the manufacturing and safety criteria described above remain satisfied, and that Paccal Vet is completely effective in treating mammary carcinoma and squamous cell carcinoma.

Conditional approval allows veterinarians to treat dogs with Paccal Vet in the approved indications. Conditional approval grants Paccal Vet seven years of market exclusivity, and gives us the right to promote the product before all of the efficacy data necessary for a full approval are available. Conditional approval also allows us to keep the product on the market for up to five years, through annual renewals, while collecting the remaining required efficacy data.

“[The] FDA’s Center for Veterinary Medicine determined that the drug’s two indications fit the ‘minor use in a major species’ category. Both mammary carcinoma and squamous cell carcinoma — within the limitations described on the label occur infrequently and in a small number of dogs each year (fewer than 70,000 dogs in the U.S. in one year).”

“The company has shown that, when used according to the label, PACCAL VET-CA1 is safe and has a ‘reasonable expectation of effectiveness.’”

Reference: FDA <http://www.fda.gov/animalveterinary/resourcesforyou/ucm402476.htm>

In order to obtain the remaining required efficacy data for full approval of Paccal Vet, we are planning a clinical trial evaluating Paccal Vet against placebo in 165 dogs with mammary carcinoma and 165 dogs with squamous-cell carcinoma. We initiated these studies in the fourth quarter of 2014. In early phase trials where one seeks to ascertain whether the dose or trial can assess a particular degree of safety there are usually no comparative treatments. That was the case for the study called *Paccal Vet in Malignant High-Grade Solid Tumors in Dogs*.

The study *Paccal Vet Prospective Single-Arm Trial in Mast Cell Tumors in Dogs* was a single-arm study. This was because the comparator used in clinical trials is the standard of care, the most commonly used treatment for the indication. When we started to develop Paccal Vet there were no chemotherapeutics approved for dogs. One can of course always compare to no treatment or the vehicle (“placebo”). With a disease such as cancer, it is not ethical not to treat, and that was the reason for the single arm study.

When it was possible for us to apply for conditional approval, discussions were held with CVM/FDA and it was concluded that data from a comparative study were not needed to obtain the conditional approval. Although, according to CVM/FDA, the number of dogs with the specific indications treated in the study *Paccal Vet in Malignant High-Grade Solid Tumors in Dogs*, was too low to meet requirements of reasonable expectation of effectiveness. Therefore it was decided, through discussions with CVM/FDA, to include dogs from a study not done by Oasmia (mammary carcinoma) and to conduct a small study (squamous cell carcinoma) in order to meet the requirements of a conditional approval.

EMA CVMP Scientific Advice and FDA protocol concurrence were requested and received for the pivotal clinical study protocol(s) for full approval. The study protocol was submitted to EMA for scientific advice. An answer was obtained on July 12, 2012 (EMA/CVMP/SAWP/296308/2012). The questions asked by Oasmia referred to study design, primary objective/end-point, the use of placebo as comparator, sample size calculations, quality of life scale, the use of anti-emetics, and the possibility to use safety data from previous studies. The answers to some of the questions were ambiguous and clarifications were requested on August 10, 2012, and answered on September 13, 2012 (EMA/CVMP/SAWP/548291/2012). EMA’s comments were addressed in the final study protocol.

The Clinical Study Protocol(s) have received FDA “concurrence” which means FDA agrees with the design of the clinical protocol(s), and as such also agrees with the numbers of dogs to be in the study(s). FDA as a status quo requires a minimum of 150 dogs. EMA does not generally require a specific minimum number of dogs such as 150 dogs, but the numbers should be based on a hypothesis that is statistically valid. Oasmia asked in scientific advice to EMA CVMP October 2013 specifically, “Does the CVMP agree that this number of dogs is sufficient?” EMA CVMP Answer (excerpted) “As outlined in the CVMP GL on statistical principles for clinical trials for veterinary medicinal products (EMA/CVMP/EWP/81976/2010) ‘the number of animals in a clinical trial should always be large enough to provide reliable answers to the questions addressed. This number is usually determined by the primary objective of the trial’. Thus, a formal sample size calculation is considered necessary in the planned confirmatory clinical trial. Based on the treatment effects specified in the company’s position, the planned sample size initially appears reasonable.”

We are conducting a study in 50 dogs for the treatment of mast cell tumors, with the aim of assessing progression free survival (as opposed to a prior study conducted with the aim of assessing the response rate of dogs with mast cell tumors to Paccal Vet, see “— Paccal Vet in Mast Cell Tumors in Dogs”). We determined the final protocol for this study based on a request we made to the EMA for scientific advice as to study design, primary objective/end-point, use of placebo as comparator, sample size calculations, quality of life scale, the use of anti-emetics, and the possibility of using safety data from previous studies. Once the data are collected, we expect to submit an MAA to the EMA for Paccal Vet, which may include data collected from any, or all, of the other studies conducted by us described below.

Whether or not to submit a NADA for the treatment of mast cell tumors depends on the results of the study. The protocol is not designed according to the requirements of CVM/FDA, but the results might allow submission nonetheless.

#### ***Paccal Vet Market***

According to the Animal Cancer Foundation, approximately six million dogs per year are diagnosed with cancer in the U.S., slightly less than 10% of the population. Based on a population of 60 million dogs in the EU, we estimate almost six million dogs per year are diagnosed with cancer in Europe. We estimate that between 36,000 and 41,250 dogs are treated annually for mammary carcinoma, while the number of diagnoses for squamous cell carcinoma in dogs is less than 10,000 annually. This is the reason Paccal Vet was eligible for conditional approval, the drug's two indications fit the “minor use in a minor species” category. As mentioned earlier both mammary carcinoma and squamous cell carcinoma occur infrequently and in a small number of dogs each year (fewer than 70,000 dogs in the U.S. each year).

Based on the referenced sources for the U.S. and Europe, we believe that the incidence rates and overall prevalence of cancer in dogs is similar for cats. Solid tumors, with or without metastatic disease, are one of the most common forms of cancer in dogs and cats. Aside from Paccal Vet, there are currently no injectable chemotherapeutic drugs specifically approved for use in pets in the U.S., although, as an alternative, human drugs are often used off-label. Taxol and Abraxane, both of which deliver paclitaxel, cannot safely be used in dogs. Taxol has toxicity associated with Cremophor E1 (polyoxyethylated castor oil) (“Cremophor”), and dogs have a resistance to human albumin, which is found in Abraxane.

The first drug to be approved specifically for the treatment of cancer in dogs was Zoetis' Palladia, a toceranib phosphate tablet, which is indicated for the treatment of mast cell tumors and launched in 2009. While Zoetis does not disclose sales of Palladia, we believe the product is well known to veterinarians.

Mammary carcinoma and squamous-cell carcinoma are two of the most common types of solid tumors in dogs. Skin cancers, which include squamous-cell carcinomas, comprise one third of all canine cancers. Mammary tumors are the most common type of cancer in female dogs, accounting for about half of all tumors and affecting up to 25% of female dogs that are not spayed.

#### ***Paccal Vet in Malignant High-Grade Solid Tumors in Dogs***

We evaluated Paccal Vet in an open-label, single arm, dose-escalating clinical field study to determine a clinically safe and effective dose and to evaluate single-dose pharmacokinetics in tumor-bearing dogs. This was our first clinical report of a Cremophor-free formulation of paclitaxel, suggesting successful administration without premedication in dogs. We ran this study as a single-arm study because the objective of this study, and other early phase studies, was to assess appropriate dosage and to assess certain particular safety aspects of Paccal Vet, for which a control group was not required.

The study included 27 dogs, with one-quarter of the dogs diagnosed with mast cell tumors, another quarter diagnosed with mammary tumors, and the others diagnosed with lymphoma, squamous cell carcinoma and other types of tumors. The dogs were treated with Paccal Vet for at least three cycles and up to five cycles, with each treatment cycle consisting of separate infusions approximately 21 days apart. The majority of dogs were treated with 150 mg/m<sup>2</sup>, which is the dose of Paccal Vet used in subsequent studies. We used data from this study to receive conditional approval in mammary carcinoma and squamous cell carcinoma from the FDA.

Efficacy was assessed as best overall response rate (“BORR”) during treatment. Response was determined using Response Evaluation Criteria in Solid Tumors (“RECIST”), the standard evaluation method for treatment of solid tumors in animals and humans, for which “complete response” is the disappearance of all target and non-target lesion(s) and no appearance of new lesion(s). “Partial response” is at least a 30% decrease (relative to baseline) of the sum of longest diameter of target lesion, non-progression of non-target lesion, and no appearances of new lesions. Twenty of the 27 dogs (74%) experienced either a complete response (9 dogs) or partial response (11 dogs) at some time during treatment. With regard to safety, Paccal Vet was well tolerated at levels at or below 150 mg/m<sup>2</sup>. The most common adverse events noted were a reduction in white blood cells, vomiting, diarrhea, fatigue and anorexia, all of which are commonly seen during chemotherapy treatment.

#### ***Paccal Vet in Mast Cell Tumors in Dogs***

The safety and efficacy of Paccal Vet for the treatment of grade II or III mast cell tumors in dogs that cannot be safely removed surgically were evaluated in a randomized, masked, controlled, multinational 14-week clinical field study. The objective was to demonstrate clinical superiority of Paccal Vet compared to active control lomustine, an oral chemotherapeutic commonly used for dogs. Efficacy was evaluated by the portion of dogs with a confirmed overall response, defined as complete response or partial response, 14 weeks after four consecutive three-week treatment cycles. This study began in October 2008.

In total, 249 dogs were randomly assigned to treatment with either 150 mg/m<sup>2</sup> Paccal Vet (168 dogs) administered as a slow intravenous infusion or 70 mg/m<sup>2</sup> lomustine (81 dogs) administered orally, every three weeks for four consecutive treatment cycles.

The majority of adverse events observed in dogs treated with Paccal Vet involved transient neutropenia (a low number of neutrophils, a form of white blood cell) that was often subclinical. Dogs treated with lomustine experienced elevated levels of liver enzymes as the most common adverse event.

The efficacy analysis found a statistically significant difference in favor of Paccal Vet, with a “p value” (the estimated probability of rejecting the hypothesis that there is no difference between the two treatment groups) of less than 0.05, which is the maximum p-value required to conclude a statistically significant result. However, the response rate in both treatment groups was surprisingly low, 1% response in the lomustine group, where there are published results of 42% response, and 7% response in the Paccal Vet group. We have developed several hypotheses to explain these low results, including the fact that dogs with grade III mast cell tumors may already be too ill to undergo further treatment. Additionally, some of the dogs included in the study had several small tumors, which are difficult to measure. It is also possible that the response of mast cell tumors to treatment may have resulted in dogs being taken off treatment too soon. When dogs in which the disease was kept stable were included in a supplementary analysis, BORR was significantly greater (23% versus 10%; p-value = .012) for Paccal Vet compared with lomustine. Paccal Vet-treated dogs were also 3.1 times more likely, compared with lomustine-treated dogs, to have a confirmed BORR at 14 weeks. This study differs from the study described below under the heading “— Paccal Vet Single-Arm Trial in Mast Cell Tumors in Dogs” because in that study, the BORR was assessed at certain pre-selected times during the treatment period, while in this study, the BORR was assessed after four treatment cycles. Because of these suboptimal results, we do not intend to rely on the results from this study for any submission.

#### ***Paccal Vet in Mammary Carcinoma***

We received conditional approval for mammary carcinoma indication from the FDA in February 2014. This approval was based on safety data for Paccal Vet and the limited efficacy data for the indication.

Efficacy data relating to mammary carcinoma were obtained from the study with Paccal Vet on malignant high-grade solid tumors. In that study, seven dogs with mammary carcinoma were treated, four of which responded to treatment (one complete response and three partial responses). Furthermore, two of the seven dogs survived over a year after the treatment was completed. In addition to the dogs from the previous study, literature data on three dogs previously treated at University of Wisconsin was added, for a total of 10 cases of mammary carcinoma, of which six responded. We included these data from the University of Wisconsin in accordance with discussions we had with the CVM in order to satisfy the reasonable expectation of effectiveness requirement to obtain conditional approval for Paccal Vet for the mammary carcinoma indication.

### ***Paccal Vet in Squamous Cell Carcinoma***

We also received conditional approval for squamous cell carcinoma indication for Paccal Vet from the FDA in February 2014. This approval was likewise based on safety data for Paccal Vet and limited efficacy data for the indication.

The study of Paccal Vet in malignant high-grade solid tumors included only three cases of squamous cell carcinoma, and as this was not enough to show reasonable expectation of efficacy, we conducted a small, exploratory study in dogs with this indication. In this study, 14 dogs with various types of squamous cell carcinoma were treated with Paccal Vet for four cycles. Two of the dogs responded to treatment and another two dogs had prolonged stable disease, which, according to the protocol, was considered a response to treatment. A dog with squamous cell carcinoma had also been treated in a compassionate use program in the U.S., and this dog was also included in the efficacy analysis, which consisted of a total of 18 dogs, with six dogs showing BORR and two dogs having prolonged periods of stable disease.

### ***Paccal Vet Single-Arm Trial in Mast Cell Tumors in Dogs***

We conducted a single-arm, open-label, multi-center, clinical trial to determine the efficacy and safety of Paccal Vet in client-owned dogs with grade II or III mast cell tumors. Mast cell tumors are graded histologically from I to III: grade I tumors are benign and local, curable with surgery alone; grade II tumors are intermediate and approximately 25% of these metastasize; and grade III tumors are advanced with high metastatic potential and short overall survival despite aggressive treatment. We ran this trial as a single-arm trial for ethical purposes — because there was no other approved chemotherapeutic for dogs at the time, there was no most commonly used treatment for the indication. It would have been unethical to administer no treatment or a placebo to a dog diagnosed with cancer for the purpose of establishing comparative results for this study. This study was completed in December 2008.

Dogs that received at least one dose of treatment (29 dogs) were included in the analysis of safety, and 28 of those dogs had tumor measurements and were included in an efficacy analysis. The dogs were administered an intravenous dose of 150 mg/m<sup>2</sup> of Paccal Vet once every 21 days for three cycles. Clinical safety was assessed by clinicopathological analyses and recording of adverse events. Following the end of the study, the owners were contacted to provide information used to assess progression free survival.

BORR at any time during treatment was seen in 54% of dogs whereas complete or partial response was observed in 31% of dogs at the end of the study. It took an average of 247 days from the start of the treatment until the cancer reappeared in the dog. Adverse events were reductions in the number of two types of white blood cells, neutrophils and leucophils. These events, which are common with chemotherapy, were short lasting and seen only sub-clinically (i.e. the dogs did not display any evidence of fever or other symptoms, other than in the blood sample analyses).

The difference between this study and the one including 249 dogs called Paccal Vet in Mast Cell Tumors in Dogs is the response rate, BORR. In this study including 29 dogs the BORR is assessed at any time during the treatment period. In the study including 249 dogs the BORR was assessed after 4 treatment cycles.

### ***Paccal Vet Planned Clinical Studies***

In order to be granted full approval in the United States for mammary carcinoma and squamous cell carcinoma in dogs, we are required to perform field studies to show efficacy of treatment. We plan to conduct randomized, placebo-controlled trials in dogs with mammary carcinoma and squamous cell carcinoma (one trial for each indication), to compare progression free survival in dogs treated with Paccal Vet compared to placebo. The study will enroll approximately 165 dogs. Dogs will be randomized to receive either a 150 mg/kg dose of Paccal Vet or placebo in a two-to-one ratio. The treatment period will consist of four cycles of therapy at three week intervals after which the dogs will be monitored until tumor progression. In the meantime, we expect Paccal Vet to remain available for the treatment of mammary carcinoma and squamous cell carcinoma pursuant to the conditional approval we received in February 2014. We initiated the study in the fourth quarter of 2014. We requested and received scientific advice from the EMA and protocol concurrence from the FDA for the protocol of this study and number of dogs studied. The FDA requires that at least 100 dogs be tested, and since we use 2:1 randomization the number of dogs needed was 150. To compensate for dogs that could not be used in the analysis another 10% was added. EMA does not require a specific minimum number of dogs to be tested, but the number should be based on a hypothesis that is statistically valid. A sample size calculation showed that we would need fewer than 165 dogs.

After consultations with the EMA, we have initiated a study of Paccal Vet in no fewer than 50 dogs for the treatment of mast cell tumors. The ongoing trial is also placebo-controlled study designed to evaluate progression free survival in dogs treated with Paccal Vet compared to placebo. Results are expected during the second half of 2016. We are currently planning to use the data from this trial to obtain regulatory approval in Europe in dogs.

#### ***Paclical & Paccal Vet Preclinical Data***

We conducted a comprehensive program of preclinical testing of Paclical, including several *in vitro* and *in vivo* studies. Key findings from our preclinical program include:

- *In vitro* studies showed that the chemotherapeutic activity of Paclical was equal to or more potent than that of Taxol in ten different rat tumor cell lines.
- The pharmacokinetic pattern of paclitaxel was investigated in rats receiving either Taxol or Paclical. Higher concentrations of total paclitaxel were observed after administration of Taxol compared to Paclical, but when studying the unbound concentrations, no obvious difference between the two formulations could be seen.
- In a plasma concentration study of 21 dogs receiving 100 – 150 mg/m<sup>2</sup> of paclitaxel as a 30 minute intravenous infusion, the distribution of paclitaxel into the tissue was rapid, and the distribution phase ended within one hour after the start of infusion.
- Hematological toxicity of Paclical was studied in rats and found to be similar to Taxol in terms of extent and duration of effect. A strong rebound in the white blood cell count followed the initial decrease, and at days 16 to 17 following a single dose, the white blood cell counts were stabilized at the baseline level.
- Repeat dose toxicity studies were performed in rats. The mortality rate at 10 mg/kg Taxol was high and the dose in the 10 mg/kg group was reduced to 5 mg/kg. All animals that received 10 mg/kg of Paclical survived.
- The safety of Paclical in dogs has been shown to be consistent with expectations for a chemotherapeutic with bone marrow suppression as the most apparent toxicity. Gastrointestinal disorders such as diarrhea and vomiting have also been commonly observed. None of the severe hypersensitivity reactions, such as anaphylactic shock, reported to occur in humans treated with other formulations of paclitaxel have been observed in dogs.
- Toxicity investigations conducted with the excipient XR-17 showed increases in liver enzymes, bile acids and total bilirubin as well as the presence of pigmented Kupffer cells at high doses (4.6-fold and 8.3-fold clinical levels for humans on a mg/m<sup>2</sup> and mg/kg basis, respectively). No histological findings of significance were observed in low dose animals. Toxic reactions were not seen until doses reached almost five times higher than the doses given to Paclical patients.

#### **Docecal**

##### ***Overview***

Docecal is our patented formulation of docetaxel, the active ingredient in Taxotere, a widely used chemotherapeutic medication that generated annual worldwide sales of more than \$2.8 billion in 2010, when its patent expired. Taxotere contains the solvent polysorbate 80, which is potentially linked to adverse side effects such as acute hypersensitivity and edema. To minimize these effects, patients typically undergo premedication with steroids. Like Paclical, Docecal is free of toxic solvents. We believe Docecal may be able to deliver equal, or potentially greater, amounts of docetaxel as Taxotere without the effects of polysorbate 80 and, if approved, compete with Taxotere and generic versions thereof. Since there are no human clinical studies in the U.S. we are not required to file an IND.



### ***Docecal Preclinical Studies***

The anti-proliferative effects of Docecal were investigated in a panel of six human cancer cell lines and compared with the effects of commercially available Taxotere using a standard cell proliferation assay. For all of the tested cell-lines, Docecal was as effective as Taxotere in inhibiting cell growth.

Rats were injected with Docecal once weekly for 28 days with doses of 4.2 mg/kg or 6.0 mg/kg or with Taxotere 4.2 mg/kg. The Docecal group showed Docecal-related signs such as erythema, paleness, wounds on the tails, limpness and local skin reactions seen as dry skin with scale formations in both sexes following both treatments. The effects were most pronounced in the 6 mg/kg group. Changes in hematology, clinical chemistry, organ mass, macroscopic and microscopic findings were seen in both sexes. In the absence of any histological examination in the Docecal 4.2 mg/kg group, the significance of these differences cannot be assessed.

A no-observed-adverse-effect level, or the highest exposure of docetaxel having no adverse effect, was not established in this study with Docecal. However, we believe that the failure to establish a no-observed-adverse-effect level has not hindered the approval process for other APIs used in the treatment of cancer and will not hinder the Docecal approval process.

### ***Docecal Planned Studies***

We have applied for permission to initiate a pharmacokinetic study, comparing Docecal with Taxotere, in first half of 2016. If successful, we plan to discuss the results and a proposed clinical development plan with both the EMA and the FDA.

We enrolled the first patient in a study in March 2016 to assess the need for pre-medication and possibly to fulfill the requirements of the Russian authorities in order to obtain market authorization in Russia and the CIS.

### **Doxophos Vet**

#### ***Doxophos Vet Overview***

Doxophos Vet is a patented formulation of doxorubicin, one of the most effective and commonly used chemotherapeutic agents for the treatment of cancer, which we are developing for the treatment of lymphoma in dogs. Lymphoma is the most common cancer in dogs, and the FDA granted MUMS designation for Doxophos Vet for the indication. Treatment with Doxophos Vet has shown reduced cardiovascular side effects compared to standard treatments with doxorubicin. We completed a dose-finding study in the fourth quarter of 2014 and the results were obtained in June of 2015. The INAD number for Doxophos Vet is 011910, which we requested on March 10, 2010.

#### ***Doxophos Vet Planned Clinical Trials***

Upon determining the dose in the dose ranging study, we initiated a proof of concept study in dogs with lymphoma during the first quarter of 2015, which as a result of the MUMS designation, may enable us to apply for a conditional approval, as we did for Paccal Vet. The aim of the study will be to assess the response rate in dogs with lymphoma, but will also monitor progression to estimate progression free survival.

A large field study with Doxophos Vet is needed to obtain full approval, and this study is planned to start following completion of the proof of concept study and discussions with FDA and EMA.

## **Doxophos**

### ***Doxophos Overview***

Doxophos is a proprietary formulation of doxorubicin. Despite the efficacy of doxorubicin, significant cardiovascular toxicity, including irreversible cardiomyopathy, has been observed and the cumulative dose should not exceed 550 mg/m<sup>2</sup>. We have filed a MAA in Russia for Doxophos as a hybrid/improved generic.

### ***Doxophos Market***

The two leading doxorubicin-based products are Adriamycin and Doxil, or Caelyx when marketed outside of the U.S. Doxil is a lipid, or fat, encapsulation of doxorubicin introduced as a replacement for Adriamycin. Treatment with Doxophos Vet has shown reduced cardiovascular side effects as compared to standard treatments with doxorubicin.

### ***Doxophos Preclinical Trials***

We conducted a preclinical trial in which rats injected with six human cancer cell lines were administered Doxophos as compared to standard doxorubicin. Doxophos was as effective in inhibiting cell growth as standard doxorubicin in all of the tested cell lines and had a comparable pharmacokinetic profile in rats.

Repeat dose toxicity in rats showed that the incidence and severity of the clinical effects were similar in the Doxophos and doxorubicin exposed rats and less frequent or less severe in rats receiving the lower dose of Doxophos. Expected changes were observed in most hematology parameters and were similar for Doxophos and standard doxorubicin treated rats.

Rats treated with standard doxorubicin had a higher incidence of fluid-filled abdomens (ascites), which could be a sign of (right sided) heart failure. However, histopathological examination failed to show any differences between the two treatments and a lower cardiotoxicity potential of Doxophos compared to standard doxorubicin was thus not seen in this study.

## **OAS-19**

### ***OAS-19 Overview***

Historically, chemotherapeutic agents were used as single agents. However, combination therapies have become standard treatment for a number of cancers, such as ovarian cancer, first line breast cancer, prostate cancer and lung cancer. OAS-19 is an XR-17 based combination of two widely-used chemotherapy drugs in a single micelle. OAS-19 applies a dual chemotherapeutic agent encapsulation and release mechanism in one infusion and may provide us with a new platform for further product candidate development. Since there are no human clinical studies in the U.S. we are not required to file an IND.

### ***OAS-19 Preclinical Studies***

Male and female rats received four intravenous administrations of OAS-19, one week apart, at the doses of 0 (micelle excipient only), 4.2, 6 and 8.5 mg/kg/week. Mortality was noted in highly-dosed males only, while effects on food consumption and body weight gain were observed at all doses and in both genders, with a dose-dependent relationship. Treatment-related changes were noted almost at all doses, albeit without a clear dose-dependent relationship, in organs/tissues of the hemolymphoietic, gastrointestinal, urinary, genital, musculoskeletal, nervous and integumentary systems. The toxic effects observed in target organs were those expected to occur after administration of the underlying agents included in OAS-19.

Under the applied conditions, 6 mg/kg was considered the maximum tolerated dose, while the lowest observed adverse effect level (LOAEL) was the lowest tested dose of 4.2 mg/kg/week.

The dose to be used in humans will be established in the first clinical trial, but it is estimated that 6 mg/kg corresponds to six to eight times the human dose.

### ***OAS-19 Planned Studies***

We plan to develop a clinical program for this product candidate.

### **Market Overview**

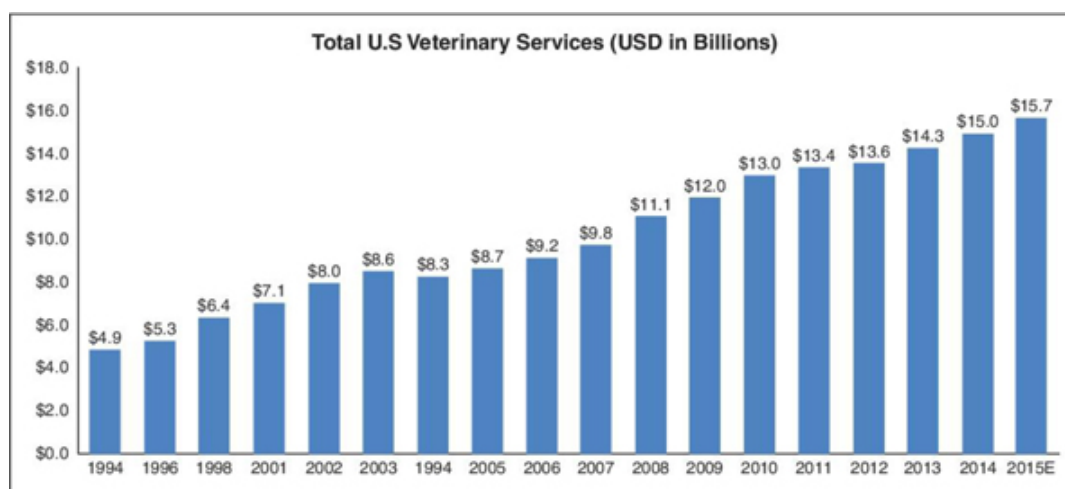
Our initial development efforts are focused on the fields of human and veterinary oncology. We believe that our XR-17 technology can be applied to address commercially attractive opportunities in these two markets based on the limitations of existing therapies.

#### ***Human Oncology Market Opportunity***

Cancer is a serious, widespread and growing disease. According to the World Health Organization (“WHO”), approximately 8.2 million people died of cancer in 2012, and it is expected to rise by 70% over the next two decades.

Despite the development and introduction of new drugs to treat cancer, chemotherapeutic agents, used in combination with other treatments such as surgery or radiation, remain the primary treatment of cancer worldwide. Chemotherapeutic agents generally work by blocking cell division, thereby inhibiting the reproduction of cancer cells and suppressing tumor growth. Many new drugs that have obtained marketing approval for the treatment of cancer are used in combination with chemotherapeutic agents. In addition, many drug candidates in development across the industry, like most chemotherapeutics, are not water soluble and will require innovative formulations to enable intravenous use. We believe that the widespread use of chemotherapeutic agents worldwide and the potential use of our formulation technology with new drug candidates present a large commercial opportunity.

#### ***Animal Health Market Opportunity***



Source: American Pet Products Association. ([http://www.americanpetproducts.org/press\\_industrytrends.asp](http://www.americanpetproducts.org/press_industrytrends.asp))

The U.S. is the single largest pet market, with 78 million pet dogs and 86 million pet cats, according to the American Pet Products Association (“APPA”) 2015 - 2016 National Pet Owners Survey. According to The European Pet Food Industry Federation 2014 Facts & Figures, there are approximately 63 million pet dogs and 72 million pet cats in the EU.

Dogs in particular are receiving increased amounts of veterinary care. According to APPA, approximately 78% of dog owners in the U.S. treated their dogs with medications in 2010, as compared to 50% in 1998. The increased spending is largely due to a changing attitude of owners toward their pets, as they increasingly view pets as family members. Accordingly, owners are willing to seek quality medical care for their pets. While the actual number of dogs in need of chemotherapy that actually received such treatment is unknown, one study estimated the number of dogs receiving cancer treatment in 2008 in the United States to be over one million, and that the average age of the dog when cancer is detected is eight years. Also, in Sweden pet insurance is becoming more widespread. It is estimated that eighty to ninety percent of dogs are covered by medical insurance, and approximately eighty percent of such insurance policies includes coverage for chemotherapy. The approximate life expectancy of dogs that do not receive treatment could be one to two months after the diagnosis, whereas for a dog that is treated with chemotherapy it could be one year from the diagnosis. It should be noted that this is an example since it is impossible to generalize the life expectancy since it depends on for instance the type of tumor and treatment.

Due to the limited number of registered available oncology treatments for companion animals, we believe that there is a significant commercial opportunity to apply our formulation technology within veterinary oncology. According to the Center for Cancer Research and CanineCancer.com, approximately six million dogs in the U.S. are diagnosed with cancer each year, of which approximately one third have cutaneous, or skin, cancers. Current treatments consist largely of surgery, chemotherapy, and radiation therapy. For dogs in need of chemotherapy, the standard of care has largely been the off-label use of injectable human chemotherapeutic agents such as cisplatin, doxorubicin, carboplatin, and vincristine. Due to the fact that existing injectable chemotherapeutic agents have been formulated for humans and have not been optimized for animals, combined with broad acceptance of their anti-cancer effect, we believe that our intravenous chemotherapy labeled specifically for use in dogs will be viewed favorably by the veterinary community.

Based on the attributes of XR-17, we believe that there is a significant commercial opportunity to apply our proprietary formulation technology within veterinary oncology to enable the safe delivery of well-established chemotherapeutics, approved for the first time specifically for animal use.

### **Competition**

Our industry is highly competitive and subject to rapid and significant technological change. While we have significant development experience and scientific knowledge, we may face competition from both large and small pharmaceutical and biotechnology companies, including specialty pharmaceutical and veterinary pharmaceutical companies and generic drug companies, as well as academic institutions, government agencies and research institutions, among others.

Our competition will be determined in part by the potential indications for which our products are developed and ultimately approved by regulatory authorities. It is likely that the timing of market introductions of some of our potential products or our competitors' products will be an important competitive factor. Accordingly, the speed with which we can develop our compounds, conduct preclinical studies and clinical trials to obtain approval and manufacture or obtain supplies of commercial quantities of any approved products should also be important competitive factors. We expect that competition among products approved for sale will be based on additional factors, such as product efficacy, safety, reliability, availability, price and patent position.

### **Human Health**

We believe that Paclical will compete, directly or indirectly, with Bristol-Myers Squibb's Taxol and its generic equivalents, Celgene's Abraxane and other cancer therapies, including alternative formulations of paclitaxel, or other chemotherapeutic agents, that have been or are being developed by other pharmaceutical and biotechnology companies.

### **Animal Health**

We expect that Paccal Vet will face competition from Palladia, made by Zoetis, Inc. We expect that Doxophos Vet will face competition from AT-004 and AT-005, made by Aratana Therapeutics, Inc., and that both Paccal Vet and Doxophos Vet will compete with the off-label use of chemotherapeutic drugs for humans.

Since the development and commercialization of new veterinary medicines is highly competitive, we expect considerable competition from major pharmaceutical, biotechnology and specialty animal health companies. We are also aware of several smaller early stage companies that are developing products for use in the pet therapeutics market.

## Strategic Alliances and Collaborations

We have entered into three separate agreements with established pharmaceutical companies for our products. Each agreement provides the pharmaceutical company with an exclusive right in a defined geographic territory to market one or more products in all indications. In return, we receive royalty payments or a profit participation, as well as milestone payments, and we retain the exclusive right with respect to the manufacture and supply of the product during the commercial life of the product. The various agreements generally are terminable upon a material breach or insolvency of either of the parties. Under all of the agreements, we supply the products at an agreed upon formula related to our production cost (subject to annual adjustment) and the pharmaceutical company establishes the price at which the products are sold in the territory.

### *Nippon Zenyaku Kogyo, Japan*

We entered into a development, supply and exclusive license agreement with Nippon Zenyaku Kogyo, Co. Ltd. ("Nippon") in April 2010 (the "Nippon Agreement"). The Nippon Agreement grants Nippon the exclusive right to market Paccal Vet in Japan. The initial term of the Nippon Agreement is the later to occur of (i) 10 years from the date of the Nippon Agreement, or (ii) upon the expiration of the patent rights granted under the Nippon Agreement. Nippon is solely responsible for all sales and marketing costs as well as the requisite clinical trials in order to obtain marketing approval for Paccal Vet in Japan.

