Initiator Pharma

INITIATOR PHARMA: Q3 2019 report

Financial Highlights

Initiator Pharma A/S is a Danish registered company, and is reporting its financial situation in Danish kroner (DKK). Initiator Pharma A/S was registered on May 2, 2016.

Third Quarter (2019-07-01 – 2019-09-30)
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -1,969 (-3,699)
• Earnings per share was DKK –0.08 (-0.21)

First Nine Months of the Year (2019-01-01 – 2019-09-30)
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -6,836 (-10,103)
• Earnings per share was DKK –0.28 (-0.71)
• Cash and bank: TDKK 12,223 (6,586)
• Solidity: 67% (91%)

Group earnings per share: period result divided by a number of 23 157 178 shares (on 2019-09-30).
Solidity: equity divided by assets.

Business highlights in Q3 2019

- On July 5th we announced that the warrant program 2019/2021, comprising a maximum of 434,197 warrants as resolved at the Annual General Meeting of 23 May 2019, had been fully subscribed.
- On August 13th we announced that the Phase 2a clinical study of IPED2015 in patients with Erectile Dysfunction was progressing well although recruitment of patients was taking slightly longer than planned, with the release of draft data from the study expected in early Q4:2019.
- On August 13th we announced that we had raised a bridge loan of SEK 5 mill with the aim of preparing the company's other candidate drug IP2018 for the start of a clinical phase 2a trial.
- On September 3rd we announced that we had been awarded a grant from Innovation Fund Denmark of up to DKK 2 mill to support the ongoing clinical development program for IPED2015.
- On September 27th we announced that the dosing of the last patients in clinical Phase 2a Proof-of-Concept trial with IPED2015 had started, with anticipated release of draft data from the study expected during December 2019.

Significant events after this reporting period

- On October 18th we announced that we had received an extension of the option agreement for the IP2018 drug candidate from Saniona until 31 March 2020 and furthermore opted to pay back the 5 MSEK bridge loan obtained earlier this year.

Comments from the CEO

A major focus for for Initiator Pharma during the third quarter of 2019 has been the Phase 2a Proof-of-concept trial. Following the succefull completion of the Phase 1 clinical trial in healthy subjects in June 2019 the first patients of the phase 2a trial were dosed in July. While the recruitment of egible patinets has taken slighliy longer than anticipated we are confident that we will be able to report top-line results from the study before year-end.

Another focus for the Company has been the preparation of the IP2018 clinical trial application. We intend to finalize the application and submit it to regulatory authorities during quarter 1, 2020. The filing of the CTA will enable us to exercise the option agreement that we have for this asset with Saniona. This will significantly strenghten the Initiator Pharma pipeline.

Initiator Pharma

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About Initiator Pharma

Initiator Pharma A/S is a Danish biotechnology company focusing on the development of innovative drugs, targeting key unmet medical needs within the central and peripheral nervous system. Our research is focusing on monoamine reuptake inhibitors, molecules that are affecting the synaptic concentrations of neurotransmitters such as dopamine, serotonin and noradrenaline. Our lead drug candidate, IPED2015 is targeting the medical condition Erectile Dysfunction (ED), and specifically patients with ED that are non-responsive to drugs within the PDE5i class, including the approved drugs Viagra©, Cialis© and Levitra©.

Initiator Pharma is based in Aarhus, Denmark. Initiator Pharma is listed on Spotlight Stock Market and has about 3.500 shareholders. Read more at www.initiatorpharma.com.

Letter from the CEO

Q3:2019 has been yet another transformational period for Initiator Pharma. We have completed the Phase 1 trial and now in the process of completing the Phase 2a trial for IPED2015, marking a significant advancement of Initiator Pharma as a company.

If successful, the Phase 2a will provide us with Proof-of-Concept for IPED2015 and lay the groundwork for a full development program for IPED2015 until market approval. With positive data we will intensify our Business Development efforts, which will allow the company´s board of directors to evaluate and select the right path forward for IPED2015 with the aim of maximizing shareholder value.

