

## INITIATOR PHARMA: PREPARING FOR THE CLINICAL PHASE

### 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. Because of this, comparing numbers refer to the time period 2016-05-02 – 2016-12-31.

<b>Fourth Quarter (2017-10-01 – 2017-12-31)</b>
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -3,863 (-713)
• Earnings per share was DKK -0.27 (-0.14)

<b>Full Year (2017-01-01 – 2017-12-31)</b>
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -9,561 (-887)
• Earnings per share was DKK -1.04 (-0.18)
• Cash and bank: TDKK 7,169 (167)
• Solidity: 64%

*Group earnings per share: period result divided by a number of 8 683 943 stocks (on 2017-12-31).  
Solidity: equity divided by assets.*

### Business highlights in Q4 2017

- In October Initiator Pharma A/S initiated its first Good Laboratory Practice (GLP) toxicology and toxicokinetic rat study at Syngene, Bangalore, India.
- In November the company received very positive preliminary results from its first Good Laboratory Practice (GLP) toxicology and toxicokinetic rat study at Syngene, Bangalore, India.
- In December the company reported that it had successfully completed an *in vivo* 28 days toxicology study in mini-pigs for its drug candidate IPED2015, thus moving the development program forward towards the Clinical Trial Application (CTA) and with the aim of initiating a Phase 1 clinical trial next year.

### Significant events after this reporting period

- In January the company announced that it had successfully completed the preclinical development of its drug candidate IPED2015. The studies were concluded ahead of the previously announced schedule and included experimental work with most of the recent positive data from the cardiovascular telemetry study, the respiratory study and a clean genotoxicity profile.
- The company announced that the company has received an Intention to Grant notice from the European Patent Office ("EPO") for its patent application for the IPDP2015 product candidate. In essence, this means that the EPO intends to approve the company's application.
- The board proposed an Extraordinary General Meeting to conduct a rights issue of up to 8 683 941 shares and 5 789 294 attached consideration-free share options of series TO1, as units. Fully subscribed rights issue provides Initiator Pharma initially with approximately SEK 19.1 million through subscription of shares and a further approximately SEK 12.7 million in the case that all attached share options are exercised. In total, approximately SEK 31.8 million before issuing costs. The company's main ambition with this financing model is that, in the case that both the now imminent rights issue and the exercise of share options of series TO1 are fully subscribed, no further capital needs to be raised to develop IPED2015 to the point which has been Initiator Pharma's main goal all along – clinical Phase 2a proof of concept.

### Comments from the CEO

"In Q4 Initiator Pharma obtained positive data from the toxicologic and toxicokinetic animal studies and in January we announced the successful completion of the preclinical development of IPED2015. The

recent advances means that we can now implement our plans for the start of clinical Phase 1 studies in humans in the middle of this year. In order to fund these plans the board of directors has decided to conduct a preferential rights issue. It is the company's ambition that if Extraordinary Assembly to be held on March 1 approves the proposal and if the share issue as well as the warrant program TO1 is fully subscribed the company will be fully funded to complete the clinical Phase IIa proof of concept for IPED2015.

**For more information, please contact**

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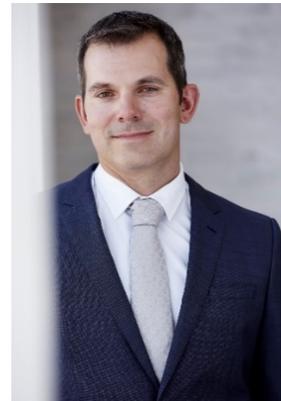
**About Initiator Pharma**

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

## Letter from the CEO

In January of 2018, we were able to announce that we had completed pre-clinical development ahead of the set schedule. The positive results of the final genotoxicity and safety pharmacology studies in the preclinical development of IPED2015 mean that we have cleared a major obstacle for the future development of IPED2015. The fact that the study was completed ahead of schedule is obviously an extra bonus, which shows the commitment and expertise of our entire team. Now the time has come to look ahead and begin to study IPED2015 in humans.



*“We now believe that we can achieve a clinical phase IIa Proof of Concept in the first half of 2019, approximately a year ahead of the original plan and at a lower cost. We believe that we, after a successful clinical phase IIa study, will have a data package for IPED2015 that is interesting to potential pharmaceutical partners. This would allow for an exit option as early as 2019.”*

Our goal now is to begin a clinical phase I study as soon as possible. Regarding the upcoming clinical development, we have made an important strategic decision which will have positive effects on both time and costs. We now believe that the clinical phase I study can be completed before the end of 2018. The clinical phase IIa study will then commence as soon as possible. Our goal is to complete it with a clinical phase IIa Proof of Concept in the first half of 2019, roughly a year ahead of the original schedule and at a lower cost for the Company and its shareholders. With a successful clinical phase IIa study, we expect to have a data package for IPED2015 which is interesting to potential pharmaceutical partners. This would then allow us to exit before the end of 2019. The board of Initiator Pharma expects the remaining development costs of IPED2015, including clinical phase IIa Proof of Concept and potential exit, to be around SEK 30 million, rather than the original estimate of SEK 50 million.

