

## INITIATOR PHARMA: YEAR END REPORT 2019

### 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.

<b>Fourth Quarter (2019-10-01 – 2019-12-31)</b>
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -2,503 (-2,508)
• Earnings per share was DKK -0.09 (-0.00)

  

<b>Full Year (2019-01-01 – 2019-12-31)</b>
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -9,339 (-12,609)
• Earnings per share was DKK -0.34 (-0.51)
• Cash and bank: TDKK 7,562 (14 491)
• Solidity: 87%

*Group earnings per share: period result divided by a number of 23 591 375 stocks (on 2019-12-31).*

*Solidity: equity divided by assets.*

### Business highlights in Q4 2019

- On October 18<sup>th</sup> we announced that we had negotiated an extension until March 31, 2020 of the option agreement with Saniona for the IP2018 drug candidate, and furthermore that we opted to pay back the 5 MSEK bridge loan obtained mid 2019.
- On December 5<sup>th</sup> we announced that the Phase 2a proof of concept study for IPED2015 had achieved statistically significant results on key efficacy endpoints in severe ED patients after a single administration of IPED2015. Moreover, no observations of critical adverse events were recorded.
- On December 23<sup>rd</sup> we announced that individuals in the board and management exercised a total of 434 197 warrants for subscription of new shares, raising approx 1,9 SEKM in proceeds to the company. The number of issued shares increases by 434 197 and the share capital increases by 45 590,685 DKK.

### Significant events after this reporting period

- None

### Comments from the CEO

"In Q4 Initiator Pharma obtained positive topline data from our Phase 2a clinical trial with IPED2015. This constitutes a major milestone and a clear validation of Initiator Pharma's lean and effective performance as a value creating biotech company, now with an emerging pipeline of two Phase 2 assets within commercially attractive indications where there is a high unmet medical need. 2020 will be a truly exciting year with a series of upcoming inflection events in the near to mid-term future"

### For more information, please contact

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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 Stockmarket and has about 3.600 shareholders. Read more at [www.initiatorpharma.com](http://www.initiatorpharma.com).*

## Letter from the CEO

Initiator Pharma ended 2019 on a very positive note as we in December announced that the topline data from the IPED2015 phase 2a clinical trial in erectile dysfunction were positive. This strengthened our conviction that our candidate drug IPED2015 has strong potential to become the medical treatment of erectile dysfunction for the PDE5i non-responders. The positive data also support our ambition to position 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.

*“To obtain data that show Proof of Concept in clinical Phase 2a was truly a gratifying moment for Initiator Pharma. We have met some challenges on the way with the recruitment of qualified subjects but despite this we have still managed to complete the trial within budget.”*



Overall, 2019 represented a transformational period for Initiator Pharma as we completed phase 1 trial and subsequently initiated the critical Phase 2a trial for IPED2015. We have advanced our portfolio and Initiator Pharma is today a clinical stage biotech company. We have completed our Phase 2a clinical trial with positive topline results and we are now eagerly awaiting the full and final dataset generated in the trial. We are looking forward to be able to share a more in-depth analysis of the results and discuss the meaning and interpretation of the results with our shareholders.

The outcome of the Phase 2a trial will enable us to further map the clinical and regulatory pathway for the remaining development program for IPED2015, including pivotal studies that will form the basis in an application for market approval. This will further highlight the full potential and value of IPED2015 for potential partners. We have now intensified our business development efforts and in our ongoing discussions and interactions, most recently in connection with the JP Morgan conference in San Francisco, we are experiencing a keen interest in Initiator Pharma and IPED2015. The general response from these interactions is an acknowledgment of the unmet medical need and how Initiator Pharma with a completely novel mechanism of action has created an attractive and safe solution to this need. Our potential partners are impressed by IPED2015 properties as a future drug and they are looking forward to a more detailed look at the results in the final report from MAC. We strongly believe that this growing interest will lead to an attractive future deal or partnership for Initiator Pharma.

*“We are looking positively at the advancement of IP2018 and believe that we are in a unique position to solve a major unmet medical need for the psychogenic erectile dysfunction patients with this candidate drug.”*

In parallel with the IPED2015 activities in the last quarter of 2019, we also continued the development of IP2018 and remain on track to file a CTA end of Q1 2020. This will trigger the exercise of the option agreement with Saniona and allow us to fully integrate IP2018 into the Initiator Pharma pipeline.