"We are very excited about the upcoming read-out of the clinical phase 2a Proof of Concept trial. Clinical pharmacological effects and efficacy will be key parameters for the continued development of IPED2015 as a first-line treatment for the PDE5i non-responders, thus solving a significant unmet medical need."

In parallell with the IPED2015 activities, we have been advancing the development of IP2018 as a drug candidate for the treatment of men suffering from depression and erectile dysfunction, which is a clear differentiation from other antidepressants on the market today. In the planned clinical phase 2a trial, Initiator Pharma intends to primarily confirm the effect of IP2018 on the erectile function of patients, and after that, if the outcome is positive, follow up with further clinical safety trials on multiple dosage parameters. The company intends to position IP2018 as a daily treatment for patients suffering from depression and sexual dysfunction and/or as a supplement to treat erectile dysfunction in patients with medically induced sexual dysfunction.

IP2018 is available to us through an option agreement with Saniona, and the agreement has allowed us to conduct a thorough evaluation and positioning of this drug candidate before advancing it to the clinic. We plan to finalize the clinical trial application (CTA) for IP2018 once the Phase 2a data from IPED2015 have been evaluated, and to submit a CTA during Q1:2020, triggering the exercise of the option agreement with Saniona and allowing us to fully integrate IP2018 into the Initiator Pharma pipeline.

"We are very pleased with the preclinical investigations and development of IP2018, and we strongly believe that we have identified a unique and attractive indication for this drug candidate. We are looking forward to advancing this program to clinical testing in a Phase 2a study in 2020, where we seek to demonstrate clinical efficacy in a patient group with high unmet medical need, offering what we believe is a significant commercial opportunities for a drug with the IP2018 profile."

I want to take this opportunity to thank the existing shareholders for your continuing support of Initiator Pharma that has enabled us to drive towards the upcoming read-out of the Phase 2a IPED2015 trial. Positive results from this study will be a major milestone for Initiator Pharma and allow further development of IPED2015 towards market approval, for the benefits of patients, the company and its shareholders.

We believe the upcoming Phase 2 read-out and the strengthening of our pipeline have potential to add considerable value for our shareholders, both short-term and long-term. This shall facilitate and support the positioning of Initiator Pharma as a capable, cost-effective and recognized biotech player adding significant value to drug candidates through well designed and conducted Proof-of-Concept clinical trials for the benefit of the company and its shareholders.

Claus Elsborg Olesen
CEO, Initiator Pharma A/S

About Initiator Pharma

Initiator Pharma is a Biotech company established in Aarhus, Denmark. Its main asset IPED2015 represents a novel treatment paradigm for the treatment of Erectile Dysfunction (ED) and will improve the quality of life for the growing number for patients (and their partners) that do not respond or cannot be treated with the current marketed medication. Initiator Pharma is based in Århus, Denmark.

Vision

Initiator Pharma will be a leading biotech company within the field of mono-amine reuptake transporters and be dedicated to the development of paradigm changing drug for unmet medical needs to the benefit of both patients and the society.

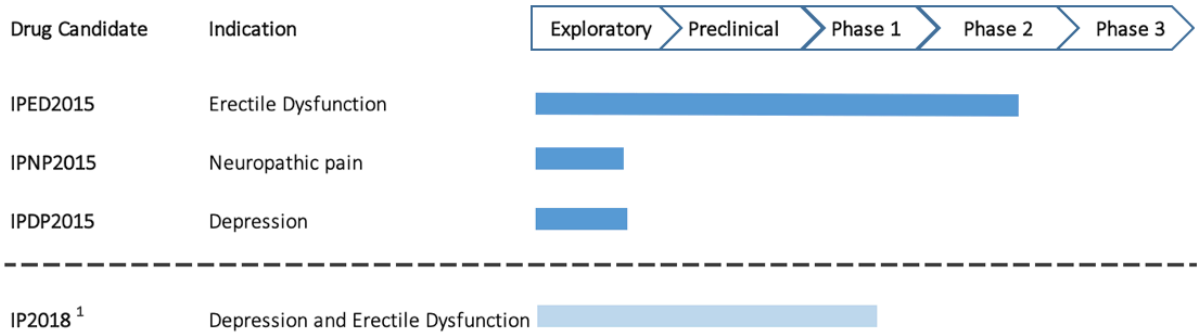
Business model

The company aims to commercialize its research efforts through the following 2 business models:

- By internal development of selected programs through the early phases of drug development before out-licensing to pharmaceutical companies who will take over the further development of Initiator Pharma's programs and typical with upfront payments, milestone and royalty payments on product sales to Initiator Pharma.
- Through early stage research and development collaboration with pharmaceutical companies who will fund the research and development activities and pay upfront, milestones and royalty payments on product sales to Initiator Pharma.