*“Since listing the Company on the stock market around a year ago, we have been able to keep a high development pace and deliver according to our plan and budget, which I consider strong proof of both the quality of our pharmaceutical candidate IPED2015 and the expertise of the team behind Initiator Pharma.”*

The life expectancy is ever increasing, and the world's population is increasingly suffering from various lifestyle diseases like diabetes and cardiovascular diseases. This means that the male part of the population is also increasingly afflicted by erectile dysfunction (ED). The medical indication ED affects a man's ability to achieve and maintain an erection, i.e. his sexual capacity. But research has shown that the problem can also have other serious consequences. The indication ED can lead to loss of self-confidence, depression, relationship problems and a general decline in quality of life. In other words, it is very important to find effective treatments for patients suffering from ED, not least because an effective treatment leads to improved mental health and a significantly improved quality of life both in the patient and his partner.

*“The single most important reason to invest in Initiator Pharma is that we can provide a solution to a very serious medical problem that affects a lot of people.”*

Today, many ED sufferers are helped by medicines such as tadalafil, vardenafil and not least sildenafil, more known under the commercial brand Viagra®. However, 30-40 per cent of all those diagnosed with ED, which is more than 150 million patients, do not respond to the treatment for various medical reasons. We founded Initiator Pharma with the idea of researching a family of pharmaceutical candidates based on MRI technology (Monoamine Reuptake Inhibitor). The main candidate in this family is IPED2015, which may constitute a new type of treatment for ED, specifically targeted at those patients who do not respond to existing treatments. Our goal has from the start been to develop IPED2015 into a clinical phase IIa Proof of Concept, an important point in our development as, at this point, we can document the effect and safety of IPED2015.

To finance the clinical phase I study and the clinical phase IIa study for a Proof of Concept, we now plan to carry out a rights issue of units equal to around SEK 30 million, of which approximately SEK 18 million can be added to the company initially and approximately SEK 12 million can be added to the company through full use of associated warrants redeemable in the fourth quarter of 2018. The main ambition of this financing model, in case both parts are fully subscribed, is for no additional capital to be needed for the development of IPED2015 to reach the point which we have had as our focal point since the start, the clinical phase IIa Proof of Concept.

*“I believe that Initiator Pharma is a good investment as IPED2015 addresses a major, currently unaddressed medical need. In combination with the strategic decision we recently made on a more efficient clinical development plan which both reduces the total cost and the schedule, we expect to achieve a proof of concept in 2019.”*

I see a number of reasons for Initiator Pharma being a good investment. Firstly, we have a pharmaceutical candidate which at a preclinical stage has shown to have good effectiveness and low toxicity, which obviously bodes well for the clinical studies. We are addressing a major market need where we have identified a niche in which a large number of patients currently lack effective treatment. Our time and cost effective development plan also means that we can achieve a proof of concept, our most important value-creating point, before the end of 2019. The single most important reason for investing in Initiator Pharma is that we can provide a solution to a very serious medical problem which affects a lot of people. With these words, I wish to invite you to invest in Initiator Pharma.

Claus Elsberg Olesen  
CEO, Initiator Pharma A/S



## 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. Because of this, comparing numbers refer to the time period 2016-05-02 – 2016-12-31.

Financial review				
TDKK	Q4:2017	Q4:2016	2017	2016
Net sales	0	0	0	0
Total operating expenses	-3 863	-713	-9 561	-887
Operating profit/loss	-3 863	-713	-9 561	-887
Cash flow from operating activities	-3 685	92	-7 784	-178
Operating margin, %	neg	neg	neg	neg
Average number of employees, #	1,5	0,5	1,5	0,5
Earnings per share, DKK	-0,27	-0,14	-1,04	-0,18
Diluted earnings per share, DKK	-0,27	-0,14	-1,04	-0,18
			<b>31.12.2017</b>	<b>31.12.2016</b>
Cash and cash equivalents			7 169	167
Equity			5 964	-371
Total equity and liabilities			9 298	563
Equity ratio, %			64 %	neg
<i>Number of shares outstanding</i>			8 683 943	4 962 254
<i>Number of shares, fully diluted</i>			8 683 943	4 962 254
<i>Weighted number of shares</i>			8 218 732	4 932 202

## Revenues and result of the operation

### Revenue

Initiator Pharma generated total revenues of TDKK 0 for the fourth quarter of 2017 (0) and TDKK 0 for the full year 2017 (0).

