FINANCIAL STATEMENT
1 January 2017 to 31 December 2017

PharmaLundensis AB (publ)
556708-8074

The English text of the Financial Statement is an unofficial office translation. In the event of any discrepancy between the Swedish and the English texts, the Swedish text shall prevail.

1. Financial statement in summary

Final quarter (1 October 2017 to 31 December 2017)
✓ Net sales in the final quarter amounted to SEK 0 (0).
✓ Loss after financial items amounted to SEK -7 368 968 (-921 308).
✓ Earnings per share* amounted to SEK -0.36 (-0.05).
✓ Equity ratio** on 31 December 2017 was 82%.

Full year (1 January 2017 to 31 December 2017)
✓ Net sales for the financial year amounted to SEK 0 (0).
✓ Loss after financial items amounted to SEK 11 648 603 (-3 938 736).
✓ Earnings per share* amounted to SEK -0.57 (-0.21).

** Loss for the period divided by 20 280 344 (18 796 418) outstanding shares.*
*** Shareholders' equity divided by total shareholders' capital.*

- The company's further development of Iodocarb aimed at reducing the release of iodine has been successful. The new iodated carbon, **Iodocarb novum**, releases around 70% less iodine while retaining the full effect of binding mercury. It can therefore be expected that the same positive effects on lung function that were shown in the first study will be achieved, but without any side effects in the thyroid. Two new clinical studies focused on Iodocarb novum will start in 2018.
- An EcoFilter® system has been developed that can eliminates all release of drug residues and multi-resistant bacteria in hospital wastewater. This technology is protected by four patent applications. Contacts have been made with a number of major actors in associated fields. Various types of financing are being considered. This project could generate large revenues in the future.
- Good progress is being made in the development of 'Bronkitstopp', a medical technical product that treats coughing and mucus during chronic bronchitis. The new manufacturing method for high-quality iodated carbon will also benefit this product. An application to the Notified Body for CE marking of 'Bronkitstopp' is being prepared. There is great interest in this product and this could lead to significant revenues in the near future.
- With the new iodated carbon recording significantly improved properties compared with the older product, the company has decided to perform future clinical studies with the new product. The COPD study recently started using IodoCarb comp has therefore been cancelled and the development expenses for this study have been capitalised for accounting purposes. The same applies for amounts reported previously in 2017. This produced a negative effect on earnings of SEK 4 061 210 for amounts capitalised in 2017 and a negative effect of SEK 1 874 060 for expenses capitalised in previous reports in 2017.

2. Project status

COPD
The company's further development of Iodocarb aimed at reducing the release of iodine has been successful. The new iodated carbon, **Iodocarb novum**, releases around 70% less iodine while retaining the full effect of binding mercury. It can therefore be expected that the same positive effects on lung capability that were shown in the first study will be achieved, but without any side effects in the thyroid. In the near future, we plan to focus the company's resources on developing Iodocarb novum as a drug, as it is expected to be easier and faster to get this treatment approved. However, after Iodocarb novum has been registered, it may be necessary to resume studies with perchlorate supplements as they appear to provide an extra, synergistic improvement in lung function. This can be especially valuable for patients suffering from a severe form of COPD. The clinical study with Iodocarb comp (iodine carbon + perchlorate) has been discontinued and capitalized development costs have been recorded for accounting reasons. Another important advantage of the new iodated carbon is that it may be possible to protect as a new patent family. We can thus obtain patents in many countries where we today do not have patent protection, while establishing even stronger protection in countries where we currently have patents. This also increases our chances to successfully implement the company's Iodocarb **Business Plan** (see page 16), based on the use of license revenues from smaller markets to finance the company's organization of registration and sales in the largest, most valuable markets, with the aim of maintaining control over the COPD project and optimize revenues in those markets. We have established contact with a number of pharmaceutical companies from Asia and Europe who may be interested in licensing our COPD drug. Two new clinical studies focused on Iodocarb novum will start in 2018.

EcoFilter®
Major progress was also made in the company's second main project, EcoFilter®. A system was developed that can eliminate all releases of drug residue and multi-resistant bacteria in hospital wastewater. The system also eliminates multi-resistant bacteria from the pipes, meaning there is no risk that the bacteria will go back into the wards and infect patients and staff. Two new patent applications were submitted to protect this concept. The company's old EcoFilter applications received positive verdicts from Swedish and international inspectors. The problem of drug emissions from healthcare buildings is highly topical and many businesses are trying to develop effective systems. We have made contact with several significant companies that are working in adjacent areas. We may choose to bring one or several partners into the project. We are also working on other forms of separate financing. A new **business plan** for EcoFilter® indicates that the system can generate significant income. By 2026 it is expected to generate a profit of EUR 54 million (see page 22). Clinical studies of the system are planned to start in the spring of 2018.

'Bronkitstopp'
Chronic bronchitis is characterized by prolonged cough, mucus in the chest and mucous membranes, and occurs in hundreds of thousands of people in Sweden alone. There is currently no effective treatment. Since iodated carbon has, in previous clinical

COPD studies, reduced cough and mucus production in patients, the company intends to develop a product to treat chronic bronchitis called 'Bronkitstopp'. This project will also benefit from the new production process for iodated carbon. We will now submit an application to the Notified Body for CE marking of 'Bronkitstopp'. There is a great interest in this product from the general public and the company receives many inquiries about it. This project is expected to generate significant revenue in the near future.

Influenza-induced lung failure

The company's new project aimed at developing a new treatment for influenza-induced pulmonary disease is highly topical at present. This year's flu virus is unusually troublesome and the existing vaccine only works against 27% of the virus[1]. Many people, including the elderly and children, have died of it. The antiviral drug Tamiflu has doubtful effects[2]. If we manage to develop effective treatment that prevents flu-induced lung complications, it can have a large market, both as a treatment for annual flu and as prevention in emergency preparedness for future "killer flu" viruses. The project is in the start-up phase.

1. http://www.vardgivarguiden.se/globalassets/behandlingsstod/smittskydd/statistik/influensa/influensasasongen-2017-2018.pdf
2. Yogendra Kumar Gupta, Meenakshi Meenu, and Prafull Mohan. The Tamiflu fiasco and lessons learnt. Indian J Pharmacol. 2015 Jan-Feb; 47(1): 11–16.

3. Significant events during the 2017 fiscal year

Patent Approved in Japan (26 January 2017)
PharmaLundensis' patent application that protects the treatment of chronic bronchitis with KI-impregnated (potassium iodide) activated carbon has now been approved in Japan (WO 2014/084763 A1). The patent will last until 2034.
CEO Dr Staffan Skogvall: I am pleased that we have now obtained the first approved patent for the company's bronchitis project. National patent applications have also been submitted in the EU, China and South Korea. PharmaLundensis plans to sell KI-impregnated activated carbon as a medical device for the treatment of chronic bronchitis. The rules for this are significantly less complicated than for medicines, so this product has the potential to reach the market relatively quickly. Sales are initially planned in our own webshop.

EcoFilter® patent approved in Sweden (3 February 2017)
The Patent and Registration Office in Sweden has announced that it is approving PharmaLundensis' patent applications that protect a central part of EcoFilter®, provided that some minor formal measures are taken that do not affect the scope of protection. The patent will be formally approved after these measures are taken.
CEO Dr Staffan Skogvall: I am pleased that we have now obtained the first approved patent for the EcoFilter® project. This patent is likely to be beneficial in negotiations with major partners and with healthcare organizations. I also hope that our international PCT application will eventually be approved and will be the basis for patent protection in many other countries.

Positive international PCT review for EcoFilter® patent (9 February 2017)
The European Patent Office has now issued a positive Written Opinion in which a number of method requirements protecting EcoFilter® are declared to meet all the requirements for patents (novelty, inventiveness and industrial applicability). This PCT application can thus be the basis for national patent applications in most countries in the world. PharmaLundensis has two patent applications to protect EcoFilter®. The present application belongs to Patent Application 2. The company recently received patent for Patent Application 1 in Sweden, see press release dated 3 February 2017.
CEO Dr Staffan Skogvall: It appears that we will have a strong patent protection for EcoFilter®. This is obviously very positive because it reduces the risk that competitors will win part of the large market for treatment of drugs in wastewater. Strong patent protection also increases our ability to attract larger partners in the EcoFilter® project.