We receive royalties of (i) 27% of Nippon's gross profits for net sales up to \$7.5 million and (ii) 36% of Nippon's gross profits for net sales above \$7.5 million. The Nippon Agreement also includes various milestone payments, the first of which, €0.55 million, we received upon entering into the Nippon Agreement. The remaining milestone payments are payable upon our achieving certain marketing approvals and net sales thresholds, including €0.7 million upon marketing authorization, €1.0 million when annual net sales reach \$7.5 million and €1.0 million when annual net sales reach \$12.5 million. We may be required to repay the first milestone payment if marketing approval cannot be obtained or if we are guilty of a breach of contract that results in the termination of the Nippon Agreement or the withdrawal of the product from the market. We may also be liable to compensate Nippon for costs incurred in relation to obtaining marketing approval.

We are responsible to Nippon for maintaining the quality of the product, but Nippon is solely responsible for pharmacovigilance. The Nippon Agreement may be terminated by either party if the other party commits a material breach or becomes insolvent. In the event that the Nippon Agreement is terminated, regardless of which party terminates the agreement and the grounds for termination, the marketing approval, if received in Japan, will be transferred to us.

### *Medison Pharma, Israel*

We entered into a supply and exclusive license agreement with Medison Pharma, Ltd. ("Medison") in May 2011 (the "Medison Agreement"). The Medison Agreement grants Medison exclusive license and distribution rights for Paclical in Israel and Turkey. The initial term of the Medison Agreement is (i) ten years from the first commercial sale of Paclical in Israel or Turkey, or (ii) the expiration of our patent rights granted under the Medison Agreement, whichever occurs later. The Medison Agreement provides that Medison will use its commercially reasonable best efforts to launch Paclical in Israel and Turkey within six months of Paclical obtaining marketing authorization, and will assume sole responsibility for sales and marketing costs. We are responsible under the Medison Agreement for obtaining marketing approval for Paclical in Israel and Turkey, while Medison is responsible for obtaining reimbursement approval.

Medison has agreed to purchase specified, minimum quantities of Paclical once all approvals have been obtained. Should the minimum purchase requirements not be met, we have the right to terminate exclusivity. We receive royalties of (i) 25% of Medison's net sales for net sales up to €7.5 million and (ii) 30% of Medison's net sales for net sales above €7.5 million. The Medison Agreement also includes milestone payments, the first of which, €0.2 million, we received upon entering into the Medison Agreement, and the second of which, €0.2 million, we are entitled to receive upon the grant of marketing authorization by the European Commission.

We are responsible under the Medison Agreement to maintain the quality of the product, but Medison is solely responsible for pharmacovigilance. The Medison Agreement may be terminated by us if Medison fails to launch Paclical in Israel and Turkey within six months of Paclical obtaining marketing authorization. The Medison Agreement may also be terminated by either party if the other party fails to remedy a material breach or becomes insolvent.

#### ***Pharmasintez, Russia***

We entered into a supply and exclusive marketing, sales and distribution agreement with the Russian pharmaceutical company Pharmasintez in February 2013 (the "Pharmasintez Agreement"). The Pharmasintez Agreement grants Pharmasintez exclusive license and distribution rights for Paclical in Russia and the CIS, as well as Ukraine, Georgia and Turkmenistan. The initial term of the Pharmasintez Agreement expires five (5) years from the date Paclical receives marketing authorization in Russia. Pharmasintez will have sole responsibility under the Pharmasintez Agreement for sales and marketing costs in Russia and the CIS. We are responsible for obtaining registration approval in Russia, including performing any clinical research required to market Paclical. Pharmasintez pays all costs relating to marketing authorization approval in the CIS, including any necessary clinical trials.

Pharmasintez has agreed to purchase specified minimum quantities of the product, and should the minimum purchase requirements not be met, we have the right to terminate exclusivity. The Pharmasintez Agreement provides that all profits from the sale of Paclical in Russia and the CIS be split evenly between us and Pharmasintez. The Pharmasintez Agreement defines profits as gross sales minus (i) our supply price (which are our production costs, subject to annual adjustment) and (ii) Pharmasintez's distribution costs. We are liable to Pharmasintez for maintaining the quality of the product and for pharmacovigilance.

The Pharmasintez Agreement may be terminated by either party if the other party commits a material breach or becomes insolvent. In the event the Pharmasintez Agreement is terminated, regardless of which party terminates the agreement and the grounds for termination, the marketing approval will be transferred to us.

Sales- and marketing approval was obtained in Russia in April 2015. The first shipment of products to Pharmasintez was delivered at the end of the same year. Paclical was entered into the Russian reimbursement system in January 2016. Russia is divided into more than 50 hospital regions. Purchases of pharmaceuticals in the Russian hospital regions are carried out through tender offers annually or on half-year basis depending on the region. We are now entering the first period where Pharmasintez can act.

#### **Intellectual Property**

Our success depends in significant part on our ability to protect the proprietary nature of XR-17, our product and product candidates, technology and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing on our proprietary rights. We have sought, and plan to continue to seek, patent protection in the U.S., the EU and other countries for our proprietary technologies. Our intellectual property portfolio consists of our trademark-protected product Paccal Vet and our product candidates Paclical, Docecal, Doxophos Vet, and Doxophos. All of these drugs are based on our excipient model developed with nanotechnology and are protected by patents in all countries which we consider to be the U.S., we already have 12 issued patents with one further pending patent application under active prosecution. All of our patents are part of one or more of ten different patent families. A patent family is a collection of patents and patent applications, regional and national, which cover an invention or a group of related inventions.

See below for information regarding the patent families currently used in our product and product candidates.

<b>Patent families</b>	<b>Products patent family applies to</b>	<b>Status (US)</b>	<b>Status (EU)</b>	<b>Status (Japan)</b>	<b>Status (Israel)</b>	<b>Status (Eurasia)</b>	<b>Expiration date</b>
Taxol containing compositions	Paccal Vet, Paclical, Docecal	Granted	Granted	Granted	—	—	2022
Anticancer compositions	Paccal Vet, Paclical, Docecal	Granted	Granted	—	—	—	2022
Water insoluble	Paccal Vet, Paclical, Docecal	Granted	Pending	Granted	—	Granted	2028
Water soluble	Doxophos Vet, Doxophos	Granted	Pending	Granted	—	Granted	2028
Tax-Dox-Mix	OAS-19	Granted	Pending	Granted	—	Granted	2028

Our strategy for intellectual property rights is intended to protect our core technologies and their application. Our protection for intellectual property rights is continually surveyed and is currently considered to be satisfactory. We are to a large extent dependent on our patents.

The term of individual patents depends upon the countries in which they are obtained. In most countries in which we have filed, the patent term is 20 years from the date of filing. In the U.S., a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent & Trademark Office ("PTO") in granting a patent, or shortened if a patent is terminally disclaimed over another patent.

The term of a patent that covers an FDA-approved drug may also be eligible for extension, which permits term restoration as compensation for the time period lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act, permit an extension of up to five years beyond the expiration of the patent. See "— Regulatory." The length of the patent term extension is related to the length of time the drug is under regulatory review. Extensions cannot extend the remaining term of a patent beyond 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions to extend the term of a patent that covers an approved drug are available in Europe and other non-U.S. jurisdictions. In the future, if and when our pharmaceutical product candidates receive FDA approval, we may apply for extensions on patents covering those products.

To protect our rights to any of our issued patents and proprietary information, we may need to litigate against infringing third parties, avail ourselves of the courts or participate in hearings to determine the scope and validity of those patents or other proprietary rights. For a more comprehensive summary of the risks related to our intellectual property, see "Risk Factors — Risks Related to Our Intellectual Property."

We require our employees, consultants, outside scientific collaborators, researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. In addition, our employment agreements with all of our employees expressly grant us the exclusive rights to any inventions or other patentable material they produce in connection with their employment with us. Swedish law provides that (i) we own the exclusive intellectual property rights to any inventions or other patentable material produced by any of our research and development employees in connection with their employment, and (ii) we own non-exclusive rights to use any inventions or other patentable material produced by any of our other employees in connection with their employment, along with a right of first refusal if the employee were to attempt to sell exclusive rights to the invention or other patentable material. Accordingly, if an employee were to seek to enforce a claim to any of our patents, we would either own the exclusive rights in the patent already or have the right to purchase such rights from the employee. We also rely on trademarks, trade secrets, know-how and continuing innovation to develop our competitive position. In addition, we have a number of domain names registered, including oasmia.se and oasmia.com.

#### **Manufacturing and Supplies**

We are responsible for the manufacture and supply of our products for commercial and clinical trial purposes. On December 3, 2013, we announced that we have successfully passed an FDA Pre-Approval Inspection of our manufacturing facility in Uppsala, Sweden. We have entered into agreements with contract manufacturers, to help us meet the anticipated demand for our products and XR-17 excipient.

On May 14, 2014, the Swedish Medicinal Products Agency had approved Oasmia's production facility concerning manufacture for sales of human pharmaceuticals in the EU. Oasmia has previously a GMP license for veterinary pharmaceuticals. Thus, Oasmia presently has a fully approved production facility for manufacture of cytostatics for the EU market.

#### ***Baxter Oncology GmbH***

We entered into a non-exclusive commercial manufacturing and supply agreement with Baxter Oncology GmbH ("Baxter Oncology") in February 2011 (the "Baxter Agreement") which we expect to utilize as manufacturing requirements increase. The Baxter Agreement provides that Baxter Oncology will be responsible for the production of Paccal Vet and Paclical once the commercial demand reaches a requisite level. Baxter will perform complete analytical testing and release of semi-finished product. Final labeling, packaging and product release for the market will be performed by Oasmia. The Baxter Agreement was expanded in June 2014 to enable inclusion of other product candidates from our product portfolio. The Baxter Agreement's initial term is for five years, with automatic one-year renewals.

The Baxter Agreement may be terminated by either party if the other party commits a material breach or becomes insolvent.

#### ***Syntagon***

We entered into a non-exclusive manufacturing agreement with Syntagon AB ("Syntagon") in August 2013 (the "Syntagon Agreement"). The Syntagon Agreement provides that Syntagon will undertake process development and production for the manufacturing of technical batches of XR-17. The manufacturing will be performed with certain process adaptations due to the increased scale. Syntagon may not sub-contract any activities it is to perform pursuant to the Syntagon Agreement without our prior written approval. Syntagon indemnifies us against any liability, claim, lawsuit or judgment that we incur due to any defective product or any other breach of the agreement by Syntagon.

The Syntagon Agreement's initial term is until December 31, 2018, with automatic one-year renewals. The Syntagon Agreement may be terminated by either party if the other party fails to cure a breach or becomes insolvent.

#### ***Raw Materials***

Our most important raw materials are two different types of retinoic acids, 13 Cis Retinoid Acid and AllTrans Retinoid Acid, and a third compound known as L-Cysteic acid methyl ester. Both of the retinoic acids are commercially available from numerous suppliers that meet our demands for quality and documentation. Sigma-Aldrich Production GmbH manufactures L-Cysteic acid methyl ester specifically for us. Prices for the raw materials have not been affected thus far by any political, environmental, or economic crises.

#### ***Commercialization***

##### ***Human Oncology***

We entered into a supply and exclusive marketing, sales and distribution agreement with the Russian pharmaceutical company Pharmasynitez in February 2013 (the "Pharmasynitez Agreement"). The Pharmasynitez Agreement grants Pharmasynitez exclusive license and distribution rights for Paclical in Russia and the CIS, as well as Ukraine, Georgia and Turkmenistan. We may retain some rights to commercialize our product candidates in the U.S. or the EU, if we receive marketing approval for our product candidates in markets which we believe it is possible to access through a focused, specialized field force. Outside of the U.S. and Europe, we expect to enter into distribution and other marketing arrangements with third parties for any of our product candidates that receive marketing approval.

Subject to receiving marketing approvals, we expect to commence commercialization activities by either entering into regional or global license and commercialization agreements, or by directly commercializing Paclical ourselves using a targeted sales force to identify key cancer centers to support the launch of the product. These activities could form the basis of a sales and marketing organization that we will use to market our other products as they may receive marketing approval.



We have entered into a collaboration agreement with Medison for the distribution of Paclical in Israel and Turkey.

### ***Veterinary Oncology***

We have entered into commercialization agreements with Nippon Zenyaku Kogyu, granting commercial rights to Paccal Vet and Paclical in Japan. We believe that the value of our veterinary oncology candidates will be enhanced by having at least one large commercial partner, given the nature of the animal health market and the broad distribution of veterinarians, as well as the fact that there are only a limited number of experienced sales professionals available, and we have limited experience in developing a sales force.

### **Facilities**

Our office is located in Uppsala, Sweden, where we lease and occupy six floors of a seven-floor building that encompasses approximately 43,000 square feet. Each floor is leased separately. The lease for the second floor expires on December 31, 2018, and the leases for the remaining floors expire on December 31, 2019. The leases can be terminated by either party with nine months' notice, and any leases that are not terminated are automatically extended for an additional term of three years. The building currently contains our entire business, including our research, laboratory and cGMP production facilities, as well as our administrative offices. We believe that our facilities are sufficient to meet our current needs.

### **Legal Proceedings**

We are not a party to any material legal proceedings.

### **Government Regulation**

Clinical trials, the pharmaceutical approval process, and the marketing of pharmaceutical products, both for animals and for humans, is intensively regulated in the U.S. and in all major foreign countries.

#### ***Human Health Product Regulation in the U.S.***

In the U.S., the FDA regulates pharmaceuticals under the Federal Food, Drug, and Cosmetic Act ("FDCA") and related regulations. Pharmaceuticals are also subject to other federal, state, and local statutes and regulations. Failure to comply with applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the imposition by the FDA of an Institutional Review Board ("IRB"), a clinical hold on trials, a refusal to approve pending applications or supplements, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval, advertising and promotion of our human and animal health products.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of Paclical or our other future human health product candidates or approval of new disease indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or elsewhere.

#### ***Marketing Approval***

The process required by the FDA before human health care pharmaceuticals may be marketed in the U.S. generally involves the following:

- nonclinical laboratory and animal tests;
- submission of an IND application which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses;
- pre-approval inspection of manufacturing facilities and clinical trial sites; and
- FDA approval of an NDA, which must occur before a drug can be marketed or sold.

We will need to successfully complete extensive additional clinical trials in order to be in a position to submit an NDA to the FDA. We must reach agreement with the FDA on the proposed protocols for our future clinical trials in the U.S. A separate submission to the FDA must be made for each successive clinical trial to be conducted during product development. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site, and an informed consent must also be obtained from each study subject. Regulatory authorities, a data safety monitoring board or the sponsor, may suspend or terminate a clinical trial at any time on numerous grounds.

Our objective is to conduct additional clinical trials for Paclical and, if those trials are successful, seek marketing approval from the FDA and other worldwide regulatory bodies. To achieve this objective, we have completed a Phase III clinical trial of Paclical for the treatment of ovarian cancer, and, are compiling the data from it. If it is successful, we expect to file for marketing approval first in the EU and then in the U.S. We plan to follow this process also with respect to the other indications that we discuss in this annual report, such as metastatic breast cancer.

For purposes of NDA approval for human health products, human clinical trials are typically conducted in phases that may overlap.

- *Phase I.* The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase II.* This phase involves trials in a limited subject population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Phase II studies may be sub-categorized to Phase IIa studies which are smaller, pilot studies to evaluate limited drug exposure and efficacy signals, and Phase IIb studies which are larger studies testing more rigorously both safety and efficacy.
- *Phase III.* This phase involves trials undertaken to further evaluate dosage, clinical efficacy and safety in an expanded subject population, often at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

All of these trials must be conducted in accordance with Good Clinical Practice (“GCP”) requirements in order for the data to be considered reliable for regulatory purposes.

### *New Drug Applications*

In order to obtain approval to market a pharmaceutical in the U.S., a marketing application must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational drug for the proposed indication. Each NDA submission requires a substantial user fee payment unless a waiver or exemption applies (such as with the Orphan Drug Designation discussed below). The NDA submission fee currently exceeds \$1,958,000, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, currently exceeding \$98,000 per product and \$526,000 per establishment. These fees are typically increased annually. The NDA includes all relevant data available from pertinent non-clinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators.

The FDA will initially review the NDA for completeness before it accepts it for filing. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Based on pivotal Phase III trial results submitted in an NDA, upon the request of an applicant, the FDA may grant a Priority Review designation to a product, which sets the target date for FDA action on the application at six to eight months, rather than the standard ten to twelve months. The FDA can extend these reviews by three months. Priority review is given where preliminary estimates indicate that a product, if approved, has the potential to provide a significant improvement compared to marketed products or offers a therapy where no satisfactory alternative therapy exists. Priority Review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

After the FDA completes its initial review of an NDA, it will communicate to the sponsor that the drug will either be approved, or it will issue a complete response letter to communicate that the NDA will not be approved in its current form and inform the sponsor of changes that must be made or additional clinical, nonclinical or manufacturing data that must be received before the application can be approved, with no implication regarding the ultimate approvability of the application.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured, even if such facilities are located overseas. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that any of the application, manufacturing process or manufacturing facilities is not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine that if the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the NDA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process for a drug requires substantial time, effort and financial resources, and this process may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase IV studies may be made a condition to be satisfied for continuing drug approval. The results of Phase IV studies can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA now has express statutory authority to require sponsors to conduct post-market studies to specifically address safety issues identified by the agency.

Any approvals that we may ultimately receive could be withdrawn if required post-marketing trials or analyses do not meet the FDA requirements, which could materially harm the commercial prospects for Paclical or Paccal Vet.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy (“REMS”) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the NDA submission. The need for a REMS is determined as part of the review of the NDA. Based on statutory standards, elements of a REMS may include “dear doctor letters,” a medication guide, more elaborate targeted educational programs, and in some cases restrictions on distribution. These elements are negotiated as part of the NDA approval, and in some cases if consensus is not obtained until after the Prescription Drug User Fee Act review cycle, the approval date may be delayed. Once adopted, REMS are subject to periodic assessment and modification.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution, or post-marketing study requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for Paclical, or obtaining approval but for significantly limited use, would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

#### *Section 505(b)(2) New Drug Applications*

Most drug products obtain FDA marketing approval pursuant to an NDA or an Abbreviated New Drug Application (“ANDA,” described below under “— The Drug Price Competition and Patent Term Restoration Act — Orange Book Listing”). A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA’s previous approval of a similar product, or published literature, in support of its application.

Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on the FDA’s previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505 (b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

### *Disclosure of Clinical Trial Information*

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public website maintained by the U.S. National Institutes of Health. Though we are not required to register, since our studies are outside of the U.S., we do so voluntarily. Information related to the product, patient population, phase of investigation, study sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed until the product or new indication being studied has been approved. Competitors may use this publicly-available information to gain knowledge regarding the design and progress of our development programs.

### *Orphan Drug Designation*

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan Drug Designation is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. In addition to providing a seven year term of market exclusivity upon final FDA approval, Orphan Drug Designation also positions a company to be able to leverage a wide range of financial and regulatory benefits, including government grants for conducting clinical trials, waiver of expensive FDA user fees for the potential submission of an NDA, and certain tax credits. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if our drug or biological candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the EU has similar but not identical benefits in the EU.

We have been granted Orphan Drug Designation for Paclical for the treatment of epithelial ovarian cancer in the U.S. and have received orphan drug status in the EU.

### *The Drug Price Competition and Patent Term Restoration Act*

The Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, requires pharmaceutical companies to divulge certain information regarding their products which have the effect of making it easier for other companies to manufacture generic drugs to compete with those products.

*Orange Book Listing.* In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement, certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use, rather than certify to a listed method-of-use patent.

If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe on the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

*Exclusivity.* Upon NDA approval of a New Chemical Entity ("NCE"), which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which time the FDA cannot receive any ANDA seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approval an ANDA for a generic drug that includes the change.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

*Patent Term Extension.* After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase — the time between IND submission and NDA submission — and all of the review phase — the time between NDA submission and approval up to a maximum of five years. The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the PTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

*Environmental Regulations.* The U.S. generally requires an environmental assessment, which discusses a company's proposed action, possible alternatives to the action, and whether the further analysis of an environmental impact statement is necessary. Certain exemptions are available from the requirement to perform an environmental assessment and an environmental impact statement. Once an exemption is claimed, a company must state to the FDA that no extraordinary circumstances exist that may significantly affect the environment. We will claim an exemption, under the category for biologic products, from the requirement to provide an environmental assessment and an environmental impact statement for Paclical, and will furthermore state to the FDA that to our knowledge, no extraordinary circumstances exist that may significantly affect the environment.

### *FDA Post-Approval Requirements*

Following the approval of an NDA, the FDA continues to require adverse event reporting and submission of periodic reports. The FDA also may require post-marketing testing, known as Phase IV testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMP after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

### *Patient Protection and Affordable Health Care Act*

In March 2010, the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, "PPACA"), was enacted, which includes measures that have or will significantly change the way health care is financed by both governmental and private insurers. The fees, discounts and other provisions of this law are expected to have a significant negative effect on the profitability of pharmaceuticals.

Many of the details regarding the implementation of PPACA are yet to be determined, and at this time, it remains unclear the full effect that PPACA would have on our business.

### *Human Health Product Regulation in the European Union*

In addition to regulations in the U.S., we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the U.S. have a process that requires the submission of a clinical trial application prior to the commencement of human clinical trials. In Europe, for example, a Clinical Trial Application ("CTA") must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, even though there is already some degree of legal harmonization in the EU Member States resulting from the national implementation of underlying EU legislation. In all cases, the clinical trials are conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under EU regulatory systems, we must submit a marketing authorization application. This application is similar to the NDA in the U.S., with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the EU by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure or (iv) national authorization procedures.

The EMA implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the EU. This procedure results in a single marketing authorization granted by the European Commission that is valid across the EU, as well as in Iceland, Liechtenstein and Norway (the “European Community”). The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated orphan drugs, and (iv) advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used for human drugs which do not fall within the above mentioned categories if the human drug (a) contains a new active substance which, on the date of entry into force of Regulation (EC) No. 726/2004, was not authorized in the European Community; or (b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization in the centralized procedure is in the interests of patients or animal health at European Community level.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of a MAA by the EMA is 210 days, though the date count stops whenever the Committee for Medicinal Products for Human Use (“CHMP”) asks the applicant for additional written or oral information, with adoption of the actual marketing authorization by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, as when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: (i) the seriousness of the disease to be treated; (ii) the absence of an appropriate alternative therapeutic approach; and (iii) anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter. We submitted an application for marketing authorization for Paclical in the first half of 2016.

The Mutual Recognition Procedure (“MRP”), for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the EU. Basically, the MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products, and is based on the principle of recognition of an already existing national marketing authorization by one or more Member States.

The characteristic of the MRP is that the procedure builds on an already existing marketing authorization in a Member State of the EU that is used as reference in order to obtain marketing authorizations in other EU Member States. In the MRP, a marketing authorization for a drug already exists in one or more Member States of the EU and subsequently marketing authorization applications are made in other EU Member States by referring to the initial marketing authorization. The Member State in which the marketing authorization was first granted will then act as the reference Member State. The Member States where the marketing authorization is subsequently applied for act as concerned Member States.

The MRP is based on the principle of the mutual recognition by EU Member States of their respective national marketing authorizations. Based on a marketing authorization in the reference Member State, the applicant may apply for marketing authorizations in other Member States. In such case, the reference Member State shall update its existing assessment report about the drug in 90 days. After the assessment is completed, copies of the report are sent to all Member States, together with the approved summary of product characteristics, labeling and package leaflet. The concerned Member States then have 90 days to recognize the decision of the reference Member State and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

Should any Member State refuse to recognize the marketing authorization by the reference Member State, on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within a timeframe of 60 days, Member States shall, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the Commission, for the start of the decision making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products or Veterinary Medicinal Products, as appropriate.



### ***Human Health Product Regulation in the Rest of World***

For other countries outside of the EU, such as countries in Eastern Europe or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements. We have submitted an application for marketing approval for Paclical in Russia, and received Russian approval on April 20, 2015. We will also initiate a Phase III clinical trial of Docecal for the treatment of metastatic breast cancer, and, if it is successful, expect to file for marketing approval in Russia in 2017.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### ***Animal Health Product Regulation in the U.S.***

Three federal regulatory agencies regulate the health aspects of animal health products in the U.S.: the FDA, the United States Department of Agriculture (the “USDA”) and the Environmental Protection Agency (the “EPA”).

The CVM regulates animal pharmaceuticals under the Food, Drug and Cosmetics Act. The USDA Center for Veterinary Biologics regulates veterinary vaccines and some biologics pursuant to the Virus, Serum, Toxin Act. The EPA regulates veterinary pesticides under the Federal Insecticide, Fungicide and Rodenticide Act. Many topical products used for treatment of flea and tick infestations are regulated by the EPA.

Our product and all of our current animal health product candidates are animal pharmaceuticals regulated by the CVM. Manufacturers of animal health pharmaceuticals, including us, must show their products to be safe, effective and produced by a consistent method of manufacture. The CVM’s basis for approving a drug application is documented in a Freedom of Information Summary. We will be required to conduct post-approval monitoring of products and to submit reports of product quality defects, adverse events or unexpected results to the CVM’s Surveillance and Compliance group.

To begin the development process for our products in the U.S., we will establish an INAD file with the CVM. We will then hold a pre-development meeting with the CVM to reach a general agreement on the plans for providing the data necessary to fulfill requirements for a New Animal Drug Application (“NADA”). During development, we will submit pivotal protocols to the CVM for review and concurrence prior to conducting the required studies. We will gather and submit data on manufacturing, safety and effectiveness to the CVM for review, and this review will be conducted according to timelines specified in the Animal Drug User Fee Act. Once all data have been submitted and reviewed for each technical section — safety, effectiveness and CMC — the CVM will issue to us a technical section complete letter as each section review is completed, and when all three letters have been issued, we will compile the Freedom of Information Summary, the proposed labeling, and all other relevant information, and submit these as an administrative NADA for CVM review. Generally, if there are no deficiencies in the submission, the NADA will be issued within four to six months after the submission of the administrative NADA. After approval, we will be required to collect reports of any adverse events and submit them to the CVM on a regular basis.

### ***Animal Health Product Regulation in the European Union***

The EMA regulates the scientific evaluation of medicines developed by pharmaceutical companies for use in the EU. Its veterinary review section is distinct from the review section for human pharmaceuticals mentioned previously. The Committee for Medicinal Products for Veterinary Use (the “CVMP”), is responsible for scientific review of the submissions for animal pharmaceuticals and vaccines but the EMA makes the final decision on the approval of products. Once a centralized marketing authorization is granted by the EMA, it is valid in all EU and European Economic Area-European Free Trade Association states. In general, the requirements for regulatory approval of an animal health product in the EU are similar to those in the U.S., requiring demonstrated evidence of purity, safety, efficacy and consistency of manufacturing processes.

The EMA is responsible for coordinating scientific evaluation of applications for marketing approval for pet therapeutics in the EU. To perform these evaluations the EMA established a specific scientific committee called the CVMP, which considers applications submitted by companies for the marketing approval of individual pet therapeutics and evaluates whether or not the medicines meet the necessary quality, safety and efficacy requirements. Assessments conducted by the CVMP are based on scientific criteria and are intended to ensure that pet therapeutics reaching the marketplace have a positive benefit-risk balance in favor of the pet population for which they are intended. Based on the CVMP's recommendation, a centralized marketing authorization is granted by the EMA, which allows the product to be marketed in any of the EU states. The CVMP is also responsible for various post-authorization and maintenance activities, including the assessment of modifications or extensions to an existing marketing authorization.

To obtain authorization from the EMA, we must submit a marketing authorization application called a dossier. The dossier is the EMA's equivalent of the FDA's NADA and includes data from studies showing the quality, safety and efficacy of the product. The CVMP reviews and evaluates the dossier. For any dossier, a rapporteur and co-rapporteur are appointed from the members of the CVMP. Their role is to lead the scientific evaluation and prepare the assessment report. The rapporteur can utilize experts to assist it in performing its assessment. The report is critiqued by the co-rapporteur and other members of the CVMP before the CVMP makes its determination. The final opinion of the CVMP is generally given within 210 days of the submission of a dossier.

#### ***Animal Health Product Regulation in the Rest of World***

Each other country has its own regulatory requirements for approving and marketing veterinary pharmaceuticals. Many country specific regulatory laws contain provisions that include requirements for labeling, safety, efficacy and manufacturers' quality control procedures to assure the consistency of the products, as well as company records and reports. With the exception of the EU, the regulatory agencies of most other countries generally refer to the FDA, USDA, EMA, and other international animal health entities, including the World Organization for Animal Health and the Codex Alimentarius Commission, in establishing standards and regulations for veterinary pharmaceuticals and vaccines.

#### ***Requirements for Approval of Veterinary Pharmaceuticals for Pets***

As a condition to regulatory approval for sale of animal products, regulatory agencies worldwide require that a product used for pets is demonstrated to be:

- be safe for the intended use in the intended species;
- have substantial evidence of effectiveness for the intended use;
- have a defined manufacturing process that ensures that the product can be made with high quality consistency; and
- be safe for humans handling the product and for the environment.

*Safe for the intended use.* To determine that a new veterinary drug is safe for use, regulatory bodies will require us to provide data from a safety study generated in laboratory dogs and cats tested at doses higher than the intended label dose, over a period of time determined by the intended length of dosing of the product. In the case of the CVM, the design and review of the safety study and the study protocol are completed prior to initiation of the study to help assure that the data generated will meet FDA requirements. These studies are conducted under rigorous quality control, including Good Laboratory Practice, to assure integrity of the data. They are designed to clearly define a safety margin, identify any potential safety concerns, and establish a safe dose for the product. This dose and effectiveness is then evaluated in the pivotal field effectiveness study where the product is studied in the animal patient population in which the product is intended to be used. Field safety data, obtained in a variety of breeds and animals kept under various conditions, are evaluated to assure that the product will be safe in the target population. Safety studies are governed by regulations and regulatory pronouncements that provide the parameters of required safety studies and are utilized by regulatory bodies in the U.S., the EU and Japan.

*Effectiveness for the intended use.* Early pilot studies may be done in laboratory dogs or cats to establish effectiveness and the dose range for each product. Data on how well the drug is absorbed when dosed by different routes and the relationship of the dose to the effectiveness are studied. When an effective dose is established, a study protocol to test the product in real world conditions is developed prior to beginning the study. In the case of the CVM, the pivotal effectiveness field study protocol is submitted for review and concurrence prior to study initiation, to help assure that the data generated will meet requirements.

The pivotal field effectiveness study must be conducted with the formulation of the product that is intended to be commercialized, and is a multi-site, randomized, controlled study, generally with a placebo control. To reduce bias in the study, the individuals conducting the assessment are not told which group is the test group and which is the placebo group. In both the U.S. and the EU, the number of patients enrolled in the pivotal field effectiveness studies is required to be at least 100 animal subjects treated with the test product and a comparable number of subjects in the control group that receive the placebo. In many cases, a pivotal field study may be designed with clinical sites in both the EU and the U.S., and this single study may satisfy regulatory requirements in both the EU and the U.S.

*Defined Manufacturing Process.* To assure that the product can be manufactured consistently, regulatory agencies will require us to provide documentation of the process by which the API is made and the controls applicable to that process that assure the API and the formulation of the final commercial product meet certain criteria, including purity and stability. The drug development process is known as Chemistry, Manufacturing and Controls (“CMC”). After a product is approved, we will be required to communicate with the regulatory bodies any changes in the procedures or manufacturing site. Both API and commercial formulations are required to be manufactured at facilities that practice cGMP.

*Safe for Humans and the Environment.* Certain exemptions are available from the requirement to provide an environmental impact statement for animal health products. Similar to the process for human health products, once an exemption is claimed, a company must state to the FDA that no extraordinary circumstances exist that may significantly affect the environment. We have claimed an exemption, under the category for drugs intended for nonfood animals, from the requirement to provide an environmental impact statement for Paccal Vet, and have stated to the FDA that to our knowledge, no extraordinary circumstances exist that may significantly affect the human environment. The FDA agrees with us that the proposed uses of our drug fall within the claimed categorical exemption and it is not aware of any extraordinary circumstances. Thus, in the U.S. we are not required to perform either an environmental assessment or an environmental impact statement. For approval in the EU, a risk assessment for potential human exposure will be required.

*Labeling, All Other Information, and Freedom of Information Summary.* We also will be required to submit the intended label for the product, and also any information regarding additional research that has been conducted with the drug, to the CVM and other regulatory bodies for review. We will draft, and submit for regulatory review, the Freedom of Information Summary for use in the U.S. This summary outlines the studies and provides substantial information that CVM uses to assess the drug’s safety and effectiveness and then publishes on its website.

### C. Organizational Structure

As per April 30, 2016, the Group consists of the parent company Oasmia Pharmaceutical AB and the subsidiaries Oasmia Animal Health AB, Qdoxx Pharma AB and Oasmia Pharmaceutical, Inc.