### Operating profit/loss

The company recognized an operating loss of TDKK 3,863 for the fourth quarter of 2017 (-713), and TDKK 9,561 for the full year 2017 (-887). The increase in operating costs in the fourth quarter of 2017 and for the full year 2017 reflects both the start-up of the preclinical development program for IPED2015 that is required before the company can progress the drug candidate into clinical trials, anticipated to start in the 2<sup>nd</sup> half of 2018, as well as increased administrative costs.

External R&D costs in the fourth quarter amounted to TDKK 2,795, compared to 0 in the same period in 2016. For the full year the external R&D costs amounted to TDKK 6,088, compared to 0 in the same period in 2016.

### Financial position

The equity as of December 31, 2017 was TDKK 5,964. Cash and cash equivalents amounted to TDKK 7,169 as of December 31, 2017. Total assets as of December 31, 2017, were TDKK 9,298.

On February 15<sup>th</sup> the company successfully completed a preferential rights issue raising approximately MDKK 15.9 gross and MDKK 14.8 net of transaction related costs. With these proceeds the company expects to have sufficient capital to fund the planned development activities through 1Q:2018.

On September 6<sup>th</sup> the board approved the subscription of warrants as part of the company's incentive program. The program was fully subscribed, with a total of 434,197 warrants being subscribed at a subscription price of SEK 0.49 per warrant, totaling net proceeds to the company of TDKK 166.

## Cash flow

In the fourth quarter of 2017 the total operating cash flow was TDKK -3,685, incl a positive change in working capital of TDKK 409. Cash flow from investment activities was TDKK -0. Cash flow from financing activities was TDKK 0.

For the full year 2017 the operating cash flow was TDKK -7,784, incl a positive change in working capital of TDKK 2,449. Cash flow from investment activities was TDKK -132 and cash flow from financing activities was TDKK 14,917.

## The share, share capital and ownership structure

At December 31, 2017, the number of shares outstanding amounted to 8,683,943. The company has as of December 31 a total of 434.197 outstanding warrants, representing 5.0% of the number of issued shares.

At December 31, 2017 the company had around 3,600 shareholders. The 25 largest shareholders in the company on December 31 owned 63,4% of all outstanding shares:

Top 25 shareholders as of December 31, 2017		
Owners	Number of shares	Shares %
BNY Mellon SA/NV (Former BNY)	929 159	10,70 %
Mikael Södergård Thomsen APS	505 946	5,83 %
Claus Olesen Holding APS	503 348	5,80 %
DanPet AB	503 348	5,80 %
Försäkringsaktiebolaget, Avanza Pension	345 659	3,98 %
Olofsson, Christian	300 000	3,45 %
Swedish Growth Fund AB	272 724	3,14 %
Nordnet Pensionsförsäkring AB	269 392	3,10 %
Feldthus, Thomas	267 143	3,08 %
Leif Andersen Consulting ApS	250 859	2,89 %
Hendriksen, Lars	170 353	1,96 %
Sv Handelsbanken Copenhagen branch	126 176	1,45 %
Christophersen, Palle	117 143	1,35 %
JP Morgan Luxembourg	100 429	1,16 %
Tha<ser Holding ApS	100 100	1,15 %
Larsen, Janus Schreiber	100 058	1,15 %
Brästrup, Claus	96 050	1,11 %
Clearstream Banking S.A, W8IMY	84 659	0,97 %
Peters, Leif Anders Rudolf	72 726	0,84 %
Aktiebolaget Skånska Bruk	70 000	0,81 %
SEB Life - CJ Wachtmeister Consult	68 148	0,78 %
Nordea Livsförsäkring Sverige AB	66 667	0,77 %
CBNY-Scharles Schwab FBO Customer	65 000	0,75 %
HCN Group AB	60 545	0,70 %
SIX SIS AG, W8IMY	60 000	0,69 %
Other shareholders	3 178 311	36,60 %
<b>Total</b>	<b>8 683 943</b>	<b>100,00 %</b>

## Personnel

As of December 31, 2017, 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 memorandum and small prospectus published in January 2017.

#### **Audit review**

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

## Annual General Meeting and Annual Report

The Annual General Meeting will be held on May 25<sup>th</sup> 2018 at 15:00 at Fredrik Nielsens Vej 2, Byggnad 1422 (Aarhus University) in Aarhus. The Board of Directors will recommend to the Annual General Meeting that no dividend is paid out for the accounting year 2017. The Annual Report will be published on the company's web page no later than May 4<sup>th</sup> 2018.