New positive review report from the Swedish Patent and Registration Office for EcoFilter® (3 March 2017)
The Swedish Patent and Registration Office has given a positive response to PharmaLundensis' Patent Application 2 for EcoFilter®. The reviewer considers that all 20 method and device requirements meet all criteria for patentability in Sweden (novelty, inventiveness and industrial applicability). In addition, the reviewer has made a number of formal observations that the company's patent consultant assesses can be resolved without difficulty. PharmaLundensis has two patent applications that protect EcoFilter®. The current application has previously received a positive Written Opinion from the European Patent Office (press release date 9 February 2017).

PharmaLundensis recently also received a patent for Patent Application 1 in Sweden (press release dated 3 February 2017).
CEO Dr Staffan Skogvall: Thanks to this decision by the Swedish Patent and Registration Office, the EcoFilter® project, will have deeper and broader patent protection in Sweden. It is particularly positive that they have approved both the method requirements and the device requirements. It now seems likely that the patent protection for EcoFilter® will be strong. PharmaLundensis is therefore well placed to take a significant part of the large and valuable market for treatment of drugs in wastewater.

New share issue oversubscribed (14 March 2017)
In PharmaLundensis' new share issue, total subscriptions were received for 529,794 units. As the issue amounted to a maximum of 494,642 units, corresponding to approximately SEK 8.9 million, the subscription rate was approximately 107%. After issue costs of approximately SEK 400,000, the company will receive approximately SEK 8.5 million. Preferential rights subscriptions accounted for 40.6% of the units. The allocation of units subscribed without preferential rights will take place in accordance with the share issue decision. The new number of shares in the company will be 20,280,344 and the share capital is SEK 1,014,017.20. The Board and CEO give a warm thanks to everyone who subscribed to the issue!

Development and patenting of systems to eliminate all drug emissions (2 May 2017)
A system for eliminating all drug emissions from hospitals has been developed and patented. The system allows for the removal of drug residues that are excreted in both urine and faeces. When connected to toilets in hospitals, EcoFilter® technology can clean materials from both bedridden and mobile patients. The system is expected to be both efficient and cost effective. Two new patent applications protect the concept.
CEO Dr Staffan Skogvall: We have now developed a system that has the potential to solve the entire major problem with drug emissions from hospitals. It is estimated that the system will be able to completely eliminate these emissions in a cost-effective manner. I am convinced that this is the right path to tackle this serious threat to human health.

Development of new, life-saving treatment for influenza-induced pulmonary disease (30 June 2017)
Every winter, the world is affected by flu epidemics. Often the symptoms are quite mild, but sometimes they become very serious. Spanish flu caused 50-100 million deaths in 1918-1919 while Asian flu (1957-1958) and Hong Kong flu (1968-1970) resulted in millions of deaths[1]. In 2009, swine influenza spread and caused a great deal of death despite modern care. Influenza viruses can cause such severe airway inflammation that air passages collapse, which cannot be addressed with today's drugs. The only remedy is to place the patient in an artificial lung[2]. This is an extremely complicated technique, and there are only ten such units in Sweden. A major influenza epidemic with a virus strain that severely worsens lung function would be a nightmare and is considered by many experts as one of the greatest threats to the future of humanity.
PharmaLundensis has been running a project for a while to counteract lung disease caused by influenza. The project is run in-house and is expected to continue in the

coming year. During this time we will carry out lab tests to investigate whether pharmacological modification of a specific mechanism can effectively treat this lung disease. After patenting, we intend to outsource this concept to larger companies. The Board estimates that a successful drug will be procured and stored by emergency preparedness organizations around the world as protection against future dangerous flu epidemics. The medication may also be used by patients who develop pulmonary symptoms from the usual seasonal flu.
CEO Dr Staffan Skogvall: This is an exciting and interesting project with great potential. In order to develop a drug against this severe lung disease, you need to have extensive knowledge about lung physiology and pathology and address the correct mechanism. I judge that we have this competence in the company.

1. https://sv.wikipedia.org/wiki/Influensa
2. https://sv.wikipedia.org/wiki/Extrakorporeal_membranoxygenering

First patent for Iodocarb comp granted (8 September 2017)
PharmaLundensis' patent application protecting activated carbon impregnated with iodine or iodine salts in combination with perchlorate (Iodocarb comp) has now been granted in South Africa. The patent lasts for at least 16 years, with the possibility of a 5-year extension. This is the first patent for Iodocarb comp that has been granted. PharmaLundensis has also filed national patent applications in nine other markets (USA, Europe, China, Japan, Chile, Israel, Saudi Arabia, South Korea and Russia). As described in the Financial Statement, dated 16 February 2017, the company has the strategy of securing patent protection in the four major markets (EU, US, Japan and China), but also in at least one smaller country per continent outside the major markets. The plan is that a pharmaceutical company in that country licenses Iodocarb comp and then is responsible for sales across the region. A pharmaceutical company in South Africa will thus be responsible for the sale of Iodocarb in the majority of the African countries.
CEO Dr Staffan Skogvall: It is very positive that the first national patent for Iodocarb comp is now granted. There is therefore a greater probability of positive results in other regions. I think we will benefit greatly from this patent which will also be able to protect the new, improved iodated carbon that we are developing.

Approved Swedish trademark registration (22 November 2017)
The Swedish Patent and Registration Office (PRV) has announced that it has approved 'Bronkitstopp PharmaLundensis' as a trademark. The trademark applies for Group 5 (Pharmaceuticals) and Group 10 (Medical Devices and Instruments). Trademark registration is valid for up to 10 years. Registration Number: 542356.
CEO Dr Staffan Skogvall: "PharmaLundensis' various projects continue to develop well, and now the name of the medical device that treats chronic bronchitis has been approved. As described in our recently published quarterly report (16 November 2017), we are awaiting the result of the ongoing adjustment of the production of iodated activated charcoal before we submit the Bronkitstopp registration application.

Patent approved in Israel for Iodocarb comp (19 December 2017)
The Israel Patent Office has announced that the patent application submitted by PharmaLundensis for Iodocarb comp (WO2015075111 "Compositions for obtaining an improved lung function comprising activated carbon comprising adsorbed iodine

and/or an adsorbed iodide salt and a sodium/iodide symporter inhibitor.") is patentable. An application was previously approved in South Africa. It is also currently being assessed in eight other markets (USA, Europe, China, Japan, Chile, Saudi Arabia, South Korea and Russia). Patent protection will be valid until 2033 and may then be extended for a further five years.
CEO Dr Staffan Skogvall: "The patent application for the combination of Iodocarb and perchlorate will now be approved in a second country. It looks very probable that it will also be approved in other markets. This means that the business plan for Iodocarb comp, as described in point 3 of our Financial Statement dated 16 February 2017, can be implemented as planned. In short, the business plan means that PharmaLundensis will licence Iodocarb comp in smaller markets and use the revenue to build registration and sales organizations in the most important markets. The aim is to maintain control over the registration process in the major markets, thus optimizing revenues while avoiding PharmaLundensis becoming dependent on major partners. This patent is expected to be applicable for the new iodated carbon, which will soon be fully developed. The addition of perchlorate appears to provide a synergistic improvement in lung function, which may enable quick and efficient treatment for COPD patients."

CEO acquires shares
In 2017 CEO Staffan Skogvall acquired a total of 27,411 shares in PharmaLundensis.

4. Important events after the end of the period

Successful development of new, high quality Iodocarb (29 January 2018).
Over the past year, PharmaLundensis has carried out a process to further develop the method of production of the company's drug candidate, Iodocarb, for treatment of chronic obstructive pulmonary disease (COPD). The aim was to obtain a significant reduction in the release of iodine from the substance while retaining the full effect of binding mercury. This substance can be expected to show the same positive effects on lung capability that were shown in the company's first COPD study, but without any side effects in the thyroid. This development process has now been completed successfully.
The new iodated carbon, Iodocarb Novum, releases around 70% less iodine at all iodine levels (3%, 6% and 9%) compared with the old iodated carbon, see Fig 1 below. The mercury-binding capability is at least as good, or better, see Fig 2 below.
CEO Dr Staffan Skogvall: The new iodated carbon provides a significantly reduced release of iodine compared with the old iodated carbon, while the mercury-binding capability is at least as good. I consider that we have therefore solved the problems relating to the side effects in the thyroid. In 2018 we plan to initiate two new clinical studies for Iodocarb Novum. We will also end the current study concerning Iodocarb comp, because the new iodated carbon releases so little iodine that there is no need for adding perchlorate. Performing clinical studies with a drug that only contains iodated carbon (without perchlorate) will significantly simplify the registration process.
Another advantage with the new iodated carbon is that it can be protected as a new patent family. We can therefore maintain patents in many countries where we currently do not have patent protection, and strengthen our protection in the countries where we do currently have approved patents.
In summary I consider that the development of the new, high-quality Iodocarb Novum is an important milestone for our COPD project. It can be the key to success for this project!

