

## INITIATOR PHARMA: ONGOING CLINICAL PHASE 1 TRIAL

### 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 (2018-10-01 – 2018-12-31)</b>
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -2,508 (-3,863)
• Earnings per share was DKK -0.00 (-0.26)

<b>Full Year (2018-01-01 – 2018-12-31)</b>
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -12,611 (-9,561)
• Earnings per share was DKK -0.51 (-1.04)
• Cash and bank: TDKK 14,491 (7,169)
• Solidity: 96%

*Group earnings per share: period result divided by 23 157 178 shares (on 2018-12-31).*

*Solidity: equity divided by total assets.*

### Business highlights in Q4 2018

- On October 3<sup>rd</sup> we announced that we had received approval for an amendment to the clinical trial protocol to the Medicines & Healthcare products Regulatory Agency, MHRA, UK as well as the Ethics Committee, EC.
- On October 29<sup>th</sup> we announced that we were ready to continue the Phase Clinical trials with IPED2015 in the week of the 12<sup>th</sup> of November.
- On November 6<sup>th</sup> we announced that we had raised SEK 12,7 in gross proceeds from the TO1 warrant program and a directed share issue in connection with the warrant program.
- On November 8<sup>th</sup> we announced that we had signed an option agreement with Saniona AB, for a phase 2 ready drug candidate.
- On November 23<sup>rd</sup> we announced that we had completed first dosing of the re-started Phase I study.

### Significant events after this reporting period

- None

### Update on the ongoing Phase 1 trial for IPED2015

The Phase 1 trial is progressing well, and no clinically significant adverse events have been observed since the restart of the trial. We are now approaching the expected clinically relevant dose levels and the current data is still supportive, and we will continue executing the trial at its current plan. We expect to report phase 1 data during H1:2019. If successful we plan to immediately progress the compound into a phase 2a clinical proof of concept trial, with headline data available mid 2019.

### Comments from the CEO

*"In Q4 we re-started the clinical phase 1 trial after the cardiovascular incident that was communicated to the market on August 22<sup>nd</sup>, and reported that the first cohort of healthy subject showed no clinical signs. We are very pleased with the progress of the Phase 1 trial and satisfied with the general conductance of the trial by MAC Clinical research, including the continuing recruitment of healthy subjects. We are looking forward to completing the Phase I study and are now preparing for the upcoming Phase 2a trial. We appreciate the support from existing and new shareholders for the*

*succesfull close of the TO1 warrant program and look forward to report data from our Proof-of- Concept study around mid-year”.*

**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

Q4 2018 has been an active quarter for Initiator Pharma with the satisfactory re-start of the Phase 1 clinical trial for IPED2015, the successful completion of the TO1 warrant program and the expansion of our pipeline with a Phase 2 ready compound through an option agreement with Saniona.

We plan to complete the ongoing clinical phase I study for IPED2015. The clinical phase IIa Proof of Concept study will then commence as soon as possible after the completion of the Phase I. Our goal is to complete the phase IIa study in the first half of 2019 – with headline results available mid-2019 - roughly a year ahead of the original schedule. With a successful clinical phase IIa study, we expect to have a data package for IPED2015 which will be interesting to potential pharmaceutical partners.

*“We are very pleased with the progress of the Phase 1 trial and satisfied with the general conductance of the trial by MAC Clinical research, including the continuing recruitment of healthy subjects. We are looking forward to continue the execution of the Phase I study and are preparing for the upcoming Phase 2a trial”*

To finance the remaining part of the clinical development of IPED2015 we relied on a full subscription of the TO1 warrants associated to the rights issues conducted back in April 2018. The TO1 warrant program was subscribed at 94% and we secured the remaining funding through a direct share issue. We now have funding to complete the Phase 2a Proof-of-Concept.

The signing of the option agreement for the drug candidate AN788, provides us with a promising Phase 2 ready compound. The agreement gives us time to fully evaluate its clinical and commercial potential at a minimal cost for the company – and potentially allow us to expand our pipeline with another clinical asset that matches and complements the current ongoing activities and the development pipeline of Initiator Pharma.

*“I believe that Initiator Pharma is a good investment as IPED2015 addresses a major, currently unaddressed medical need. With the potential in-licensing of another phase 2 ready drug candidate we are in a position to build a strong portfolio of clinical stage drug candidates - based on the same technological platform – with significant potential for both patients and shareholders.”*

I see a number of reasons for Initiator Pharma being a good investment. Firstly, we have IPED2015 which until now in both phase 1 and preclinical studies has shown to have good effectiveness and low toxicity, which obviously bodes well for the continuing clinical studies. We are addressing the treatment of Erectile Dysfunction, a major market where we expect to treat/help a large number of patients currently lacking effective treatment. Our time and cost effective development plan also means that we can achieve Proof-of-Concept for IPED2015 - the key value inflection point in our development program – during 2019.