## Financial calendar

Year-End Report 2017	February 21, 2018
Interim Report Q1	May 25, 2018
Interim Report Q2	August 24, 2018
Interim Report Q3	November 23, 2018
Year-End Report 2018	February 22, 2019

Aarhus, February 20, 2018

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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

<b>Statement of income</b>				
<b>TDKK</b>	<b>Q4:2017</b>	<b>Q4:2016</b>	<b>2017</b>	<b>2016</b>
Gross loss	-3 482	-532	-8 180	-700
Staff costs	-359	-175	-1 297	-175
Depreciation and write-downs	-22	-6	-84	-12
<b>Operating profit/loss</b>	<b>-3 863</b>	<b>-713</b>	<b>-9 561</b>	<b>-887</b>
Other financial expenses	-298	-5	-801	-5
<b>Profit after financial items</b>	<b>-4 161</b>	<b>-718</b>	<b>-10 362</b>	<b>-892</b>
Tax	1 780	0	1 780	0
<b>Net profit for the period</b>	<b>-2 381</b>	<b>-718</b>	<b>-8 582</b>	<b>-892</b>

<b>Statement of financial position</b>		
<b>TDKK</b>	<b>2017</b>	<b>2016</b>
<b>ASSETS</b>		
Patents	78	101
<b>Intangible assets</b>	<b>78</b>	<b>101</b>
Fixture, fittings, tools and equipment	134	64
<b>Property, plant and equipment</b>	<b>134</b>	<b>64</b>
<b>Fixed assets</b>	<b>212</b>	<b>165</b>
Other receivables	182	32
Tax credit	1 735	0
Prepayments	0	199
<b>Current receivables</b>	<b>1 917</b>	<b>231</b>
<b>Cash and cash equivalents</b>	<b>7 169</b>	<b>167</b>
<b>Current assets</b>	<b>9 086</b>	<b>398</b>
<b>Assets</b>	<b>9 298</b>	<b>563</b>
<b>EQUITY AND LIABILITIES</b>		
Share capital	912	521
Other contributed capital	14 361	
Retained earnings	-9 308	-892
<b>Equity</b>	<b>5 964</b>	<b>-371</b>
Other payables	3 334	934
<b>Current liabilities other than provisions</b>	<b>3 334</b>	<b>934</b>
<b>Liabilities other than provisions</b>	<b>3 334</b>	<b>934</b>
<b>Equity and liabilities</b>	<b>9 298</b>	<b>563</b>

## Statement of changes in shareholder equity

TDKK	Contributed capital	Retained earnings	Total
<b>January 1, 2017</b>	<b>521</b>	<b>-892</b>	<b>-371</b>
Increase of capital	391	14 360	14 751
Issue of warrants		166	166
Profit/loss for the period	0	-8 582	-8 582
<b>December 31, 2017</b>	<b>912</b>	<b>5 052</b>	<b>5 964</b>

## Statement of cash flow

TDKK	Q4:2017	Q4:2016	2017	2016
Operating profit/loss	-3 863	-713	-9 561	-887
Amortisation, depreciation and impairment losses	22	6	84	12
Changes in working capital	409	799	2 449	703
<b>Cash flow from operating activities before financial items</b>	<b>-3 432</b>	<b>92</b>	<b>-7 028</b>	<b>-173</b>
Interest income received	45	0	118	0
Interest expense paid	-343	-5	-919	-5
Tax credit	45	0	45	0
<b>Cash flow from operating activities</b>	<b>-3 685</b>	<b>87</b>	<b>-7 784</b>	<b>-178</b>
<b>Investing activities</b>				
Investment in tangible assets	0	-65	0	-65
Investments in intangible assets	0	0	-132	-112
Investments in other financial assets	0	0	0	0
<b>Cash flow from investing activities</b>	<b>0</b>	<b>-65</b>	<b>-132</b>	<b>-177</b>
<b>Financing activities</b>				
New share issue	0	0	14 751	521
Issue of warrants	0	0	166	0
<b>Cash flow from financing activities</b>	<b>0</b>	<b>0</b>	<b>14 917</b>	<b>521</b>
<b>Increase/decrease in cash and cash equivalents</b>	<b>-3 685</b>	<b>22</b>	<b>7 002</b>	<b>167</b>
<b>Cash and cash equivalents at the end of period</b>	<b>7 169</b>	<b>167</b>	<b>7 169</b>	<b>167</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