IP2018 is a candidate drug for the combined treatment of 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.

*“Initiator Pharma has proven its ability to deliver candidate drugs that provide a solution to a very serious medical problem that affects a lot of people.”*

In addition to the progress we have made in 2019, I see good reasons for Initiator Pharma's ability to create value going forward. Firstly, with IPED2015 we are addressing a major unmet need targeting a segment where a large number of patients, the PDEi non-responders, currently lack an effective treatment. Secondly, the development of IP2018 will instigate a paradigm shift for patients suffering from psychogenic erectile dysfunction with a first in class treatment that can increase these patients' quality of life in a significant way. I look forward to Initiator Pharma's future progress with confidence.

With these words, I would like to thank all existing shareholders and welcome new shareholders to become part of an exciting future together with a biotech company that soon will have two clinical Phase 2 assets in development.

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:

Program	Profile	Indication	Discovery & Preclinical	Phase 1	Phase 2
<b>IPED2015</b>	DAT(SERT/NET)	Erectile dysfunction (Organic)			
<b>IP2018*</b>	SERT>DAT>>NET	Erectile dysfunction (Psychogenic)			
<b>IPDP2015</b>	DAT/SERT/NET	Depression			
<b>IPNP2015</b>	DAT/SERT/NET	Neuropathic Pain			

\*Option agreement with Saniona AB

IPED2015, our most advanced drug candidate, is a novel drug candidate for the treatment of patients suffering from *organic* 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 ED in patients suffering from ED due to metabolic syndrome and diabetes.

In Q4 IPED2015 successfully completed the Phase 2a trial and the final report from the study is expected during Q1 2020.

In Q4:18 we announced that we had secured an option agreement for in-licensing IP2018, a clinical stage compound, from Saniona. IP2018 is a monoamine reuptake inhibitor, belonging to the same class of drugs as our other portfolio drugs. The option agreement has allowed us time until March 31, 2020 to evaluate the data package and potential positioning of IP2018 before entering a full license agreement anticipated within the option period. The drug candidate has through Phase 1 studies already conducted been de-risked to a high extent, and we are currently planning to conduct a cost-effective Phase IIa, Clinical Proof of Concept study for the treatment of *psychogenic* Erectile Dysfunction (mainly caused by anxiety and depression), a patient population with a high unmet medical need.

## **IPED2015:**

### **Data from the Phase 2a clinical proof of concept study**

The Phase IIa study which included patients suffering from severe Erectile Dysfunction (ED) has been completed satisfactorily. The study has demonstrated promising statistically significant efficacy data on ED. Besides, there has been no reporting of critical safety observations which is in line with the previously reported results from the Phase I trial in healthy volunteers. Further analysis of the data and report writing has been initiated by MAC, and final report is expected later in Q1 of 2020.

### **Phase 2a Study Design**

The Phase II part study for IPED2015 included twelve patients suffering from severe ED who were enrolled after a thorough selection and screening process and dosed with a single dose of IPED2015 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 with stimulus challenge assessment (Erotic Movie presentation) to assess penile rigidity and tumescence. RigiScan is a state-of-the-art model to evaluate erectile function. Safety and PK was also assessed during the trial.

### **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 unmet medical need. This is exactly our primary target group and will clearly distinguish us from the PDE5i drugs, where patent expiry results in increasing price pressure from generics. In 2015 the ED 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.

## **IP2018:**

### **Development plans for IP2018**

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	Q4:2019	Q4:2018	2019	2018
Net sales	0	0	0	0
Total operating expenses	-2 503	-2 508	-9 339	-12 611
Operating profit/loss	-2 503	-2 508	-9 339	-12 611
Cash flow from operating activities	-2 534	-916	-8 554	-13 582
Operating margin, %	neg	neg	neg	neg
Average number of employees, #	0,5	0,5	1,0	1,0
Earnings per share, DKK	-0,06	0,00	-0,34	-0,51
Diluted earnings per share, DKK	-0,06	0,00	-0,34	-0,51
			<b>31.12.2019</b>	<b>31.12.2018</b>
Cash and cash equivalents			7 562	14 491
Equity			9 908	16 570
Total equity and liabilities			11 438	17 328
Equity ratio, %			87%	96%
<i>Number of shares outstanding</i>			23 591 375	23 591 375
<i>Number of shares, fully diluted</i>			24 459 769	24 025 572
<i>Weighted number of shares</i>			24 242 671	20 081 616

## Revenues and result of the operation

### Revenue

Initiator Pharma generated total revenues of TDKK 0 for the fourth quarter of 2019 (0) and TDKK 0 for the full year 2019 (0).