Fig 1: Release of iodine from new (blue) and old type of Iodocarb.

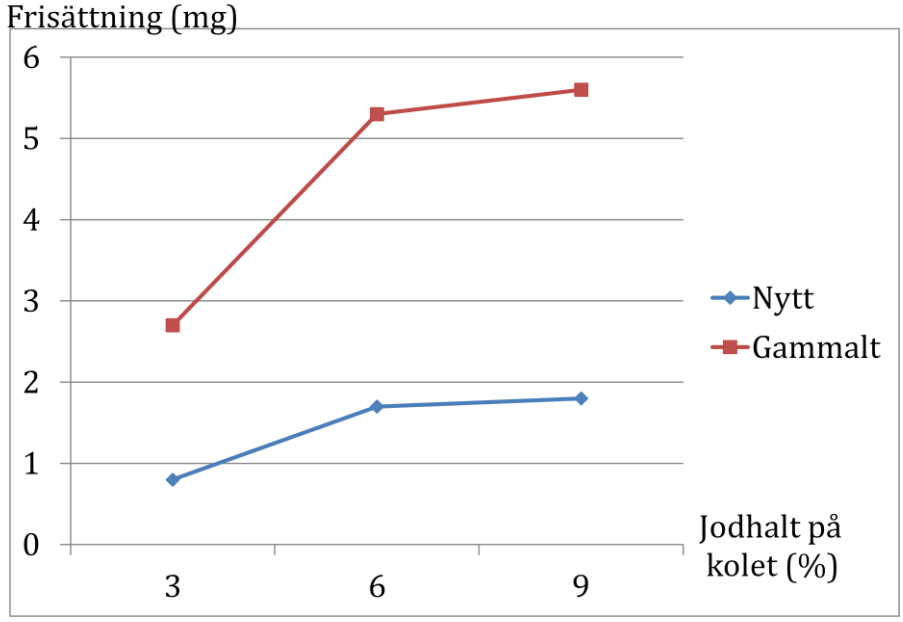
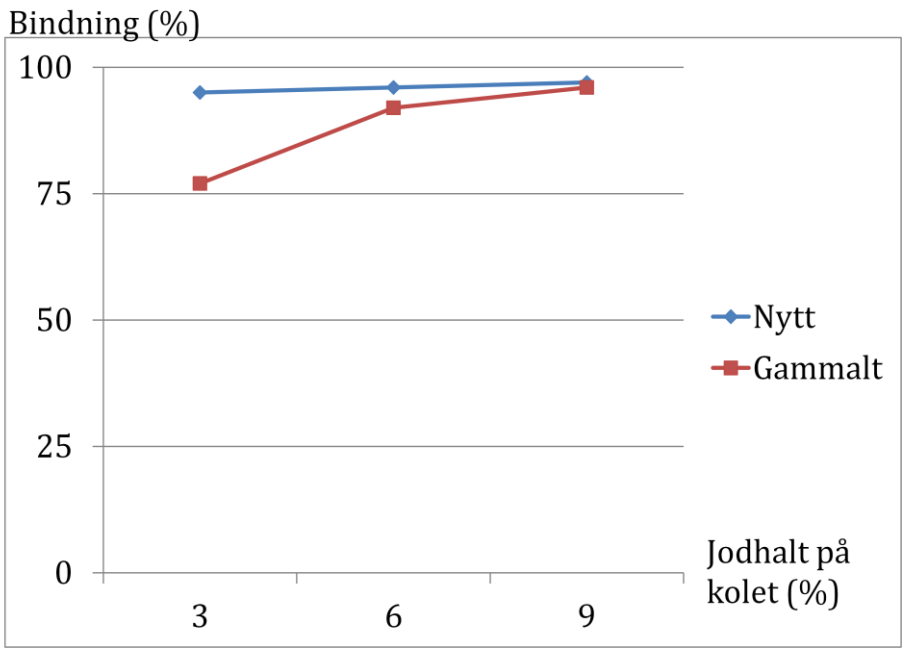


Fig 2: Mercury binding capacity in new (blue) and old type of Iodocarb.



5. CEO's statement

In 2017 we worked hard to address the side effects on the thyroid caused by iodine release from iodated carbon. To my great pleasure, this further development was successful! The new iodated carbon, **Iodocarb novum**, releases significantly less iodine, but the mercury-binding effect is at least as good. It is common in drug development that you first identify an important effect of a substance and then modify the properties of the substance to eliminate any side effects. This procedure is called lead optimization. I now estimate that the new iodated carbon can work well in the future and I look forward to conducting new COPD studies with it. I think we now have good opportunities for achieving positive results in upcoming clinical trials, both regarding positive outcomes and side effects.
The company's other main project, EcoFilter®, is extremely topical. There are regular reports in the media about increasing antibiotic resistance in society. Recently, the Public Health Agency of Sweden presented a report that predicts a doubling of antibiotic resistance in Sweden by 2030 and a four-fold increase by 2050[1]. This will mean additional costs of SEK 16 billion for the healthcare system. Hospital sewage systems have been described as hotspots for multi-resistant bacteria[2]. Authorities across Europe are calling for the development of systems that can prevent this problem. It is in this perspective that one should see the possibilities of our EcoFilter® system. I think that PharmaLundensis, thanks to our expertise, creativity and patent protection, is perfectly positioned to lead developments in this area.
'Bronkitstopp' is clearly a long-awaited treatment. We are regularly being asked when it will become available. We are now submitting an application to the Notified Body for CE marking of 'Bronkitstopp' for treatment of chronic bronchitis. I hope the product will be ready soon.

The company's new project for developing a new treatment for influenza-induced lung failure is also very topical because this year's flu virus is unusually difficult. Many people, both the elderly and children, have died of it. At the moment we are in the process of acquiring appropriate testing equipment. It will take a while to speed up the trials. I find this a very interesting project.
Looking back, the past year was very positive for PharmaLundensis with many significant advances in all our projects.
Yours sincerely,
Dr Staffan Skogvall, CEO

1. https://www.dagensmedicin.se/artiklar/2018/01/25/fyra-ganger-fler-antibiotikaresistenta-2050/
2. Hocquet D, Muller A, Bertrand X. What happens in hospitals does not stay in hospitals: antibiotic-resistant bacteria in hospital wastewater systems. J Hosp Infect. 2016 Aug;93(4):395-402.

6. Detailed information about the company's activities

A. IodoCarb comp – a new effective treatment for COPD

Summary
PharmaLundensis' COPD project is based on a unique treatment method that strongly increases the removal of heavy metals such as mercury from the body, thus restoring the normal capability of the lungs. A first clinical trial showed a significant improvement in lung functionality among COPD patients, but with side effects on the thyroid induced by iodine. The test substance has now been modified to release much less iodine. Clinical studies with the new test substance are intended to start in 2018 with the aim of establishing its clinical effects on lung capability. An effective drug for COPD could generate sales of over USD 1-2 billion per year. It is PharmaLundensis' aim to launch Iodocarb on the market within 2-3 years.

Background

Chronic Obstructive Pulmonary Disease (COPD) is a common and severe lung disease affecting more than 500,000 people in Sweden and around 400 million people in the world, corresponding to a global prevalence of 11.7 % in the age group of 30 years or above[1]. Patients experience impaired physical fitness, increasing breathlessness, coughing, and a number of other symptoms. The disease is usually progressive in spite of all existing treatment. Every year, around 3,000 people die in Sweden, and around 3 million throughout the world, from COPD.

1. Davies Adeloye et al. Global and regional estimates of COPD prevalence: Systemic review and meta-analysis. J Glob Health. 2015 Dec; 5(2): 020415.

Causes of COPD

COPD has traditionally been seen as mainly caused by tobacco smoke. Tobacco smoke contains many hazardous substances such as carbon monoxide, nicotine, tar, irritants and other noxious gases. There are also considerable amounts of heavy metals in the smoke such as lead, cadmium and mercury[1]. No one knows what component in the smoke that is the most harmful to the lungs.

Today, more and more people in the world are affected by COPD without smoking. It is now considered that air pollutants and various industrial emissions are also important risk factors for COPD[2].