#### Subsidiaries

	Country of incorporation	Ownership	Votes
Qdoxx Pharma AB	Sweden	100%	100%
Oasmia Animal Health AB	Sweden	100%	100%
Oasmia Pharmaceutical, Inc.	USA	100%	100%

#### D. Property, Plant and Equipment

See "—B. Business Overview—Facilities" for a description of our leased premises. Our equipment includes computers, office equipment, furniture and manufacturing equipment with a net book value at April 30, 2016 and 2015 of TSEK 21,172 and TSEK 22,852, respectively. Our manufacturing equipment is owned by the Company and placed in Uppsala and in Germany for the use by a Company vendor who provides contract manufacturing services to the Company. The net book value of our manufacturing equipment at April 30, 2016 was TSEK 18,144. None of our equipment is leased and there are no liens or encumbrances on our equipment.

We currently do not have any material commitments to acquire tangible fixed assets; however, it is possible that we may need to acquire additional manufacturing equipment in the near-term. It is uncertain at this time what, if any, additional manufacturing equipment we may need to acquire. The timing and amount of any manufacturing equipment purchases we make in the future will be determined based on the terms and conditions and Company needs.

#### ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable

#### ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

##### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this annual report. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this annual report for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

#### A. Operating Results Overview

##### Overview

We are a pharmaceutical company focused on innovative treatments within human and animal oncology. Our product and product candidates utilize a proprietary, nanoparticle formulation technology that is designed to facilitate the administration of intravenously-delivered active pharmaceutical ingredients, without the addition of toxic solvents. We believe our formulation may result in improved safety, efficacy and ease of administration over existing drugs. Our initial development and commercialization efforts are focused on creating novel formulations of well-established chemotherapeutic drugs that can be used for the treatment of cancer in both humans and companion animals. We have four human oncology product candidates in pre-clinical and/or clinical development, and two veterinary oncology product candidates. We disclosed positive Overall Survival results from Phase III study of our lead human product for treatment of ovarian cancer in the April, 2016. In February 2014, we received conditional approval by the United States Food and Drug Administration ("FDA") for our initial veterinary oncology product.

Our lead products utilize paclitaxel, the active ingredient of Taxol and Abraxane, two widely used cancer drugs marketed by Bristol-Myers Squibb and Celgene, respectively. Based on the potential benefits of our proprietary formulation technology, we are pursuing a strategy to replace the use of existing paclitaxel-based products in multiple cancers with our novel formulations. Our formulation is currently called Paclical for human indications, and is marketed under the name Paccal Vet-CA1 ("Paccal Vet") for veterinary indications. In the submission of a marketing authorization application (MAA) to the European Medicines Agency (EMA), the name Apealea is used instead of Paclical. We own the global commercial rights to Paclical, excluding Israel, Turkey, Russia, the Commonwealth of Independent States ("CIS"), Ukraine, Georgia and Turkmenistan. We have licensed the commercial rights to Paccal Vet for sale in Japan, Russia and the CIS. Paclical received marketing approval in Russia and the CIS in April 2015.

Since we do not have sales and marketing operations, we have entered into various licensing and distribution agreements with established pharmaceutical companies to sell Paclical, Paccal Vet, and our other product candidates. We have entered into an agreement with Pharmasintez for the commercialization of Paclical in Russia and the CIS, as well as Ukraine, Georgia and Turkmenistan, and a separate agreement with Medison Pharma for the commercialization of Paclical in Israel and Turkey. Furthermore, we have entered into an agreement with Nippon Zenyaku Kogyo for the commercialization of Paccal Vet in Japan.

Paccal Vet is the first injectable chemotherapeutic agent authorized for marketing for the treatment of squamous cell carcinoma (a cancer occurring in certain cells in the skin and the lining of other organs) and mammary carcinoma (a cancer occurring in the lining of the milk ducts of the mammary glands) in dogs. We received conditional approval by the FDA for Paccal Vet for the treatment of mammary carcinoma and squamous cell carcinoma under the Minor Use and Minor Species ("MUMS") designation in the U.S. MUMS designation is a status similar to orphan designation for human drugs, making the sponsor eligible for incentives to support the approval or conditional approval of the designated drug, including seven years of market exclusivity in the U.S. For a description of the qualifications for Paccal Vet to receive the MUMS designation, conditional approval and full approval for dogs, see "Business — Overview." We believe Paccal Vet can be on the market for up to five years, through annual renewals, while we collect remaining required effectiveness data for full approval. We are currently planning additional efficacy studies in dogs to collect all the necessary efficacy data for full U.S. approval of Paccal Vet for mammary carcinoma and squamous cell carcinoma.

From our inception through April 30, 2016, marketing and distribution agreements have yielded net cash of SEK 87.83 million in upfront fees and milestone payments and SEK 8.0 million in royalties and sales revenue.

In addition to these partnerships, we will eventually directly commercialize Paclical ourselves using a targeted sales strategy or find a collaboration partner depending on our possibility to negotiate satisfactory terms for Oasmia. Currently we retain the rights to commercialize Paclical outside of Russia, CIS, Turkey and Israel. On August 4, 2015, we announced the results of a preliminary study of a head-to-head pharmacokinetic comparison between Paclical and Abraxane, which found that the concentration of both total and unbound paclitaxel in plasma was similar.

We are a newly-commercial stage company with one veterinary product conditionally approved, and one product for human use approved for marketing and sale, and given our recent change from development stage to commercial stage, we have not generated any significant revenue other than milestone payments from our commercial partners. We have incurred significant net losses since our inception on April 15, 1988. We incurred net losses of SEK 141.54 million, SEK 117.50 million and SEK 105.11 million for the fiscal years ended April 30, 2016, April 30, 2015 and April 30, 2014. These losses have resulted principally from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. As of April 30, 2016, we had a deficit accumulated during development stage of SEK 626.61 million and cash, cash equivalents and short-term investments of SEK 46.21 million. We expect to continue to incur operating losses in the near future as we continue our clinical and preclinical development programs, apply for marketing approval for our product candidates and, subject to obtaining regulatory approval of our product candidates, establish sales and marketing partnerships in preparation for the potential commercialization of our product candidates.

Oasmia has two products approved, but this does not yet create a sufficient cash flow from its own business. For this reason, Oasmia continuously works with various financing alternatives. This work includes that the company is in discussions with potential partners for licensing of distribution and sales rights, negotiations with new and existing investors, financiers and lenders and that the company ensures enough resources to secure that forecasted future revenue streams from regions where the company's products registered, are realized.

Available consolidated liquid assets and unutilized credit facilities as of April 30, 2016 are not sufficient to provide the required capital to pursue the planned activities during the next 12 months. In light of available financing alternatives and the recent developments in the Company, the Board of Directors assesses that the prospects for financing of the Company's operations in the coming year are good. Should funding not be obtained in sufficient quantities there is a risk that the conditions for continued operation do not exist.

Other than what is disclosed in this annual report, there are at present no significant trends known to us that are reasonably likely to have a material effect on our financial situation.

#### **Events after balance sheet date of April 30, 2016**

##### **Oasmia confirmed on-going negotiations regarding licensing of Paclical/Apealea and XR-17**

Oasmia confirmed that the Company is in on-going negotiations with partners regarding both licensing of the XR-17 platform and the Company's product candidates focusing on Paclical<sup>®</sup>/Apealea<sup>®</sup>. Timing for announcing partnerships are difficult to predict.

##### **Extended bank loan**

Oasmia has received an extension of the existing loan of MSEK 20 with a maturity date of June 30, 2016 until September 30, 2016. The other loan terms and conditions are unchanged.

##### **Convertible loan**

In June 2016, Oasmia has issued 42 convertibles at a nominal price of SEK 1,000,000 per convertible bond, which provided the company with SEK 37 million after deducting issue costs. The convertible loan matures June 9, 2017, unless conversion takes place before then. The loan bears 8.5 percent interest rate and can be converted at a price of SEK 12.00 per share. Full conversion would result in the issuance of 3.5 million Ordinary Shares.

##### **Trend information**

We are currently in an early stage to commercialize products on the market. Accordingly, any trends within the markets in which we operate are expected to have more direct impact on our business in the event that we are successful in commercializing Paclical and Paccal Vet CA-1.

Over the past few years, there has been increasing pressure to reduce drug prices in the developed markets as a consequence of political initiatives and regulations aiming to curb continuous increases in healthcare spending. We expect this trend to continue in the years ahead and accordingly any revenue we may earn in the future will likely be negatively affected by such political initiatives and regulations. However, we believe spending in the healthcare industry, as compared to many other industries, is less linked to economic trends. Furthermore, while falling drug prices in the mature drug markets such as the U.S. and the EU are having a negative impact on general sales growth levels for the biopharmaceutical industry as a whole in those markets, we expect such sales growth to continue at higher levels in emerging markets. We also expect that demographic developments, increased treatment penetration, especially in newly established drug markets, and better diagnostic tools will result in continuing growth in overall global drug sales.

##### **Financial Operations Overview**

*Net sales.* We generate net sales pursuant to agreements with our commercial partners. These agreements generally include some of the following sources of revenue: an initial payment, additional milestone payments dependent upon the achievement of certain clinical, regulatory or commercial milestones, invoiced supply price for products delivered to commercial partners and royalties on product sales of licensed products when such product sales occur. Net sales also include amounts earned from the sale of miscellaneous supplies, such as sterile water. We recognize net sales when the amount earned can be measured in a reliable way and when we have determined it is likely that future economic benefits will accrue to us and certain criteria have been met, which will vary based on specific contractual arrangements. Revenue from licensing arrangements and product sales during the fiscal year ended April 30, 2016 amounted to SEK 6,077 thousand, for the fiscal year ended April 30, 2015 amounted to SEK 2,002 thousand and for the fiscal year ended April 30, 2014 amounted to zero.

*Change in inventory of products in process and finished goods*

Change in inventory of products in process and finished goods consists of the change in book value of products in process and finished goods and refers to manufacturing of ordered products which are planned to be sold on the Russian market during the coming months.

*Capitalized development cost.* Capitalized development cost consists of expenditures for materials and services used in development of the intangible asset and employee benefit expenses for staff engaged in developing the intangible asset. Expenditures for research and development operations are generally expensed as they occur. Development costs which are attributable to clinical trials and registration are capitalized to the extent that they are expected to generate future economic benefits. We have determined that the beginning of Phase III trials is the earliest point for capitalization of development expense. This has been applied for Paccal Vet and Paical, for which all conditions for capitalization are fulfilled. These conditions are generally met when it is probable that expected future economic benefits attributable to an asset will flow to us and the asset's cost can be measured reliably. The disclosure of the development costs in Phase III is accounted for gross, i.e. the costs are included in various operating expenses whereas the capitalized part is disclosed on a specific line in the income statement.

*Other operating income.* Other operating income comprises revenues that are not generated in the ordinary course of business. Other operating income as per April 30, 2014 primarily consists of an insurance compensation amounting to SEK 4.25 million. As per April, 2015, other operating income primarily consists of grants received for staff amounting to SEK 153 thousand. There were no insurance compensation and no grants received for staff in the year ended April 30, 2016.

*Operating expenses.* Operating expenses includes four categories described below.

*Raw materials, consumables and goods for resale.* Raw materials, consumables and goods for resale consist of materials and consumables for manufacturing of pharmaceuticals for sales, clinical trials, cost of analysis for such pharmaceuticals and handling of waste.

*Other external expenses.* Other external expenses consist mainly of external fees paid for clinical trials, fees paid for regulatory, administration and other services such as rent of facility and cost for utilities.

*Employee benefit expenses.* Employee benefit expenses consist of salaries to employees, remuneration to board members, social security cost and other employee benefits and expenses.

*Depreciation and amortization.* Depreciation consists of depreciation for machinery, equipment and patents. The capitalized development expense is not yet subject to amortization.

*Financial income.* Financial income consists primarily of interest earned by investing our cash reserves in short-term interest-bearing deposit accounts.

*Financial expenses.* Financial expenses consist primarily of interest expense on interest-bearing loans.

*Income taxes.* As a Swedish resident trading equity, we are subject to Swedish corporate taxation. Since we have been loss-making since inception, no corporate taxes have been recorded.

**Results of operations***Comparison of Fiscal Years Ended April 30, 2016 and April 30, 2015*

	<b>Year Ended April 30,</b>	
	<b>2016</b>	<b>2015</b>
	<b>(in TSEK)</b>	
Net sales	6,373	2,070
Change in inventory of products in progress and finished goods	9,509	-
Capitalized development cost	16,727	16,797
Other operating income	2	221
Operating expenses	(165,302)	(127,313)
Financial income	786	210
Financial expense	(9,634)	(9,482)
Income taxes	-	-
Income for the period	(141,539)	(117,497)

*Net sales*

	<b>Year Ended April 30,</b>	
	<b>2016</b>	<b>2015</b>
	<b>(in TSEK)</b>	
Net sales	6,373	2,070

Revenues from royalties and sales of products were SEK 6,077 thousand in the year ended April 30, 2016 and 2,002 in the year ended April 30, 2015.

Revenues from sales of research collaboration amounted to SEK 200 thousand in the year ended April 30, 2016 and zero in the fiscal year ended April 30, 2015. There were revenues from sales of water for injection amounting to SEK 125 thousand in the year ended April 30, 2016 and SEK 68 thousand in 2015.

*Change in inventory of products in progress and finished goods*

	<b>Year Ended April 30,</b>	
	<b>2016</b>	<b>2015</b>
	<b>(in TSEK)</b>	
Change in inventory of products in progress and finished goods	9,509	-

Change in inventory of products in progress, amounting to SEK 9,509 thousand in the year ending April 30, 2016, is derived from the production of goods that are intended to be sold on the Russian market. This production has led to the building up of both raw material and consumables stocks and finished and semi-finished products stocks.

*Capitalized development cost*

	<b>Year Ended April 30,</b>	
	<b>2016</b>	<b>2015</b>
	<b>(in TSEK)</b>	
Capitalized development cost	16,727	16,797

Capitalized development cost decreased by SEK 70 thousand, or 0,4 %, from SEK 16.80 million in the year ended April 30, 2015 to SEK 16.73 million in the year ended April 30, 2016. In both years there were two product candidates, Paccal Vet and Paclical, subject to capitalization. For Paclical, capitalization increased by SEK 0.79 million, from SEK 9.19 million to SEK 9.98 million. For Paccal Vet, capitalization decreased by SEK 0.86 million from SEK 7.61 million to SEK 6.75 million in the year ending April 30, 2016. The main reason for the increase in capitalization regarding Paclical is increased regulatory expenses in connection to the application for marketing approval in the EU.



*Other operating income*

	<u>Year Ended April 30,</u>	
	<u>2016</u>	<u>2015</u>
	(in TSEK)	
Other operating income	2	221

For the year ended April 30, 2016, other operating income decreased to SEK 2 thousand, compared to SEK 221 thousand in the prior year. The decrease was primarily related to grants received for staff amounting to SEK 153 thousand in the prior year compared to zero for the year ended April 30, 2016.

*Operating expenses*

	<u>Year Ended April 30,</u>	
	<u>2016</u>	<u>2015</u>
	(in TSEK)	
Raw materials, consumables and goods for resale	4,733	10,062
Other external expenses	98,104	60,739
Employee benefit expenses	57,661	50,530
Depreciation, amortization and impairment	4,804	5,190
Other operating expenses	-	792
Total operating expenses	165,302	127,313

Operating expenses including depreciation and amortization increased by SEK 37.99 million, or 29.8%, from SEK 127.3 million to SEK 165.3 million, for the year ended April 30, 2016 compared to the year before.

The increase in other external expenses is mainly related to expenses for clinical trials initiated in the fiscal year, primarily the Docecal and XR-17 studies. Furthermore expenses for purchasing of raw materials and essentials for production in Oasmia and its contract manufacturers have increased in order to meet the need for products both for sales and clinical trials. The increase in employee benefit expenses is mainly due to increased payroll expenses which in turn is mainly related to strengthening of the management team and finance department and the annual payroll assessment.

*Financial income*

	<u>Year Ended April 30,</u>	
	<u>2016</u>	<u>2015</u>
	(in TSEK)	
Financial income	786	210

Financial income in the year ended April 30, 2016 amounted to SEK 0.79 million, compared to SEK 0.21 million in previous year. The increase is mainly due to increased foreign exchange gains related to bank balances in foreign currencies.

*Financial expense*

	<u>Year Ended April 30,</u>	
	<u>2016</u>	<u>2015</u>
	(in TSEK)	
Financial expense	9,634	9,482

Financial expense is primarily attributable to interest on loans from Nexttobe. In December 30, 2015, the loan of SEK 87 million and accrued interest amounting to SEK 7.4 million was replaced by a new loan. The new loan amounts to SEK 94.4 million and matures December 30, 2016. Interest expenses on the loan from Nexttobe amounts to SEK 7.6 million in the year ended April 30, 2016 compared to SEK 8.3 million in the year ended April 30, 2015.

Furthermore, Oasmia has a bank loan from Nordea amounting to SEK 20 million with a maturity in December 30, 2016. Interest expense for this loan was SEK 0.4 million in the fiscal year ending April 30, 2016 and SEK 1.1 million 2015. Oasmia Pharmaceutical AB has SEK 20 million placed in a restricted interest fund accounts as a pledge for the bank loan.

Financial expenses also consist of exchange losses related to bank balances in foreign currencies. Exchange losses from bank balances in foreign currencies increased by SEK 1.2 million in the year ended April 30, 2016 compared to the year ended April 30, 2015.

**Comparison of Fiscal Years Ended April 30, 2015 and April 30, 2014**

	<b>Year Ended April 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(in TSEK)</b>	
Net sales	2,070	60
Capitalized development cost	16,797	29,464
Other operating income	221	4,454
Operating expenses	(127,313)	(132,069)
Financial income	210	192
Financial expense	(9,482)	(7,213)
Income taxes	-	-
Income for the period	(117,497)	(105,112)

*Net sales*

	<b>Year Ended April 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(in TSEK)</b>	
Net sales	2,070	60

Revenues from royalties and sales of products were SEK 2,002 thousands in the year ended April 30, 2015 and zero in the year ended April 30, 2014.

There were revenues from sales of sterile water amounting to SEK 68 thousands in the year ended April 30, 2015 and SEK 60 thousands in 2014.

*Capitalized development cost*

	<b>Year Ended April 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(in TSEK)</b>	
Capitalized development cost	16,797	29,464

Capitalized development cost decreased by SEK 12.66 million, or 43%, from SEK 29.46 million in the year ended April 30, 2014 to SEK 16.80 million in the year ended April 30, 2015. In both years there were two product candidates, Paccal Vet and Paclical, subject to capitalization. For Paclical, capitalization went down by SEK 10.48 million, from SEK 19.68 million to SEK 9.2 million as the Phase III study for this product candidate is in its final stages. For Paccal Vet, capitalization decreased by SEK 2.18 million from SEK 9.79 million to SEK 7.61 million in the year ending April 30, 2015. This was a result of a new complementary Phase III study that was started in the second quarter of the fiscal year ending April 30, 2013.

*Other operating income*

	<b>Year Ended April 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(in TSEK)</b>	
Other operating income	221	4,454

For the year ended April 30, 2015, other operating income decreased to SEK 0.22 million, compared to SEK 4.45 million in the prior year. The decrease was primarily due to the amount the fiscal year ending April 30, 2014 consisting mainly of insurance compensation related to faulty production equipment amounting to SEK 4.25 million.

*Operating expenses*

	<b>Year Ended April 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(in TSEK)</b>	
Raw materials, consumables and goods for resale	10,062	6,835
Other external expenses	60,739	75,189
Employee benefit expenses	50,530	45,101
Depreciation, amortization and impairment	5,190	4,941
Other operating expenses	792	3
Total operating expenses	127,313	132,069

Operating expenses including depreciation and amortization decreased by SEK 4.6 million, or 4%, from SEK 132.07 million to SEK 127.3 million, for the year ended April 30, 2015 compared to the year before.

Raw materials, consumables and goods for resale increased by SEK 3.23 million which was due to higher demand of raw materials in research and development.

Other external expenses decreased by SEK 14.45 million due to a number of factors. Method development of production methods decreased by SEK 3.6 million compared to prior year. Financial activities, mainly related to external services in connection with the potential stock listing in the U.S decreased by SEK 3.5 million. External expenses in clinical trials decreased by SEK 1.95 million in animal health and by SEK 9.47 million in human health.

Expenses for premises and rent of production facilities increased by SEK 1.66 million and consultancy fees by SEK 1.9 million.

Employees benefit expenses increased by SEK 5.43 million due to annual wage adjustments, hiring of more qualified staff and a new pension plan.

*Financial income*

	<b>Year Ended April 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(in TSEK)</b>	
Financial income	210	192

Financial income in the year ended April 30, 2015 amounted to SEK 0.21 million, compared to SEK 0.19 million for the year before.

*Financial expense*

	Year Ended April 30,	
	2015	2014
	(in TSEK)	
Financial expense	9,482	7,213

Financial expense is primarily attributable to interest on loans from Nexttobe. Interest expense was higher in the year ended April 30, 2015 than in the previous year due to the maturity of the loan and an increased interest rate. The loan was provided to the Company in three portions. The first portion, for SEK 25 million, was provided in February 2012. The second portion, for SEK 65 million, was in May 2012. The third portion of SEK 15 million was provided in September 2012, amounting to a total loan of SEK 105 million. The interest rate was fixed at 5% for all portions of the loan until December 31, 2013. From January 1, 2014, the interest was set to 8.5%. This component amounted to an additional interest expense of SEK 1.87 million years ended April 30, 2015.

Furthermore, Oasmia was granted a bank loan from Nordea amounting to SEK 40 million, with a term from December 1, 2013. This loan was replaced by a new loan of SEK 20 million in December 2014. Interest expense for this loan was SEK 0.65 million in the fiscal year ending April 30, 2015 and SEK 1.06 million in 2014.

**Jumpstart Our Business Startups Act (“JOBS Act”)**

On April 5, 2012, the JOBS Act was signed into law in the United States. The JOBS Act permits an emerging growth company such as us to take advantage of relief from certain regulatory burdens that are otherwise generally applicable to public companies. Among the relief available is an exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act in the assessment of an emerging growth company’s internal control over financial reporting. We have elected to rely on this exemption and will not provide such an attestation from our auditors. In addition, we are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements afforded by the JOBS Act, including the exemption from complying with any requirement that may be adopted by PCAOB regarding mandatory audit firm rotation or requiring any supplement to the auditor’s report provide additional information about the audit and the financial statements (auditor discussion and analysis).

We will remain an emerging growth company until the earliest of (a) the last day of our fiscal year during which we have total annual gross revenue of at least \$1.0 billion; (b) the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering; (c) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a “large accelerated filer” under the Exchange Act, which would occur if the market value of our ADSs that are held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter. Once we cease to be an emerging growth company, we will not be entitled to the exemptions and other relief provided in the JOBS Act.

**B. Liquidity and Capital Resources.*****Sources of funds***

Our primary uses of cash are to fund research and development expenses and capital expenditures. However, since we during 2015/2016 have launched Paclical in Russia and entered into a commercialization phase we have an increasing use of cash for production of commercial products.

In recent years, we have largely funded our operations and growth from loans, share issuances and milestone payments from our partners and licensees. Our cash flows may fluctuate, are difficult to forecast and will depend on many factors including:

- the realization of revenue from our product and product candidates, which will rely upon the timing of regulatory approvals, the marketing efforts of our commercial partners, and the price levels achieved by our partners;
- The need of additional funds in a period with increasing commercial activities depending on increasing production and growing working capital;
- the extent of success in our pre-clinical and clinical stage research programs which will determine the amount of funding required to further the development of our product candidates;

- the outcome, timing and cost of regulatory approvals of Paccal Vet, Paclical, Doxophos Vet and our other product candidates;
- the timing of achievement of the milestones receivable if Paccal Vet, Paclical, Doxophos Vet and our other product candidates are approved and launched in the U.S. and elsewhere;
- the extent to which we seek to retain development rights to our pipeline of new product candidates or whether we seek to license such candidates to a partner who will fund future research and development expenditure in return for a right to share in future commercial revenue;
- the terms and timing of new strategic collaborations;
- the number and characteristics of the product candidates that we seek to develop;
- the costs involved in filing and prosecuting patent applications and enforcing and defending potential patent claims; and
- the costs of hiring additional skilled employees to support our continued growth.

#### ***Borrowing and unutilized credit facilities***

On April 30, 2016 we had the following loans and credit lines: (i) one loan from Nexttobe amounting to SEK 94.4 million, due December 30, 2016 with an fixed annual interest rate of 8.5%, (ii) one loan from Nordea Bank AB (“Nordea”) amounting to SEK 20 million with an interest rate pegged to the Stockholm Interbank Offered Rate (“STIBOR”) one week plus 2%, (iii) 28 convertible debt instruments of SEK 1 million each, due April 14, 2017 with an interest rate of 8.5 %, (iv) one unutilized SEK 5 million credit facility with Nordea with a variable interest rate upon utilization, and (v) one unutilized credit facility of SEK 40 million with Alceco, with a fixed interest rate of 5% upon utilization.

Available consolidated liquid assets and unutilized credit facilities as of April 30, 2016 are not sufficient to provide the required capital to pursue the planned activities during the next 12 months. In light of available financing alternatives and the recent developments in the Company, the Board of Directors assesses that the prospects for financing of the Company’s operations in the coming year are good. Should funding not be obtained in sufficient quantities there is a risk that the conditions for continued operation do not exist.

#### ***Comparison of Fiscal Years Ended April 30, 2016 and April 30, 2015***

##### *Summary of cash flows*

	<b>Year Ended April 30,</b>	
	<b>2016</b>	<b>2015</b>
	<b>(in TSEK)</b>	
Cash flow from operating activities	(128,126)	(107,666)
Cash flow from investing activities	10,066	(69,755)
Cash flow from financing activities	117,449	156,017

##### *Cash flow from operating activities*

The negative cash flow from operating activities for the fiscal year ended April 30, 2016, SEK 128.13 million, consists of the operating income loss, SEK 132.69 million, adjusted for depreciation and amortization, SEK 4.81 million, positive changes in working capital, SEK 0.63 million, plus interest received, SEK 0.79 million, less interest paid, SEK 1.66 million. The significant items in the changes in working capital included an increase in accounts payable of SEK 13.22 million, an increase in inventories of SEK 11.30 million, an increase in accounts receivable of SEK 4.80 million and an increase in other current liabilities of SEK 4.08 million.

*Cash flow from investing activities*

For the fiscal year ended April 30, 2016, cash flow provided in investing activities amounted to SEK 10.07 million. This amount included intangible assets of SEK 17.96 million, which consisted of capitalized development costs of SEK 16.73 million and patents of SEK 1.23 million. Investments in tangible assets amounted to SEK 1.97 million, which primarily related to the purchase of production equipment.

Disposal of short term investments generated SEK 30 million in cash.

*Cash flow from financing activities*

For the fiscal year ended April 30, 2016, cash flow provided by financing activities amounted to SEK 117.45 million. This amount mainly consisted of new share issues of SEK 106.2 million, issue of convertible instruments of SEK 28 million and issue expenses of SEK 16.8 million.

In October, 2015 Oasmia completed a stock listing on the Nasdaq Capital Market in New York, and a thereby conducted an Initial Public Offering, which increased the number of Ordinary Shares by 7,684,500 and 1,280,750 Warrants were issued. Each of these Warrants can be exercised for ADSs, each of which represents three Ordinary Shares at an exercise price of USD 4.06 per ADS, or USD 1.35 per share. For these Warrants, the purchase price was USD 0.0025 each and the Company was provided with SEK 27 thousand. In addition, 140,352 underwriters' warrants have been issued as partial payment to the underwriters. These warrants can each be exercised for one ordinary share at an exercise price of USD 1.69 each. The gross issue amount was SEK 88.723 million which after deductions for issue expenses, amounting to SEK 13.366 million provided the Company with net proceeds of SEK 75.357 million.

In April, 2016, a private placement was consummated wherein another 1,666,666 Ordinary Shares were issued. The issue price was SEK 10.50 per share and gross proceeds provided the Company with SEK 17.5 million in proceeds.

In connection with the above mentioned private placement, 28 convertible debt instruments at a price of SEK 1,000,000 each were also issued, which provided the Company with TSEK 28,000 in gross proceeds. After deductions for issue expenses amounting to TSEK 3,408, the share issue and issue of convertible debt instruments provided the company in April 2016 with TSEK 42,092 in liquidity. The convertible debt instruments are due on April 14, 2017 if conversion is not made before then. The loan carries an interest of 8.5 % and can be converted to a price of SEK 11.70 per share. Full conversion would entail that 2,393,162 new share were issued.

On October 22, 2015, Oasmia entered into an agreement with Nexttobe whereby the Nexttobe loan will be extended through December 2016. The new loan amounts to SEK 94.4 million and will be due December 30, 2016.

On December 5, 2013, we reported that we were granted a new bank loan from Nordea. Since January 1, 2015, the Company has SEK 20 million placed in a blocked fixed income fund as a pledge for the SEK 20 million bank loan. The current SEK 20 million bank loan has a maturity date of September 30, 2016.

*Comparison of Fiscal Years Ended April 30, 2015 and April 30, 2014**Summary of cash flows*

	<b>Year Ended April 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(in TSEK)</b>	
Cash flow from operating activities	(107,666)	(86,899)
Cash flow from investing activities	(69,755)	(35,682)
Cash flow from financing activities	156,017	107,865

*Cash flow from operating activities*

The negative cash flow from operating activities for the fiscal year ended April 30, 2015, SEK 107.67 million, consists of the operating income loss, SEK 108.23 million, adjusted for depreciation and amortization, SEK 5.19 million, divestment and disposal of tangible assets, SEK 0.79 million, and negative changes in working capital, SEK 4.10 million, plus interest received, SEK 0.06 million, less interest paid, SEK 1.38 million. The significant items in the changes in working capital included a decrease in accounts payable of SEK 3.49 million, an increase in inventories of SEK 3.68 million and an increase in other current liabilities of SEK 3.05 million.

*Cash flow from investing activities*

For the fiscal year ended April 30, 2015, cash used in investing activities amounted to SEK 69.76 million. This amount included intangible assets of SEK 17.41 million, which consisted of capitalized development costs of SEK 16.80 million and patents of SEK 0.61 million. Investments in tangible assets amounted to SEK 3.62 million, which primarily related to the purchase of production equipment.

Excess cash of net SEK 50 million has been invested in short term investments.

*Cash flow from financing activities*

For the fiscal year ended April 30, 2015, cash flow provided by financing activities amounted to SEK 156.02 million. This amount consisted of a new share issue of SEK 176.02 million net of issue expenses and decrease in liability to credit institutions.

On July 3, 2014, the Company consummated a SEK 50 million directed share issue that provided the Company with SEK 46.83 million after issue expenses. It was directed at a number of international institutional investors and investors in Sweden. In the aggregate, 2,500,000 Ordinary Shares were issued at a price of SEK 20 per share. The total number of shares amounted to 88,072,330 afterwards. The increase in number of the Ordinary Shares was approximately 3%.

On December 12, 2014, Oasmia announced the final result in the right issue in the total amount of SEK 176.15 million (before transaction related costs), of which SEK 35.28 million by means were set-off of debt to Nexttobe AB.

On October 22, 2015, Oasmia entered into an agreement with Nexttobe whereby the Nexttobe loan will be extended through December 2016. The new loan amounts to SEK 94.4 million and will be due December 30, 2016.

On December 5, 2013, we reported that we were granted a new bank loan from Nordea. Since January 1, 2015, the Company has SEK 20 million placed in a blocked fixed income fund as a pledge for the SEK 20 million bank loan. The current SEK 20 million bank loan has a maturity date of September 30, 2016.

**C. Research and Development, Patents and licenses, etc.**

For a description of Oasmia's Research and Development projects and activities please see Item 4. B.

***Research and Development Expenses***

Research and development expenses are incurred for the development of new products and processes and include conducting clinical trials, development materials, payroll, including scientists and professionals for product registration and approval, external advisors and the allotted cost of manufacturing facility for research and development purposes. Expenditures for research and development are expensed as they occur. Development costs attributable to clinical trials and registration are capitalized to the extent that they are expected to generate future economic benefits. We have determined the beginning of Phase III as the earliest point for capitalization of development expense. This has been applied to two pharmaceutical candidates, for which all conditions for capitalization are fulfilled. Funds spent on research and development as included in the income statement lines, is disclosed below.

*Comparison of Fiscal Years Ended April 30, 2016 and April 30, 2015*

	Year Ended April 30,	
	2016	2015
	(in TSEK)	
Raw materials, consumables	1,208	7,394
Other external expenses	68,934	44,487
Employee benefit expenses	39,951	35,019
Depreciation	3,518	3,925
<b>Total spent on research and development activities</b>	<b>113,611</b>	<b>90,825</b>

*Comparison of Fiscal Years Ended April 30, 2015 and April 30, 2014*

	Year Ended April 30,	
	2015	2014
	(in TSEK)	
Raw materials, consumables	7,394	6,771
Other external expenses	44,487	56,810
Employee benefit expenses	35,019	33,219
Depreciation	3,925	3,826
<b>Total spent on research and development activities</b>	<b>90,825</b>	<b>100,626</b>

The reason research and development expenses are not disclosed separately for each product candidate is that all costs cannot be allocated to each product candidate separately.