Project portfolio

In 2016 Initiator Pharma acquired three potential drug candidates from Saniona. All three drug candidates belong to the drug class known as Monoamine reuptake inhibitors:



[1] *Covered by an exclusive option agreement with Saniona until March 31, 2020*

IPED2015, our most advanced drug candidate, is a novel drug candidate for the treatment of patients suffering from Erectile Dysfunction (ED) that do not respond to the currently marketed drugs in the PDE5i class (e.g. Viagra®, Cialis®,Levitra®). IPED2015 by having a dual action, both a central effect initiating erection and a peripheral effect potentiating erection through smooth muscle relaxation, is unique and aimed for treatment of erectile dysfunction in patients suffering from erectile dysfunction due to metabolic syndrome and diabetes.

IPED2015 entered clinical development in H2:2018, and in June 2019 we reported the successful completion of the phase 1 (single ascending dose) program. We immediately progressed IPED2015 into a carefully planned Phase 2a, and we expect to complete enrollment in this proof of concept study shortly, with headline data available Q4:19.

In Q4:18 we announced that we had secured a 1 year exclusive option agreement for IP2018, a Phase 2 ready compound that has previously undergone clinical development for anxiety and depressive disorders but it has never be tested in a Phase 2 clinical trial. During H1 we have undertaken a thorough preclinical evaluation of the drug candidate. Based on the results of this evaluation we now plan to

exercise the option and to pursue the clinical development of IP2018 for the treatment of men suffering from depression and erectile dysfunction. During Q3 we announced that we had obtained a 6 month extension of the initial option agreement. We now plan to finalize the CTA for a Phase 2a study for IP2018 once the data from the ongoing Phase 2a for IPED2015 have been evaluated and before end Q1:2020, triggering the option exercise on IP2018.

Additional details on the clinical development of IPED2015

In the Phase I healthy subject part multiple cohorts each consisting of 5-8 subjects (3 on IPED2015; 2 on placebo or 6 on IPED2015; 2 on placebo, respectively) were enrolled to the MAC Phase I unit, Manchester, UK and in-housed during the dosing and observation period. Doses were escalated from cohort to cohort based on safety data, PK and pharmadynamic assessments interim data review done by the MAC medical team and Initiator Pharma. This was done after each dosing cohort and before dosing to the next cohort. Dosing was stopped when significant levels of safety observations were made.

In the Phase II part of the study, twelve erectile dysfunction patients were enrolled after a thorough selection and screening process and dosed with a single dose of IPED2015 (the highest tolerated dose from the healthy subject study) and placebo in a cross-over study design. The patients were enrolled to the MAC Phase I unit, Manchester, UK and in-housed during the dosing and observation period. Efficacy assessment was done with the RigiScan device in relation to stimulus challenge assessment (Erotic Movie presentation) to assess penile rigidity and tumescence. This is a state-of-the-art model to assess erectile function. Safety and PK was also assessed during the trial. Data handling, statistical analysis and reporting of the study outcome is currently ongoing at MAC. As previously communicated we anticipate to announce top-line results from the study during the month of December.

Erectile Dysfunction (ED) Market

The current number of ED patients is estimated to about 150 mio men worldwide and a number that is estimated to increase to more than 300 mio by 2025. About 30-40% of these patients will not respond to the current treatment and represent a significant unmeet medical need. This is exactly our primary target group and will clearly distinguish us form the PDE5i drugs, where patent expiry results in increasing price pressure from generics. In 2015 the erectile dysfunction market generated about 4 bn USD and Initiator Pharma strongly believes that targeting the PDE5i non-responders will allow us to receive premium pricing for IPED2015 and thereby generate substantial commercial value for Initiator Pharma.