1. M. Chiba and R. Masironi. Toxic and trace elements in tobacco and tobacco smoke. Bull World Health Organ. 1992; 70(2): 269–275.
2. Li Li, Jun Yang, Yun-Feng Song, Ping-Yan Chen & Chun-Quan Ou. The burden of COPD mortality due to ambient air pollution in Guangzhou, China. *Scientific Reports* **6**, Article number: 25900 (2016).

Hypothesis

PharmaLundensis' project is based on the hypothesis that the content in tobacco smoke of heavy metals such as lead, cadmium and mercury play a key role in the development of COPD[1+2]. A significant association between obstructive lung disease and serum cadmium and lead concentrations has previously been found[3]. When smoke is inhaled, a considerable amount of heavy metals such as mercury (Hg) will be retained in the airway epithelial cells, because they have a high oxidative capacity[4]. As

a result, epitelial cells convert Hgo to Hg2+ which is trapped within them. The build-up in the airways of heavy metals from the smoke impairs a crucial relaxant mechanism located in the epithelium. It has previously been shown by Dr Staffan Skogvall that a specific type of epithelial cells, so-called neuroepithelial endocrine (NEE) cells, release a powerful relaxing factor that normally keeps the airways open[5]. According to the hypothesis, the release of this relaxing factor decreases when heavy metals build up in the epithelial cells as a result of smoking, causing a gradual closure of mainly the small airways. This causes the airway obstruction that is typical for COPD.

1. M. Chiba and R. Masironi. Toxic and trace elements in tobacco and tobacco smoke. Bull World Health Organ. 1992; 70(2): 269–275.
2. Suzuki T, Shishido S, Urushiyama K. Mercury in cigarettes. Tohoku J Exp Med. 1976 Aug;119(4):353-6.
3. Haala K.Rokadia' ShikharAgarwal,Serum Heavy Metals and Obstructive Lung Disease: Results From the National Health and Nutrition Examination Survey. Volume 143, Issue 2, February 2013, Pages 388-397.
4. Khayat A, Dencker L.Whole body and liver distribution of inhaled mercury vapor in the mouse: influence of ethanol and aminotriazole pretreatment. J Appl Toxicol. 1983 Apr;3(2):66-74.
5. Skogvall S, Korsgren M, Grampp W. Evidence that neuroepithelial endocrine cells control the spontaneous tone in guinea pig tracheal preparations. J Appl Physiol. 1999 Mar;86(3):789-98.

New and effective treatment of COPD with Iodocarb

PharmaLundensis' COPD treatment IodoCarb is a substance that effectively binds and removes heavy metals from the body. Iodocarb consists of activated charcoal with adsorbed iodine. Activated charcoal is widely used in medicine to remove toxic substances from patients exposed to them[1]. If a patient comes to an emergency unit with poisoning symptom the patient will be given activated charcoal to bind the poison. By impregnating the activated charcoal it with iodine the capacity for binding heavy metals increases dramatically (metal binding capacity increases by more than 100 times, i.e. 10,000%)[2+3].

1. Neuvonen PJ, Olkkola KT. Oral activated charcoal in the treatment of intoxications. Role of single and repeated doses. Med Toxicol Adverse Drug Exp. 1988 Jan-Dec;3(1):33-58.
2. Henning K-D and Schäfer S. Impregnated activated carbon for environmental protection. Gas Sep Purif 1993 Vol 7(4):235-240.
3. Yoshimi Matsumura. Adsorption of mercury vapor on the surface of activated carbons modified by oxidation or iodization. Atmospheric Environment (1967), Volume 8, Issue 12, December 1974, Pages 1321-1327.

Mechanism of action

It is considered that Iodocarb acts by binding and removing heavy metals from the body. The substance can be mixed in water and drunk. How can oral Iodocarb, which is not absorbed in the body but merely passes through the intestine, improve the lung function? Heavy metals often display an enterohepatic recirculation where they are excreted by the liver in the bile, enters the small intestine and is subsequently readsorbed into the body again further down the small intestine[1+2]. As a result, it is very difficult for the body to excrete heavy metals. When Iodocarb is present in the

small intestine, heavy metals excreted in the bile are adsorbed to the iodated activated charcoal and excreted in the faeces, rather than being readsorbed back into the body. This breaks the enterohepatic recirculation, thereby allowing a greatly increased excretion of heavy metals.

1. Huang W, Zhang P, Xu H, Chang S, He Y, Wang F, Liang G. A novel route for the removal of bodily heavy metal lead (II). Nanotechnology. 2015 Sep 25;26(38):385101.
2. Clarkson TW. Factors involved in heavy metal poisoning. Fed Proc [01 Apr 1977, 36(5):1634-1639].

Significantly improved lung function by Iodocarb in clinical study

PharmaLundensis has conducted a double-blind, placebo-controlled, parallel-group clinical study involving 40 patients with moderate COPD that were given Iodocarb or placebo[1]. In the Iodocarb group, patients showed a statistically significant improvement of FEV_1 baseline by 130 ml compared to placebo, corresponding to 8.2% improvement. Correlation statistics revealed that the improvement of FEV_1 baseline was significantly correlated both to FEV_1 post-bronchodilator and FEV_1 post-exercise values. Furthermore, Iodocarb improved Home CAT-score by around 20%. No serious adverse effects directly related to the treatment were recorded. However, 8 patients in the Iodocarb group showed changes of the thyroid hormone levels. The thyroid side-effects were caused by some iodine leaving the carbon and entering the body. This can be reduced in two ways, through Iodocarb comp and Iodocarb novum.

1. Skogvall S, Erjefält JS, Olin AI, Ankerst J, Bjermer L. Oral iodated activated charcoal improves lung function in patients with COPD. Respir Med. 2014 Jun;108(6):905-9

Iodocarb comp

In order to reduce the absorption of iodine in the body, perchlorate can be added to the treatment. Perchlorate has been used for many years to treat thyreotoxicosis[1] and works by inhibiting the body's iodine pump. This reduces the absorption of iodide in the intestine[2], the thyroid[3] and the kidneys[4]. The treatment using Iodocarb and perchlorate is called Iodocarb comp. Preliminary experiments suggest a reduction of the thyroid side-effects. Surprisingly, they also suggest that perchlorate improves lung function. This synergistic improvement may be caused by perchlorate reducing the speed of the release of iodine from the activated carbon as a result of the inhibition of the intestinal iodine pump, thereby allowing Iodocarb to bind heavy metals for a longer time.

1. Morgans, ME and Trotter, WR. Treatment of thyreotoxicosis with potassium perchlorate. Lancet. 1954 Apr 10;266(6815):749-51.
2. Nicola JP, Basquin C, Portulano C, Reyna-Neyra A, Paroder M, Carrasco N. The Na+/I- symporter mediates active iodide uptake in the intestine. Am J Physiol Cell Physiol. 2009 Apr;296(4):C654-62. doi: 10.1152/ajpcell.00509.2008.
3. Wolff J. Perchlorate and the thyroid gland. Pharmacol Rev. 1998 Mar;50(1):89-105.
4. Spitzweg C1, Dutton CM, Castro MR, Bergert ER, Goellner JR, Heufelder AE, Morris JC. Expression of the sodium iodide symporter in human kidney. Kidney Int. 2001 Mar;59(3):1013-23.

Iodocarb Novum

PharmaLundensis has successfully further developed the manufacturing process for Iodocarb and produced a new iodated carbon with significantly reduced leakage of

iodine but with the same capability to bind mercury. This new iodated carbon is called Iodocarb novum. Because the release of iodine is so low it need not be combined with perchlorate, and this is expected to simplify and speed up the registration process for this drug. It may also be possible to give the patient a higher dose of Iodocarb, which may result in an even larger improvement of the lung function than what was found in the previous clinical study (130 ml improvement of FEV_1 baseline compared to placebo[1]). However, after Iodocarb novum has been registered, it may be necessary to resume studies with perchlorate supplements as they appear to provide an extra, synergistic improvement in lung function. This can be especially valuable for patients suffering from a severe form of COPD. The clinical study using IodoCarb comp (iodated charcoal + perchlorate) has been cancelled and the development expenses for this study have therefore been capitalised for accounting purposes.