*Intangible assets; Amortization and impairment tests*

Amortization of the intangible assets is carried out on a straight-line basis over the period that the expected benefits are expected to generate earnings for the company, which is from the date that commercial sale to final customers is commenced. This point in time frequently occurs after receiving full approval for the indication (e.g., a cancer-type) of a product candidate in a specific market.

At the end of each fiscal year, we perform an assessment of whether there is a need for impairment of the capitalized development cost. The impairment test on intangible assets is based on a discounted cash flow model per cash generating unit (CGU). The CGUs are the regional markets for the two product candidates in Phase III. We have made the judgment that there is no need for impairment since of the two pharmaceutical candidates that are capitalized one has already received conditional approval, and approval for the other lies, according to management estimates, within the foreseeable future. We estimate that future profits motivate the value of the assets.

The impairment tests requires us to use a number of assumptions, including market factors specific to the pharmaceutical business, potential pricing for our product and product candidates, the amount and timing of estimated future cash flows and the time value of money. In general, cost estimates (cash outflows) can normally be estimated with a higher degree of accuracy than revenues (cash inflows). Some specific areas of uncertainty are described below.

We have no history on which to base our forecasts. The cytostatic market for dogs is completely new so for this segment there is no product on which to study volumes and prices. The cytostatic market for human use is well known but there have been substantial changes in recent years as patents have expired and generic products have been introduced. One product whose patent has not expired is Abraxane, which is commercially available in many countries, with a higher price than that of generic products but with notable differences in price in those countries where it is on the market.

One further market uncertainty is that we do not yet have distributors or licensees for our human product candidates in the majority of countries and therefore have not received any parameters by which to estimate our net sales.

Another uncertainty is cost of goods sold. The only experience that we have with manufacturing is with small-scale production in our plant in Uppsala. We expect that large scale production in Uppsala and elsewhere will reduce the cost of goods sold per unit over time.



Our estimates have been calculated by the following procedures.

#### ***Animal Health***

We have access to statistics for the number of dogs in the U.S. and the rates of cancer incidence among dogs. We cannot be certain how many dogs with cancer will be treated so we have estimated very small numbers of sales for the first few years. We also cannot be certain what revenue can be derived per patient. We have received estimates from Abbott Animal Health for the amounts dog owners are willing to pay for treatment, not specifically for cytostatic but for other treatments (as there have been no cytostatic for dogs available on any market before we received conditional approval for Paccal Vet from the FDA). Cost of goods sold has been estimated by calculating all components at our plant and at the plants of our sub-contractor.

#### ***Human Health***

We have access to figures on populations per country, cancer incidents per year, per cancer type and per country as well as net sales and prices for existing cytostatic. We also have access to the number of patients treated with taxanes. Of this figure we have estimated very small numbers for the first few years. Cost of goods sold has been estimated in the same way as in animal health above.

Since until just recently we had no product approved, we have not been able to verify any of our estimates. There have been no major changes to any of our assumptions, other than that we have had to move back our estimate of the first year of market approval per product due to the approval processes with the relevant authorities taking more time than we had originally anticipated.

If our products are not approved, or the probability of their approval is diminished, capitalized expenditures will be carried as expenses. We annually evaluate whether a need for impairment exists for all intangible assets.

#### **D. Trend information**

See "Item 5.A Operating results"

#### **E. Off-balance Sheet Arrangements.**

As of April 30, 2016, we have no off-balance sheet arrangements that have or are reasonably likely to have current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity or capital resources.

#### **F. Tabular disclosure of contractual obligations.**

The following table summarizes our contractual commitments and obligations as of April 30, 2016.

	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than 1 year</b>	<b>1 – 3 years (in TSEK)</b>	<b>3 – 5 years</b>	<b>More than 5 years</b>
Operating lease obligations <sup>(1)</sup>	26,397	6,362	16,413	985	2,637
Purchase obligations <sup>(2)</sup>	131,006	25,193	85,658	20,155	-
Interest Payments	7,782	7,782	-	-	-
Short-term debt obligations <sup>(3)</sup>	142,395	142,395	-	-	-
<b>Total contractual cash obligations</b>	<b>307,580</b>	<b>181,732</b>	<b>102,071</b>	<b>21,140</b>	<b>2,637</b>

- (1) Consists of the leasing of premises, lease of office equipment and lease of car. Leasing of premises amounts to SEK 5.9 million, lease of office equipment SEK 0.2 million and lease of car SEK 0.2 million in the year ending April 30, 2017. The expiration dates for the leasing contracts regarding premises are April 30, 2017, January 31, 2018, December 31, 2018, December 31, 2019, March 31, 2020 and December 31, 2023. Leases automatically extend for an additional 1-3 years if not terminated within 6-9 months' notice.
- (2) Consists of a purchase contract with obligations for Oasmia to purchase a minimum number of product vials for each contract year.
- (3) Short-term obligations include repayment of loan to Nexttobe AB of SEK 94.4 million, repayment of loan to Nordea of SEK 20.00 million and repayment of convertible debt instruments of SEK 28 million.

Contracts with our vendors that allow us to cancel the contract on short notice without financial penalty are excluded from the above table.

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

### A. Directors and senior management.

The following table sets forth the names, ages and positions of our executive officers and directors as of the date of this Annual Report:

Name	Age	Position
<b>Executive Director:</b>		
Julian Aleksov	50	Executive Chairman of the Board
<b>Executive Officers:</b>		
Mikael Asp	53	Chief Executive Officer and Head of Quality Assurance
Amir Tatarevic	44	Chief Operating Officer
Anders Blom	46	Executive Vice President
<b>Non-Executive Directors:</b>		
Bo Cederstrand	77	Director
Horst Domdey	64	Director
Alexander Kotsinas	48	Director
Hans Liljeblad	59	Director
Lars Bergkvist	52	Director
Hans Sundin	71	Director

The following is a brief summary of the business experience of our executive officers and directors. The current business address for all of our executive officers and directors is Vallongatan 1, 752 28, Uppsala, Sweden.

#### **Executive Officers**

*Julian Aleksov* is a co-founder of Oasmia, and has served as Chief Executive Officer and a director since 1999, though he was a director of Oasmia's predecessor from 1998 to 1999. On May 28, 2015, he resigned as our Chief Executive Officer and was appointed as our Executive Chairman of the Board. He is an economist with extensive experience in coordinating research projects and strategic development of global intellectual property assets. Prior to becoming the CEO, he oversaw our research and strategic development within bio-organic chemistry, with a focus on retinoids and alpha-protein bindings, while also managing our global intangible assets registrations and financing. He has been a partner and member of the board of Alceco, one of our principal stockholders, since 2000. He attended the Deutsche Schule in Stockholm for his basic education, and thereafter studied economics on several levels.

*Anders Blom* has served as Executive Vice President since September 1, 2014. He has 15 years of experience from international strategic business development and finance at Galderma (former Q-Med AB) and Pharmacia. Anders was previously CEO of Nexttobe which is also the second largest shareholder in Oasmia. Nexttobe is a life science focused venture capital firm based in Uppsala. He has a Master of Business Administration degree from Uppsala University.

*Amir Tatarevic* has served as Chief Operating Officer since 2016 and the Head of Logistics, Purchasing and Clinical Supply since 2005, and was also the Acting Head of Production since from 2010 to 2013. He has worked in the pharmaceutical industry for almost 15 years, and prior to joining Oasmia, he held positions at Pharmalink and Meda AB. He has completed coursework in Logistics, Economics, and Corporate Finance at FolkUniversitetet in Stockholm.

*Mikael Asp* has served as Head of Quality Assurance since 2013. On May 28, 2015, he was appointed as our Chief Executive Officer. He has 25 years of experience with a variety of companies in the international pharmaceutical sector including Xellia, Pfizer, Wyeth and Pharmacia in research and development, production and quality assurance. He has been a Qualified Person since 2013. He has a Master's degree in chemical engineering from Royal Institute of Technology, Stockholm.

#### ***Non-Executive Directors***

*Bo Cederstrand* has been a director since 2000 and was Chairman of the Board from 2000 to 2011. He has approximately 40 years of experience as CEO and partner in a number of small and medium-sized companies specializing in pets or pet products, most of which he founded. He has extensive experience in international trade and production and has been very active within trade branch associations. He has been a partner and member of the board of Alceco, one of our principal stockholders, since 2000. He is a deputy board member at Fruges Aktiebolag AB and was a previous board member of Arkenbutikerna. He studied at the Stockholm School of Economics.

*Alexander Kotsinas* has served on our board of directors since September 2013. He is currently a partner at Nexttobe AB since 2011, and he has been Vice President at Investor AB and has worked at Ericsson. He was the Vice President and CFO at Q-Med AB from 2008 to 2011, and was the CFO at Life Europe AB in 2007 and at Tre-Hi3G Access AB from 2003 to 2006. He has a Master of Science degree in Applied Physics from the Royal Institute of Technology, Stockholm and a Bachelor of Science Economics from the Stockholm School of Economics.

*Horst Domdey* has served on our board of directors since 2011. He has extensive experience in the biochemistry and molecular biology industries. He is the Chairman of the Munich Biotech Cluster and the President and CEO of BioM Munich Biotech Development AG and BioM Biotech Cluster Development GmbH. Since 2003, he has been the scientific director of the Bavarian Genome Network BayGene, and since 2011 he has been the coordinator of the Bavarian Center for Molecular Biosystems BioSysNet. He co-founded Switch Biotech AG and MediGene AG, one of the first biotech companies in Germany. He is a member of the supervisory board of MediGene AG. In 1996, he successfully led the Munich Biotech Initiative into the German BioRegio Competition, and in 2010 the Munich Biotech Cluster became — under his leadership — one of the winners in the German Leading Edge Cluster Competition. He has previously held various positions at Max-Planck-Institut für Biochemie, the Swiss Institute for Experimental Cancer Research (ISREC), the University of California and the California Institute of Technology, among others. Since 1994 he has been a Professor for Biochemistry at the University of Munich. He has a Dr. rer nat in Biochemistry and a Dr. habil. from Ludwig Maximilian's University of Munich.

*Hans Liljeblad* has served on our board of directors since May 2015. From 2008 through the present, he has been a partner at the law firm KLA Karlerö Liljeblad Advokatbyrå. Mr. Liljeblad was awarded a degree from the University of Oslo, Scandinavian Institute of Maritime Law in 1983, a law degree from the University of Stockholm in 1985 and a degree from the New York University Studies in Maritime Law in 1986. Mr. Liljeblad is a member of the Swedish Bar Association as well as the International Bar Association.

*Lars Bergkvist* has served on our board of directors since May 2015. From 2001 through 2011, he was the chief executive officer at Arken Zoo. Since 2012, he has acted as the chairman of the board of Jaktia AB, Master Design AB and Chainformation AB, as a member of the board of directors of FDT AB, a public company, and as a member of the advisory board of Skyltspektrum AB. He received a degree in Accounting and Finance from Stockholm's School of Economics in 1986.

*Hans Sundin* has served as Senior Vice President and Director since 2014. Before that he served as Executive Vice President between 2008 and 2014. He has been in the pharmaceutical industry for over 40 years, and has extensive international experience with several pharmaceutical companies at senior management levels in manufacturing, quality control, project management, and business development. He is currently the owner and Managing Director of Loxia Consulting AB, a company he founded in 2006 that serves the pharmaceutical industry with general management and operational consultancy services. From 2007 to 2008, he was the CEO and a director of Vitamex Manufacturing AB, and from 2000 to 2005 he was the Vice President of Business Development and a Divisional Manager at Pharmadule Emtunga AB, an engineering and modular plant company. He has been a Qualified Person since 2011. He has a Masters of Pharmaceutical Science degree from Uppsala University.

## B. Compensation

### Compensation of Directors and Executive Management Board

The following discussion provides the amount of compensation paid, and benefits in kind granted, by us to our directors and executive officers for services in all capacities to us for the year ended April 30, 2016.

#### Directors Compensation

For the year ended April 30, 2016, the table below sets forth the compensation paid to our directors. Mr. Aleksov was named as the Executive Chairman of the Board on May 28, 2015 and contemporaneously resigned from his position as our Chief Executive Officer. The compensation in the case of Mr. Aleksov reflects the compensation paid for his services as our Chief Executive Officer from May 1, 2015 until May 28, 2015 and as Executive Chairman of the Board from May 28, 2015 until April 30, 2016.

#### Year Ended April 30, 2016 Directors Compensation

Name	Salary/ Fees	Annual Bonus	Benefits Excluding Pension (In TSEK)	Pension Benefit	Total
Joel Citron <sup>(1)</sup> <i>Chairman of the Board</i>	26				26
Julian Aleksov <i>Executive Chairman of the Board and former Chief Executive Officer</i>	1,635 <sup>(2)</sup>	35	582 <sup>(3)</sup>	422	2,674
Bo Cederstrand <i>Director</i>	150		20		170
Horst Domdey <i>Director</i>	150		47		197
Alexander Kotsinas <sup>(4)</sup> <i>Director</i>	—				
Hans Sundin <sup>(5)</sup> <i>Director</i>	883		99		982
Hans Liljeblad <i>Director</i>	200		62		262
Lars Bergkvist <i>Director</i>	125		39		164

- (1) Mr. Citron resigned as a member of the board of directors on May 28, 2015.
- (2) This amount represents Mr. Aleksov's salary as our CEO until May 28, 2015 and then from then and until April 30, 2016 as our Executive Chairman of the Board. Mr. Aleksov does not receive any additional compensation for his services as a director.
- (3) This amount represents the value of Mr. Aleksov's private health insurance.
- (4) Mr. Kotsinas has waived his right to receive remuneration for his service as a Director.
- (5) Mr. Sundin is an employee as well as a director and has a salary.

Remuneration of the Chairman of the Board and members of the board of directors is decided at each annual general meeting. There is no remuneration for participation in the nomination committee or any of the other committees. Upon special agreement, we pay members of the board of directors their compensation through a company wholly owned by the board member. In such cases, the invoice amount is increased by social security and VAT. Accordingly, board member fees for Mr. Citron were paid through wholly owned Miankoma Partners. Mr. Liljeblad was paid through Advokatfirman Liljeblad och Co KB and Mr. Bergkvist was paid through Axli AB.

#### *Executive Officers Compensation*

With the exception of our Executive Chairman and Executive Vice President, the compensation for each executive officer is comprised solely of base salary, 4.5% pension allocation of base salary, directors' and officers' liability insurance, and the medical benefits described below. The Executive Chairman also receives private health insurance and received pension allocations. The total amount of compensation paid to executive officers, whether or not a director, for the year ended April 30, 2016 was TSEK 13,330.

#### *Bonus Plans*

We do not currently pay bonuses to any director or employee.

#### *Options and Incentive Programs*

We do not currently have any option or incentive programs for directors or employees.

#### *Health care and medical care*

We offer our employees free medical care and free medicine up to the Swedish high-cost protection ceilings of SEK 1,100 and SEK 2,200, respectively. We also have an agreement with a provider of occupational health services.

#### *Employment Agreements*

##### *Julian Aleksov*

Mr. Aleksov signed an employment agreement with us on January 1, 2000 to serve as our Chief Executive Officer but is presently our Executive Chairman of the Board; this change in title had no impact on his compensation. The employment agreement is for an unspecified term. As of April 30, 2016, he receives a base salary of SEK 1,620,000 per annum, reviewed annually, plus private health insurance and pension allocations. He does not receive a bonus or any additional perquisites or other annual compensation. The health insurance he receives is worth SEK 3,768 annually. His contribution pension plan is handled through Carnegie Investment Bank, with an annual pension contribution of SEK 421,750 since the beginning of the last full fiscal year, compared to SEK 497,900 as of the end of the previous fiscal year. He does not receive any additional compensation for serving as a director.

In the event Mr. Aleksov's employment is terminated by us, Mr. Aleksov shall be entitled to notice of 24 months. If he voluntarily decides to terminate his employment, the notice shall be six months. There is no agreement or arrangement for Mr. Aleksov to receive any severance payments or any additional payments should we undergo a change of control.

*Hans Sundin*

Mr. Sundin signed an employment agreement with us on July 1, 2008 to serve as our Executive Vice President, Qualified Person. The employment agreement is for an unspecified term. On October 1, 2014, Mr. Sundin's employment agreement was amended to change his title to "Senior Vice President". In addition, the agreement was amended to change his work time to 50% and his salary to SEK 681,600 per annum, reviewed annually, which represents 50% of what his annual salary would be if he were a full-time employee. He does not receive a bonus, perquisites, pension or any other annual compensation.

If we terminate Mr. Sundin's employment, he shall be entitled to notice of one month. If he voluntarily decides to terminate his employment, the notice shall be one month. There is no agreement or arrangement for Mr. Sundin to receive any severance payments or any additional payments should we undergo a change of control.

*Anders Blom*

Mr. Blom joined our company on September 1, 2014. As of April 30, 2016, he receives a base salary of SEK 1,545,300 per annum, reviewed annually. His pension plan follows a staircase model whereas his pension allocation is based on his salary. He does not receive any other bonus, perquisites, pension or any other annual compensation.

If we terminate Mr. Blom's employment, he shall be entitled to a notice period of six (6) months. If he voluntarily decides to terminate his employment, the notice period shall be three (3) months. There is no agreement or arrangement for Mr. Blom to receive any severance payments or any additional payments should we undergo a change of control.

*Mikael Asp*

Mr. Asp signed an employment agreement with us on January 7, 2013. The employment agreement is for an unspecified term. As of April 30, 2016, he receives a base salary of SEK 1,308,000 per annum, reviewed annually. He does not receive a bonus, perquisites, pension or any other annual compensation.

If we terminate Mr. Asp's employment, he shall be entitled to a notice period of twelve (12) months. If he voluntarily decides to terminate his employment, the notice period shall be three (3) months. There is no agreement or arrangement for Mr. Asp to receive any severance payments or any additional payments should we undergo a change of control.

*Amir Tatarevic*

Mr. Tatarevic joined our company on January 31, 2005. As of April 30, 2016, he receives a base salary of SEK 924,000 per annum, reviewed annually. He does not receive any other bonus, perquisites, pension or any other annual compensation.

If we terminate Mr. Tatarevic's employment, he shall be entitled to a notice period of number of month six (6) months. If he voluntarily decides to terminate his employment, the notice period shall be three (3) months. There is no agreement or arrangement for Mr. Tatarevic to receive any severance payments or any additional payments should we undergo a change of control.

### *Limitations on Liability and Indemnification Matters*

Under the Swedish Income Tax Act, if a company directly indemnifies a member of the board of directors or an executive officer or otherwise holds him or her harmless, the amount expended will be regarded as salary upon which we must pay social security contributions, and the director or officer will also be liable for income tax on any such expended amount. Therefore, we maintain directors and officers insurance through Chubb Insurance Company of Europe and Navigators to insure our directors and executive officers against certain liabilities incurred based on their capacity as a director or an executive officer.

### **C. Board practice**

#### *Board Composition*

Our affairs are managed under the direction of our board of directors, which is currently composed of seven members. Three of our directors, i.e., Messrs. Domdey, Liljebad and Bergkvist, qualify as independent directors under Rule 5605(a)(2) of the Nasdaq Marketplace Rules. Messrs. Aleksov, Cederstrand, Sundin and Kotsinas are not considered independent under Nasdaq or SEC rules. Directors are elected at each annual general meeting for one-year terms. None of our directors, or our executive officers, has any family relationship with any other director or executive officer, except that Mr. Aleksov is the partner of Mr. Cederstrand's daughter and the father of two of his grandchildren.

#### *Tasks of the Board of Directors*

The board of directors manages our affairs on behalf of our shareholders. The board of directors acts in accordance with the Swedish Companies Act (SFS 2005:551) ("Swedish Companies Act"), our Articles of Association, internal regulations and directions given by the general meeting. In addition, the board of directors shall ensure that we comply with the Swedish Corporate Governance Code, NASDAQ Stockholm's Rule Book for Issuers as well as other applicable laws and regulations. The principal tasks of the board of directors include the following:

- establishing our overall operational goals and strategy;
- appointing, evaluating and, if necessary, dismissing the chief executive officer;
- evaluating our management and deciding if any significant changes in our organization and business need to be made;
- analyzing our financial situation;
- ensuring that there is an effective system for follow-up and control of our operations;
- ensuring that our internal control of the financial development is satisfactory and that information concerning the financial development is correctly communicated in our financial reports;
- ensuring that there is a satisfactory process for monitoring our compliance with laws and other regulations relevant to our operations, including applicable accounting standards and other requirements for listed companies;
- defining necessary guidelines to govern our ethical conduct; and

- ensuring that our external communications are transparent and that they are accurate, reliable and relevant.

#### *Committees of the Board of Directors and Corporate Governance*

The committees of our board of directors consist of an audit committee, a compensation committee and a nomination committee. Each of these committees has the responsibilities described below. Our board of directors may also establish other committees from time to time to assist in the discharge of its responsibilities.

Subject to certain exceptions, the rules of Nasdaq permit a foreign private issuer to follow its home country practice in lieu of certain Nasdaq listing requirements. The Nasdaq listing requirements with respect to which we rely on this exemption, and the corresponding requirements imposed on us by Swedish law and corporate governance guidelines and the listing requirements of NASDAQ Stockholm, are set forth in the table below.

#### **Nasdaq Listing Requirement**

#### **Swedish requirements**

A majority of the board of directors must consist of independent directors

Policy that an issuer must have (i) a majority of the board of directors be independent directors, (ii) only one director may also be an executive employee of the issuer, and (iii) two independent directors should also not be related to major shareholders (i.e., those who own 10% or more of the Ordinary Shares), or the issuer must explain why the board of directors did not comply with this policy.

Non-executive directors must meet on a regular basis without management present

Policy that the board of directors must meet at least once annually with the issuer's auditors without management present or the issuer must explain why the board of directors did not comply with this policy.

All members of the nominating committee must be independent

Policy that (i) the nominating committee should consist of at least three members, two of which are independent directors, (ii) the CEO and other executive employees should not serve on the nominating committee, and (iii) one member of the nominating committee should not be related to major shareholders, or the issuer must explain why the board of directors did not comply with this policy.

Proxies must be solicited and proxy statements provided for all shareholder meetings

Mandatory requirement that notice of shareholder meeting must include information relating to the matters to be decided at the shareholder meeting, how to cast votes by proxy and where to find a proxy form.

Shareholder approval must be sought for the implementation of certain equity compensation plans and issuances of ordinary shares

Policy that (i) the notice of shareholder meeting should include the nomination committee's suggestion for chairman of the issuer, and (ii) the nomination committee should issue a statement on the issuer's website explaining its proposals regarding the board of directors, or the issuer must explain why the board of directors did not comply with this policy.

Mandatory provision applying certain supermajority shareholder approval thresholds for implementation of certain equity compensation plans and certain issuances of new shares that deviate from existing shareholders' preferential rights.

We are not required to follow the Nasdaq listing requirements set forth above with respect to having a majority of our board of directors be independent.



#### *Audit Committee*

The members of our audit committee are Dr. Horst Domdey, Mr. Hans Liljeblad and Mr. Lars Bergkvist, all of whom qualify as an “independent director” as such term is defined in Rule 10A-3 under the Exchange Act. Mr. Lars Bergkvist serves as chair of the audit committee. Our board of directors has determined that Mr. Bergkvist is a financial expert as contemplated by the rules of the SEC implementing Section 407 of the Sarbanes Oxley Act of 2002. Our audit committee meets at least twice per year with the external auditors and our independent registered public accounting firm without executive board members present and oversees the monitoring of our internal controls, accounting policies and financial reporting and provides a forum through which our external auditors and independent registered public accounting firm reports. The audit committee also oversees the activities of the external auditors and our independent registered public accounting firm, including their appointment, reappointment, or removal as well as monitoring of their objectivity and independence. In addition, the audit committee considers the fees paid to the external auditors and independent registered public accounting firm and determines whether the fee levels for non-audit services, individually and in aggregate, relative to the audit fee are appropriate so as not to undermine independence.

#### *Compensation Committee*

The members of the compensation committee are Mr. Bo Cederstrand, Dr. Horst Domdey, Mr. Alexander Kotsinas, Mr. Lars Bergkvist and Mr. Liljeblad. Each of the members, except for Messrs. Cederstrand and Kotsinas, qualifies as an independent director under Rule 5605(a)(2) of the Nasdaq Marketplace Rules. Mr. Hans Liljeblad serves as chair of the compensation committee. Our compensation committee reviews, among other things, the performance of our executive directors and sets the scale and structure of their remuneration and the basis of their employment agreements with due regard to the interests of the shareholders. No director has a service agreement with a notice period exceeding one year. During the year ended April 30, 2014, there was one meeting of the compensation committee.

#### *Nomination Committee*

The nomination committee consists of three members. The first member, currently Mr. Bo Cederstrand, represents the largest shareholder Alceco International S.A. The second member, currently Mr. Alexander Kotsinas, represents the second largest shareholder Nexttobe. The third member is Mr. Aleksov. Mr. Cederstrand serves as chair of the nomination committee and oversees the evaluation of the board of directors’ performance. The primary task of the nomination committee is to present candidates for the board of directors and the Chairman of the Board and to decide their compensation. The nomination committee also presents proposals to the annual general meeting of possible remuneration for committee work and remuneration of external auditor. Proposals of the nomination committee are made public no later than when notice of the annual general meeting is sent. The nomination committee’s mandate extends to when the next nomination has been made public. The nomination committee meets at least once a year.

#### **D. Employees**

As of April 30, 2016, we had 75 employees, all of them are located in Sweden. We have never had a work stoppage and none of our employees is represented by labor unions or covered by collective bargaining agreements. The competence and experience of our employees are among Oasmia’s most important assets. Drug development is a complex process which requires many specialist competencies. A total of 73% of Oasmia’s employees have a university degree and one third of these also have a Ph.D. Many nationalities are represented among the employees, creating a positive, challenging and dynamic work environment. Oasmia strives to continually improve and ensure a healthy and safe work environment. Oasmia will continue to be a safe, healthy and pleasant workplace.

The table below sets forth a breakdown of our employees as at end of each of the past fiscal years by main category of activity.

	As of April 30, 2016	As of April 30, 2015	As of April 30, 2014
Quality control, quality assurance and production	38	39	39
Accounting, human resources and administration	12	13	11
Research and development	8	9	9
Clinical development	3	6	8
Regulatory affairs	5	3	4
Logistics, clinical supply and facility Management	4	4	3
Public relations and communications, IT	2	2	2
Legal	1	1	1
Chief Executive Officer, Executive Vice President	2	2	1
<b>Total</b>	<b>75</b>	<b>79</b>	<b>78</b>

#### E. Share ownership

See "Item 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS —A. Major Shareholders."

### ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

#### A. Major Shareholders

The following table and related footnotes set forth information with respect to the beneficial ownership of the Ordinary Shares, as of July 31, 2016, by: (i) each of our directors and executive officers, and (ii) each person known to us to own beneficially more than 5% of the Ordinary Shares as of July 31, 2016. As of July 31, 2016, we had 107,209,310 Ordinary Shares issued and outstanding.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of Ordinary Shares owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. These Ordinary Shares that the person has the right to acquire within 60 days, however, are not included in the computation of the percentage ownership of any other person. Ownership of the Ordinary Shares by the "principal shareholders" identified below has been determined by reference to our share register, which provides us with information regarding the registered holders of the Ordinary Shares but generally provides limited, or no, information regarding the ultimate beneficial owners of such Ordinary Shares. As a result, we may not be aware of each person or group of affiliated persons who beneficially owns more than 5% of the Ordinary Shares.

Unless otherwise indicated, the business address for each of the shareholders in the table below is c/o Oasmia Pharmaceutical AB, Vallongatan 1, 752 28, Uppsala, Sweden.

Name of Beneficial Owner	Ordinary Shares Beneficially Owned	
	Number	Percent
<b>Greater than 5% Shareholders</b>		
Alceco International S.A.	25,536,445	23.82
Nexttobe AB <sup>(1)</sup>	19,602,173	18.28
<b>Directors and Executive Officers</b>		
Julian Aleksov <sup>(2)</sup>	25,686,241	23.96
Bo Cederstrand <sup>(3)</sup>	25,662,445	23.94
Hans Sundin	6,000	*
Mikael Asp	15,150	*
Amir Tatarevic	25,711	*
Anders Blom	30,000	*
Horst Domdey	—	
Alexander Kotsinas <sup>(4)</sup>	19,602,173	18.28
Hans Liljeblad	—	
Lars Bergkvist	—	
<i>All Named Executive Officers and Directors as a Group (10 persons)</i>	45,491,275	42.43

\* Less than one percent.

- (1) The business address for Nexttobe is Dag Hammarskjölds väg 40, 751 83 Uppsala, Sweden. Mr. Kotsinas is the control person of Nexttobe.
- (2) Consists of 25,536,445 shares held through Alceco and 149,796 held by Mr. Aleksov separately. Messrs. Aleksov and Cederstrand are the control persons of Alceco.
- (3) Consists of 25,536,445 shares held through Alceco and 126,000 held by Mr. Cederstrand separately. Messrs. Aleksov and Cederstrand are the control persons of Alceco.
- (4) Includes the shares held through Nexttobe.

Our shareholders do not have different voting rights. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

The following table sets forth information with respect to the beneficial ownership of our ordinary shares by our major shareholders, which means shareholders that beneficially own 5% or more of our ordinary shares, as of July 31, 2016, July 31, 2015 and July 31, 2014, each being the most recent practicable date before reporting for the last three fiscal years.

Name	2014		2015		2016	
	# of Shares	% of issued Shares*	# of Shares	% of issued Shares*	# of Shares	% of issued Shares*
Alceco International S.A. <sup>(1)</sup>	36,706,941	41.68%	35,178,112	35.95%	25,536,445	23.82%
Nexttobe AB <sup>(2)</sup>	17,641,956	20.03%	19,602,173	20.03%	19,602,173	18.28%

(1) Messrs. Aleksov and Cederstrand are the control persons of Alceco.

(2) The business address for Nexttobe is Dag Hammarskjölds väg 40, 751 83 Uppsala, Sweden. Mr. Kotsinas is the control person of Nexttobe.

## B. Related Party Transactions

### *Transactions with major shareholders and companies controlled by major shareholders*

Alceco, Oasmia's largest shareholder, see item 7 A Major Shareholders, has made a credit facility of SEK 40 million available to us. The credit facility is valid until December 2016, and is renewed automatically for one-year terms, unless terminated by either party at least three months prior to an expiration date. This credit facility was utilized to the tune of TSEK 35 during part of the financial year but at April 30, 2016 this credit facility was completely unused, as was the case at April 30, 2015. The interest rate on any utilized credit amount is 5%. During the financial year ending April 30, 2015, Oasmia paid SEK 0.51 million to Alceco as guarantee fee for their commitment as guarantor of the new share issue in December 2014.

No other transactions took place between Alceco and Oasmia.

Nexttobe, Oasmia's second largest shareholder, see "Item 7 A. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS.", has, except for the paid in proceeds from share issues, see next section, had the following transactions with Oasmia during the last three fiscal years in million SEK:

in SEK million except Interest rate	April 30, 2016	April 30, 2015	April 30, 2014
Financial loan from Nexttobe as per April 30	94.4	87.00	105.00
Accrued interest as per April 30	2.7	2.4	11.5
Interest rate, percent	8.5	8.5	8.5

In the rights issue that was completed in December 2014, Nexttobe AB, Nexttobe used a part of the outstanding loan and the accrued interest of SEK 35.28 million in total as payment for shares subscribed for. In December 2014 Oasmia paid interest of SEK 0.12 million to Nexttobe AB.

In the financial year ending April 30, 2016, SEK 7.4 million of accrued interest has been capitalized and added to the loan. The loan matures on December 30, 2016.

Ardenia Investment Ltd, a company controlled to equal parts by Oasmia's founders Bo Cederstrand and Julian Aleksov, is registered as the applicant and holder of the patents which forms the basis for Oasmia's business. Through an agreement between Ardenia and Oasmia, the rights to these patents have been transferred to Oasmia. Ardenia cross charges their administration costs for these patents.

Cross charged costs and Oasmia's outstanding liability as per April 30 last three fiscal years, million SEK:

	May 1, 2015 – April 30, 2016	May 1, 2014- April 30, 2015	May 1, 2013 – April 30, 2014
Cross charged administration costs	2.23	1.40	4.68
Liability as per April 30	0.00	0.00	0.00

#### ***Transactions with Group companies***

The Oasmia group consists of the parent company Oasmia Pharmaceutical AB and the Swedish subsidiaries Oasmia Animal Health AB and Qdoxx Pharma AB and the Nevada-registered subsidiary Oasmia Pharmaceutical, Inc.

The Swedish subsidiaries have been dormant the last three years and have had only minor administration costs which have been covered by the parent company.

No sales of goods or services have taken place between the parent company and the Swedish subsidiaries.

Oasmia Pharmaceutical, Inc. was founded in June 2015 by the parent company with a capital contribution of SEK 1.15 million to finance its initial activities. Apart from this, there were no transactions between the Parent Company and Oasmia Pharmaceutical, Inc. and there were no intra-Group balances at closing day.