Additional details on the IP2018 program

IP2018 is a monoamine reuptake inhibitor for the treatment of psychogenic erectile dysfunction (mainly caused by anxiety and depression) mainly targeting the serotonin instead of the dopamine system. IP2018 is different from our frontrunner IPED2015 for organic erectile dysfunction (mainly caused by diabetes and age), primarily targeting the dopamine system.

- Due to the unique profile, IP2018 will, if successful, treat patients suffering major depressive disorder where the majority also suffer from comorbid sexual dysfunction or treatment-emergent sexual dysfunction.

- IP2018 has demonstrated an excellent safety profile in a single dose study and the proof of mechanism PET study, confirming the safety and the mechanism of action of our extensive package of preclinical data.

- IP2018 is efficacious in animal models of depression (forced swim and tail suspension tests) and erectile function (intracavernosal pressure to mean arterial pressure ratio) as well as in several mouse anxiety models.

- IP2018 is targeting a clear unmet medical need.

IP2018 raises the serotonin levels in the brain, and in its preclinical trials, Initiator Pharma has shown that IP2018 has an effect on both depression and erectile function, which is a clear differentiation from other antidepressants on the market today. In the planned clinical phase 2a trial, Initiator Pharma intends to primarily confirm the effect of IP2018 on the erectile function of patients and thereafter, if the outcome is positive, follow up with further clinical safety trials on multiple dosage parameters. The company intends to position IP2018 as a daily treatment for patients suffering from depression and sexual dysfunction and/or as a supplement to treat erectile dysfunction in patients with medically induced sexual dysfunction.

Depression is a mood disorder that affects feelings, thoughts, and behaviour and leads to a variety of emotional and physical illnesses. If left untreated, depression significantly reduces quality of life and may ultimately result in premature death from medical conditions or suicide. The main treatments for depression are drugs that modulate the levels of serotonin, noradrenaline and dopamine by either inhibiting the reuptake of these signalling substances (“reuptake inhibitors”) or by influencing their degradation. A key side effect of the currently available antidepressants is their significant impact on male sexual function (desire-arousal-excitement-orgasm). In a survey, it was observed that 41.7 % of men discontinued psychiatric medications due to perceived sexual side effects (Rosenberg KP et al “A survey of sexual side effects among severely mentally ill patients taking psychotropic medications: impact on compliance”, J. Sex Marital Ther. 2003;29(4):289-96). Between 14 and 35 % of young men experience ED. The causes of ED can be caused by psychological, neurological, or lifestyle issues. ED can also be the result of side effects of specific medications (including some antidepressants), performance anxiety, depression, schizophrenia, and other psychological disorders.

Major depressive disorder is one of the main causes of disability worldwide due to its high prevalence and associated impairments. Lifetime prevalence is 14.3 % in high-income countries. The Global Burden of Disease study showed a 37.5 % burden increase due to major depressive disorder from 1990 to 2010, and major depressive disorder is the second leading cause of Disability Adjusted life years in 2020. About 13 % of all Americans take anti-depression medication summing up to more than 23 million prescriptions per year (National Center for Health Statistics). The global revenue for antidepressants is forecasted to reach $18 bn in 2020. The biggest players, accounting for more than 60% of the antidepressant drugs sold, are Pfizer, Eli Lilly, GlaxoSmithKline, AstraZeneca and H. Lundbeck A/S - all facing a significant patent cliff over the next few years, with revenues projected to be hit hard by generics and biosimilars. All current marketed drugs have to varying degree been associated with erectile dysfunction emphasising the need to develop an attractive and superior alternative.

Financial review

Initiator Pharma A/S is a Danish registered company, and is reporting its financial figures in Danish kroner (DKK). Initiator Pharma A/S was registered on May 2, 2016.