### Operating profit/loss

The company recognized an operating loss of TDKK 2,503 for the fourth quarter of 2019 (-3,863), and TDKK 9,339 for the full year 2019 (-9,561). The reduction in operating costs for the full year reflects the progression of IPED2015 through the preclinical program and the start-up of the clinical phase 1 in 2018, as well as TDKK 928 in recognized grant in Q4:2019.

External R&D costs in the fourth quarter amounted to TDKK 2,212, compared to 1,156 in the same period in 2018. For the full year the external R&D costs amounted to TDKK 6,259, compared to 8,666 in the same period in 2018.

### Financial position

The equity as of December 31, 2019 was TDKK 9,908. Cash and cash equivalents amounted to TDKK 7,562 as of December 31, 2019. Total assets as of December 31, 2019, were TDKK 11,438.

### Cash flow

In the fourth quarter of 2019 the total operating cash flow was TDKK -2,534, incl a negative change in working capital of TDKK 1,873. Cash flow from investment activities was TDKK 0. Cash flow from financing activities was TDKK -2,126, reflecting the repayment of the bridge loan in Q4 that we raised in Q3 as well as the exercise of incentive warrants by the board and management in December.

For the full year 2019 the operating cash flow was TDKK -8,554, incl a negative change in working capital of TDKK 1,072. Cash flow from investment activities was TDKK 0 and cash flow from financing activities was TDKK 1,625.

## The share, share capital and ownership structure

At December 31, 2019, the number of shares outstanding amounted to 23,591,375. The company has as of December 31 a total of 868,394 outstanding warrants, representing 3.7% of the number of issued shares.

At December 31, 2019 the company had around 3,900 shareholders. The 25 largest shareholders in the company on December 31 owned 44,8% of all outstanding shares:

Top 25 shareholders as of December 31, 2019		
Owners	Number of shares	Shares %
Försäkringsaktiebolaget, Avanza Pension	1 360 498	5,77%
BNY Mellon SA/NV (Former BNY)	1 031 127	4,37%
Ålandsbanken i ägares ställe	1 004 398	4,26%
Claus Olesen Holding APS	692 738	2,94%
UBS Switzerland AG	639 535	2,71%
Nordnet Pensionsförsäkring AB	602 545	2,55%
DanPet AB	537 438	2,28%
Mikael Södergård Thomsen APS	505 946	2,14%
Lars Hendriksen A/S	489 717	2,08%
Peters, Dan	451 511	1,91%
Handelsbanken Copenhagen non-danish clients	320 000	1,36%
Thauser Holding ApS	295 156	1,25%
Härlin, Thomas	261 300	1,11%
Leif Andersen Consulting ApS	250 859	1,06%
Coolmate ApS	242 416	1,03%
Clearstream Banking S.A, W8IMY	225 754	0,96%
Muller, Christina Matthias	220 000	0,93%
Feldthus, Thomas	216 034	0,92%
JPM Chase NA	212 689	0,90%
Olin, Lennart	205 146	0,87%
Wall, Magnus	170 509	0,72%
Olofsson, Christian	168 924	0,72%
Hendriksen, Lars	165 119	0,70%
Kaa, Michael Nicolai Lägård	156 594	0,66%
SEB Life International Assurance	131 727	0,56%
Other shareholders	13 033 695	55,25%
<b>Total</b>	<b>23 591 375</b>	<b>100,00%</b>

## Personnel

As of December 31, 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 22, 2020
Annual General Meeting	May 22, 2020
Interim Report Q2	August 21, 2020
Interim Report Q3	November 20, 2020
Year-End Report 2020	February 19, 2021

Aarhus, February 21, 2020

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Magnus Persson - Chairman

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Henrik Moltke – Board member