#### ***Stock Lending Agreement***

To facilitate the orderly closing of the initial offering of ADSs and due to timing considerations related to the technical issuance and registration of new Ordinary Shares under Swedish law, under the terms of a Stock Lending Agreement dated October 23, 2015, by and among the Company and Alceco and certain of its affiliates, Alceco and such affiliates agreed to loan temporarily to the Company 7,368,480 Ordinary Shares (the "Borrowed Shares") in connection with the initial deposit of Ordinary Shares into the American Depositary Receipt Program immediately prior to and concurrent with the consummation of the offering and in connection with any future exercise of the Warrants.

We issued to the custodian, whose role is more fully described in the section entitled "Description of American Depositary Shares, and the custodian has deposited into the American Depositary Receipt Program, 7,684,500 Ordinary Shares. Following receipt from us of the newly issued Ordinary Shares equal to the number of the Borrowed Shares, the custodian returned the Borrowed Shares underlying the ADSs to Alceco. In all events, the ADS that were offered and sold represent the same number of Ordinary Shares in the American Depositary Receipt Program.

A similar Stock Lending Agreement will be entered into in order to facilitate the issuance of ADSs upon exercise of the Warrants.

We agreed to indemnify and hold harmless Alceco for any damages in connection with the Stock Lending Agreement and the transactions contemplated thereunder.

***Transactions with related individuals***

For transactions with related individuals, see item 6 B. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES Compensation

**C. Interests of Experts and Counsel**

Not Applicable

**ITEM 8. FINANCIAL INFORMATION**

**A. Consolidated statements and other financial information**

See Item 18. Financial Statements, which contains our financial statements prepared in accordance with IFRS.

**B. Significant Changes**

Not applicable.

**ITEM 9. THE OFFER AND LISTING**

**A. Offering and Listing Details**

See "Item 9. C. Markets" for information regarding the price history of our stock.

**B. Plan of Distribution**

Not Applicable.

**C. Markets**

The Ordinary Shares have been trading on NASDAQ Stockholm under the symbol "OASM" since June 24, 2010 and on the Frankfurt Stock Exchange under the symbol "OMAX" since January 24, 2011 and NASDAQ Capital Market under symbol "OASM" since October 23, 2015.

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of the Ordinary Shares on NASDAQ Stockholm and the Frankfurt Stock Exchange and ADSs on NASDAQ Capital Markets, in kronor and U.S. dollars, in Euros and U.S. dollars and U.S dollars, respectively. U.S. dollar per ordinary share amounts have been translated into U.S. dollars at \$1.00 = SEK 8.3781 and \$1.00 = €0.8829] based on the certified foreign exchange rates published by the Federal Reserve Bank of New York on August 19, 2016.

*NASDAQ Stockholm*

	Krona		Dollar	
	Price Per Ordinary Share		Price Per Ordinary Share	
	High	Low	High	Low
<b>Annual (Year Ended April 30):</b>				
2012	14.60	6.60	1.74	0.79
2013	13.55	4.70	1.62	0.56
2014	29.80	10.00	3.56	1.19
2015	23.00	18.30	2.75	2.18
2016	19.20	8.30	2.29	0.99
<b>Quarterly (Fourth Quarter Ended April 30):</b>				
Second Quarter 2014	18.20	11.90	2.17	1.42
Third Quarter 2014	23.90	16.80	2.85	2.01
Fourth Quarter 2014	29.80	18.60	3.56	2.22
First Quarter 2015	23.00	18.80	2.75	2.24
Second Quarter 2015	22.10	18.30	2.64	2.18
Third Quarter 2015	20.80	18.30	2.48	2.18
Fourth Quarter 2015	22.50	19.00	2.69	2.27
First Quarter 2016	19.20	17.00	2.29	2.03
Second Quarter 2016	18.30	11.25	2.18	1.34
Third Quarter 2016	12.65	10.15	1.51	1.21
Fourth Quarter 2016	13.20	8.30	1.58	0.99
First Quarter 2017	13.75	8.90	1.64	1.06
Second Quarter 2017 (through Aug 19, 2016)	10.40	9.50	1.24	1.13
<b>Most Recent Six Months:</b>				
March 2016	11.90	8.30	1.42	0.99
April 2016	13.20	11.45	1.58	1.37
May 2016	13.75	11.75	1.64	1.40
June 2016	12.90	8.90	1.54	1.06
July 2016	10.50	9.25	1.25	1.10
August 2016 (through Aug 19, 2016)	10.40	9.50	1.24	1.13

*Frankfurt Stock Exchange*

	Euro		Dollar	
	Price Per Ordinary Share		Price Per Ordinary Share	
	High	Low	High	Low
<b>Annual (Year Ended April 30):</b>				
2012	1.60	0.71	1.82	0.80
2013	1.63	0.53	1.84	0.60
2014	3.31	1.13	3.75	1.28
2015	2.48	1.87	2.81	2.12
2016	2.10	0.89	2.38	1.01
<b>Quarterly (Fourth Quarter Ended April 30):</b>				
Second Quarter 2014	2.10	1.34	2.38	1.51
Third Quarter 2014	2.74	1.86	3.10	2.11
Fourth Quarter 2014	3.31	2.00	3.75	2.27
First Quarter 2015	2.48	1.99	2.81	2.26
Second Quarter 2015	2.41	1.93	2.73	2.19
Third Quarter 2015	2.21	1.87	2.50	2.12
Fourth Quarter 2015	2.36	2.00	2.67	2.27
First Quarter 2016	2.10	1.76	2.38	2.00
Second Quarter 2016	1.93	1.18	2.18	1.34
Third Quarter 2016	1.35	1.06	1.53	1.20
Fourth Quarter 2016	1.40	0.89	1.59	1.01
First Quarter 2017	1.44	0.94	1.63	1.06
Second Quarter 2017 (through Aug 19, 2016)	1.08	0.96	1.22	1.09
<b>Most Recent Six Months:</b>				
March 2016	1.31	0.89	1.48	1.01
April 2016	1.40	1.20	1.59	1.36
May 2016	1.44	1.24	1.63	1.40
June 2016	1.42	0.94	1.61	1.06
July 2016	1.09	0.95	1.23	1.08
August 2016 (through Aug 19, 2016)	1.08	0.96	1.22	1.09

*NASDAQ Capital Markets*

	Dollar	
	Price Per ADS (1)	
	High	Low
<b>Annual (Year Ended April 30):</b>		
2016 (from listing October 23, 2015)	4.70	2.94
<b>Quarterly (Fourth Quarter Ended April 30):</b>		
Second Quarter 2016 (from listing October 23, 2015)	4.29	3.70
Third Quarter 2016	4.29	3.26
Fourth Quarter 2016	4.70	2.94
First Quarter 2017	4.87	3.05
Second Quarter 2017 (through Aug 19, 2016)	3.59	3.05
<b>Most Recent Six Months:</b>		
March 2016	4.25	2.94
April 2016	4.70	3.99
May 2016	4.87	4.17
June 2016	4.55	3.05
July 2016	3.50	3.10
August 2016 (through Aug 19, 2016)	3.59	3.05

(1) Each ADS represents three (3) Ordinary Shares.

**D. Selling Shareholders**

Not applicable.

**E. Dilution**

Not applicable

**F. Expenses of the Issue**

Not applicable.

**ITEM 10. ADDITIONAL INFORMATION****A. Share capital.**

Not applicable

**B. Memorandum and articles of association**

Our Articles of Association were amended on September 28, 2015 to raise the range for share capital and number of authorized shares. The share capital shall be no less than SEK 8,500,000 and not more than SEK 20,000,000 and the number of shares shall be no less than 85,500,000 and not more than 200,000,000.

Except as set forth above, we incorporate by reference the description of our Articles of Association as in effect upon the closing of our IPO contained in the F-1 registration statement (File No. 333-205515) originally filed with the SEC July 6, 2015, as amended.

#### C. Material contracts.

Except as otherwise disclosed in this annual report (including the Exhibits) and in the F-1 registration statement (File No. 333-205515) originally filed with the SEC July 6, 2015, as amended., we are currently not, and have not been in the two years preceding publication of this annual report, party to any material contract, other than contracts entered into in the ordinary course of business, fully described in the section entitled "Item 4.B Business overview".

#### D. Exchange controls

There is no Swedish legislation affecting a) the import or export of capital or b) the remittance of dividends, interest or other payments to non-resident holders of our securities except that, subject to the provisions in any tax treaty, dividends are subject to withholding tax.

#### E. Taxation

### TAXATION

**HOLDERS OF OUR ADSs ARE HEREBY NOTIFIED THAT THEY SHOULD SEEK SPECIFIC ADVICE BASED ON THEIR PARTICULAR CIRCUMSTANCES FROM AN INDEPENDENT TAX ADVISOR WITH RESPECT TO THE APPLICATION TO THEM OF U.S. FEDERAL INCOME TAX RULES, AS WELL AS ANY APPLICABLE STATE, LOCAL, NON-U.S. OR OTHER TAX CONSEQUENCES, AS A RESULT OF THEIR PURCHASE, OWNERSHIP AND DISPOSITION OF THE ADSs.**

#### Material U.S. Federal Income Tax Considerations

Subject to the limitations described below, the following is a summary of the material U.S. federal income tax consequences of the purchase, ownership and disposition of ADSs to a "U.S. Holder." Non-U.S. Holders are urged to consult their own tax advisors regarding the U.S. federal income tax consequences to them of the purchase, ownership and disposition of ADSs. For purposes of this discussion, a "U.S. Holder" is a beneficial owner of ADSs that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the U.S.;
- a corporation (including any entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the U.S., any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income tax purposes regardless of its source; or
- a trust (A) if a court within the U.S. is able to exercise primary jurisdiction over the trust's administration and one or more U.S. persons have the authority to control all its substantial decisions, or (B) if, in general, it was in existence on August 20, 1996, was treated as a U.S. person under the Code (as defined below) on the previous day and made a valid election to continue to be so treated.

The term "Non-U.S. Holder" means a beneficial owner of ADSs that, for U.S. federal income tax purposes, is or is treated as an individual, corporation, trust or estate and is not a U.S. Holder. The term "Holder" means U.S. Holders and Non-U.S. Holders.



This discussion is based on current provisions of the Internal Revenue Code of 1986 (the "Code"), applicable U.S. Treasury Regulations promulgated thereunder, and administrative and judicial decisions as of the date hereof, all of which are subject to change, possibly on a retroactive basis (and any such change could affect the continuing accuracy of this discussion). We will not seek a ruling from the Internal Revenue Service (the "IRS") with regard to the U.S. federal income tax treatment of the ADSs and, therefore, there can be no assurance that the IRS will agree with the conclusions set forth below.

This summary does not purport to be a comprehensive description of all of the tax considerations that may be relevant to each person's decision to purchase ADSs. This discussion does not address all aspects of U.S. federal income taxation that may be relevant to any particular U.S. Holder based on its particular circumstances. In particular, this discussion considers only U.S. Holders that own or will own ADSs as capital assets within the meaning of section 1221 of the Code and does not address the potential application of U.S. federal alternative minimum tax or the U.S. federal income tax consequences to U.S. Holders that are subject to special treatment, including:

- broker dealers or insurance companies;
- U.S. Holders who have elected mark-to-market accounting;
- tax-exempt organizations or pension funds;
- regulated investment companies, real estate investment trusts, insurance companies, financial institutions or "financial services entities";
- U.S. Holders who hold ADSs as part of a "straddle," "hedge," "constructive sale" or "conversion transaction" or other integrated investment;
- U.S. Holders who own or owned, directly, indirectly or by attribution, at least 10% of the voting power of our Ordinary Shares;
- U.S. Holders whose functional currency is not the U.S. Dollar;
- persons holding ADSs in connection with a trade or business outside of the United States; and
- certain expatriates or former long-term residents of the United States.

This discussion does not consider the tax treatment of holders that are partnerships (including entities treated as partnerships for U.S. federal income tax purposes) or other pass-through entities or persons who hold ADSs through a partnership or other pass-through entity. Partnerships or partners of a partnership holding any ADSs should consult their own tax advisors regarding the tax considerations associated with holding ADSs. In addition, this discussion does not address any aspect of state, local or non-U.S. tax laws, or the possible application of U.S. federal gift or estate tax.

#### ***Taxation of Dividends Paid on ADSs***

Assuming that we are not a PFIC (as discussed below), a U.S. Holder will be required to include in gross income as a dividend the U.S. Dollar amount of any distribution paid on ADSs, including the amount of non-U.S. taxes, if any, withheld from the amount paid, on the date the distribution is received to the extent the distribution is paid out of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Distributions in excess of such earnings and profits will be applied against and will reduce the U.S. Holder's basis in its ADSs and, to the extent in excess of such basis, will be treated as gain from the sale or exchange of ADSs. We do not intend to calculate our earnings and profits for U.S. federal income tax purposes. Therefore, a U.S. Holder should expect that a distribution generally will be treated as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital under the rules set forth above.

Dividends are generally taxed at ordinary income rates. However, a maximum U.S. federal income tax rate of 20% will apply to “qualified dividend income” received by individuals (as well as certain trusts and estates), provided that certain eligibility requirements are met. In particular, a U.S. Holder will not be entitled to this rate: (i) if the U.S. Holder has not held our ADSs for at least 61 days of the 121-day period beginning on the date which is 60 days before the ex-dividend date; or (ii) to the extent the U.S. Holder is under an obligation to make related payments on substantially similar or related property. Any days during which a U.S. Holder has diminished its risk of loss on our ADSs are not counted towards meeting the 61-day holding period. “Qualified dividend income” includes dividends paid on shares of “qualified foreign corporations” (which term excludes PFICs) if the foreign corporation is eligible for the benefits of a comprehensive income tax treaty with the United States which contains an exchange of information program (a “qualifying treaty”). If we are a PFIC in the year in which a dividend is paid or the preceding year, we will not be a “qualified foreign corporation” and the dividend will not qualify for the reduced rate of tax (even assuming that a reduced rate is available at such time). Because of the uncertainty of these matters, including whether or not we are or will be a PFIC, there is no assurance that any dividends paid on the ADSs will be eligible for these preferential rates in the hands of such a U.S. Holder, and any dividends paid on the ADSs that are not eligible for these preferential rates will be taxed as ordinary income to U.S. Holders. Dividends received by corporate shareholders do not qualify for the preferential tax rate discussed above; moreover, dividends from a non-U.S. corporation generally will not qualify for the dividends received deduction generally available to U.S. corporate shareholders.

Distributions paid on our ADSs generally will be foreign-source passive income for U.S. foreign tax credit purposes.

#### ***Taxation of the Sale or Exchange of ADSs***

Unless a non-recognition rule applies, on a sale, exchange or other disposition of ADSs, a U.S. Holder generally will recognize gain or loss in an amount equal to the difference between the U.S. Dollar amount realized on such sale or exchange and the U.S. Holder’s adjusted tax basis in such ADSs determined in U.S. Dollars. The initial tax basis of ADSs to a U.S. Holder will be the U.S. Holder’s U.S. Dollar cost for ADSs.

Subject to the application of the PFIC rules discussed below, such gain or loss generally will be capital gain or loss and will be long-term capital gain or loss if the U.S. Holder’s holding period of the ADSs exceeds one year at the time of the disposition. Individual U.S. Holders are generally subject to a maximum tax rate of 20% on long-term capital gain. Corporate U.S. Holders do not have a preferential rate on capital gains and their capital gain income generally is subject to U.S. federal income tax at the same rate as ordinary income. The deductibility of capital losses is subject to limitations. Gain or loss recognized by a U.S. Holder on a sale or exchange of ADSs generally will be treated as U.S.-source income or loss for U.S. foreign tax credit purposes.

#### ***Taxation on Exercise, Sale or Lapse of Warrants***

There are no tax consequences to U.S. Holders on the exercise of the Warrants. A U.S. Holder’s tax basis in the ADSs acquired through the exercise of the Warrants is the exercise price plus the cost of the warrants (\$.01 per Warrant). A U.S. Holder’s holding period in shares acquired through an exercise of the warrants commences on the date of exercise. The ADSs so acquired are then treated in the same manner as the U.S. Holder’s other ADSs, discussed above (and are also subject to the PFIC rules discussed below).

If a U.S. Holder sells the Warrants, he will recognize gain to the extent that the proceeds of the sale exceed his tax basis in the Warrants. For individual U.S. Holders this gain will be long term capital gain if the Warrants have been held for more than a year at the time of sale, and short-term capital gain if held for a year or less.

No gain is recognized by a U.S. Holder on the expiration of the Warrants. A U.S. Holder would have a capital loss on the expiration of the Warrants equal to his tax basis in the Warrants.

#### ***Foreign Tax Credit Considerations***

We expect that we will be required to withhold non-U.S. taxes upon payment to a U.S. Holder of a dividend. If any such withholding were required, a U.S. Holder will have the option of claiming the amount of any non-U.S. income taxes withheld on a dividend distribution either as a deduction from gross income or as a dollar-for-dollar credit against its U.S. federal income tax liability. The amount of foreign income taxes that may be claimed as a credit in any year is subject to complex limitations, which must be determined on an individual basis by each U.S. Holder.

### *Passive Foreign Investment Company Status*

There may be adverse tax consequences to U.S. Holders if we are determined to be a PFIC. We will be a PFIC if

(i) 75% or more of our gross income in any taxable year is passive income. Passive income includes interest, dividends, certain royalties, certain rents and annuities, and amounts derived by the investment of funds raised in our initial public offering of ADSs and other offerings. Passive income also includes our pro rata share of the gross income of any company (U.S. or foreign) that is treated as a corporation for U.S. federal income tax purposes and of which we are considered to own, directly or indirectly, 25% or more of the shares by value (a "25% subsidiary"), or

(ii) the average value of our assets that are held for the production of, or produce, passive income is 50% or more of the average value of our total assets during the taxable year. In making this determination, according to the IRS, "the average value of [our] assets for the taxable year [is] the average of the fair market values of [our] assets determined as of the end of each quarterly period during [our] taxable year." For purposes of determining whether we are a PFIC our assets include our pro rata share of the assets of any 25% subsidiary.

The determination of whether we are a PFIC is thus made annually and is based upon the composition of our income and assets and the nature of our activities. Further, each of our subsidiaries is separately tested to determine if it is a PFIC and, if we are a PFIC, any of our subsidiaries could also be a PFIC with respect to a U.S. Holder.

Based on the Code, Treasury Regulations promulgated under the Code and IRS guidance, there can be no assurance that we are not a PFIC now and, if not a PFIC now, that we will not become a PFIC in the future. If we are a PFIC, and a U.S. Holder does not make an election to treat us as a "qualified electing fund" (a "QEF") or does not make a "mark-to-market election" (as described below) the following consequences would arise:

- Excess distributions by us to such a U.S. Holder would be taxed in a special way. "Excess distributions" are amounts received by a U.S. Holder with respect to the ADSs in any taxable year that exceed 125% of the average distributions received by such U.S. Holder from us in the shorter of either the three previous years or such U.S. Holder's holding period for ADSs before the current taxable year. Excess distributions must be allocated ratably to each day that a U.S. Holder has held the ADSs. A U.S. Holder must include amounts allocated to the current taxable year and amounts allocated to certain years prior to us being a PFIC in its gross income as ordinary income for that year. A U.S. Holder must pay tax on amounts allocated to each prior taxable year when we were a PFIC at the highest rate in effect for that year on ordinary income and the tax is subject to an interest charge at the rate applicable to deficiencies for income tax.
- A disposition of shares in, or a distribution by, one of our subsidiaries that is a PFIC will trigger the excess distributions rules described above.
- The entire amount of gain that is realized by a U.S. Holder upon the sale or other disposition of ADSs will also be considered an excess distribution and will be subject to tax as described above.
- A U.S. Holder's tax basis in shares of the ADSs that were acquired from a decedent would not receive a step-up to fair market value as of the date of the decedent's death but would instead be equal to the decedent's basis, if lower.

In addition, if we are a PFIC, the lower rate of taxation applicable to qualified dividend income derived by certain non-corporate U.S. Holders, as discussed above, would not apply to dividends paid with respect to our ADSs.

If a U.S. Holder of PFIC shares makes a timely QEF election with respect to its PFIC shares, then in lieu of the consequences described above, the U.S. Holder would be required to include in income each year its pro-rata share of the PFIC's net capital gain and ordinary income. If we are a PFIC, we would need to make available the information necessary in order for a U.S. Holder to make this election, but, assuming that we were characterized as a PFIC, we have not made a decision as to whether or not we would make this information available. Therefore, U.S. Holders should not assume that they would be able to make a QEF election with respect to the ADSs.

Alternatively, a U.S. Holder that holds “marketable stock” in a PFIC may avoid the imposition of the additional tax and interest described above by making a mark-to-market election in the first year of its holding period for its PFIC shares. We believe that the ADSs will be “marketable stock” for purposes of the mark-to-market election. Generally, stock will be considered “marketable stock” if it is “regularly traded” on a “qualified exchange” within the meaning of the applicable Treasury regulations. A class of stock is regularly traded during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. However, there can be no certainty that the ADSs will continue to be sufficiently traded such as to be treated as “regularly traded”. If a U.S. Holder were to make a timely mark-to-market election with respect to ADSs that it will own at the close of its taxable year, such electing U.S. Holder would for the year of the election and each subsequent taxable year include as ordinary income or, to the extent of prior ordinary income, ordinary loss based on the increase or decrease in the market value of such U.S. Holder’s ADSs for such taxable year. An electing U.S. Holder’s tax basis in its ADSs will be adjusted to reflect any such income or loss. Any gain or loss on the sale of ADSs will be ordinary income or loss, except that any loss will be ordinary loss only to the extent of the previously included net mark-to-market gain. An election to mark-to-market applies to the year for which the election is made and to subsequent years unless the IRS consents to the revocation of the election. The election is terminated for any year in which the PFIC shares are not “marketable stock”. If we were a PFIC and then were to cease being a PFIC, a U.S. Holder that marked its ADSs to market would not include mark-to-market gain or loss with respect to its ADSs for any taxable year that we were no longer a PFIC. If we again were to become a PFIC in a taxable year after a year in which we were not a PFIC, a U.S. Holder’s original mark-to-market election, unless revoked or terminated, would continue to apply and such U.S. Holder would be required to include any mark-to-market gain or loss in such year.

A mark-to-market election applies only to the non-U.S. corporation for which it is made. If any of our subsidiaries were to be a PFIC, a U.S. Holder likely would remain subject to the excess distribution rules with respect to its indirectly owned shares in any such subsidiary even if such U.S. Holder has made a mark-to-market election in our respect.

If we are a PFIC for any year during which a U.S. Holder holds ADSs we will generally continue to be treated as a PFIC with respect to the U.S. Holder for all succeeding years during which the U.S. Holder holds ADSs, even if we cease to meet the threshold requirements for PFIC status. As noted above, if a U.S. Holder was permitted to make a mark-to-market election and did so in a timely manner, we will not be treated as a PFIC with respect to such U.S. Holder for any year in which we do not meet the threshold requirements for PFIC status. The same rule appears to apply in the case of a U.S. Holder who was permitted to, and timely made, a QEF election, although the issue is not entirely free from doubt.

A U.S. Holder that owns any shares of a foreign corporation classified as a PFIC is generally required to file Form 8621 (Return by a Shareholder of a Passive Foreign Investment Company or a Qualified Electing Fund) in each year that such shares are held.

U.S. Holders are urged to consult their tax advisors about the PFIC rules and the related filing requirements. Our U.S. counsel expresses no opinion with respect to our PFIC status in any prior taxable year or the current taxable year which ends April 30, 2017, and also expresses no opinion with respect to any predictions regarding our PFIC status in the future.

#### ***Certain Reporting Obligations***

Section 6038D of the IRC generally requires U.S. individuals (and possibly certain entities that have U.S. individual owners) to file IRS Form 8938 if they hold certain “specified foreign financial assets,” the aggregate value of which exceeds \$50,000 on the last day of the taxable year (or the aggregate value of which exceeds \$75,000 at any time during the taxable year). (Higher reporting thresholds apply to married taxpayers filing joint returns and to taxpayers living outside the U.S.) The definition of specified foreign financial assets includes not only financial accounts maintained in foreign financial institutions, but also, unless held in accounts maintained by a financial institution, any stock or security issued by a non-U.S. person including the ADSs. In general, if we were to be treated as a PFIC, a U.S. Holder would not be required to report ownership of the ADSs under Section 6038D of the IRC if such ownership were reported on Form 8621 described above under “Passive Foreign Investment Company Status” and that fact is noted on the Form 8938. U.S. Holders should consult their own tax advisors to determine whether they are subject to any Form 8938 filing requirements.

***Foreign Account Tax Compliance Act***

Under certain circumstances, we or our paying agent may be required, pursuant to Sections 1471 through 1474 of the Code and the regulations promulgated thereunder, any agreement entered into pursuant to Section 1472(b) of the Code, or any U.S. or non-U.S. fiscal or regulatory legislation, rules, guidance notes or practices adopted pursuant to any intergovernmental agreement entered into in connection with the implementation of such sections of the Code or analogous provisions of non-U.S. law ("FATCA"), to withhold U.S. tax at a rate of 30% on all or a portion of payments of dividends or other corporate distributions which are treated as "foreign pass-thru payments" made on or after January 1, 2017, if such payments are not in compliance with FATCA. Such payments can generally be made in compliance with FATCA if the paying agent obtains from the payee a Form W-9 or other information establishing an exemption from such withholding. The rules regarding FATCA and "foreign pass-thru payments," including the treatment of proceeds from the disposition of ADSs, are very complex and U.S. Holders are encouraged to consult their own tax advisors on the impact of the FATCA rules on them.

***Medicare Tax on Net Investment Income***

Effective for taxable years beginning after December 31, 2012, a 3.8% tax is generally imposed on the net investment income in excess of certain thresholds of certain individuals and on the undistributed net investment income of certain estates and trusts. For these purposes, "net investment income" will generally include interest, dividends (including dividends, if any, paid with respect to the ADSs), annuities, royalties, rent, net gain attributable to the disposition of property not held in a trade or business (including net gain from the sale, exchange or other taxable disposition of ADSs) and certain other income, but will be reduced by any deductions properly allocable to such income or net gain. U.S. Holders are advised to consult their own tax advisors regarding additional taxation of net investment income.

***U.S. Information Reporting and Backup Withholding***

A U.S. Holder is generally subject to information reporting requirements with respect to dividends paid in the United States on ADSs and proceeds paid from the sale, exchange, redemption or other disposition of ADSs. A U.S. Holder is subject to backup withholding (currently at 28%) on dividends paid in the United States on ADSs and proceeds paid from the sale, exchange, redemption or other disposition of our ADSs unless the U.S. Holder is a corporation, provides an IRS Form W-9 to the payor or the paying agent, or otherwise establishes a basis for exemption.

Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be credited against a U.S. Holder's U.S. federal income tax liability, and a U.S. Holder may obtain a refund from the IRS of any excess amount withheld under the backup withholding rules, provided that certain information is timely furnished to the IRS. U.S. Holders are urged to consult their own tax advisors regarding the application of backup withholding and the availability of and procedures for obtaining an exemption from backup withholding in their particular circumstances.

The foregoing discussion of certain material U.S. federal income tax considerations is for general information only and is not tax advice. Accordingly, each U.S. Holder should consult with his, her or its own tax advisor regarding U.S. federal, state, local and non-U.S. income and other tax consequences of the acquisition, holding and disposing of the ADSs.

**F. Dividends and Paying Agents**

Not applicable.

**G. Statement by Experts**

Not applicable.

**H. Documents on Display**

We are subject to the informational requirements of the Exchange Act. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K in limited circumstances; however, we may elect to make additional information available on Form 6-K.

We are not required to disclose certain other information that is required from U.S. domestic issuers, including but not limited to detailed executive compensation disclosure and quarterly disclosure as to our assessment of our internal control over financial reporting. Also, as a foreign private issuer, we are exempt from the rules of the Securities Exchange Act of 1934 prescribing the furnishing of proxy statements to shareholders and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Securities Exchange Act of 1934.

As a foreign private issuer, we are also exempt from the requirements of Regulation FD (Fair Disclosure) that, generally, are meant to ensure that select groups of investors are not privy to specific information about an issuer before other investors. We are, however, still subject to the anti-fraud and anti-manipulation rules of the SEC, such as Rule 10b-5. Since many of the disclosure obligations required of us as a foreign private issuer are different than those required by other U.S. domestic reporting companies, our shareholders, potential shareholders and the investing public in general should not expect to receive information about us in the same amount and at the same time as information is received from, or provided by, U.S. domestic reporting companies. We are liable for violations of the rules and regulations of the SEC, which do apply to us as a foreign private issuer.

You may inspect and copy reports and other information filed with the SEC at the Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330 FREE. In addition, the SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

#### **I. Subsidiary Information**

See "ITEM 4. INFORMATION ON THE COMPANY - C. Organizational Structure" and "Exhibit F-8; Notes to the Consolidated Financial Statements - NOTE 26 HOLDINGS IN GROUP COMPANIES"

#### **ITEM 11 QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

##### **A. Quantitative and Qualitative Disclosures about Credit, Market and Other Risk**

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position, results of operations or cash flows due to adverse changes in financial market prices and rates, including interest rates, foreign exchange rates and market prices, of financial instruments. Our market risk exposure is a result of interest rates, foreign currency exchange rates and market prices.

##### ***Interest Rate Risk***

Oasmia has on April 30, 2016 SEK 139.9 million as interest-bearing loans, consisting of a loan from its second largest shareholder (Nexttobe AB) of SEK 94.4 million, a bank loan of SEK 20.0 million and a convertible loan of SEK 25.5 million.

The bank loan matures on September 30, 2016, and carries an interest rate which is tied to Stockholm Interbank Offered Rate (Stibor) and is thus directly exposed to the risk that the market interest rates would increase.

The shareholder loan has a fixed interest rate until it matures on December 30, 2016. The convertible loan falls due on April 14, 2017, and the interest rate until then is fixed. Both these loans are thus independent from the short term development of the market interest rates, but there is a risk that these loans at maturity will be prolonged or replaced by other loans to less favorable terms.

##### ***Foreign Currency Exchange Risk***

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the SEK, our functional and reporting currency, mainly against the Euro but also against USD and other currencies. Although the SEK is our functional currency, a certain portion of our expenses are denominated in Euro. Our Euro expenses consist principally of payments made to sub-contractors and consultants for clinical trials and other research and development activities as well as payments made to purchase raw material and to subcontractors for producing our products. Our sales revenue is to the largest part denominated in EUR.

If the SEK fluctuates significantly against the Euro, it may have a negative impact on our results of operations. To date, fluctuations in the exchange rates have not materially affected our results of operations or financial condition for the periods under review.

We have not entered into any currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange.

#### **Market Price Risk**

Oasmia has invested in fixed income funds, on April 30, 2016, having a fair value of SEK 20.0 million. These funds are traded in an active financial market and can be realized in one to two banking days. An official market price is made public each trading day, and this constitutes the funds' fair value.

Fluctuations in the market price of the funds might negatively affect our income statement. However, as these funds invest in short-term securities from safe issuers, it is assessed that the market price risk is low.

#### **Item 11 D. Safe Harbor**

Not applicable

### **ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

#### **A. Debt Securities**

Not applicable

#### **B. Warrants and Rights**

See Item 12 D

#### **C. Other Securities**

Not applicable.

#### **D. American Depositary Shares**

##### **ADSs**

The Bank of New York Mellon, as depositary, has registered and delivered American Depositary Shares, also referred to as ADSs. Each ADS represents three (3) Ordinary Shares (or a right to receive three (3) Ordinary Shares) deposited with the principal Stockholm office of Skandinaviska Enskilda Banken AB, acting as custodian for the depositary (but see "Related Party Transactions — Stock Lending Agreement" for the mechanics of closing and the timing of share issuances). Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The depositary's office at which the ADSs will be administered is located at 101 Barclay Street, New York, New York 10286. The Bank of New York Mellon's principal executive office is located at One Wall Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC. If you hold ADSs directly, you are a registered ADS holder, also referred to as an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Swedish law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR. Directions on how to obtain copies of those documents are provided under the heading "Where You Can Find Additional Information" on page 148 .

#### Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on Ordinary Shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

#### Cash.

The depositary will convert any cash dividend or other cash distribution we pay on the Ordinary Shares into U.S. Dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. The depositary will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. See the heading "Taxation" appearing on page 98. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.

#### Shares.

The depositary may distribute additional ADSs representing any Ordinary Shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new Ordinary Shares. The depositary may sell a portion of the distributed Ordinary Shares (or ADSs representing those Ordinary Shares) sufficient to pay its fees and expenses in connection with that distribution.

#### Rights to purchase additional shares.

If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. In that case, you will receive no value for them. The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.



**Other Distributions.**

The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register Ordinary Shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.

**Deposit, Withdrawal and Cancellation**

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive Ordinary Shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs for the purpose of withdrawal at the depositary's office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the Ordinary Shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Alternatively, upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

## Voting Rights

How do you vote?