Financial review

TDKK	3Q:2019	3Q:2018	9M:2019	9M:2018	2018
Net sales	0	0	0	0	0
Total operating expenses	-1 969	-3 699	-6 836	-10 103	-12 611
Operating profit/loss	-1 969	-3 699	-6 836	-10 103	-12 611
Cash flow from operating activities	-3 029	-3 559	-6 020	-12 666	-13 582
Operating margin, %	neg	neg	neg	neg	neg
Average number of employees, #	1	1	1	1	1
Earnings per share, DKK	-0,08	-0,21	-0,28	-0,71	-0,63
Diluted earnings per share, DKK	-0,08	-0,15	-0,28	-0,43	-0,53
	30.09.2019	**30.09.2018**			**31.12.2018**
Cash and cash equivalents	12 223	6 586			14 491
Equity	9 957	7 819			16 570
Total equity and liabilities	14 795	8 601			17 328
Equity ratio, %	67 %	91 %			96 %
Number of shares outstanding	*23 157 178*	*17 367 884*	*23 157 178*	*17 367 884*	*23 157 178*
Number of shares, fully diluted	*24 459 769*	*23 591 375*	*24 459 769*	*23 591 375*	*24 025 572*
Weighted number of shares	*24 459 769*	*17 367 884*	*24 170 304*	*14 473 237*	*20 081 616*

Revenues and result of the operation

Revenue

Initiator Pharma generated total revenues of TDKK 0 for the third quarter of 2019 (0) and TDKK 0 for the first nine months of 2019 (0).

Operating profit/loss

The company recognized an operating loss of TDKK 1,969 for the third quarter of 2019 (-3,699). For the first nine months of the year the operating loss was TDKK 6,836 (-10,103). The reduction in operating costs for the first nine months of the year compared to the same period last year reflects the high level of activity last year in preparations for the start of the clinical phase as well as the communicated delays in the Phase 2a study this year.

External R&D costs in the third quarter amounted to TDKK 767, compared to TDKK 2,514 in the same period in 2018. For the first nine months of the year external R&D costs totalled TDKK 3,791 compared to TDDK 7,510 in same period in 2018.

Financial position

The equity as of September 30, 2019 was TDKK 9,957. Cash and cash equivalents amounted to TDKK 12,223 as of September 30, 2019 and total assets were TDKK 14,759.

Cash flow

In the third quarter of 2019 the total operating cash flow was TDKK -3,029 (TDKK -3,559), incl a negative change in working capital of TDKK 1,066 (TDKK 55). Cash flow from investment activities was TDKK -0 (TDKK 0). Cash flow from financing activities was TDKK 3,751 (TDKK 121).

For the first nine 2019 the operating cash flow was TDKK -6,020 (TDKK -12,666), incl a positive change in working capital of TDKK 801 (TDKK -2,503). Cash flow from investment activities was TDKK -0 (TDKK 0) and cash flow from financing activities was TDKK 3,571 (TDKK 12,083).

On August 13 we announced that we had raised a SEK 5 mill (DKK ca 3.5 mill) bridge loan. The purpose of the loan was to enable the company to accelerate the Phase 2 enabling activities for IP2018, the drug candidate covered by the option agreement with Saniona. Subsequent to raising the bridge loan we were awarded a grant of up to DKK 2 mill from InnovationsFonden in Denmark. On October 18th we announced that we had secured a 6 month extension of the option agreement with Saniona and on this basis we decided to make an early repayment of the bridge loan.

The share, share capital and ownership structure
At September 30, 2019, the number of shares outstanding amounted to 23,157,178. The company has as of September 30 a total of 1,302,591 outstanding warrants, representing 5.6% of the number of issued shares.