1. Skogvall S, Erjefält JS, Olin AI, Ankerst J, Bjermer L. Oral iodated activated charcoal improves lung function in patients with COPD. Respir Med. 2014 Jun;108(6):905-9

Use of Iodocarb comp and Iodocarb Novum depends on the severity of disease

Patients with light-moderate COPD can be expected to have good results from Iodocarb Novum (without supplements of perchlorate). The advantage here is that it is expected to be easier and faster to get this treatment approved. However, when treating patients with severe COPD it may be appropriate to add perchlorate (Iodocarb comp) to get the added benefit of the synergistic improvement of the lung function.

Future clinical COPD studies

In the coming year, PharmaLundensis will initiate two new clinical studies:

1. Study involving 10-20 patients to establish that Iodocarb novum has no thyroid side effects.
2. Phase 2 study to determine the effects of Iodocarb Novum on lung function and walk test (60-80 patients) regarding COPD disease.

Treatment of air pollution-induced COPD (as opposed to tobacco smoke)

As mentioned above, an increasing number of patients today get COPD as a result of air pollution, rather than smoking. Air pollution, especially from the burning of fossil fuel, contains considerable amounts of heavy metals, just like tobacco smoke[1+2]. Since the toxic factors that cause COPD may be heavy metals in both cases, Iodocarb can also be expected to be able to treat air pollution-induced COPD. It may even be possible to PREVENT the development of COPD among inhabitants of polluted environments. This could be of great interest to people living in Asian cities where air pollution is high, who would not have to leave their homes.

1. Honda A, Tsuji K, Matsuda Y, Hayashi T, Fukushima W, Sawahara T, Kudo H, Murayama R, Takano H. Effects of air pollution-related heavy metals on the viability and inflammatory responses of human airway epithelial cells. Int J Toxicol. 2015 Mar-Apr;34(2):195-203.
2. https://www.epa.gov/international-cooperation/mercury-emissions-global-context#types

Patent protection

The main patent for Iodocarb (WO2009067067) is valid in most countries in the EU, China, Japan and Russia. Patent protection lasts at least until 2028 and is likely to be extended for another 5 years.

A national patent to protect Iodocarb comp (WO2015075111) in South Africa has

recently been granted, and patent is pending in USA, Europe, China, Japan, Chile, Israel, Saudi Arabia, South Korea and Russia. Patent protection lasts until 2033 and may be extended for another 5 years.
Patents for Iodocarb Novum are expected to cover many more markets, and extend protection on markets where patents already exist.

Potential for large revenues from Iodocarb
The costs of treating COPD are massive. In the United States, the costs in 2010 were USD 32.1 billion, which is expected to increase to USD 49 billion by 2020[1]. In other parts of the world, costs are also very high. Even though there is no effective treatment for COPD currently available, drugs against lung diseases generated a total of USD 25 billion in sales in 2012[2]. Throughout the world, there were approximately 400 million patients with COPD in 2010, and numbers increase each year[3]. Even if only 1% of these patients used IodoCarb at an annual cost of SEK 5,000, this would generate sales of SEK 20 billion / year (4 million patients x SEK 5,000 = SEK 20 billion in sales). Thus the income for PharmaLundensis from this project could be very large.

Business Plan
A quick and simple option that many smaller companies use to earn revenue from their drug candidates is to license them to a major pharmaceutical company and then get milestone remuneration and royalties. Such an arrangement might have the main advantage that the big company takes over the registration and marketing of the substance, while the small company does not have to build up large administrative units. The main drawback, however, is that the small company often receives a rather modest royalty, at best maybe 3-5%. Another significant disadvantage is that large companies often work in parallel with many projects, so there is a risk that the small company's projects will be neglected and delayed and may never generate any major revenue.
Another alternative, and according to the PharmaLundensis Board a better alternative, is that the company builds its own registration and sales organization in some core markets and then outsources the product on other markets in the world. In this way, license income from smaller markets finances costs in the major markets while PharmaLundensis maintains control over the registration process and sales in the largest markets and can optimize these revenues. A requirement for this to be carried out is that PharmaLundensis has patent protection in the relevant markets. The original COPD patent protects most countries in Europe, Russia, China and Japan. The company also has national patent applications in 10 countries to protect Iodocarb comp (USA, Europe, China, Japan, Chile, South Africa, Israel, Saudi Arabia, South Korea and Russia). Note that in addition to the four major markets, patent applications have also been submitted in at least one country per continent. The idea is that a pharmaceutical company in that country licenses Iodocarb and is responsible for sales across the region. Furthermore, Iodocarb novum is expected to result in patent protection in even more countries.

The future
If the planned COPD studies involving Iodocarb novum show good improvement of the lung function (at least 130 ml as obtained in the previous COPD study) without thyroid side-effects, it is likely that IodoCarb will be approved as a new COPD drug.

Through staggered, fast-track registration, Iodocarb may reach the market relatively quickly. PharmaLundensis ambition is to get the treatment on the market within 2-3 years.

B. EcoFilter®

Summary
PharmaLundensis is developing EcoFilter, which is a system that eliminates all release of drug residues and multi-resistant bacteria in hospital wastewater. In addition, it removes all multi-resistant bacteria from hospital sewage pipes, thereby eliminating the risk of multi-resistant bacteria entering hospital wards through pipes and infecting patients. Drug residues isolated from the sewage water will be sent for high-temperature destruction, while purified water can be released to the municipal wastewater system. We know of no other project or system that has all these capacities.

Background

The increasing resistance to antimicrobial medicinal products represents one of the major emerging threats to human health. Antibacterial medicinal products can be found with increasing frequency in wastewater and sewage sludge, and in parallel, an increased level and frequency of resistant bacteria in the environment has been observed. In a study on the occurrence of E. coli in sewage and sludge, it was shown that microorganisms with resistances to antibacterial medicinal products accumulated in the sludge. E. coli strains were found which were resistant to 16 out of 24 tested antibacterial medicinal products (penicillins, cephalosporins, aminoglycosides, quinolones, and others); the highest resistance rate (up to 57%) was found for tetracycline[1].

Current municipal sewage treatment plants are unable to remove drug residues and antibiotic resistant bacteria. On the contrary, it has been suggested that these plants promote the spread of antibiotic resistance[2+3]. If inadequately treated sludge is used as fertiliser in fields, plants may be contaminated and infect animals and humans, as shown in several cases[4].

In particular, hospital effluents are important contributors to the medicines released in the environment through urban effluents. In the EU, hospitals contribution to medicinal products environmental load is estimated at about 10% of urban effluents[5]. However, this share can be higher, as shown for instance in Denmark, where it is estimated that 24% of the total antibiotic load in the Copenhagen originates from hospitals. This figure rises to 43% if non-problematic penicillins are disregarded. When it comes to life-saving broad-spectrum antibiotics, most are used primarily in hospitals. As a result, hospitals are hotspots for antimicrobial-resistant bacteria and play a major role in both their emergence and spread[6]. Large numbers of resistant bacteria will be ejected from hospitals via wastewater systems. To make matters even worse, in wastewater treatment plants antibiotic resistance genes are transferred between bacterial species. Consequently, large amounts of multi-resistant bacteria are released in the environment.

1. Reinthaler FF, Posch J, Feierl G, Wüst G, Haas D, Ruckenbauer G, Mascher F, Marth E. Antibiotic resistance of E. coli in sewage and sludge. Water Res. 2003 Apr;37(8):1685-90.
2. Karen L. Jury , Stuart J. Khan , Tony Vancov , Richard M. Stuetz & Nicholas J. Ashbolt. Are Sewage Treatment Plant Promoting Antibiotic Resistance? Critical Reviews in Environmental Science and Technology Volume 41, 2011 – Issue 3, Pages 243-270.
3. Rizzo L, Manaia C, Merlin C, Schwartz T, Dagot C, Ploy MC, Michael I, Fatta-Kassinos D. Urban wastewater treatment plants as hotspots for antibiotic resistant bacteria and genes spread into the environment: a review. Sci Total Environ. 2013 Mar 1;447:345-60.

4. Heaton JC, Jones K. Microbial contamination of fruit and vegetables and the behaviour of enteropathogens in the phyllosphere: a review. J Appl Microbiol. 2008 Mar;104(3):613-26. Epub 2007 Oct 9.
5. Kümmerer K. Antibiotics in the aquatic environment–a review–part I. Chemosphere. 2009 Apr;75(4):417-34.
6. Hocquet D, Muller A, Bertrand X. What happens in hospitals does not stay in hospitals: antibiotic-resistant bacteria in hospital wastewater systems. J Hosp Infect. 2016 Aug;93(4):395-402.