ADS holders may instruct the depositary how to vote the number of deposited Ordinary Shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of Sweden and the provisions of our articles of association or similar documents, to vote or to have its agents vote the Ordinary Shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

Except by instructing the depositary as described above, you won't be able to exercise voting rights unless you surrender your ADSs and withdraw the Ordinary Shares. However, you may not know about the meeting enough in advance to withdraw the Ordinary Shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your Ordinary Shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise voting rights and there may be nothing you can do if your Ordinary Shares are not voted as you requested.

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to Deposited Securities, if we request the Depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least [45] days in advance of the meeting date.

Pursuant to the terms of the deposit agreement, the holders of ADSs will be required to pay the following fees:

- a fee of \$5.00 or less per 100 American Depositary Shares (or portion thereof) for the delivery or cancellation of ADS.
- a fee of \$.05 or less per American Depositary Share (or portion thereof) for any cash distribution to you
- a fee of \$.05 or less per ADS per annum for depositary services
- Registration or transfer fees
- Expenses of the depositary (costs for converting foreign currency to U.S. dollars and cost for cable, telex and facsimile transmissions)
- Taxes and other governmental charges the depositary or the custodian have to pay on any ADS or share underlying an ADS, for example share transfer, taxes, stamp duty or withholding taxes.

The Depositary may collect any of its fees by deduction from any cash distribution payable, or by selling a portion of any securities to be distributed, to owners that are obligated to pay those fees.

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers or other service providers that are affiliates of the depositary and that may earn or share fees or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as an agent, fiduciary or broker on behalf of any other person and earns revenue, including, without limitation, fees and spreads that it will retain for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion will be the most favorable rate that could be obtained at the time or as to the method by which that rate will be determined, subject to its obligations under the deposit agreement.

**Payment of Taxes**

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your American Depositary Shares to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

**Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities**

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

## Amendment and Termination

### *How may the deposit agreement be amended?*

We may agree with the depository to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depository for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depository notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.*

### *How may the deposit agreement be terminated?*

The depository will initiate termination of the deposit agreement if we instruct it to do so. The depository may initiate termination of the deposit agreement if

- 60 days have passed since the depository told us it wants to resign but a successor depository has not been appointed and accepted its appointment;
- we delist our Ordinary Shares from an exchange on which they were listed and do not list the shares on another exchange;
- we appear to be insolvent or enter insolvency proceedings;
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement is terminated, the depository will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depository may sell the deposited securities. After that, the depository will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depository will sell as soon as practicable after the termination date.

After the termination date and before the depository sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depository may refuse to accept a surrender for the purpose of withdrawing deposited securities if it would interfere with the selling process. The depository may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depository will continue to collect distributions on deposited securities, but, after the termination date, the depository is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

## Limitations on Obligations and Liability

### *Limits on our Obligations and the Obligations of the Depository; Limits on Liability to Holders of ADSs*

The deposit agreement expressly limits our obligations and the obligations of the depository. It also limits our liability and the liability of the depository. We and the depository:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith;
- are not liable if we are or it is prevented or delayed by law or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;

- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person.

In the deposit agreement, we and the depository agree to indemnify each other under certain circumstances.

#### **Requirements for Depository Actions**

Before the depository will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of Ordinary Shares, the depository may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depository may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depository or our transfer books are closed or at any time if the depository or we think it advisable to do so.

#### **Your Right to Receive the Shares Underlying your ADSs**

ADS holders have the right to cancel their ADSs and withdraw the underlying Ordinary Shares at any time except:

- when temporary delays arise because: (i) the depository has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

### **Pre-release of ADSs**

The deposit agreement permits the depository to deliver ADSs before deposit of the underlying Ordinary Shares. This is called a pre-release of the ADSs. The depository may also deliver Ordinary Shares upon cancellation of pre-released ADSs (even if the ADSs are canceled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying Ordinary Shares are delivered to the depository. The depository may receive ADSs instead of shares to close out a pre-release. The depository may pre-release ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made represents to the depository in writing that it or its customer owns the shares or ADSs to be deposited; (2) the pre-release is fully collateralized with cash or other collateral that the depository considers appropriate; and (3) the depository must be able to close out the pre-release on not more than five business days' notice. In addition, the depository will limit the number of ADSs that may be outstanding at any time as a result of pre-release, although the depository may disregard the limit from time to time if it thinks it is appropriate to do so.

### **Direct Registration System**

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depository to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depository of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depository will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depository's reliance on and compliance with instructions received by the depository through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depository.

### **Shareholder communications; inspection of register of holders of ADSs**

The depository will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depository will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

### **Warrants**

The following summary of certain terms and provisions of the Warrants is not complete and is subject to, and qualified in its entirety by the provisions of the form of the ADS Warrant Agreement, also referred to as the Warrant Agreement, under which the Warrants are issued and which governs the terms and conditions of the Warrants and which is incorporated by reference herein.

### **Exercisability**

For every two initial ADSs sold, we issued one Warrant to purchase one ADS. The ADS and Warrants were separately issued. The Warrants are exercisable at any time up to the date that is ten (10) years from the closing date of the offering. The Warrants are exercisable, at the option of each holder, by delivering to the Warrant Agent a duly executed exercise notice together with the Warrants to be exercised and payment in full of the exercise price for the number of ADS purchased upon such exercise, together with the ADS issuance fee of \$0.05 per ADS and other applicable charges and taxes. Unless otherwise provided in the Warrant Agreement, the holder will not have the right to exercise Warrants to the extent that the holder (together with its affiliates), after giving effect to the exercise, would beneficially own in excess of 4.99% of the outstanding ordinary shares outstanding, after giving effect to the exercise, as such percentage ownership is determined in accordance with the Warrant Agreement. Currently there are 1,280,750 Warrants outstanding.

**Exercise Price**

The exercise price per ADS is \$4.06 per ADSs. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the ordinary shares or the ADSs and also upon any distributions of assets, including cash, stock or other property to the holders of ordinary shares.

**Rights as a Stockholder**

Except as otherwise provided in the Warrant Agreement, a holder of Warrants, as such, does not have the rights or privileges of a holder of the ADSs, including any voting rights, until the holder exercises those Warrants and ADSs underlying the Warrants are issued.

**PART II****ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES****A. Defaults**

Not applicable.

**B. Arrears and Delinquencies**

Not applicable.

**ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS****A. Material Modifications to the Rights of Security Holders**

Not applicable.

**E. Use of Proceeds**

The following use of proceeds information relates to our initial public offering, at \$ 4.06 per ADS, of 2,561,500 ADS representing 7,684,500 ordinary shares and 1,280,750 warrants, at \$0.0025 per warrant, to buy ADS's representing 3,842,250 ordinary shares, which included the partial exercise of the underwriters' option to purchase additional ADS's and Warrants. The aggregate offering price and the amount that we registered in connection with our initial public offering was \$10,482,892, before underwriting discounts and commissions and offering expenses payable by us. The registration statement on Form F-1, file no. 333-205515, for our initial public offering was filed on July 6, 2015 and subsequently amended, and declared effective by the SEC on October 22, 2015. Following the sale of the ADSs in connection with the closing of our initial public offering, the offering terminated. Rodman & Renshaw, a unit of H.C. Wainwright & Co. and Joseph Gunnar & Co. acted as joint book-running managers for the offering.

We received proceeds of \$ 8,835,442 from our initial public offering, net of \$ 1,567,450 of underwriting discounts and offering expenses paid by us. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. To date, we have used all of the net proceeds of the offering, primarily to fund our research and product development activities, but also to fund production development, including validation batches as well as general and administrative costs. We used the net proceeds we received from our initial public offering as disclosed in our registration statement on Form F-1.

We will receive none of the proceeds from the sale of the ADSs by the holders of Warrants who choose to exercise them. However, we will receive up to \$5,199,717 in the aggregate from such holders if they exercise in full, on a cash basis, the Warrants to purchase 1,280,750 ADSs issued to the purchasers of ADSs in the initial public offering. We would expect that proceeds of any such exercise of Warrants would be used for working capital.

## **ITEM 15. CONTROLS AND PROCEDURES**

### **A. Disclosure Controls and Procedures**

We maintain a set of disclosure controls and other procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act are recorded, processed, summarized and reported, within the time periods specified and in accordance with the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act are accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of April 30, 2016.

It should be noted that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment and makes assumptions about the likelihood of future events. There can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. Based on the evaluation of our disclosure controls and procedures as of April 30, 2016, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level in timely alerting them to material information required to be included in our periodic SEC reports.

### **B. Management's Annual Report on Internal Control over Financial Reporting**

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

### **C. Attestation Report of the Registered Public Accounting Firm**

This Annual Report does not include an attestation report of our registered public accounting firm due to the transition period established by rules of the SEC for newly public companies and the JOBS Act that provides an exemption for emerging growth companies.

### **D. Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the financial year ended April 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting



In connection with the audit of our financial statements as of and for the fiscal year ended April 30, 2015, 2014 our independent registered public accounting firm reported to our audit committee that it had identified a material weakness in our internal control over financial reporting related to inadequate financial statement preparation and review procedures. During the year ended April 30, 2016, we have performed remedial activities described below to address the material weakness identified by our independent registered public accounting firm. As there has not yet been a sufficient time period to perform testing of the operating effectiveness of internal controls that has been implemented it cannot be concluded that the material weakness previously identified has been fully remediated. Under standards established by the Public Company Accounting Oversight Board (United States), a material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. Specifically, our independent registered public accounting firm determined that we did not have adequate procedures and controls to ensure that accurate financial statements could be prepared and reviewed on a timely basis, including:

- sufficient resources and processes in place, including controls in the finance and accounting department, to adequately perform a timely financial statement close process resulting in errors in period-end accruals related to capitalized research and development expenses.
- adequate internal review processes in place over critical accounting areas including timely operation whereby management identifies and resolves significant or complex accounting matters.

As a result of this material weakness, during the financial year 2015/2016 we have implemented the following changes:

- continued to improve necessary procedures to capture all expenses for capitalized research and development expenses;
- further enhanced the internal review processes of critical and significant accounting areas by involving the management group deeper in such judgments and estimates;
- strengthened the finance department by recruitments and organizational change and by hiring additional personnel;
- improved know how of IFRS standards, as adopted by the IASB, through additional education in IFRS standards and also specific SEC reporting in the U.S.;
- Continued to implement and improve formalized written policies and procedures for the timely accrual of capitalized research and development expenses;
- enhanced oversight procedures in an effort to ensure that the accrual process has been performed prior to finalization of the financial statements at each reporting period; and
- formalized accounting evaluation of non-routine judgments and estimations.

We concurred with the findings in the previous fiscal year from our independent registered public accounting firm. We have been working to remediate the material weakness. The actions that we took were subject to ongoing senior management review and audit committee oversight; however, as there has not yet been a sufficient time period to perform testing of the as operating effectiveness of internal controls that has been implemented it cannot be concluded that the material weakness previously identified has been fully remediated. We will continue to strengthen our processes, however our initiatives may not prove to be successful to avoid any material weakness in the future.

We will be required to disclose changes made in our internal control over financial reporting and procedures on a semi-annual basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We could be an “emerging growth company” for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management’s assessment might not. Additional undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur additional expenses of remediation, and adversely affect our reputation, financial condition and operating results

**ITEM 16 A. AUDIT COMMITTEE FINANCIAL EXPERT**

Our board of directors has determined that Mr. Bergkvist is an audit committee financial expert, as that term is defined by the SEC, and is independent in accordance with NASDAQ rules.

**ITEM 16 B. CODE OF ETHICS**

We have adopted a Code of Business Conduct and Ethics, which applies to all of our board members and employees, including our principal executive, principal financial and principal accounting officers. Our Code of Business Conduct and Ethics is intended to meet the definition of "code of ethics" under Item 16B of Form 20-F under the Exchange Act.

Our Code of Business Conduct and Ethics is available on our website at [www.oasmia.com](http://www.oasmia.com). The information contained on our website is not incorporated by reference in this Annual Report.

Any amendments or waivers from the provisions of our Code of Business Conduct and Ethics will be made only after approval by our audit committee and will be disclosed on our website promptly following the date of such amendment or waiver.

**ITEM 16 C. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Our auditors, Ernst & Young AB, have performed the following services for the Company during the past two years:

	May 1, 2015 – Apr 30, 2016 (TSEK)	May 1, 2014 – Apr 30, 2015 (TSEK)
Auditing	1,390	1,405
Auditing related fees	2,459	1,363
Tax consulting	32	35
All Other fees	131	112
<b>TOTAL</b>	<b>4,012</b>	<b>2,915</b>

All services provided to the Company by Ernst & Young AB are reviewed and approved by our audit committee in advance of commencement of services.

**ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES**

Not applicable.

**ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

In the financial year ending April 30, 2016, no purchases of our equity securities were made by or on behalf of the Company or any affiliated purchaser.

**ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT**

Not applicable

**ITEM 16G. CORPORATE GOVERNANCE**

#### ***Number of Directors***

Under the Swedish Companies Act, a public company shall have a board of directors consisting of at least three board members. More than half of the directors shall be resident within the European Economic Area (unless otherwise approved by the Swedish Companies Registration Office). The actual number of board members shall be determined by a shareholders' meeting, within the limits set out in the company's articles of association. Under the Swedish Code, only one director may also be a senior executive of the relevant company or a subsidiary. The Swedish Code includes certain independence requirements for the directors, and requires the majority of directors be independent of the company and at least two directors also be independent of major shareholders.

#### ***Removal of Directors***

Under the Swedish Companies Act, directors appointed at a general meeting may be removed by a resolution adopted at a general meeting, upon the affirmative vote of a simple majority of the votes cast.

#### ***Vacancies on the Board of Directors***

Under the Swedish Companies Act, if a board member's tenure should terminate prematurely, the other members of the board of directors shall take measures to appoint a new director for the remainder of the term, unless the outgoing board member was an employee representative. If the outgoing board member was elected by the shareholders, then the election of a new board member may be deferred until the time of the next annual general meeting, providing there are enough remaining board members to constitute a quorum.

#### ***Annual General Meeting***

Under the Swedish Companies Act, within six months of the end of each fiscal year, the shareholders shall hold an ordinary general meeting (annual general meeting) at which the board of directors shall present the annual report and auditor's report and, for a parent company which is obliged to prepare group accounts, the group accounts and the auditor's report for the group. Shareholder meetings shall be held in the city where the board of directors holds its office. The minutes of a shareholders' meeting must be available on the company's website no later than two weeks after the meeting.

#### ***Special Meeting***

Under the Swedish Code, a board of directors may call an extraordinary general meeting if a shareholder minority representing at least ten per cent of the company's shares so requests, and under both the Swedish Code and the Swedish Companies Act, the board of directors may convene an extraordinary general meetings whenever it believes reason exists to hold a general meeting prior to the next ordinary general meeting. The board of directors shall also convene an extraordinary general meeting when an auditor of the company or owners of not less than one-tenth of all shares in the company demand in writing that such a meeting be convened to address a specified matter.

#### ***Notices***

Under the Swedish Companies Act, a general meeting of shareholders must be preceded by a notice. The notice of the annual general meeting of shareholders must be issued no sooner than six weeks and no later than four weeks before the date of an annual general meeting. In general, notice of other extraordinary general meetings must be issued no sooner than six weeks and no later than three weeks before the meeting. Public limited companies must always notify shareholders of a general meeting by advertisement in the Swedish Official Gazette and on the company's website.

#### ***Preemptive rights***

Under the Swedish Companies Act, shareholders of any class of shares have a preemptive right to subscribe for shares issued of any class in proportion to their shareholdings. The preemptive right to subscribe does not apply in respect of shares issued for consideration other than cash or of shares issued pursuant to convertible debentures or warrants previously granted by the company. The preemptive right to subscribe for new shares may also be set aside by a resolution passed by two thirds of the votes cast and shares represented at the shareholders' meeting resolving upon the issue.

### Shareholder Vote on Certain Transactions

In matters which do not relate to elections and are not otherwise governed by the Swedish Companies Act or the Articles of Association, resolutions shall be adopted at the general meeting by a simple majority of the votes cast. In the event of a tied vote, the chairman shall have the casting vote. For matters concerning securities of the company, such as new share issuances, and other transactions such as private placements, mergers, and a change from a public to a private company (or vice-versa), the articles of association may only prescribe thresholds which are more greater than those provided in the Swedish Companies Act.

Unless otherwise prescribed in the articles of association, the person who receives the most votes in an election shall be deemed elected. In general, a resolution involving the alteration of the articles of association shall be valid only when supported by shareholders holding not less than two-thirds of both the votes cast and the shares represented at the general meeting. The Swedish Companies Act lays out numerous exceptions for which a higher threshold applies, including restrictions on certain rights of shareholders, limits on the number of shares shareholders may vote at the general meeting, and changes in the legal relationship between shares.

#### ITEM 16 H. MINE SAFETY DISCLOSURE

Not applicable.

#### ITEM 17. FINANCIAL STATEMENTS

We have responded to Item 18 in lieu of this item.

#### ITEM 18. FINANCIAL STATEMENTS

The Financial Statements filed as part of this Annual Report begin on page F-1.

#### Exhibit index

Exhibit Number	Description of Exhibit
1.1	Articles of Association of Oasmia Pharmaceutical AB; incorporated by reference to exhibit 3.1 to the Registration Statement on Form F-1 filed with the SEC on July 6, 2015.
2.2	Form of Deposit Agreement between Oasmia Pharmaceutical AB, The Bank of New York Mellon, as Depository Bank, and Owners and Holders from time to time of American Depositary Shares issued thereunder; incorporated by reference to exhibit 4.1 to the Registration Statement on Form F-6 filed with the SEC on July 24, 2015 with respect to ADSs representing ordinary shares prior to the effectiveness of this registration statement.
2.3	Form of American Depositary Receipt (included in Exhibit 2.2).
2.4	Form of ADS Warrant Agent Agreement between Oasmia Pharmaceutical AB and The Bank of New York Mellon; incorporated by reference to exhibit 4.2 to the Registration Statement on Form F-1/A filed with the SEC on October 9, 2015.
2.5	Form of Warrant Certificate (included in Exhibit 2.4).
4.1	Underwriting Agreement between Oasmia Pharmaceutical AB and Ladenburg Thalmann & Co. Inc.; incorporated by reference to exhibit 1.1 to the Registration Statement on Form F-1/A filed with the SEC on October 9, 2015.
4.2	Lease Agreement dated January 1, 2009 (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.1 to the Registration Statement on Form F-1 filed with the SEC on July 6, 2015.
4.3	Lease Agreement dated January 1, 2011 (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.2 to the Registration Statement on Form F-1 filed with the SEC on July 6, 2015.
4.4	Lease Agreement dated January 1, 2009 (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.3 to the Registration Statement on Form F-1 filed with the SEC on July 6, 2015.
4.5	Lease Agreement dated January 1, 2009 (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.4 to the Registration Statement on Form F-1 filed with the SEC on July 6, 2015.

- 4.6 Lease Agreement dated January 1, 2009 (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.5 to the Registration Statement on Form F-1 filed with the SEC on July 6, 2015.
- 4.7 Lease Agreement dated January 1, 2009 (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.6 to the Registration Statement on Form F-1 filed with the SEC on July 6, 2015.
- 4.8 Distribution Agreement dated July 8, 2009, between Oasmia Pharmaceutical AB and Abbott Laboratories; incorporated by reference to exhibit 10.7 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.9 First Amendment to Distribution Agreement dated December 31, 2012, between Oasmia Pharmaceutical AB and Abbott Laboratories; incorporated by reference to exhibit 10.8 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.10 Development, Supply and Exclusive License Agreement dated April 21, 2010, between Oasmia Pharmaceutical AB and Nippon Zenyaku Kogyo Co. Ltd.; incorporated by reference to exhibit 10.9 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.11 Supply and Exclusive License Agreement dated May 9, 2011, between Oasmia Pharmaceutical AB and Medison Pharma, LTD; incorporated by reference to exhibit 10.10 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.12 Non-Exclusive Toll Manufacturing Agreement dated August 6, 2013, between Oasmia Pharmaceutical AB and Syntagon AB; incorporated by reference to exhibit 10.11 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.13 Credit Contract dated October 1, 2012, between Oasmia Pharmaceutical AB and Alceco International S.A. (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.12 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.14 Simple Debt Letter dated December 19, 2014, between Oasmia Pharmaceutical AB and Nexttobe AB (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.13 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.15 Loan Agreement dated December 17, 2014, between Oasmia Pharmaceutical AB and Nordea Bank AB (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.14 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.16 Employment Contract dated September 30, 2014, between Oasmia Pharmaceutical AB and Anders Blom (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.15 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.17 Employment Contract dated May 8, 2014, between Oasmia Pharmaceutical AB and Anders Lundin (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.16 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.18 Employment Contract dated April 1, 2008, together with the addendums thereto dated May 27, 2013 and September 30, 2013, between Oasmia Pharmaceutical AB and Annette Ljungmark (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.17 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.19 Employment Contract dated October 1, 2014, between Oasmia Pharmaceutical AB and Hans Sundin (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.18 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.20 Employment Contract dated April 1, 2008, together with the addendums thereto dated June 5, 2013 and September 30, 2013, between Oasmia Pharmaceutical AB and John Cosby (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.19 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.21 Employment Contract dated January 1, 2001, together with an addendum thereto dated January 1, 2001, between Oasmia Pharmaceutical AB and Julian Aleksov (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.20 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.22 Employment Contract dated November 30, 2008, together with the addendums thereto dated May 27, 2013 and September 30, 2013, between Oasmia Pharmaceutical AB and Margareta Eriksson (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.21 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.23 Employment Contract dated October 4, 2012, together with an addendum thereto dated September 30, 2013, between Oasmia Pharmaceutical AB and Mikael Asp (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.22 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.
- 4.24 Supply and Exclusive Marketing, Sales and Distribution Agreement dated February 1, 2013, between Oasmia Pharmaceutical AB and Joint Stock Company "Pharmasyntez;" incorporated by reference to exhibit 10.23 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015.

- 4.25 Commercial Manufacturing and Supply Agreement dated February 16, 2011, between Baxter Oncology GmbH and Oasmia Pharmaceutical AB; incorporated by reference to exhibit 10.24 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015. Confidential treatment granted for this agreement by the SEC on October 27, 2015. The confidential portions of the Exhibit have been omitted and are marked by an asterisk.
- 4.26 Master Manufacturing Agreement dated April 25, 2014, between Baxter Oncology GmbH and Oasmia Pharmaceutical AB; incorporated by reference to exhibit 10.25 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015. Confidential treatment granted for this agreement by the SEC on October 27, 2015. The confidential portions of the Exhibit have been omitted and are marked by an asterisk.
- 4.27 First Addendum to the Master Manufacturing Agreement dated May 20, 2014, between Baxter Oncology GmbH and Oasmia Pharmaceutical AB; incorporated by reference to exhibit 10.26 to the Registration Statement on Form F-1/A confidentially filed with the SEC on June 12, 2015. Confidential treatment granted for this agreement by the SEC on October 27, 2015. The confidential portions of the Exhibit have been omitted and are marked by an asterisk.
- 4.28 Lease Agreement dated May 1, 2014 (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.27 to the Registration Statement on Form F-1 filed with the SEC on July 6, 2015.
- 4.29 Lease Agreement dated May 1, 2015 (unofficial English translation from Swedish original); incorporated by reference to exhibit 10.28 to the Registration Statement on Form F-1 filed with the SEC on July 6, 2015.
- 4.30 Letter of Termination of Zoetis, Inc. to Oasmia Pharmaceutical AB's CEO dated May 18, 2015; incorporated by reference to exhibit 10.29 to the Registration Statement on Form F-1 filed with the SEC on July 6, 2015.
- 4.31 Form of Stock Lending Agreement, between Alceco International S.A. and Oasmia Pharmaceutical AB; incorporated by reference to exhibit 10.30 to the Registration Statement on Form F-1/A filed with the SEC on September 16, 2015.
- 8.1 Subsidiaries of the Registrant. Filed herewith.
- 9.1 Registrant's Application for Waiver of Requirements of Form 20-F, Item 8.A.4 dated May 29, 2014; incorporated by reference to exhibit 99.1 to the Registration Statement on Form F-1 confidentially filed with the SEC on May 30, 2014.
- 12.1 Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.
- 12.2 Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.
- 13.1 Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.
- 13.2 Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.
- 15.1 Press release dated August 4, 2015; incorporated by reference to exhibit 99.5 to the Registration Statement on Form F-1/A filed with the SEC on August 14, 2015.

**SIGNATURES**

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

OASMIA PHARMACEUTICAL AB

By: /s/ MIKAEL ASP

Name: Mikael Asp

Title: *Chief Executive Officer*

Date: August 26, 2016

**Oasmia Pharmaceutical AB**

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of Oasmia Pharmaceutical AB

We have audited the accompanying consolidated statements of financial position of Oasmia Pharmaceutical AB as of April 30, 2016 and 2015, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended April 30, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Oasmia Pharmaceutical AB at April 30, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended April 30, 2016, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has recurring losses from operations and an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young AB  
Ernst & Young AB

Uppsala  
July 7, 2016

**CONSOLIDATED INCOME STATEMENT**

TSEK	NOTE	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
Net sales	4	6,373	2,070	60
Change in inventories of products in progress and finished goods	7	9,509	-	-
Capitalized development costs	5	16,727	16,797	29,464
Other operating income	6,13	2	221	4,454
Raw materials, consumables and goods for resale	7,13	(4,733)	(10,062)	(6,835)
Other external expenses	8,9,13	(98,104)	(60,740)	(75,189)
Employee benefit expenses	10	(57,661)	(50,530)	(45,101)
Depreciation, amortization and impairment	11,12	(4,804)	(5,190)	(4,941)
Other operating expenses	11	-	(792)	(3)
<b>Operating income</b>	14	<b>(132,691)</b>	<b>(108,225)</b>	<b>(98,091)</b>
Financial income		786	210	192
Financial expenses		(9,634)	(9,482)	(7,213)
<b>Financial income and expenses - net</b>	13,15	<b>(8,848)</b>	<b>(9,272)</b>	<b>(7,021)</b>
<b>Income before taxes</b>		<b>(141,539)</b>	<b>(117,497)</b>	<b>(105,112)</b>
Income taxes	16	-	-	-
<b>Income for the year</b>		<b>(141,539)</b>	<b>(117,497)</b>	<b>(105,112)</b>
Income for the year attributable to:				
Parent Company shareholders		(141,539)	(117,497)	(105,112)
Earnings per share before and after dilution, SEK	17	(1.39)	(1.28)	(1.27)

**CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**

TSEK	NOTE	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
<b>Income for the year</b>		<b>(141,539)</b>	<b>(117,497)</b>	<b>(105,112)</b>
<b>Other comprehensive income</b>				
Items that may subsequently be transferred to the income statement:				
Translation differences		(19)	-	-
<b>Total other comprehensive income</b>		<b>(19)</b>		
<b>Comprehensive income for the year</b>		<b>(141,557)</b>	<b>(117,497)</b>	<b>(105,112)</b>
Comprehensive income for the year attributable to:				
Parent Company shareholders		(141,557)	(117,497)	(105,112)
Comprehensive earnings per share, before and after dilution, SEK		(1.39)	(1.28)	(1.27)

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

TSEK	Note	APR 30, 2016	APR 30, 2015
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	11	21,172	22,852
Capitalized development costs	5	409,900	393,173
Other intangible assets	12	11,936	11,852
Financial non-current assets		2	2
<b>Total non-current assets</b>		<b>443,010</b>	<b>427,879</b>
<b>Current assets</b>			
Inventories	7	16,638	5,341
Accounts receivable - trade	18	4,903	105
Other current receivables	18,20	1,929	2,566
Prepaid expenses and accrued income	18,19	2,885	1,687
Short-term investments	18,24	20,006	50,153
Cash and cash equivalents	18	26,208	26,837
<b>Total current assets</b>		<b>72,570</b>	<b>86,690</b>
<b>TOTAL ASSETS</b>		<b>515,579</b>	<b>514,569</b>
<b>EQUITY</b>			
<b>Equity and reserves attributable to Parent Company shareholders</b>			
Share capital	21	10,721	9,786
Other capital provided		941,961	850,996
Reserves		(19)	-
Retained earnings, including income for the year		(626,610)	(485,071)
<b>Total equity</b>		<b>326,053</b>	<b>375,710</b>
<b>Current liabilities</b>			
Liabilities to credit institutions	18,24	20,000	20,000
Convertible loan	17,18	25,549	-
Other borrowings	18,25	94,395	87,000
Accounts payable	18	27,236	14,017
Other current liabilities	22	2,068	1,796
Accrued expenses and deferred income	18,23	20,278	16,045
<b>Total current liabilities</b>		<b>189,527</b>	<b>138,858</b>
<b>Total liabilities</b>		<b>189,527</b>	<b>138,858</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>515,579</b>	<b>514,569</b>

Any contingent liabilities and pledged assets are reported in note 24.

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

TSEK	Note	Attributable to Parent Company shareholders				Total equity
		Share capital	Other capital provided	Reserves*	Retained earnings	
<b>Opening balance as of May 1, 2013</b>		<b>8,177</b>	<b>573,439</b>	-	<b>(262,463)</b>	<b>319,153</b>
Comprehensive income for the year		-	-	-	(105,112)	(105,112)
New share issue	21	380	71,820	-	-	72,200
Issue expenses		-	(4,335)	-	-	(4,335)
<b>Closing balance as of April 30, 2014</b>		<b>8,557</b>	<b>640,924</b>	-	<b>(367,574)</b>	<b>281,907</b>
<b>Opening balance as of May 1, 2014</b>		<b>8,557</b>	<b>640,924</b>	-	<b>(367,574)</b>	<b>281,907</b>
Comprehensive income for the year		-	-	-	(117,497)	(117,497)
New share issue	21	1,229	224,916	-	-	226,145
Issue expenses		-	(14,844)	-	-	(14,844)
<b>Closing balance as of April 30, 2015</b>		<b>9,786</b>	<b>850,996</b>	-	<b>(485,071)</b>	<b>375,710</b>
<b>Opening balance as of May 1, 2015</b>		<b>9,786</b>	<b>850,996</b>	-	<b>(485,071)</b>	<b>375,710</b>
Income for the year		-	-	-	(141,539)	(141,539)
Other comprehensive income		-	-	(19)	-	(19)
<b>Comprehensive income for the year</b>		<b>0</b>	<b>0</b>	<b>(19)</b>	<b>(141,539)</b>	<b>(141,557)</b>
Warrants		-	27	-	-	27
Equity part from issue of convertible loan	18	-	382	-	-	382
New share issues	21	935	105,261	-	-	106,196
Issue expenses		-	(14,706)	-	-	(14,706)
<b>Closing balance as of April 30, 2016</b>		<b>10,721</b>	<b>941,961</b>	<b>(19)</b>	<b>(626,610)</b>	<b>326,053</b>

\* Translation differences

## CONSOLIDATED CASH FLOW STATEMENT

TSEK	Note	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
<b>Operating activities</b>				
Operating income before financial items		(132,691)	(108,225)	(98,091)
Adjustments for non-cash items				
Depreciation and amortization	11,12	4,804	5,190	4,941
Income from divestment/disposal of tangible assets	11	0	792	3
Interest received	15	786	56	192
Interest paid	15	(1,664)	(1,384)	(617)
<b>Cash flow from operating activities before changes in working capital</b>		<b>(128,766)</b>	<b>(103,570)</b>	<b>(93,571)</b>
<b>Changes in working capital</b>				
Change in inventories	7	(11,297)	(3,684)	(769)
Change in accounts receivable - trade	18	(4,798)	(56)	(49)
Change in other current receivables	18,19,20	(561)	77	1,721
Change in accounts payable	18	13,218	(3,486)	10,419
Change in other current liabilities	18,22,23,25	4,077	3,055	(4,650)
<b>Cash flow from operating activities</b>		<b>(128,126)</b>	<b>(107,665)</b>	<b>(86,899)</b>
<b>Investing activities</b>				
Investments in intangible assets	5,12	(17,960)	(17,406)	(33,545)
Divestment of intangible assets	12	-	1,200	-
Investments in property, plant and equipment	11	(1,974)	(3,621)	(2,138)
Divestment of property, plant and equipment	11	0	72	-
Investments in short-term investments	18	-	(80,000)	-
Divestment of short-term investments	18	30,000	30,000	-
<b>Cash flow from investing activities</b>		<b>10,066</b>	<b>(69,755)</b>	<b>(35,682)</b>
<b>Financing activities</b>				
Increase in liabilities to credit institutions	18	-	-	80,000
Decrease in liabilities to credit institutions	18	-	(20,000)	(40,000)
Loans raised	25	35	-	-
Loans repaid	25	(35)	-	-
Convertible loan	18	28,000	-	-
Warrants	17	27	-	-
New share issues	21	106,196	190,861	72,200
Issue expenses	21	(16,774)	(14,844)	(4,335)
<b>Cash flow from financing activities</b>		<b>117,449</b>	<b>156,017</b>	<b>107,865</b>
<b>Cash flow for the period</b>		<b>(610)</b>	<b>(21,404)</b>	<b>(14,716)</b>
<b>Translation differences</b>		<b>(19)</b>	<b>-</b>	<b>-</b>
<b>Cash and cash equivalents at beginning of year</b>		<b>26,837</b>	<b>48,241</b>	<b>62,956</b>
<b>Cash and cash equivalents at end of year</b>	18	<b>26,208</b>	<b>26,837</b>	<b>48,241</b>

**Significant non-cash transactions**

As part of the Group's refinancing in 2014, 1,960,217 new shares were issued to Nexttobe AB in settlement of SEK 35.28 million principal and interest outstanding on the loan.