At September 30, 2019 the company had around 3,500 shareholders. The 25 largest shareholders in the company on September 30 owned 47.3% of all outstanding shares:

Top 25 shareholders as of September 30, 2019		
Owners	Number of shares	Shares %
Försäkringsaktiebolaget, Avanza Pension	1 373 814	5,93 %
BNY Mellon SA/NV (Former BNY)	1 065 814	4,60 %
Ålandsbanken i ägares ställe	1 001 223	4,32 %
Nordnet Pensionsförsäkring AB	823 560	3,56 %
Claus Olesen Holding APS	692 738	2,99 %
UBS Switzerland AG	625 467	2,70 %
DanPet AB	537 438	2,32 %
Mikael Södergård Thomsen APS	505 946	2,18 %
Lars Hendriksen A/S	476 096	2,06 %
Peters, Dan	451 511	1,95 %
Sv Handelsbanken Copenhagen branch	323 491	1,40 %
Olin, Lennart	300 911	1,30 %
Thauser Holding ApS	295 156	1,27 %
Härlin, Tobias	273 450	1,18 %
Leif Andersen Consulting ApS	250 859	1,08 %
Feldthus, Thomas	250 143	1,08 %
Coolmate ApS	242 416	1,05 %
Clearstream Banking S.A, W8IMY	225 754	0,97 %
Müller, Christian Matthias	220 000	0,95 %
Olofsson, Christian	218 924	0,95 %
SEB Life International Assurance	181 728	0,78 %
Wall, Magnus	170 509	0,74 %
Hendriksen, Lars	170 353	0,74 %
Kaae, Michael Nicolai Lägård	156 594	0,68 %
Berg, Charlotte	129 553	0,56 %
Other shareholders	12 193 730	52,66 %
Total	**23 157 178**	**100,00 %**

Personnel

As of September 30, 2019, the number of employees was 1, of which 0 were women. Initiator Pharma follows a strategy of using an extensive network of consultants to support the development activities in the company. Such a strategy is well established in the biotech industry and ensures the company the optimal balance of access to leading edge expertise, costs and flexibility.

Operational risks and uncertainties

All business operations involve risk. Managed risk-taking is necessary to maintain good profitability. Risk may be due to events in the external environment and may affect a certain industry or market. Risk may also be specific to a certain company.

The main risks and uncertainties which Initiator Pharma is exposed to are related to drug development, the company's collaboration agreements, competition, technology development, patent, regulatory requirements, capital requirements and currencies.

A more detailed description of the company's risk exposure and risk management is included in the prospectus published in March 2018.

Audit review

This Interim Report has not been subject to review by the company´s auditor.

Financial calendar

Interim Report Q1	May 23, 2019
Annual General Meeting	May 23, 2019
Interim Report Q2	August 23, 2019
Interim Report Q3	November 22, 2019
Year-End Report 2019	February 21, 2020

Aarhus, November 21, 2019

Magnus Persson - Chairman	Henrik Moltke – Board member
Peter Holm – Board member	Claus Olesen – Board member and CEO

Financial Statements

Statement of income

TDKK	3Q:2019	3Q:2018	9M:2019	9M:2018	2018
Gross loss	-1 755	-3 428	-5 953	-9 230	-11 437
Staff costs	-192	-249	-817	-807	-1 086
Depreciation and write-downs	-22	-22	-66	-66	-88
Operating profit/loss	**-1 969**	**-3 699**	**-6 836**	**-10 103**	**-12 611**
Other financial expenses	-16	63	-51	-126	-93
Profit/loss	**-1 985**	**-3 636**	**-6 887**	**-10 229**	**-12 704**
Tax					2 406
Net profit for the period	**-1 985**	**-3 636**	**-6 887**	**-10 229**	**-10 298**

TDKK	30.09.2019	30.09.2018	2018
ASSETS			
Patents, acquired rights	39	62	56
Intangible assets	**39**	**62**	**56**
Other fixtures, fittings, tools and equipment	19	85	68
Property, plant and equipment	**19**	**85**	**68**
Fixed assets	**58**	**147**	**124**
Other receivables	108	133	307
Income tax receivables	2 406	1 735	2 406
Prepayments	0	0	0
Current receivables	**2 514**	**1 868**	**2 713**
Cash and cash equivalents	**12 223**	**6 586**	**14 491**
Current assets	**14 737**	**8 454**	**17 204**
Assets	**14 795**	**8 601**	**17 328**
EQUITY AND LIABILITIES			
Contributed capital	2 432	1 824	2 432
Retained earnings	7 525	5 995	14 138
Equity	**9 957**	**7 819**	**16 570**
Loan	3 478		
Trade payables	841	495	239
Other payables	519	287	519
Current liabilities other than provisions	**4 838**	**782**	**758**
Liabilities other than provisions	**4 838**	**782**	**758**
Equity and liabilities	**14 795**	**8 601**	**17 328**