Problems with today's hospital wastewater systems

Hospital sewage systems today have four important problems that must be addressed by a new wastewater treatment system:

1. Release of large amounts of pharmaceutical drugs in the hospital wastewater.
2. Release of multi-resistant bacteria and resistance genes in the hospital wastewater.
3. Epidemics in hospital patients caused by spread of multi-resistant bacteria from the hospital wastewater system.
4. Spread of multi-resistant bacteria from patients carrying them.

1. Release of antibiotics and other pharmaceutical drugs in the hospital wastewater.

Most patients are treated with pharmaceutical drugs at the hospital. The drugs are excreted in urine and faeces and flushed down the patients toilets. As a result, the wastewater contains high amounts of many pharmaceuticals which can have ecotoxic effects[1]. An especially important group is broad-spectrum antibiotics, which can lead to the development of multi- resistant bacteria in nature[2].

1. Frédéric O, Yves P. Pharmaceuticals in hospital wastewater: their ecotoxicity and contribution to the environmental hazard of the effluent. Chemosphere. 2014 Nov;115:31-9.
2. Gullberg E, Cao S, Berg OG, Ilbäck C, Sandegren L, Hughes D, et al. (2011) Selection of Resistant Bacteria at Very Low Antibiotic Concentrations. PLoS Pathog7(7): e1002158.

2. Release of multi-resistant bacteria and resistance genes in the hospital wastewater.

Large amounts of antibiotics are used in hospitals to treat patients with infections. The antibiotics are excreted in the urine and faeces and flushed down the patients' toilets. This leads to a continuous presence of large amounts of antibiotics in the hospital sewage pipes. As is always the case when large amounts of bacteria are exposed to antibiotics for a long time, the bacteria in the hospital sewage system become resistant to the drugs. Consequentially, hospital sewage water contains large amounts of multi-resistant bacteria[1]. These bacteria can spread and infect humans and animals. In addition, resistant bacteria supply antibiotic resistance genes that can spread to other bacteria especially in municipal treatment plants, which subsequently can infect vegetables, animals and people[2]. Furthermore, it has been shown that animal vectors such as Rattus norvegicus living in hospital sewage systems carry pathogens responsible for fatal diseases in humans as a result of the large outflow of antibiotics and antibiotic-resistant bacteria into the wastewater systems[3].

What happens in hospitals does not stay in hospitals: antibiotic-resistant bacteria in hospital wastewater systems. J Hosp Infect. 2016 Aug;93(4):395-402.
2. Rizzo L, Manaia C, Merlin C, Schwartz T, Dagot C, Ploy MC, Michael I, Fatta-Kassinos D. Urban wastewater treatment plants as hotspots for antibiotic resistant bacteria and genes spread into the environment: a review. Sci Total Environ. 2013 Mar 1;447:345-60. doi: 10.1016/j.scitotenv.2013.01.032. Epub

2013 Feb 7.
3. Hansen TA, Joshi T, Larsen AR, Andersen PS, Harms K, Mollerup S, Willerslev E, Fuursted K, Nielsen LP, Hansen AJ. Vancomycin gene selection in the microbiome of urban Rattus norvegicus from hospital environment. Evol Med Public Health. 2016 Aug 3;2016(1):219-26.

3. Epidemics in hospital patients caused by multi-resistant bacteria from the hospital waste water system.

There are many factors that have been found to contribute to contamination of clinical areas resulting in serious epidemics in hospital patients, including faulty sink, shower and toilet design, clean items stored near sluices, and frequent blockages and leaks from waste pipes[1]. Blockages can be caused by paper towels, patient wipes, or improper use of bedpan macerators. Furthermore, it has been demonstrated that bacteria in standard sink water traps in seven days form a bio-film that extends up to the sink valve. When the tap is flushed afterwards, bacteria sprout up to a meter around the sink, after which the bacteria can infect patients[2]. If the bacteria are multi-resistant, they can cause very serious epidemics.

1. Breathnach AS, Cubbon MD, Karunaharan RN, Pope CF, Planche TD. Multidrug-resistant Pseudomonas aeruginosa outbreaks in two hospitals: association with contaminated hospital waste-water systems. J Hosp Infect. 2012 Sep;82(1):19-24.
2. Shireen Kotay, Weidong Chai, William Guilford, Katie Barry and Amy J. Mathers. Spread from the Sink to the Patient: in situ Study Using Green Fluorescent Protein (GFP) Expressing- Escherichia coli to Model Bacterial Dispersion from Hand Washing Sink Trap Reservoirs. Appl Environ Microbiol. 2017 Mar 31:83(8).

4. Spread of multi-resistant bacteria from patients carrying them.

Many patients in hospitals, especially those receiving longer care, carry multi-resistant bacteria in their intestines or urinary tracts[1]. As a result, large amounts of multi-resistant bacteria are flushed down in hospital toilets every day. In the hospital sewage pipes these bacteria can spread and multiply and return to the hospital ward as describe above, infecting other patients. Furthermore, the multi-resistant bacteria can leave the hospital in the wastewater and spread its resistant genes to other bacteria in the municipal treatment plant and infect even more people.

1. Hogardt M, Proba P, Mischler D, Cuny C, Kempf VA, Heudorf U. Current prevalence of multidrug-resistant organisms in long-term care facilities in the Rhine-Main district, Germany, 2013. Euro Surveill. 2015;20(26):pii=21171.

EcoFilter® Technology

The EcoFilter® technology consists of the use of evaporators to remove water from liquids containing drug residues, as described in PharmaLundensis Patent application 1. The basis for this separation is that water boils away at 100 degrees while drug needs 600-800 degrees or more to evaporate. By removing nearly all water from the waste water with dissolved drugs, the drug residues are isolated and can easily be sent for destruction. Compare with a teaspoon of salt poured into a pan of boiling water. First, the salt dissolves and disappears, but if you boil away all the water, the salt will deposit on the walls of the pan. It will then be easy to collect the salt deposits for further treatment. This is a robust and well-proven technology that we use in a new way. However, the system generates large amounts of waste material and in Patent application 2 we describe how the amount of waste material can be reduced, making the process much more economical.

There are many other practical issues that also need to be solved to establish a functioning system in a hospital. This is protected in EcoFilter® Patent Applications 3 + 4, which have not yet been published.

Positive results in clinical trials with EcoFilter® prototype
Studies with a prototype to clarify the capacity of EcoFilter® to remove urinary antibiotics from patients treated with very high doses of broad spectrum antibiotics have been carried out. The tests showed:

- That untreated urine from these patients contained extremely high amounts of antibiotics with a very pronounced antibacterial effect. Thus, the antibiotics had not been broken down or metabolized to a significant extent as it passed through the body.
- That urine treated with EcoFilter® completely lacked antibacterial effect - all antibiotics had been eliminated.
- Thus, EcoFilter® fully meets all required cleaning requirements.

In these tests, the antibacterial effect was evaluated by a biological bioassay where the germicidal effect of urine on bacteria growing on culture plates was determined. The following broad spectrum antibiotics were included in the test: Bensylpenicillin, Cefotaxim, Cefuroxim, Cloxacillin, Erytromycin, Metronicazol, Rifampicin, Trimetoprim-sulfa and Piperacillin-tazobaktam.
The tests are described in greater detail here:
Rapport 1 och Rapport 2
1. http://www.pharmalundensis.se/wp-content/uploads/2015/05/PharmaLundensis-press-140701.pdf
2. http://www.pharmalundensis.se/wp-content/uploads/2015/05/EcoFilter.pdf

Competitors
The methods to eliminate drug residues from hospital effluents are just developing, and there is probably no company which at present can offer a fully functional system for removal pharmaceutical drugs and multi-resistant bacteria from hospital waste water systems. However, there are several groups that work with this problem using various methods.
Akademiska sjukhuset in Uppsala, Sweden has a pilot project with ozone.
http://www.akademiska.se/press#/pressreleases/reningsverk-paa-akademiska-ska-minska-antibiotikaresistens-1242668
It is not expected that this project can reduce the amount of multi-resistant bacteria or resistance genes in hospital sewage systems.
In Linköping, Sweden, a treatment plant for removal of drug residues from municipal waste water is being built. For the purpose, ozone is used. It is expected to remove 90 % of drug residues.
https://www.tekniskaverken.se/innovation/rening-av-lakemedelsrester/