**NOTES****NOTE 1 GENERAL INFORMATION**

Oasmia Pharmaceutical AB (Reg. No. 556332-6676 and the Parent Company of the Oasmia Group) is a limited company domiciled in Stockholm, Sweden. The address of the company is Vallongatan 1, Uppsala, where the Parent Company has its office, manufacturing facility and conducts research. The company's shares are listed on NASDAQ Stockholm, NASDAQ Capital Market and on the Frankfurt Stock Exchange.

**NOTE 2 ACCOUNTING POLICIES**

The principal accounting policies applied in these financial statements are set out below.

**Assumptions and uncertainties related to going concern**

Oasmia has incurred losses through and including its fiscal year ending April 30, 2016. As of April 30, 2016, Oasmia had an accumulated deficit of SEK 626.61 million. The cash flow from operating activities has also been negative.

Oasmia has two products approved, but this does not yet create a sufficient cash flow from its own business. For this reason, Oasmia continuously works with various financing alternatives. This work includes that the company is in discussions with potential partners for licensing of distribution and sales rights, negotiations with new and existing investors, financiers and lenders and that the company ensures enough resources to secure that forecasted future revenue streams from regions where the company's products registered, are realized.

Available consolidated liquid assets and unutilized credit facilities as of April 30, 2016 are not sufficient to provide the required capital to pursue the planned activities during the next 12 months. In light of available financing alternatives and the recent developments in the Company, the Board of Directors assesses that the prospects for financing of the Company's operations in the coming year are good. Should funding not be obtained in sufficient quantities there is a risk that the conditions for continued operation do not exist.

**Basis of preparation**

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) and interpretations issued by the International Financial Reporting Interpretations Committee (IFRIC). Furthermore, the recommendation RFR 1, Supplementary accounting regulations for Groups, issued by the Swedish Financial Reporting Board, has been applied.

The preparation of financial statements in conformity with IFRS requires the use of certain critical estimates for accounting purposes. It also requires management to exercise its judgment in applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 3.

**The Group's accounting policies****Changes in accounting policies****New policies 2015/16**

None of the standards and interpretations required for the first time for the financial year that began on May 1, 2015 had a material impact on the consolidated financial statements.

**New IFRS standards and interpretations effective financial year 2016/17 or later that may impact Oasmia's financial reporting:*****IFRS 15 Revenue from Contracts with Customers***

This standard comes into force on January 1, 2018 and will thus be applied by Oasmia as from the financial year 2018/2019.

The standard will first and foremost replace IAS 18 Revenue, which is the standard that regulates the reporting of revenues at the present time. Under IFRS 15 the basic principle for when revenue may be recognized is when the acquiring party can use a good or can draw benefit from a service, while IAS 18 concentrates more on when risk is transferred from the vendor to the purchaser. IFRS 15 also requires considerably more disclosures than IAS 18. IFRS 15 is expected to impact Oasmia's financial reporting. However, it is still difficult to decide the extent of the impact, as this is very much dependent on how Oasmia's revenue situation develops in the two years up until the time when IFRS 15 comes into force.

**IFRS 9 Financial instruments**

This standard will come into force on January 1, 2018, that is to say that it will be applied by Oasmia as from the financial year 2018/2019.

IFRS 9 will replace IAS 39 Financial Instruments and as regards the classification and assessment of financial instruments will involve simplifications compared to IAS 39. The introduction of this standard is not assessed to have any material impact on Oasmia's financial reports.

**IFRS 16 Leases**

This standard will come into force on January 1, 2019, which means that it will be applied by Oasmia as from the financial year 2019/2020.

IFRS 16 states that at the beginning of a leasing agreement the lessee shall recognize the right to use the leased assets in the balance sheet and at the same time a leasing liability shall be recognized. Depreciation shall be applied to the assets during the time they are used and leasing rates will be recognized both as part-payment of the leasing liability and as an interest expense in the income statement. The leasing liability may also be revalued during the duration of the contract depending on whether certain circumstances, such as new leasing terms and conditions, are introduced. However, there will be two exceptions. Leased assets of a low value and short-term leasing (with a duration of no more than 12 months) will be exempted from the obligation to capitalize the right to use an asset and to enter the expected leasing payments as a liability.

The introduction of IFRS 16 is expected to impact Oasmia's financial reporting. The extent of the impact is being investigated by the company.

None of the other standards and interpretations which have not yet come into force is expected to have a material impact on the Group.

**Subsidiaries**

Subsidiaries are companies where the Parent Company has a controlling interest. The Parent Company has a controlling interest in a company when it is exposed to or is entitled to variable return from its holding in the company and is able to affect the return through its controlling interest in the company. Subsidiaries are included in the consolidated accounts as from the day on which the controlling interest is transferred to the Group. They are excluded from the consolidated accounts as from the day on which the controlling interest ends.

The acquisition method is applied to the recognition of acquisitions of subsidiaries. This means that acquired assets and liabilities are initially measured at fair value. If a deviation then arises against the acquisition cost, this is recognized as goodwill in the consolidated balance sheet when the deviation is positive and as an expense in the income statement if it is negative.

Eliminations are made for intra-Group transactions and balance-sheet items, and for unrealized gains on transactions between Group companies.

**Translation of foreign currencies**

The Parent Company uses SEK as its functional currency and reporting currency. Transactions in foreign currency are translated to the functional currency according to the exchange rates on the transaction date. Translation profits or losses arising from payments for such transactions and from translation of monetary assets and liabilities in foreign currency at closing day exchange rates are recognized in operations. Currency gains and losses arising from the translation of bank accounts in foreign currencies are recognized under Net financial items.

Individual subsidiaries have another functional currency than SEK. In the presentation of the consolidated balance sheet the current rate method is used, whereby assets and liabilities are translated to the closing day rate of exchange while revenues and expenses are translated using the average exchange rate for the year. The translation differences that thus arise are recognized in other comprehensive income.

**Segment reporting**

An operating segment is a part of a company that conducts business activities from which revenues can be generated and costs can be incurred, and for which independent financial information is available. Furthermore, the operating results of the segment are reviewed on a regular basis by the company's chief operating decision maker as the basis for the decision on allocation of resources to the segment and the evaluation of its result. The Group management has been identified as the chief operating decision maker. Group management assesses the business as a whole, that is as one segment, and therefore does not include information by segment in the accounts. Note 4 reports the division of revenues into product groups and geographic markets as well as the value of non-current assets in Sweden and in other countries. Information is also provided about the customer structure in the same note.

**Property, plant and equipment**

Property, plant and equipment are recognized at acquisition cost, with deductions for depreciation. The acquisition cost includes expenses directly attributable to the acquisition of the asset.

Additional expenses are added to the carrying amount of the asset or are recognized as a separate asset, depending on what is most suitable, only when it is probable that the future economic benefits connected with the asset will prove beneficial to the Group and the acquisition cost of the asset can be measured in a reliable way. The carrying amount of the replaced part will be removed from the balance sheet. All other types of repairs and maintenance are recognized as expenses in the income statement in the period in which they arise.

Assets are depreciated on a straight-line basis in order to distribute their acquisition cost to the calculated residual value over the calculated utilization period, as follows:

- |  |            |
|--|------------|
| • Vehicles                             | 3-5 years  |
| • Inventories and production equipment | 5-15 years |
| • Leasehold improvements               | 20 years   |

The residual values and utilization period of the assets are reviewed at every closing day and are adjusted as required. A carrying amount of an asset is immediately depreciated to its recoverable amount if the carrying amount exceeds its estimated recoverable amount. Profits and losses from divestments are established by a comparison between the sales revenue and the carrying amount and are recognized in Other operating income or Other operating expenses.

**Intangible assets****Capitalized development costs**

Expenditures for research are expensed immediately. Development costs which are attributable to production and tests of novel or improved products are capitalized to the extent that they are expected to generate future economic benefits. Oasmia capitalizes development costs consisting of the company's work on clinical trials in phase III for the product candidates Paical/Apealea and Paccal Vet and for which all the preconditions for capitalization pursuant to IAS 38 have been met.

It is the assessment of the company that it is technically possible to complete the product candidates and make them available for sale, and that the beginning of a phase III study is the earliest time when all criteria for capitalization can be met. This assessment is made in the light of several factors.

Both products are based on a well-known and well-documented substance, paclitaxel, and Oasmia's own excipient XR17. The company can therefore reuse data for both product candidates when applying for market approval and this can potentially lead to a shorter path to approval.

The company has both the resources and the competence to itself produce these two products for our clinical studies preceding a phase III study. Production takes place in approved premises with employed personnel.

The company both intends and is able to sell these products in various markets, both through existing distributors or through its own sales channels.



The oncology markets for both humans and pets are both large and growing, which means that the company assesses that it is possible that these products will be able to generate considerable economic benefits in the future.

Other development costs are recognized as an expense as and when they arise. Development costs previously recognized as an expense are not capitalized as an asset in subsequent periods. Straight-line amortization is applied to capitalized development costs over the period in which the expected benefits are expected to accrue to the company, and is begun when a normal level of commercial sales to end customers has been achieved.

**Other intangible assets**

The Group capitalizes fees to authorities for patents to the extent they are expected to generate future economic benefits. They are recognized at acquisition cost, reduced by the accumulated amortizations. Amortization is performed on a straight-line basis in order to distribute the cost over the estimated utilization period. The estimated utilization period for patents is a maximum of 20 years.

The capitalized patent expenses comprise registration costs such as initial expenses for e.g. authorities and legal fees. The gain or loss arising when an intangible asset is divested or disposed of is determined as the difference between the settlements received and the carrying amount and is recognized in Other operating income or Other operating expenses.

**Inventories**

Inventories are recognized at the lowest of acquisition cost and net realizable value. The acquisition cost is established by using the first in, first out method (FIFO).

The acquisition cost for Raw materials and necessities consists of the purchase price invoiced by the supplier. The acquisition cost for Work in progress and for Finished goods consist of the costs for the constituent raw materials, with a mark-up for manufacturing costs and quality control costs.

The net realizable value is the estimated sales price in the operating activities, with deductions for applicable variable selling expenses.

**Impairment of non-financial assets**

The capitalized development costs which are not yet current are not amortized, but are instead evaluated annually for any impairment needs. Group management performs an estimation of the expected utilization period of the assets at every financial statement. If there are indications that an asset's value has diminished, the Group establishes the recoverable amount of the asset. This amount is the highest net realizable value of the asset, with deductions for selling expenses and its value in use. The asset is amortized down to the recoverable amount via the income statement. In order to establish the impairment need, the assets are grouped into cash generating units, which is the smallest group of assets that enables positive cash flows that are essentially independent of the cash flow from other assets or groups of assets. The Group presently has no assets with indeterminable utilization periods.

**Financial instruments**

Financial instruments are agreements that give rise to a financial asset or liability. Financial assets are cash, equity instruments in other companies and such agreements that give entitlement to cash or other financial assets. Financial liabilities are agreements that oblige the company to pay cash or other financial assets to another company.

This means that there are several receivables and liabilities that are not financial instruments. For example receivables or liabilities that can be expected to be settled other than in cash or through other financial assets are not dealt with in accordance with the accounting principles that apply to financial instruments. The same applies to receivables or liabilities that are not based on agreements.

Financial instruments are recognized in the statement of financial position when Oasmia is one of the parties in the conditions of the agreement governing the instrument. A financial asset is removed from the statement of financial position when the rights in the agreement are terminated, as they have been realized or Oasmia loses control of them. A financial liability is removed from the statement of financial position when the obligation in the agreement has been fulfilled or in some other way ceases to apply.

Each time a report is drawn up an assessment is made as to whether there are circumstances indicating that a financial asset needs to be written down. If there is a need for impairment, the amount written down is identified in the income statement.

Oasmia's financial instruments are reported at fair value or at amortized cost:

- Fair value is the price that would be obtained if an asset were sold or paid in the settling of a liability in an orderly transaction between knowledgeable and independent parties.
- Amortized cost is the value at which the asset or liability was valued when it was acquired plus or minus certain adjustments in value.

Financial instruments are divided into different categories depending on their nature and the method used in their valuation. Oasmia reports its financial instruments in three such categories:

- Financial assets and liabilities valued at fair value in the income statement. Changes in fair value are recognized in the income statement. This category includes:
  - o Short-term investments in fixed income funds.
- Loans receivable and accounts receivable  
This category includes:
  - o Cash and cash equivalents valued at nominal value. Where they are denominated in a currency other than SEK, they are translated at the closing day rate of exchange.
  - o Accounts receivable, other current receivables and accrued revenues are valued at amortized cost.
- Financial liabilities valued at amortized cost  
This category includes:
  - o Borrowings and liabilities to credit institutions which are valued at nominal value as they have a short duration.
  - o A convertible loan
  - o Accounts payable and accrued expenses valued at the value they are expected to be paid at.

For further disclosures on Oasmia's financial instruments, please see Note 18 Financial instruments and financial risks.

#### **Share capital**

Common shares are classified as equity. Transaction costs which can be attributed directly to new share issues or options are recognized, net after tax, in equity as a deduction from the funds generated by the issue.

#### **Income tax**

Tax revenues and expenses are constituted by current and deferred tax. Current tax is the tax calculated on the taxable income of each legal entity in the Group for the current or a previous period. Deferred tax is tax on temporary differences between assets' and liabilities' carrying amount and tax base. A deferred tax revenue also arises to the extent that the tax effect of loss carry-forward is entered as a deferred tax asset. However, a deferred tax asset is only recognized to the extent that there are convincing reasons that a future taxable surplus will be available, against which the deferred tax asset can be offset. As it is not yet possible to reliably calculate when Oasmia will achieve such a surplus, no deferred tax assets have been recognized.

#### **Employee benefits**

##### **Current remuneration**

Current remuneration to employees is calculated without discounting and is recognized as an expense when the services concerned are obtained.

**Pension obligations**

The Group has defined contribution pension plans. A defined contribution plan is a pension plan under which the Group pays fixed contributions to a separate legal entity. The Group has no legal or constructive obligations to pay further contributions if this legal entity does not hold sufficient assets to pay all employee benefits relating to employee service in the current and prior periods. Defined contribution pension plan obligations are recognized as employee benefits as and when they are earned by employees carrying out services for the company in any given period. Prepaid contributions are recognized as an asset to the extent that a cash refund or a reduction in future payments is available to the Group.

**Severance pay**

Severance pay is awarded when notice is given to an employee by Oasmia before the normal pension date, or when an employee accepts voluntary resignation in exchange for such payments. The Group recognizes severance pay when it is obliged either to give notice to the employee according to a detailed formal plan without the possibility of recall, or to pay remuneration when notice is given as a result of an offer made to encourage voluntary resignation. Benefits which are due more than 12 months after closing day are discounted to the present value.

**Revenue recognition**

Revenues comprise the fair value of what has been received or will be received for sold goods, services and necessities as a result of the Group's business operations. Revenue is recognized without value added tax, and after elimination of intra-Group sales. The Group recognizes revenue when the amount can be measured in a reliable manner, it is likely that future economic benefits will accrue to the Group and certain criteria have been fulfilled for each of the business activities of the Group described below.

**a) Sales of goods**

Revenues from sales of goods are recognized at the time when they are delivered to customers, licensees or distributors. This is the time when ownership rights are transferred to the recipient of the goods.

In addition to sales of registered pharmaceuticals, sales may be conducted before a drug has been registered, in the following two cases. In the first case, the purchaser is a hospital pharmacy or veterinary clinic where the company's clinical trials are ongoing. In the second case, the purchaser is a treating clinic that has decided to test a drug that has not yet been approved, as registered drugs have not had the desired effect. Both cases are called compassionate use and the Parent Company has had such sales. In such cases delivery and invoicing of the product are performed at the same time and the revenue is recognized at this time.

**(b) Contract assignments**

Contract assignments carried out are recognized as revenue to the extent that they have been completed at the end of the reporting period, that is by gradual revenue recognition.

**(c) Sale of necessities**

Oasmia sells necessities, in the form of sterile water that has been produced in the company's facility, to another company. The resulting revenues are recognized upon delivery.

**(d) Royalties**

Royalty revenues arise when a licensee recognizes sales in its market. Royalty revenues are recognized in the same period as the licensee's sales.

**Leasing**

Leasing whereby a significant part of the risks and benefits of ownership is retained by the lessor is classified as operational leasing. Payments made during the lease term (after deduction of any incentives from the lessor) are carried as an expense in the income statement on a straight-line basis over the term of the lease. Oasmia has no financial leasing.

**Dividends**

Dividends paid to the Parent Company's shareholders are recognized as liabilities in the consolidated financial statements in the period in which the dividends are approved by Parent Company shareholders.

**Cash flow**

Cash flow statements are prepared using the indirect method.

**NOTE 3 SIGNIFICANT ESTIMATES AND ASSUMPTIONS FOR ACCOUNTING PURPOSES**

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the current circumstances.

**Significant estimates and assumptions for accounting purposes**

The Group makes estimates and assessments about the future. The resulting estimates for accounting purposes will by definition seldom correspond to the actual result. The estimates and assessments that entail a considerable risk of significant adjustments in the carrying amounts for assets and liabilities in the next financial year are listed below.

**(a) Impairment tests for intangible assets**

The Group capitalizes development costs for two drug candidates Paclical and Paccal Vet. The capitalized development costs for the financial year ending April 30, 2016 amounted to TSEK 16,727 compared to TSEK 16,797 as per April 30, 2015 and TSEK 29,464 as per April 30, 2014. The Group's accumulated capitalized development costs, as of April 30, 2016, amounted to TSEK 409,900 compared to TSEK 393,173 as of April 30, 2015. An assessment is performed annually of whether there is a need for impairment of the capitalized development costs. Oasmia's impairment tests show that there is no need for impairment. Market approval has been received for Paclical in Russia for the indication of ovarian cancer in humans and conditional market approval has been received for Paccal Vet in the USA for the indications of mammary carcinoma and squamous cell carcinoma in dogs. In Oasmia's assessment, more market approvals can be expected in the foreseeable future and expected future profits justify the value of the assets. If the other market approvals were not to be received, if a considerably lower price than expected was received per treatment, if the market share was lower, or if the likelihood of receiving approval were to decrease, parts of the capitalized expenditure would be carried as expenses. As of April 30, 2016 capitalized expenditure amounted to 126 % compared to 105 % as of April 30, 2015 of the equity at the same time. The Group annually evaluates whether a need for impairment exists for all intangible assets, in accordance with the accounting policies described in Note 2.

**(b) Licensing revenues**

The Parent Company enters into licensing and distribution agreements with other companies. Such agreements include certain milestone payments with a risk of repayment, depending on success in product development and registration. The Parent Company continuously evaluates whether such conditions have changed, been eliminated or been realized, in accordance with the accounting policies described in Note 2.

**(c) Income taxes**

The Group is required to pay tax in Sweden. The Group's companies have so far showed negative taxable income, and as a result significant taxable deficits exist in the Group. There are at present no sufficiently convincing indications as to when loss carry-forward will be able to be utilized against future profits, and thus no deferred tax asset has been taken into consideration in the balance sheet.

Accumulated taxable deficits in the Group are described in Note 16.

**(d) Contingent assets**

The company has filed to sue a supplier of WFI-equipment regarding delivered equipment that the company considers to be faulty. The total estimated loss that this faulty equipment has caused the company amounted to TSEK 14,500, and Oasmia has so far received insurance compensation of TSEK 4,250. Should the legal action be successful, Oasmia is demanding approximately TSEK 9,500. The trial has not yet begun and it is therefore not practically possible to state when any payment will be received. The company's legal counsel has advised management that it is likely that the legal action will be successful, but as this is uncertain no asset has been recognized in the Statement of Financial Position.

**Important judgements when applying the company's accounting policies**

The Group capitalizes development costs for two pharmaceutical candidates, Paclical/Apealea and Paccal Vet. The company assesses that the beginning of a phase III study is the earliest time when all criteria for capitalization can be fulfilled. It is at this time that the company can assess whether it is technically possible to complete the intangible asset so that it can be used or sold. If the Group should make the judgment that all capitalization criteria are no longer fulfilled, these assets would be written off against Group income.

At least once a year, normally when the annual financial statements are prepared, the Group's tangible and intangible assets are tested to see if there is a need for impairment. Tests may also be carried out if management assesses that there have been significant changes in the assumptions that can affect the result of the tests. The question is whether the recoverable amount of the asset is greater than its carrying amount. Usually these Group assets have no stated market value, and the company therefore applies the value in use method. One of the important assets that are the subject of impairment testing is the item capitalized development costs for Paccal Vet and Paclical/Apealea. The impairment testing is based on management's forecasts for the future economic development of the products Paccal Vet and Paclical/Apealea. These forecasts are partly based on available statistics, primarily on the incidence of cancer per type of cancer, but also on management's assessment of future development that cannot be supported by external statistics or comparative data. The result of the impairment testing consists of seeing if the value in use is greater than the carrying amount of the assets. If this is the case, no impairment is performed. If on the other hand the value in use is less than the carrying amount, the asset is written down to its recoverable amount.

The Group capitalizes expenditures for patents because they are expected to generate future economic benefits. If the Group should make the judgment that they will no longer generate future economic benefits, these assets would be written off against the Group's income.

#### NOTE 4 SEGMENT INFORMATION

The Group currently has only one segment and therefore reports no information by segment.

The Group has its registered office in Sweden. All net sales derive from sales to external customers, and are shown below divided up into product categories and geographic area.

##### Net sales per product category

TSEK	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
Sales of necessities	96	68	60
Sales of goods and royalty revenues	6,077	2,002	-
Contract assignments	200	-	-
<b>Total</b>	<b>6,373</b>	<b>2,070</b>	<b>60</b>

##### Net sales per geographic area

TSEK	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
Russia	6,019	-	-
Sweden	125	68	60
Other countries	229	2,002	-
<b>Total</b>	<b>6,373</b>	<b>2,070</b>	<b>60</b>

Net sales in Russia of TSEK 6,019 in the financial year ending April 30, 2016 derive from one specific customer with its registered office in Russia. Revenue from external customers in other countries amounted to TSEK 2,002 in the financial year ended April 30, 2015 and came from sales to a customer based in the USA

Non-current assets located in Sweden as per April 30, 2016 amount to TSEK 437,297 compared to TSEK 421,973 as of April 30, 2015 and TSEK 408,523 as of April 30, 2014 and non-current assets located in another country as per April 30, 2016 amount to TSEK 5,713 compared to TSEK 5,905 as of April 30, 2015 and TSEK 5,584 as of April 30, 2014.

**NOTE 5 CAPITALIZED DEVELOPMENT COSTS**

TSEK	MAY 1, 2015 – APR 30, 2016			MAY 1, 2014 – APR 30, 2015			MAY 1, 2013 – APR 30, 2014		
	Paclical	Paccal Vet	Total	Paclical	Paccal Vet	Total	Paclical	Paccal Vet	Total
Opening acquisition cost	290,108	103,065	393,173	280,919	95,457	376,376	261,242	85,669	346,911
Capitalized expenditure for the year	9,980	6,747	16,727	9,189	7,608	16,797	19,677	9,788	29,464
<b>Closing accumulated acquisition cost</b>	<b>300,088</b>	<b>109,812</b>	<b>409,900</b>	<b>290,108</b>	<b>103,065</b>	<b>393,173</b>	<b>280,919</b>	<b>95,457</b>	<b>376,376</b>
Opening accumulated amortization	-	-	0	-	-	0	-	-	0
Amortization for the year	-	-	0	-	-	0	-	-	0
<b>Closing accumulated amortization</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Closing carrying amount</b>	<b>300,088</b>	<b>109,812</b>	<b>409,900</b>	<b>290,108</b>	<b>103,065</b>	<b>393,173</b>	<b>280,919</b>	<b>95,457</b>	<b>376,676</b>

Capitalized development costs amounted to TSEK 16,727 for the financial year ended April 30, 2016 compared to TSEK 16,797 as of April 30, 2015 and TSEK 29,464 as of April 30, 2014. Research and development costs which were not capitalized amounted to TSEK 96,884 for the financial year ended April 30, 2016 compared to TSEK 74,028 in the financial year ending April 30, 2015 and TSEK 71,162 in the financial year ending April 30, 2014. Total cost for research and development, capitalized and expensed, amounted TSEK 113,611 compared to TSEK 90,825 as of April 30, 2015 and TSEK 100,626 as of April 30, 2014.

**NOTE 6 OTHER OPERATING INCOME**

TSEK	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
Insurance compensation	-	26	4,250
State support (new start jobs)	-	153	204
Exchange-rate differences	2	42	-
<b>Total</b>	<b>2</b>	<b>221</b>	<b>4,454</b>

**NOTE 7 INVENTORIES**

TSEK	APR 30, 2016	APR 30, 2015
Raw materials and necessities	7,129	5,341
Work in progress	4,137	-
Finished goods	5,372	-
<b>Total</b>	<b>16,638</b>	<b>5,341</b>

During the financial year ended April 30, 2016 goods of TSEK 2,383 compared to TSEK 2,439 as of April, 2015 and TSEK 0 as of April 30, 2014 were carried as an expense and goods valued at TSEK 229 compared to TSEK 0 as of April 30, 2015 and 2014 have been written down.

The change in the items "Work in progress" and "Finished goods" during the year are recognized in the income statement in "Change in inventories of products in progress and finished goods".

**NOTE 8 REMUNERATION TO AUDITORS**

TSEK	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
<b>Ernst &amp; Young AB</b>			
Auditing	1,390	1,405	425
Auditing activities in addition to auditing	2,459	1,363	4,930
Tax consulting	32	35	-
Other services	131	112	-
<b>Total</b>	<b>4,012</b>	<b>2,915</b>	<b>5,355</b>

Auditing involves reviews of the Annual Report, of the accounting records, and of the management of the Board of Directors and CEO, and other tasks that the company's auditors are required to undertake. Auditing activities in addition to auditing include review of interim reports and quality assurance services.

**NOTE 9 LEASING**

The Group has no financial leasing agreements, but has operational leasing agreements that primarily consist of leases for facilities. There are no variable fees. Leasing costs (minimum lease payments) were TSEK 5,930 for the financial year ended April 30, 2016 compared to TSEK 5,303 as of April 30, 2015 and TSEK 4,272 as of April 30, 2014. The future minimum lease payments for operational leases are as follows (TSEK):

Financial year	Operational leasing	
	APR 30, 2016	APR 30, 2015
2015/2016	-	5,294
2016/2017	6,362	3,943
2017/2018	6,013	895
2018/2019	5,878	545
2019/2020	4,522	192
2020/2021	985	-
<b>Total</b>	<b>23,760</b>	<b>10,869</b>

**NOTE 10 EMPLOYEES AND REMUNERATION****Average number of employees**

	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
Women	35	37	37
Men*	40	38	37
<b>Total*</b>	<b>75</b>	<b>75</b>	<b>74</b>

\* The comparative figure has been adjusted in the financial year May 1, 2014 – Apr 30, 2015 compared to last year's financial statements.

All employees have their employment and carry out their main duties in Sweden.

**Salaries and benefits**

<b>TSEK</b>	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
Board	3,169	1,495	941
CEO and other senior executives	6,171	6,891	7,288
Other employees	32,160	28,786	26,846
Defined contribution pension plans, incl. Fora	2,668	2,043	371
Defined medical benefits	276	39	4
<b>Total salary and remuneration</b>	<b>44,445</b>	<b>39,256</b>	<b>35,449</b>
Social security contributions by law and agreement	11,677	10,492	9,462
Special employer's contribution, pension expenses	717	488	90
<b>Total salaries, remuneration and social security</b>	<b>56,840</b>	<b>50,236</b>	<b>45,002</b>

**Benefits for senior executives****Board of Directors and Board committees**

Remuneration of the Chairman of the Board of Directors and Board members is decided by the Annual General Meeting. There is no remuneration for participation in the Nomination Committee. Board fees for Joel Citron are invoiced through wholly-owned Miankoma Partners, Hans Liljeblad is invoiced through wholly-owned Advokatfirman Liljeblad & Co KB and Lars Bergkvist is invoiced through wholly-owned Axli AB in accordance with the decision of the Annual General Meeting and by special agreement with Oasmia Pharmaceutical AB. Except for what is described in Transactions with key people in senior positions in Note 25, no other remuneration such as salary, pension premium or other benefits has been paid.

The Chairman of the Board is entitled to health insurance and pension insurance pursuant to an agreement whereby the company shall pay an amount corresponding to 25 percent of the pensionable annual salary to any chosen pension insurance company.

**CEO**

Remuneration of the CEO consists of a fixed salary. The remuneration is reviewed annually on April 1. According to the CEO's agreement regarding individual health insurance and pension insurance, the company shall pay an annual amount corresponding to 4.5 percent of the CEO's pensionable annual salary. If a termination notice is given by the employer, a 12-month term of notice applies. If a termination notice is given by the CEO, the term of notice is 3 months.

**Terms of employment for other senior executives**

Remuneration to other senior executives consists of fixed salary and pension insurance corresponding to 4.5 % of the pensionable annual salary. Salaries are reviewed annually on April 1.



## Remuneration to Board and senior executives

TSEK	MAY 1, 2015 – APR 30, 2016			
	Base salary/ Board fees	Social security incl. special employer's contribution	Pension/ Sickness benefits	Variable remuneration
Chairman of the Board Joel Citron <sup>1)</sup>	26	-	-	-
Chairman of the Board Julian Aleksov <sup>2)</sup>	1,635	582	422	35
Board member, Bo Cederstrand	150	20	-	-
Board member, Horst Domdey	150	47	-	-
Board member, Alexander Kotsinas <sup>3)</sup>	-	-	-	-
Board member, Hans Sundin	883	99	-	-
Board member, Hans Liljeblad <sup>4)</sup>	200	62	-	-
Board member, Lars Bergkvist <sup>4)</sup>	125	39	-	-
CEO Mikael Asp <sup>5)</sup>	1,299	470	55	1
Other senior executives (4 persons) <sup>6)</sup>	4,792	1,544	615	79
<b>Total</b>	<b>9,260</b>	<b>2,863</b>	<b>1,092</b>	<b>115</b>

1) Resigned in May 2015

2) Elected Chairman of the Board in May 2015. Julian Aleksov is the Executive Chairman of the Board and is paid a salary

3) Mr. Kotsinas has waived his right to receive remuneration for his service as a Director.

4) Elected as Board member in May 2015

5) Appointed new CEO in May 2015

6) In February 2016 management was increased by one person. Three senior executives resigned in February and March 2016

## May 1, 2014 – Apr 30, 2015

<b>TSEK</b>	<b>BASE SALARY/ BOARD FEES</b>	<b>SOCIAL SECURITY INCL. SPECIAL EMPLOYER'S CONTRIBUTION</b>	<b>PENSION/ SICKNESS BENEFITS</b>	<b>VARIABLE REMUNERATION</b>
Chairman of the Board, Joel Citron	175	-	-	-
Board member, Jan Lundberg <sup>(1)</sup>	75	8	-	-
Board member, Bo Cederstrand	150	15	-	-
Board member, Martin Nicklasson <sup>(1)</sup>	75	24	-	-
Board member, Horst Domdey	150	47	-	-
Board member, Alexander Kotsinas <sup>(2)</sup>	-	-	-	-
Board member, Hans Sundin <sup>(3)</sup>	870	89	17	-
Board member and CEO, Julian Aleksov	1,455	477	279	25
Other senior executives (6 persons) <sup>(4)</sup>	5,279	1,492	467	132
<b>Total</b>	<b>8,229</b>	<b>2,151</b>	<b>762</b>	<b>157</b>

(1) Resigned in September 2014.

(2) Alexander Kotsinas has waived remuneration for work on the Board.

(3) Elected as Board member in September 2014. Hans Sundin is executive Board member and receives salary.

(4) In August and October 2014 the management team was increased by 2 people. One senior executive left the company in September 2014.

TSEK	May 1, 2013 – Apr 30, 2014			
	BASE SALARY/ BOARD FEES	SOCIAL SECURITY INCL. SPECIAL EMPLOYER'S CONTRIBUTION	PENSION/ SICKNESS BENEFITS	VARIABLE REMUNERATION
Chairman of the Board, Joel Citron	175	-	-	41
Board member, Jan Lundberg	150	15	-	-
Board member, Bo Cederstrand	150	15	-	-
Board member, Martin Nicklasson	150	47	-	-
Board member, Horst Domdey	150	47	-	-
Board member, Alexander Kotsinas <sup>(1)</sup>	-	-	-	-
Board member and CEO, Julian Aleksov	1,267	463	253	39
Other senior executives (8 persons) <sup>(2)</sup>	5,842	1,491	17	140
<b>Total</b>	<b>7,884</b>	<b>2,078</b>	<b>271</b>	<b>221</b>

(1) Elected as Board member in September 2013 and has waived remuneration for work on the Board.

(2) Two senior executives left the company during the financial year, in November 2013 and April 2014.