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Peter Holm – Board member

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Claus Olesen – Board member and  
CEO

## Financial Statements

### Statement of income

TDKK	Q4:2019	Q4:2018	2019	2018
Gross loss	-2 413	-2 207	-8 366	-11 437
Staff costs	-69	-279	-886	-1 085
Depreciation and write-downs	-21	-22	-87	-87
<b>Operating profit/loss</b>	<b>-2 503</b>	<b>-2 508</b>	<b>-9 339</b>	<b>-12 609</b>
Other financial expenses	-585	33	-636	-94
<b>Profit after financial items</b>	<b>-3 088</b>	<b>-2 475</b>	<b>-9 975</b>	<b>-12 703</b>
Tax	1 687	2 406	1 687	2 406
<b>Net profit for the period</b>	<b>-1 401</b>	<b>-69</b>	<b>-8 288</b>	<b>-10 297</b>

**Statement of financial position**

<b>TDKK</b>	<b>2019</b>	<b>2018</b>
<b>ASSETS</b>		
Patents	34	56
<b>Intangible assets</b>	<b>34</b>	<b>56</b>
Fixture, fittings, tools and equipment	4	69
<b>Property, plant and equipment</b>	<b>4</b>	<b>68</b>
<b>Fixed assets</b>	<b>37</b>	<b>125</b>
Other receivables	1 286	307
Tax credit	1 687	2 406
Contributed capital in arrears	866	0
<b>Current receivables</b>	<b>3 839</b>	<b>2 713</b>
<b>Cash and cash equivalents</b>	<b>7 562</b>	<b>14 491</b>
<b>Current assets</b>	<b>11 401</b>	<b>17 204</b>
<b>Assets</b>	<b>11 438</b>	<b>17 328</b>
<b>EQUITY AND LIABILITIES</b>		
Contributed capital	2 477	2 432
Retained earnings	7 431	14 139
<b>Equity</b>	<b>9 908</b>	<b>16 571</b>
Trade payables	1 141	238
Other payables	389	520
<b>Current liabilities other than provisions</b>	<b>1 530</b>	<b>758</b>
<b>Liabilities other than provisions</b>	<b>1 530</b>	<b>758</b>
<b>Equity and liabilities</b>	<b>11 438</b>	<b>17 329</b>

**Statement of changes in shareholder equity**

TDKK	Contributed capital	Retained earnings	Total
<b>January 1, 2019</b>	<b>2 432</b>	<b>14 140</b>	<b>16 571</b>
Increase of capital	46	1 306	1 351
Other equity postings		273	273
Profit/loss for the period		-8 288	-8 288
<b>December 31, 2019</b>	<b>2 477</b>	<b>7 431</b>	<b>9 908</b>

**Statement of cash flow**

TDKK	Q4:2019	Q4:2018	2019	2018
Operating profit/loss	-2 503	-2 508	-9 339	-12 611
Amortisation, depreciation and impairment losses	21	22	87	88
Changes in working capital	-1 873	-198	-1 072	-2 702
<b>Cash flow from operating activities before financial items</b>	<b>-4 355</b>	<b>-2 684</b>	<b>-10 323</b>	<b>-15 225</b>
Financial income paid	-585	33	-636	-93
Tax credit	2 406	1 735	2 406	1 735
<b>Cash flow from operating activities</b>	<b>-2 534</b>	<b>-916</b>	<b>-8 553</b>	<b>-13 583</b>
<b>Investing activities</b>				
Investment in tangible assets	0	0	0	0
Investments in intangible assets	0	0	0	0
Investments in other financial assets	0	0	0	0
<b>Cash flow from investing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Financing activities</b>				
New share issue	1 351	8 798	1 351	20 760
Issue of warrants	0	23	273	144
Proceeds from loan	-3 478			
<b>Cash flow from financing activities</b>	<b>-2 127</b>	<b>8 821</b>	<b>1 625</b>	<b>20 904</b>
<b>Increase/decrease in cash and cash equivalents</b>	<b>-4 661</b>	<b>7 905</b>	<b>-6 929</b>	<b>7 321</b>
<b>Cash and cash equivalents at the end of period</b>	<b>7 562</b>	<b>14 491</b>	<b>7 562</b>	<b>14 491</b>

## 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