It is not expected that this project can reduce the amount of multi-resistant bacteria or resistance genes in hospital sewage systems.
Herlev Hospital in Denmark uses several techniques to remove drugs from the wastewater (membrane bioreactor, ozone, activated carbon, and Ultraviolet (UV)

rays). This results in a high level of purification, but the process is complicated and expensive. Furthermore, it is not expected that this project can reduce the amount of multi-resistant bacteria or resistance genes in hospital sewage systems.
https://www.dhigroup.com/global/news/2016/08/hospital-wastewater-from-a-pollution-problem-to-new-water-resources

Swedish authorities wish to eliminate drug emissions
Today, there is a great understanding that drug emissions in nature are harmful and that drug residues must therefore be removed from wastewater. The Swedish Environmental Protection Agency has investigated if it is possible to clean away hazardous remains and recently presented its report
Naturvårdsverket 2017 Rening av Läkemedelsrester.
A summary of the report is available in Swedish at SVT News: Sverigesradio.se

The Swedish Environmental Protection Agency considers that it may be possible to prevent drug emissions by providing municipal treatment plants with more efficient technologies such as carbon filters or ozone treatment. After rebuilding the largest treatment plants, the Swedish Environmental Protection Agency estimates the additional cost of cleaning at up to SEK 600 million per year. This refers to annual operating expenses, and the initial investment required would cost many more millions. About half of all wastewater would then be purified from pharmaceuticals. Other organizations point to a number of difficulties with today's technology. A report from the Swedish University of Agricultural Sciences describes a pilot project at Uppsala University Hospital in which there was an attempt to remove drug residues from urine:
Eskebaek 2016 – Rening Läkemedelsrester i urin. Here, it appears that the bio-carbon adsorbed antibiotics up to a maximum of 55% in trials. Less particle size, longer contact time and shaking were required for better bonding. The addition of ozone yielded only a few percent reduction in antibiotic levels, while the addition of enzymes (Pharem Biotech) to break down the antibiotic did not work at all. Other problems identified in the Swedish Environmental Protection Agency's report are that it will take time to develop existing technology to suit large-scale treatment, as well as to fund and implement the expansion. In Switzerland, which is perceived as a pioneer country, the goal is to have effective cleaning of drug emissions by 2040, which is 25 years after the law came into force in January 2016.

Business Plan
The project is expected to be commercialized in three phases:
1. Installation at some hospitals in Sweden during the testing of the system.
2. Installation at most hospitals in Sweden and the rest of the Nordic countries. The hospitals subscribe to the system and pay a first elevated fee to cover the installation of the system. Expected revenue 2026: EUR 45.5 million, costs: EUR 31 million, profit: EUR 14.5 million.
3. Licensing of the PharmaLundensis systems to local companies in the recycling industry in other EU countries. Licensing to already established local players is expected to increase the acceptance of the system and provide a faster market penetration. Expected license fee approximately 10% of sales.

Expected license revenue 2026: EUR 44.5 million, costs: EUR 5 million, profit: EUR 39.5 million.

Overall, this gives an expected profit of EUR 54 million in 2026.

C. Treatment for chronic bronchitis

Background
Chronic bronchitis is characterized by persistent coughing and mucus production. Many people feel distressed by constantly having to clear their throats. Bronchitis can lead to the more serious disease, COPD. Chronic bronchitis is common and occurs in hundreds of thousands of people in Sweden often together with COPD. There is no effective treatment today. The condition can be alleviated by stopping smoking.

Improvement of cough and mucus production was demonstrated in clinical COPD study
In the completed clinical COPD study, patients reported a decrease in discomfort relating to coughing and mucus production compared to placebo. This result will be the basis for registration of this medical device.

New, more effective iodated charcoal
PharmaLundensis has developed a variation of iodated activated charcoal which may be suitable for the treatment of chronic bronchitis. This product is described in patent application WO2014084763, which was recently granted in Japan. Patent is pending in EU, China and South Korea. Of particular interest is that this application discloses that impregnation with 1.6 % iodine salt provides an equally effective mercury binding as impregnation with 8 % elemental iodine. This means that iodine salt is at least 5-10 times more effective than elemental iodine.

Registration of 'Bronkitstopp' as medical device
PharmaLundensis intends to register the new, more efficient type of iodated charcoal as a medical device for the treatment of chronic bronchitis (CE certification). The basis for registration is that the substance has no primary pharmacological, metabolic or endocrinological function (otherwise it would be classed as a drug), but instead it is thought to work by binding mercury in the intestine. Regulatory work for CE certification of the substance in progress. CE certification for a medical device enables sales across the EU. The name of the medical device in Sweden is planned to be 'Bronkitstopp'.

Sales
Once the product has been CE certified, it will be possible to start selling it. There may be sales in the company's own webshop, as well as through one or more pharmacy chains. Expansion can take place in more markets in Europe, such as Japan and China. The new manufacturing process for iodated charcoal can also lead to patenting opportunities in many more markets. Patients would take one capsule daily.

The regulatory work continues with 'Bronkitstopp'
Now that the company's further development of Iodocarb to reduce iodine release has proven successful, the regulatory work on 'Bronkitstopp' can be resumed. The application to the Notified Body for CE certification of the medical device product will be submitted during the spring.

D. Flu-induced Respiratory Failure

Every winter, the world is affected by flu epidemics. Often the symptoms are quite mild, but sometimes they become very serious. The Spanish flu caused 50-100 million deaths in 1918- 1919 and even the Asian flu (1957-58) and the Hong Kong flu (1968-70) resulted in millions of dead[1]. Today, the swine flu of 2009 spread and caused a great deal of death despite modern care. Influenza viruses can cause such severe airway inflammation that they collapse, which cannot be addressed with today's drugs. The only possibility is to place the patient in an artificial lung[2]. This is an extremely complicated technique, which can only be made available to a handful of patients. A major influenza epidemic of a virus strain that severely worsens lung function would be a nightmare and considered by many experts as one of the greatest threats to the future of humanity.

PharmaLundensis develops a treatment for flu-induced lung failure. Laboratory experiments will be performed to clarify if pharmacological modification of a specific mechanism can effectively treat this pulmonary disease. If the project is successful, we aim to patent and licence the treatment to larger partners. The board considers that a successful medicine will be acquired and stored by emergency preparedness organizations around the world as protection against future dangerous flu epidemics. In addition, an effective drug will be useful to many patients with pulmonary symptoms from the yearly seasonal flu.

1. https://sv.wikipedia.org/wiki/Influensa
2. https://sv.wikipedia.org/wiki/Extrakorporeal_membranoxygenering

7. The PharmaLundensis share

Shares in PharmaLundensis AB (publ) were first listed on 6 July 2010 on AktieTorget, which is a securities company under the supervision of Sweden's Finansinspektionen, and operates a trading platform called MTF (Multilateral Trading Facility). On 31 December 2017, the number of shares in the company amounted to 20,280,344. There is only one type of share. Each share entails equal rights to share in the company's assets and earnings and entitles the holder to one vote at the Annual General Meeting.

8. Risks

There are always risks in biotech companies. These include, inter alia, the ability to meet the emerging capital needs of the projects, the effects of the test substance and side effects in clinical trials, permissions from authorities, the company's ability to retain key personnel, existing and future competitors, sustainability of the patents, general business climate, currency risk and political risks. There is no guarantee that the healthcare provider chooses to use EcoFilter® to reduce drug release. Decisions on the use of the system may be delayed, for political, administrative or other reasons. It can not be ruled out that the system works worse than expected or that there are practical problems. It is not certain that patent applications for EcoFilter® will be granted or that granted patents have sufficient commercial strength. The bronchitis product may not be CE certified. It is possible that it is more advantageous to develop the product as a drug or otherwise. It is also not certain that any sales of such a product will generate larger revenues. Furthermore, it is not certain that patent applications will be granted or that granted patents have sufficient commercial strength. Furthermore, it is not certain that the project for the treatment of flu-induced lung failure will be successful, nor that such treatment can be patent-protected or generate significant revenues for the company.

9. Proposed allocation of earnings

The Board and CEO propose that no dividend be paid for the 2017 fiscal year.

10. Ownership of the company, 31 December 2017

Person	Position at PharmaLundensis	Shares as of 31-12-17	Ownership (%)	Shares as of 31-12-16	Ownership (%)	Options
SkåneÖrnen AB*		8 159 189	40,2	8 150 106	43,4	0
Staffan Skogvall	CEO and Board member	2 581 068	12,7	2 562 412	13,6	0
Linus Sjödahl via Sjödahl Konsult	Chairman of the Board	1 184	0	1100	0	100 000**
Jonas Erjefält	Board member	0	0	0	0	100 000***
Ingela Skogvall-Svensson	Board member	0	0	0	0	100 000***
>3000 shareholders		9 538 903	47,0	8 082 800	43,0	

* Owned by Skogvall family, Staffan Skogvall is the signatory of the company and Board member but not an owner.
** Options issued privately by CEO Staffan Skogvall and thus do not dilute holdings of other shareholders.
*** Options issued following decision made by AGM on 17 June 2015. Options may be utilised from 1 July 2018 to 31 July 2018 with maximum dilution of 1.1%.