#### Gender distribution on the Board and in management

	APR 30, 2016		APR 30, 2015		APR 30, 2014	
	Number on closing day	Number of men	Number on closing day	Number of men	Number on closing day	Number of men
Board members	7	7	5	5	7	7
CEO and other senior executives	4	4	7	5	7	5

#### Health care and medical care

Oasmia offers its employees free medical care up to the cost ceiling and free medicines up to the cost ceiling. Oasmia has also signed an agreement with a provider of occupational health services.

**NOTE 11 PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consist of vehicles, inventory and production equipment, leasehold improvements, and construction in progress and advance payments for machinery and equipment.

## GROUP, MAY 1, 2015 – APR 30, 2016

TSEK	Vehicles	Inventories and production equipment	Leasehold improvements	Construction in progress and advance payments for machinery and equipment	Total
Opening acquisition cost	148	40,557	8,205	1,241	50,151
Investments for the year	-	1,802	172	-	1,974
Reclassifications	-	1,141	-	(1,141)	0
Sales/disposals	(148)	-	-	-	(148)
<b>Closing accumulated acquisition cost</b>	<b>0</b>	<b>43,500</b>	<b>8,378</b>	<b>100</b>	<b>51,977</b>
Opening depreciation	(148)	(24,667)	(2,484)	0	(27,299)
Depreciation for the year	-	(3,231)	(423)	-	(3,654)
Sales/disposals	148	-	-	-	148
<b>Closing accumulated depreciation</b>	<b>0</b>	<b>(27,898)</b>	<b>(2,907)</b>	<b>0</b>	<b>(30,805)</b>
<b>Closing carrying amount</b>	<b>0</b>	<b>15,602</b>	<b>5,471</b>	<b>100</b>	<b>21,172</b>

Sales/disposals of non-current assets have not had any impact on earnings during the financial year ending April 30, 2016 compared to TSEK 792 in the financial year ending April 30, 2015.

## GROUP, MAY 1, 2014 – APR 30, 2015

TSEK	Vehicles	Inventories and production equipment	Leasehold improvements	Construction in progress and advance payments for machinery and equipment	Total
Opening acquisition cost	148	38,439	8,512	1,413	48,512
Investments for the year	-	2,005	175	1,441	3,621
Reclassifications	-	852	-	(852)	0
Sales/disposals	-	(739)	(482)	(761)	(1,982)
<b>Closing accumulated acquisition cost</b>	<b>148</b>	<b>40,557</b>	<b>8,205</b>	<b>1,241</b>	<b>50,151</b>
Opening depreciation	(148)	(21,503)	(2,460)	0	(24,111)
Depreciation for the year	-	(3,893)	(412)	-	(4,305)
Sales/disposals	-	729	388	-	1,117
<b>Closing accumulated depreciation</b>	<b>(148)</b>	<b>(24,667)</b>	<b>(2,484)</b>	<b>0</b>	<b>(27,299)</b>
<b>Closing carrying amount</b>	<b>0</b>	<b>15,890</b>	<b>5,721</b>	<b>1,241</b>	<b>22,852</b>

A purchase sum of TSEK 72 was received in the financial year ending April 30, 2015 from the sale of non-current assets compared to TSEK 0 in the financial year ending April 30, 2014. This sum corresponded to the carrying amount. Disposals affected results by TSEK 792 in the financial year ending April 30, 2015 compared to TSEK 0 in the financial year ending April 30, 2014, as reported under Other operating expenses.

**NOTE 12 OTHER INTANGIBLE ASSETS**

Other intangible assets consist of the costs of patents.

TSEK	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015
Opening acquisition cost	22,382	22,973
Investments for the year	1,233	609
Divestments	-	(1,200)
Disposals	-	-
<b>Closing accumulated acquisition cost</b>	<b>23,615</b>	<b>22,382</b>
Opening accumulated amortization	(10,529)	(9,645)
Amortization for the year	(1,150)	(884)
Disposals	-	-
<b>Closing accumulated amortization</b>	<b>(11,679)</b>	<b>(10,529)</b>
<b>Closing carrying amount</b>	<b>11,936</b>	<b>11,852</b>

**NOTE 13 CURRENCY DIFFERENCES – NET**

Currency differences are recognized in the income statement as follows:

TSEK	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
Other operating income	2	42	-
Raw materials, consumables and goods for resale	-	(1,249)	(636)
Other external expenses	478	-	-
Financial items - net	(480)	(11)	15
<b>Total</b>	<b>0</b>	<b>(1,218)</b>	<b>(621)</b>

**NOTE 14 OPERATING INCOME**

Operating income for the financial year ending April 30, 2016 was TSEK (132,691) compared to TSEK (108,225) for the financial year ending April 30, 2015 and TSEK (98,091) for the financial year ending April 30, 2014. Of the Group's recognized operating expenses of TSEK 165,273 in the financial year ending April 30, 2016 TSEK 127,313 in the financial year ending April 30, 2015 and TSEK 132,069 in the financial year ending April 30, 2014, TSEK 16,727 was recognized as capitalized development costs in the financial year ending April 30, 2016 compared to TSEK 16,797 in the financial year ending April 30, 2015 and TSEK 29,464 in the financial year ending April 30, 2014.

**NOTE 15 FINANCIAL INCOME AND EXPENSES**

TSEK	MAY 1, 2015 - APR 30, 2016	Group MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
<b>Financial income</b>			
Interest revenues from bank accounts, short-term investments and alike	1	170	176
Exchange-rate differences	785	40	16
<b>Total</b>	<b>786</b>	<b>210</b>	<b>192</b>
<b>Financial expenses</b>			
Interest expenses on loans, credit and other interest expenses	(8,234)	(9,431)	(7,212)
Other financial expenses	(135)	-	-
Exchange rate differences	(1,265)	(51)	(1)
<b>Total</b>	<b>(9,634)</b>	<b>(9,482)</b>	<b>(7,213)</b>

**NOTE 16 INCOME TAXES**

The Parent Company and two subsidiaries have their fiscal domicile in Sweden, where the tax rate for the 2015/16 financial year is 22 % compared to 22 % for the financial years 2014/2015 and 2013/2014. In addition, a subsidiary has its fiscal domicile in the USA.

The income tax on Group earnings before tax is shown in the table below:

TSEK	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
Income before taxes	(141 539)	(117 497)	(105,112)
Issue expenses not included in earnings	(14 706)	0	-
Non-taxable revenues	0	(1)	0
Non-deductible expenses	607	366	973
Impairment of holdings in subsidiaries	-	-	-
<b>Taxable income</b>	<b>(155 638)</b>	<b>(117 132)</b>	<b>(104,139)</b>
Income tax according to current tax rates in Sweden	34 240	25 769	22,911
Taxable deficits for which no deferred tax asset is recognized	(34 240)	(25 769)	(22,911)
<b>Tax expense</b>	<b>0</b>	<b>0</b>	<b>0</b>

During the year the Parent Company requested the Swedish Tax Agency for a review of previous years' income tax returns. This has increased the loss carry-forward by TSEK 46,204.

At April 30, 2016 the Group had accumulated loss carry-forward from previous years and from the financial year amounting to TSEK 723,234 compared to TSEK 521,391 as of April 30, 2015 and TSEK 404,260 as of April 30, 2014. There are at present no sufficiently convincing reasons to assume that loss carry-forward will be able to be utilized against future profits, and thus no deferred tax asset has been recognized in the balance sheet.

**NOTE 17 EARNINGS PER SHARE**

Earnings per share are calculated by dividing earnings attributable to Parent Company shareholders by a weighted number of common shares outstanding during the period.

	MAY 1, 2015 - APR 30, 2016	MAY 1, 2014 - APR 30, 2015	MAY 1, 2013 - APR 30, 2014
Earnings attributable to Parent Company shareholders (TSEK)	(141,539)	(117,497)	(105,112)
Weighted average number of common shares outstanding (thousands)*	101,753	91,655	82,848
Earnings per share (SEK per share)*	(1.39)	(1.28)	(1.27)

\* Historical values have been recalculated taking into account capitalization issue elements in the rights issue carried out in the third quarter of 2014/15.

The following instruments outstanding have not given rise to any dilution effect at April 30, 2016, but may do so in the future:

	Number of warrants and convertibles	Total possible number of shares
Warrants that can be converted to three shares	1,280,750	3,842,250
Warrants that can be converted to one share	140,352	140,352
Convertible instruments	28	2,393,162
<b>Total possible number of shares</b>		<b>6,375,764</b>

**NOTE 18 FINANCIAL INSTRUMENTS AND FINANCIAL RISKS****Financial risks**

Oasmia's business, like all business activities, is subjected to a large number of risks. In general these may be divided into such risks that directly affect the Group's financial situation (financial risks) and such risks that only affect the financial situation indirectly (operational risks). What operational risks Oasmia is subjected to and how these are managed is described in the sections Management Discussion and Analysis and in Risk Factors.

Financial risks can be divided up into such risks that affect the Group's financial instruments and other financial risks. The latter affect other assets and liabilities and equity.

The financial risks that Oasmia's financial instruments are to varying extents subjected to are primarily:

- **Credit risk**, meaning the risk that a debtor does not pay its liability to Oasmia.
- **Liquidity risk**, meaning the risk that Oasmia does not have sufficient funds to pay a liability when it falls due for payment or that a lack of liquidity significantly limits Oasmia in its business operations.
- **Market risk**, meaning the risk that values that are dependent on the development of the financial markets affect the value of Oasmia's financial instruments negatively.

The market risks that affect Oasmia's financial instruments are primarily:

- *Market price risk: the market price of the fixed income funds that Oasmia has invested in.*
- *Currency risk: exchange rates for the currencies that Oasmia's financial instruments are denominated in.*
- *Interest-rate risk: Stockholm Interbank Offered Rate (Stibor), which the interest on Oasmia's bank loans is tied to.*

The following sensitivity analysis shows the effect in TSEK if each parameter were to change by 1 percent, and, in the case of the interest-rate risk, if the percentage level were to change by 1 percent:

Financial instrument	Parameter	Market price risk		Currency risk		Interest-rate risk	
		APR 30, 2016	APR 30, 2015	APR 30, 2016	APR 30, 2015	APR 30, 2016	APR 30, 2015
		Short-term investments	Market price +/- 1 percent	200	500	-	-
Financial liabilities	Interest rate +/- 1 percentage point	-	-	-	-	30	100
Accounts payable and other current liabilities	Currency rate +/- 1 percent	-	-	250	100	-	-

These risks, how they are managed and what financial instruments are affected by them are discussed further below in the sections “Financial risk management” and “Financial instruments”.

Two main Other financial risks for Oasmia can be identified at present:

- **Financing risk:** Oasmia does not yet find itself in a commercialization stage, which means that revenues and cash flows generated from sales are not yet sufficient to cover the Group’s capital and liquidity requirements. The financing risk therefore entails the risk that Oasmia cannot manage to find existing and new owners who are willing to contribute equity and creditors who are prepared to give loans to a sufficient extent until the company’s own sales have reached a sufficient size.
- **Impairment risk:** As is described in Note 3 “Significant estimates and assumptions for accounting purposes” the value of “Capitalized development costs” has been tested in a comprehensive impairment test. This test is based on a number of assumptions concerning the time for regulatory market approval and the future development of above all market size, market penetration, demand and price structure in different markets. There is a risk that these parameters later develop in a negative way that could not be foreseen when the testing was performed and that an impairment requirement thereby then arises for all or parts of the intangible assets. Bearing in mind that in the Statement of Financial Position at April 30, 2016 these constitute 80%, compared to 76% in previous year of the total assets, such impairment may have considerable consequences for the Group’s financial position.

#### Financial risk management

The Group financial policy determined by the Board regulates how management should identify financial risks and, when possible and necessary, take measures to limit risk.

Risk consists of two components:

- **The risk that a negative events occurs**
- **The risk that there are great consequences if a negative event were to occur**

A correct assessment of risk, and thus a decision on appropriate risk management measures, is based on a true assessment of both these components. Obviously there can be situations where it is not profitable to actively take measures to prevent a negative event even if there is a risk that it may occur, if at the same time the consequences of such a negative event are small. In such a case it is probably best to accept the risk.

In other cases, where the consequences of a negative event may be more extensive, risk management can consist of taking certain measures to try to minimize both components. Depending on the nature of the risk, these measures can be directed more at one or the other of them. In certain cases, above all where market risk is concerned, the individual company can often not influence the risk parameters at all. In those cases risk management is directed entirely at reducing the consequences of negative events.



Credit and liquidity risks are mainly largely governed by events that can be managed through active preventive work.

The dominant financial risks for Oasmia are financing and consequently liquidity risks, as described above. This means that most of the financial risk management work is directed at these two risks. In practice, this means that company management is constantly working on finding and developing different financing opportunities, through both creditors and owners.

#### Financial instruments

Oasmia's financial instruments can be divided into the following categories:

- Financial assets valued at fair value
- Loans receivable and accounts receivable
- Financial liabilities valued at amortized cost

#### Financial instruments by category

April 30, 2016

TSEK	Financial assets valued at fair value	Loans receivable and accounts receivable	Financial liabilities valued at amortized cost	Total
<b>Financial assets</b>				
Accounts receivable	-	4,903	-	4,903
Other current receivables	-	24	-	24
Accrued income	-	0	-	0
Short-term investments	20,006	-	-	20,006
Cash and cash equivalents	-	26,208	-	26,208
<b>Total financial assets</b>	<b>20,006</b>	<b>31,135</b>	<b>0</b>	<b>51,141</b>
<b>Financial liabilities</b>				
Liabilities to credit institutions	-	-	20,000	20,000
Convertible loan	-	-	25,549	25,549
Other borrowings	-	-	94,395	94,395
Accounts payable	-	-	27,236	27,236
Accrued expenses	-	-	11,693	11,693
<b>Total financial liabilities</b>	<b>0</b>	<b>0</b>	<b>178,873</b>	<b>178,873</b>

## April 30, 2015

TSEK	Financial assets valued at fair value	Loans receivable and accounts receivable	Financial liabilities valued at amortized cost	Total
<b>Financial assets</b>				
Accounts receivable	-	105	-	105
Other current receivables	-	30	-	30
Accrued income	-	-	-	0
Short-term investments	50,153	-	-	50,153
Cash and cash equivalents	-	26,837	-	26,837
<b>Total financial assets</b>	<b>50,153</b>	<b>26,972</b>	<b>0</b>	<b>77,125</b>
<b>Financial liabilities</b>				
Liabilities to credit institutions	-	-	20,000	20,000
Convertible loan	-	-	-	-
Other borrowings	-	-	87,000	87,000
Accounts payable	-	-	14,017	14,017
Accrued expenses	-	-	8,053	8,053
<b>Total financial liabilities</b>	<b>0</b>	<b>0</b>	<b>129,070</b>	<b>129,070</b>

**Financial assets valued at fair value**

These consist of fixed income funds to the tune of TSEK 20,006 as of April 30, 2016 compared to TSEK 50,153 as of April 30, 2015 that invest in safe fixed income securities and other fixed income instruments. Most of the securities in these funds mature after more than 3 months and they have therefore been reported in the Statement of Financial Position as Short-term investments.

The fixed income funds are traded in an active financial market and can be realized in one to two banking days. An official market price is made public each trading day, and this constitutes the funds' fair value.

Of the fixed income funds, TSEK 20,000 as of April 30, 2016 compared to TSEK 20,000 as of April 30, 2015 is pledged (frozen) as collateral for bank loans. Please see "Liabilities to credit institutions" under the heading "Financial liabilities valued at amortized cost" below and Note 24 "Contingent liabilities and pledged assets". The changes in value during the financial year ending April 30, 2016 amounted TSEK (49) compared to TSEK 153 in the financial year ending April 30, 2015 and TSEK 0 in the financial year ending April 30, 2014 and these have been reported in the Income Statement as financial expenses.

These fixed income funds are affected by a market price risk, which means the risk that the market value falls. However, as these funds invest in short-term securities from safe issuers, it is assessed that the market risk is low.

**Loans receivable and accounts receivable**

- Cash and cash equivalents to the tune of TSEK 26,208 as of April 30, 2016 compared to TSEK 26,837 as of April 30, 2015 consist of bank balances of TSEK 26,054 as of April 30, 2016 compared to TSEK 26,837 as of April 30, 2015 in Swedish commercial banks and of a bank balance of TSEK 155 as of April 30, 2016 compared to TSEK 0 as of April 30, 2015 in an American commercial bank. Of cash and cash equivalents, TSEK 195 as of April 30, 2016 compared to TSEK 39 as of April 30, 2015 is balances in foreign currency. These have been translated using the Swedish Riksbank's end-of-month quotation at closing day. That part of the liquid assets which are in other currencies than SEK has an underlying currency risk, which means that there is a risk that the exchange rates for these currencies develop negatively. As the absolute values are small, it is assessed that this risk is negligible.
- Accounts receivable of TSEK 4,903 as of April 30, 2016 compared to TSEK 105 as of April 30, 2015.

- Other current receivables and accrued income of TSEK 24 as of April 30, 2016 compared to TSEK 30 as of April 30, 2015.

TSEK	APR 30, 2016	APR 30, 2015
Accounts receivable	4,903	105
Other current receivables	24	30
Accrued income	-	-
<b>Total</b>	<b>4,927</b>	<b>135</b>

#### Accounts receivable

Accounts receivable divided up by currency:

Currency	APR 30, 2016		APR 30, 2015	
	Value in currency	Recognized in SEK	Value in currency	Recognized in SEK
EUR	531	4,863	-	-
USD	1	5	-	-
SEK	35	35	105	105
<b>Total</b>		<b>4,903</b>		<b>105</b>

Age of accounts receivable relative to due date:

	APR 30, 2016	APR 30, 2015
Not yet due	35	105
Past due date:	-	-
1- 30 days	-	-
31-60 days	4,868	-
<b>Total</b>	<b>4,903</b>	<b>105</b>

Accounts receivable are recognized at the value at which they are estimated they will be received. Accounts receivable in foreign currency have been translated at the closing day exchange rate. Accounts receivable include both a currency risk and a credit risk. No provisions have been made for bad debt losses as the amounts due are expected to be received shortly.

Of Other current receivables, TSEK 24 as of April 30, 2016, TSEK 30 as of April 30, 2015, was overdue at closing day. The entire amount of TSEK 24 as of April 30, 2016 compared to TSEK 30 as of April 30, 2015, is denominated in foreign currency.

These financial instruments are reported at amortized cost, which in this case means the value which it is estimated will be received. This value equals the fair value of these financial instruments. They include a credit risk and a currency risk.

#### Financial liabilities valued at amortized cost

- Borrowings to the tune of TSEK 94,395 as of April 30, 2016 compared to TSEK 87,000 as of April 30, 2015 comprise a loan from Nexttobe AB, Oasmia's second largest shareholder. The fair value of the loan as of April 30, 2016 amounts to TSEK 93,510.

The loan carries a fixed interest of 8.5%, which is to be paid when the loan matures on December 30, 2016. During the financial year ending April 30, 2016 interest expenses for this loan amounting to TSEK 7,616 compared to TSEK 8,324 in financial year ending April 30, 2015 and TSEK 6,458 in financial year ending April 30, 2014, were reported in the income statement as financial expenses. As the interest rate is fixed up until maturity, there is no interest-rate risk, but there is a liquidity risk.

In addition to this loan, Oasmia also has a loan commitment of TSEK 40,000 as of April 30, 2016 compared to TSEK 40,000 as of April 30, 2015 from the largest shareholder, Alceco International S.A. None of this loan commitment has been made use of.

TSEK	APR 30, 2016	APR 30, 2015
Loan	94,395	87,000
<b>Total</b>	<b>94,395</b>	<b>87,000</b>

- The convertible loan of TSEK 25,549 as of April 30, 2016 compared to TSEK 0 as of April 30, 2015 and April 30, 2014 respectively comprises 28 convertible instruments of SEK 1,000,000 each. In this case, the amortized cost equals fair value.

The convertible loan falls due on April 14, 2017 unless conversion takes place at an earlier date. The loan carries interest of 8.5% and can be converted at a price of SEK 11.70 per share. Full conversion would mean that 2,393,162 new shares are issued.

Compared to a bond loan, a convertible loan includes not only an entitlement to receive interest but also the opportunity to receive a certain number of shares instead of repayment of the loan. This additional advantage means that the rate of interest of the convertible loan is lower than market interest rates for a corresponding bond loan. The fair value of the benefit to Oasmia due to this lower rate of interest, TSEK 382, is booked, after deductions for issue expenses, directly against equity. The pure loan part of the convertible instruments, that is to say excluding the above-mentioned equity part, is recognized, with deductions for issue expenses, at its fair value as a liability in the balance sheet when it is first booked. Interest expenses are subsequently calculated in accordance with the effective interest method and are charged to the income statement.

As the interest rate up until maturity is pursuant to a written agreement, there is a liquidity risk but no interest-rate risk.

TSEK	APR 30, 2016	APR 30, 2015
Convertible loan	25,549	-
<b>Total</b>	<b>25,549</b>	<b>0</b>

- Liabilities to credit institutions to the tune of TSEK 20,000 as of April 30, 2016 compared to TSEK 20,000 as of April 30, 2015 comprise a bank loan that matures on September 30, 2016. The amortized cost equals fair value. The interest rate is tied to Stibor and there is thus both an interest-rate risk and a liquidity risk attached to this loan. During the financial year ending April 30, 2016, interest of TSEK 364 compared to TSEK 1,056 in the financial year ending April 30, 2015 and TSEK 665 in the financial year ending April 30, 2014 for this loan was recognized as financial expenses in the income statement.

TSEK	APR 30, 2016	APR 30, 2015
Bank loan	20,000	20,000
<b>Total</b>	<b>20,000</b>	<b>20,000</b>

Oasmia has pledged fixed income funds amounting to TSEK 20,000 as of April 30, 2016 compared to TSEK 20,000 as of April 30, 2015 as collateral for this loan, with the creditor as beneficiary. See "Financial assets valued at fair value" above.

In addition to this loan, Oasmia also has a granted but unutilized overdraft facility amounting to TSEK 5,000 as of April 30, 2016 compared to TSEK 5,000 as of April 30, 2015. A chattel mortgage has been taken out with the bank as collateral for this overdraft facility. See Note 24 "Contingent liabilities and pledged assets".

- Accounts payable to the tune of TSEK 27,236 as of April 30, 2016 compared to TSEK 14,017 as of April 30, 2015, and Accrued expenses and deferred income of TSEK 11,693 as of April 30, 2016 compared to TSEK 8,053 as of April 30, 2015, in total TSEK 38,929 as per April 30, 2016 compared to TSEK 22,070 as of April 30, 2015, comprise small liabilities to a large number of suppliers and accrued interest for the above-mentioned loan. Amortized cost equals fair value. Of this figure, TSEK 23,026 as of April 30, 2016 compared to TSEK 11,137 as of April 30, 2015 is liabilities in a currency other than SEK. These involve a currency risk. In addition to this currency risk, there is also a liquidity risk attached to these liabilities.

#### NOTE 19 PREPAID EXPENSES AND ACCRUED INCOME

TSEK	APR 30, 2016	APR 30, 2015
Prepaid rent	1,036	854
Prepaid insurance premiums	578	116
Other prepaid expenses	1,271	717
<b>Total</b>	<b>2,885</b>	<b>1,687</b>

#### NOTE 20 OTHER CURRENT RECEIVABLES

TSEK	APR 30, 2016	APR 30, 2015
VAT receivable	1,897	2,532
Other current receivables	32	35
<b>Total</b>	<b>1,929</b>	<b>2,566</b>

#### NOTE 21 SHARE CAPITAL

Specifications of changes in equity are presented in this report immediately after the statement of financial position. The total number of shares as of April 30, 2016 was 107,209,310 type A compared to 97,858,144 as of April 30, 2015 and 85,572,330 as of April 30, 2014 with a quota value of SEK 0.10 per share. All issued shares have been fully paid for. The development of the number of shares since May 1, 2013 is shown below.

	Number of shares	Share capital, SEK
<b>Opening balance, May 1, 2013</b>	<b>81,772,330</b>	<b>8,177,233</b>
2014 Private placement*	3,800,000	380,000
<b>Closing balance, Apr 30, 2014</b>	<b>85,572,330</b>	<b>8,557,233</b>
<b>Opening balance, May 1, 2014</b>	<b>85,572,330</b>	<b>8,557,233</b>
2014 Private placement *	2,500,000	250,000
2014 Rights issue	9,785,814	978,581
<b>Closing balance, Apr 30, 2015</b>	<b>97,858,144</b>	<b>9,785,814</b>
2015 New share issue	7,684,500	768,450
2016 Private placement*	1,666,666	166,667
<b>Closing balance, Apr 30, 2016</b>	<b>107,209,310</b>	<b>10,720,931</b>

\* Private placement to a limited number of investors.

**NOTE 22 OTHER CURRENT LIABILITIES**

TSEK	APR 30, 2016	APR 30, 2015
Employee withholding tax/social security contributions	2,068	1,796
<b>Total</b>	<b>2,068</b>	<b>1,796</b>

**NOTE 23 ACCRUED EXPENSES AND DEFERRED INCOME**

TSEK	APR 30, 2016	APR 30, 2015
Accrued personnel costs	8,585	7,992
Accrued costs for clinical trials	5,030	2,844
Accrued interest expenses	2,890	2,463
Other accrued expenses	2,856	1,819
Deferred income	917	927
<b>Total</b>	<b>20,278</b>	<b>16,045</b>

**NOTE 24 CONTINGENT LIABILITIES AND PLEDGED ASSETS****Contingent liabilities**

The Group had no contingent liabilities during the period.

**Pledged assets**

The Parent Company has TSEK 20,000 as of April 30, 2016 compared to TSEK 20,000 as of April 30, 2015, invested in a frozen fixed income account as collateral for a bank loan in the corresponding amount. The Parent Company has taken out a chattel mortgage of TSEK 8,000 as of April 30, 2016 compared to TSEK 8,000 as of April 30, 2015, with a bank as collateral for an overdraft facility of TSEK 5,000 as of April 30, 2016 compared to TSEK 5,000 as of April 30, 2015, and as the limit for a foreign currency derivative of TSEK 3,000 as of April 30, 2016 compared to TSEK 3,000 as of April 30, 2015.

**NOTE 25 TRANSACTIONS WITH RELATED PARTIES****Group companies**

As per April 30, 2016, the Group consists of the Parent Company Oasmia Pharmaceutical AB, the Swedish subsidiaries Qdoxx Pharma AB and Oasmia Animal Health AB and the American subsidiary Oasmia Pharmaceutical, Inc. The subsidiaries are 100% owned and thus under the control of the Parent Company. For further information on the Group, please refer to Note 26 Holdings in Group companies.

**Intra-Group transactions**

There has been no sale of goods between the Parent Company and the subsidiaries during the year.

Oasmia Pharmaceutical AB contributed operating capital of TSEK 17 during the financial year ending April 30, 2016 compared to TSEK 31 during the financial year ending April 30, 2015 and TSEK 40 during the financial year ending April 30, 2014 to Qdoxx Pharma AB and TSEK 4 to Oasmia Animal Health AB during the financial year ending April 30, 2016 compared to TSEK 4 during the financial year ending April 30, 2015 and TSEK 2 during the financial year ending April 30, 2014. An amount of KUSD 135, recognized as TSEK 1,148 in the financial year ending April 30, 2016 compared to TSEK 0 in the financial years ending April 30, 2015 and 2014 respectively, was paid as share capital and a shareholder's contribution to Oasmia Pharmaceutical Inc. Apart from this, there were no transactions between the Parent Company and Oasmia Pharmaceutical, Inc and there were no intra-group balances at closing day.

Oasmia Pharmaceutical AB's debt to Qdoxx Pharma AB amounted to TSEK 99 as of April 30, 2016 compared to TSEK 116 as of April 30, 2015 and TSEK 87 as per April 30, 2014 at closing day and its debt to Oasmia Animal Health AB amounted to TSEK 205 as of April 30, 2016 compared to TSEK 208 as of April 30, 2015 and TSEK 197 as of April 30, 2014.

**Group contributions from Oasmia Pharmaceutical AB to the subsidiaries**

No Group contributions were paid in the financial year ending April 30, 2016. During the financial year ending April 30, 2015 the Parent Company paid a Group contribution of TSEK 60 to Qdoxx Pharma AB compared to TSEK 80 during the financial year ending April 30, 2014 and TSEK 15 during the financial year ending April 30, 2015 to Oasmia Animal Health AB compared to TSEK 0 during the financial year ending April 30, 2014.

**Transactions with key people in senior positions**

For salaries and remuneration to the Board and senior executives, please refer to Note 10. Companies associated with some of the Board members invoiced Oasmia during the year for advisory and legal services rendered. The fees in this connection were in line with market rates and totaled TSEK 251 as of April 30, 2016 compared to TSEK 0 as of April 30, 2015 and April 30, 2014 respectively.

**Financial loan transactions with related parties**

On April 30, 2016 there was a credit facility of TSEK 40,000 compared to TSEK 40,000 as of April 30, 2015, available to Oasmia from Alceco International S.A., the company's largest shareholder. If the facility is utilized the interest rate is 5%. This credit facility was utilized to the tune of TSEK 35 during part of the financial year but at April 30, 2016 this credit facility was completely unused, as was the case at April 30, 2015.

On April 30, 2016 Oasmia had a loan from Nexttobe AB, Oasmia's second largest shareholder, amounting to TSEK 94,395 compared to TSEK 87,000 as of April 30, 2015. The loan carries fixed interest rate of 8.5%, which is to be paid when the loan matures on December 30, 2016. At April 30, 2016 the accrued interest expense for the loan amounted to TSEK 2,653 compared to TSEK 2,431 in financial year ending April 30, 2015.

**Other transactions with related parties**

Ardenia Investment Ltd, which is equally controlled by Oasmia's founders Bo Cederstrand and Julian Aleksov, is registered as the applicant for and the holder of the underlying patents for Oasmia's business. Pursuant to an agreement between Ardenia and Oasmia, the rights to these patents have been transferred to Oasmia. Ardenia re-charged for administrative expenses for these patents during the year. These invoices amounted to TSEK 2,233 in the financial year ending April 30, 2016 compared to TSEK 1,404 in the financial year ending April 30, 2015. Oasmia has no obligations to Ardenia at April 30, 2016.

**NOTE 26 HOLDINGS IN GROUP COMPANIES**

As per April 30, 2016			Ownership	Votes %
Parent Company	Reg. No.	Domicile	%	
Qdoxx Pharma AB	556609-0154	Uppsala, Sweden	100	100
Oasmia Animal Health AB	556519-8818	Uppsala, Sweden	100	100
Oasmia Pharmaceutical, Inc.	E0300362015-6	Nevada, USA	100	100

As per April 30, 2015			Ownership	Votes %
Parent Company	Reg. No.	Domicile	%	
Qdoxx Pharma AB	556609-0154	Uppsala, Sweden	100	100
Oasmia Animal Health AB	556519-8818	Uppsala, Sweden	100	100

**NOTE 27 KEY DEFINITIONS**

**Earnings per share:** Income for the year attributable to Parent Company shareholders divided by the weighted average number of shares, before and after dilution, in the period.

The key figures above are assessed to be relevant to the type of business activities conducted by Oasmia and contribute to an increased understanding of the financial report.

**SUBSIDIARIES OF THE COMPANY**

Subsidiary Name	Jurisdiction of Incorporation/Formation
Oasmia Pharmaceutical, Inc.	State of Nevada
Oasmia Animal Health AB	Sweden
Qdoxx Pharma AB	Sweden



**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER**

I, Mikael Asp, certify that:

1. I have reviewed this annual report on Form 20-F of Oasmia Pharmaceutical AB;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: August 26, 2016

/s/ Mikael Asp

Name: Mikael Asp

Title: Chief Executive Officer (Principal Executive Officer)

**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER**

I, Julian Aleksov, certify that:

1. I have reviewed this annual report on Form 20-F of Oasmia Pharmaceutical AB;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: August 26, 2016

/s/ Julian Alexsov

Name: Julian Aleksov

Title: Chief Financial Officer (Principal Financial Officer)

**PRINCIPAL EXECUTIVE OFFICER CERTIFICATION  
PURSUANT TO 18 U.S.C. SECTION 1350**

In connection with this Annual Report of Oasmia Pharmaceutical AB (the "Company") on Form 20-F for the year ended April 30, 2016 as filed with the Securities and Exchange Commission (the "SEC") on or about the date hereof (the "Report"), I, Mikael Asp, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to the Company and will be retained by the Company and furnished to the SEC or its staff upon request.

Date: August 26, 2016

/s/ Mikael Asp

Name: Mikael Asp

Title: Chief Executive Officer (Principal Executive Officer)

**PRINCIPAL EXECUTIVE OFFICER CERTIFICATION  
PURSUANT TO 18 U.S.C. SECTION 1350**

In connection with this Annual Report of Oasmia Pharmaceutical AB (the "Company") on Form 20-F for the year ended April 30, 2016 as filed with the Securities and Exchange Commission (the "SEC") on or about the date hereof (the "Report"), I, Julian Aleksov, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to the Company and will be retained by the Company and furnished to the SEC or its staff upon request.

Date: August 26, 2016

/s/ Julian Aleksov

Name: Julian Aleksov

Title: Chief Financial Officer (Principal Financial Officer)