Statement of changes in shareholder equity

TDKK	Contributed capital	Retained earnings	Total
January 1, 2019	**2 432**	**14 138**	**16 570**
Increase of capital			
Profit/loss for the period		-6 614	-6 614
September 30, 2019	**2 432**	**7 524**	**9 956**

Statement of cash flow

TDKK	3Q:2019	3Q:2018	9M:2019	9M:2018	2018
Operating profit/loss	-1 969	-3 699	-6 836	-10 103	-12 611
Amortisation, depreciation and impairment losses	22	22	66	66	88
Changes in working capital	-1 066	55	801	-2 503	-2 701
Cash flow from operating activities before financial items	**-3 013**	**-3 622**	**-5 969**	**-12 540**	**-15 224**
Other financial expenses	-16	63	-51	-126	-93
Tax credit					1 735
Cash flow from operating activities	**-3 029**	**-3 559**	**-6 020**	**-12 666**	**-13 582**
Investing activities					
Investment in intangible assets					
Investments in tangible assets					
Cash flow from investing activities	**0**	**0**	**0**	**0**	**0**
Financing activities					
New share issue				11 962	20 760
Issue of warrants	273	121	273	121	144
Proceeds from loan	3 478		3 478		
Cash flow from financing activities	**3 751**	**121**	**3 751**	**12 083**	**20 904**
Increase/decrease in cash and cash equivalents	**722**	**-3 438**	**-2 268**	**-583**	**7 322**
Cash and cash equivalents at the end of period	**12 223**	**6 586**	**12 223**	**6 586**	**14 491**

Business terms - glossary

CNS
The Central Nervous System, a part of the nervous system consisting of the brain and spinal cord.

CTA
Clinical Trial Application which a pharmaceutical company file to EMA in order to obtain permission to ship and test an experimental drug in Europe before a marketing application for the drug has been approved. The approved application is called an Investigational New Drug (IND) in the US.

EMA
European Medicines Agency

Erectile Dysfunction
Erectile dysfunction (ED) or impotence is sexual dysfunction characterized by the inability to develop or maintain an erection of the penis during sexual activity in humans.

FDA
US Food and Drug Administration

IND
Investigational New Drug is a program by which a pharmaceutical company obtains permission to ship and test an experimental drug in the US before a marketing application for the drug has been approved. In Europe, the application is called a Clinical Trial Application (CTA).

IPED2015
IPED2015, our most advanced drug candidate, is a novel drug candidate for the treatment of patients suffering from Erectile Dysfunction (ED) that do not respond to the currently marketed drugs in the PDE5i class (e.g. Viagra©, Cialis©,Levitra©)

Monoamine re-uptake inhibitor
A monoamine reuptake inhibitor (MRI) is a drug that acts as a reuptake inhibitor of one or more of the three major monoamine neurotransmitters serotonin, norepinephrine, and dopamine by blocking the action of one or more of the respective monoamine transporters.

Neuropathic pain
Neuropathic pain is a complex, chronic pain state that usually is accompanied by tissue injury. With neuropathic pain, the nerve fibers themselves may be damaged, dysfunctional, or injured. These damaged nerve fibers send incorrect signals to other pain centers.

PDE5 inhibitor
A drug used to block the degradative action of the PDE5 enzyme in the smooth muscle cells lining the blood vessels supplying the corpus cavernosum of the penis. These drug, incl Viagra©, Cialis© and Levitra© are used in the treatment of erectile and were the first effective oral treatment available for the condition.

Financial Glossary

Earnings per share
Profit/loss for the period divided by the average number of shares outstanding at the end of the period

EBIT
Earnings Before Interest and Taxes (Operating profit/loss)

Equity ratio
Shareholders' equity as a proportion of total assets

Diluted earnings per share
Profit/loss for the period divided by the average number of shares after dilution at the end of the period

Operating margin
EBIT as proportion of revenue