11. Financing
The existing funding is expected to be sufficient for a considerable part of 2018. There is a possibility that the company will receive revenues in 2018, for example from licensing agreements, from the treatment of chronic bronchitis or from the EcoFilter® project. However, it is also possible that a future new share issue may be applicable.

12. Annual Report
PharmaLundensis is planning to publish its annual report for the 2017 financial year ion the company's website (www.pharmalundensis.se) and AktieTorget's (www.aktietorget.se) website in May 2018. The Annual General Meeting is scheduled to be held in June 2018 in Lund, Sweden. The exact date of the Annual General Meeting will be presented at the latest in connection with the notice of the Annual General Meeting.

13. Review by auditors
The interim report has not been reviewed by the company's auditor.

14. Principles for the preparation of the interim report
The interim report has been prepared in accordance with the same accounting principles as in the company's annual accounts for the financial year ended 31st December 2016, that is, in accordance with the Annual Accounts Act and the Swedish Accounting Standards Board, BFNAR 2012:1.

15. Future financial reports
Q1: 17 May 2018
Q2: 16 August 2018-
Q3: 15 November 2018
Financial Statement: 21 February 2019

16. Submission of interim report
Lund, Sweden
15 February 2018
PharmaLundensis AB (publ)
Board of Directors

Income statement in summary

(SEK)	1 Oct 2017 - 31 Dec 2017 *3 months*	1 Oct 2016 - 31 Dec 2016 *3 months*	1 Jan 2017 - 31 Dec 2017 *12 months*	1 Jan 2016 - 31 Dec 2016 *12 months*
Net sales	0	0	0	0
Operating expenses				
Other external expenses	-2 889 871	-731 893	-6 455 715	-5 238 447
Personnel costs	-460 764	-247 947	-1 204 807	-1 297 791
Depreciation of tangible assets	-102 956	-102 267	-408 454	-408 454
Capitalized development expenditures	145 833	161 137	481 925	3 007 759
Other operating expenses	-4 061 210		-4 061 210	
Operating loss	**-7 368 968**	**-920 970**	**-11 648 261**	**-3 936 933**
Financial items				
Interest income and similar items	-	56	-	431
Interest expenses and similar items	-	-394	-342	-2 234
Loss after financial items	**-7 368 968**	**-921 308**	**-11 648 603**	**-3 938 736**
Loss before tax	**-7 368 968**	**-921 308**	**-11 648 603**	**-3 938 736**
Net loss for the period	**-7 368 968**	**-921 308**	**-11 648 603**	**-3 938 736**

Balance sheet in summary

(SEK)	31 Dec 2017	31 Dec 2016
ASSETS		
Fixed assets		
Intangible assets		
Capitalized expenditure for development and similar	5 729 434	9 308 719
Tangible assets		
Equipment, tools, fixtures and fittings	1 063 481	1 471 935
Financial assets		
Other securities held as fixed assets	1 000	1 000
Total fixed assets	**6 793 915**	**10 781 654**
Current assets		
Current receivables		
Other current receivables	206 395	121 164
Prepaid expenses and accrued income	193 792	182 679
Total current receivables	**400 187**	**303 843**
Cash and bank balances	2 107 825	1 451 209
Total current assets	**2 508 012**	**1 755 052**
TOTAL ASSETS	**9 301 927**	**12 536 706**

Balance sheet in summary, continued

(SEK)	31 Dec 2017	31 Dec 2016
EQUITY AND LIABILITIES		
Equity		
Restricted equity		
Share capital	1 014 017	939 821
Fund for development expenditures	1 178 480	3 007 759
	2 192 497	**3 947 580**
Non-restricted equity		
Share premium reserve	50 909 580	42 580 220
Profit or loss brought forward	-33 799 012	-31 689 555
Loss for the period	-11 648 603	-3 938 736
	5 461 965	**6 951 929**
Total equity	**7 654 462**	**10 899 509**
Liabilities		
Current liabilities		
Account payable - trade	598 329	452 941
Other liabilities	39 396	16 780
Accrued expenses and deferred income	1 009 740	1 167 476
	1 647 465	**1 637 197**
TOTAL EQUITY AND LIABILITIES	**9 301 927**	**12 536 706**
Pledged assets and contingent liabilities		
Pledged assets		
Bank funds	None	50 000
Contingent liabilities	None	None

Change in equity, summary

2016

(SEK)	Share capital	Fund for develop-ment expendit-ures	Share premium reserve	Profit or loss brought forward	Loss for the period	Total
At start of the year	939 821		42 580 220	-24 951 581	-3 730 215	14 838 245
As allocated by AGM				-3 730 215	3 730 215	0
Ongoing new share issue	-64 298		-7 051 408			-7 115 706
New share issues during the year	64 298		7 051 408			7 115 706
Changes in development expenditures		3 007 759		-3 007 759		0
Loss for the period					-3 938 736	-3 938 736
At year-end	**939 821**	**3 007 759**	**42 580 220**	**-31 689 555**	**-3 938 736**	**10 899 509**

2017 (12 months)

(SEK)	Share capital	Fund for develop-ment expendit-ures	Share premium reserve	Profit or loss brought forward	Loss for the period	Total
At start of the year	939 821	3 007 759	42 580 220	-31 689 555	-3 938 736	10 899 509
As allocated by AGM				- 3 938 736	3 938 736	0
New share issues during the year	74 196		8 329 360			8 403 556
Changes in development expenditures		-1 829 279		1 829 279		0
Loss for the period					-11 648 603	-11 648 603
At year-end	**1 014 017**	**1 178 480**	**50 909 580**	**-33 799 012**	**-11 648 603**	**7 654 462**

In 2015, following the decision of the Annual General Meeting of 16 June 2015, 200,000 subscription warrants were issued to two Board members, which resulted in an increase of SEK 40,000 in non-restricted equity. Option rights may be exercised during the period from 1 July 2018 to 31 July 2018 and may lead to maximum dilution of around 1.1%.

In connection with the new share issue, which was registered on 9 June 2017, 494,642 subscription warrants were issued. Each warrant entitles the holder to subscribe for 1 new share during the period 1 March 2020 to 31 March 2020 for SEK 6. This can lead to a maximum dilution of 2.44%.

Cash flow statement in summary

(SEK)	1 Oct 2017 - 31 Dec 2017 3 months	1 Oct 2016 - 31 Dec 2016 3 months	1 Jan 2017 - 31 Dec 2017 12 months	1 Jan 2016 - 31 Dec 2016 12 months
Operating activities				
Operating loss	-7 368 968	-920 970	-11 648 261	-3 936 933
Depreciation	102 956	102 267	408 454	408 454
Interest received	-	56	-	431
Interest paid	-	-394	-342	-2 234
Adjustment for items not included in cash flow	5 935 270	25 000	4 061 210	-
Cash flow from operating activities before changes in working capital	**-1 330 742**	**-794 041**	**-7 178 939**	**-3 530 282**
Change in working capital				
Increase/decrease in receivables	5 703	171 924	-96 344	188 518
Increase/decrease in current liabilities	172 045	-376 548	10 268	780 394
Change in working capital	**177 748**	**-204 624**	**-86 076**	**968 912**
Cash flow from operating activities	**-1 152 994**	**-998 665**	**-7 265 015**	**-2 561 370**
Investing activities				
Purchase of intangible assets	-145 833	-161 137	-481 925	-3 007 759
Cash flow from investing activities	**-145 833**	**-161 137**	**-481 925**	**-3 007 759**
Financing activities				
New share issue/share capital	-	-	8 403 556	-
Subscribed paid capital	-	-	-	5 775 000
Cash flow from financing activities	**0**	**0**	**8 403 556**	**5 775 000**
Change in cash and cash equivalents	-1 298 827	-1 159 802	656 616	205 871
Cash and cash equivalents at start of period	3 406 652	2 611 011	1 451 209	1 245 338
Cash and cash equivalents at end of period	**2 107 825**	**1 451 209**	**2 107 825**	**1 451 209**

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