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.

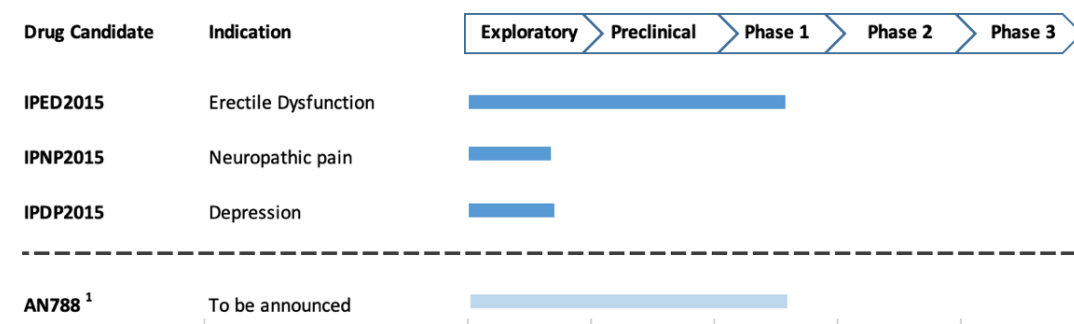
## Business model

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:



<sup>1</sup> One year exclusive option agreement, entered in November 2018

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 we expect to report phase 1 data during H1:2019. If successful we plan to immediately progress the compound into a phase 2a clinical proof of concept trial, with headline data available mid 2019.

In Q4:18 we announced that we had secured a 1 year exclusive option agreement for AN788, 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. Initiator Pharma intends to reposition the drug candidate based on our expertise with monoamine-reuptake inhibitors. The drug candidate has through the clinical studies already conducted been de-risked to a significant degree, and may therefore be assessed in a cost-effective Phase IIa, Clinical Proof of Concept study in a patient population with a high unmet medical need.

## **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 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.

## 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	Q4:2018	Q4:2017	2018	2017
Net sales	0	0	0	0
Total operating expenses	-2 508	-3 863	-12 611	-9 561
Operating profit/loss	-2 508	-3 863	-12 611	-9 561
Cash flow from operating activities	-916	-3 685	-13 582	-7 784
Operating margin, %	neg	neg	neg	neg
Average number of employees, #	0,5	1,5	1,0	1,5
Earnings per share, DKK	0,00	-0,26	-0,51	-1,04
Diluted earnings per share, DKK	0,00	-0,26	-0,51	-1,04
			<b>31.12.2018</b>	<b>31.12.2017</b>
Cash and cash equivalents			14 491	7 169
Equity			16 570	5 964
Total equity and liabilities			17 328	9 298
Equity ratio, %			96 %	neg
<i>Number of shares outstanding</i>			23 157 178	8 683 943
<i>Number of shares, fully diluted</i>			24 025 572	9 118 140
<i>Weighted number of shares</i>			20 081 616	8 218 732

## Revenues and result of the operation

### Revenue

Initiator Pharma generated total revenues of TDKK 0 for the fourth quarter of 2018 (0) and TDKK 0 for the full year 2018 (0).

### Operating profit/loss

The company recognized an operating loss of TDKK 2,508 for the fourth quarter of 2018 (-3,863), and TDKK 12,611 for the full year 2018 (-9,561). The increase 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 early H2:2018.

External R&D costs in the fourth quarter amounted to TDKK 1,156, compared to 2,795 in the same period in 2017. For the full year the external R&D costs amounted to TDKK 8,666, compared to 6,088 in the same period in 2017.

### Financial position

The equity as of December 31, 2018 was TDKK 16,570. Cash and cash equivalents amounted to TDKK 14,491 as of December 31, 2018. Total assets as of December 31, 2018, were TDKK 17,328.

On April 5<sup>th</sup> the company successfully completed a preferential rights issue raising approximately MDKK 13.8 gross and MDKK 12.1 net of transaction related costs. In connection with the share issue the company issued 5,789,294 T01 warrants, with each warrant giving the right to subscribe to one share at a share price of SEK 2,20 during Q4. On November 6<sup>th</sup> the company announced that 94.4% of the T01 warrant program was subscribed for. Combined with a directed share issue of 326,451 shares the T01 warrant program raised approx MDKK 9.2 before transaction related costs.

With these proceeds the company expects to have sufficient capital to fund the planned development activities through 2019 and the data read-out from the clinical phase 2 proof of concept trial.

## Cash flow

In the fourth quarter of 2018 the total operating cash flow was TDKK -2,864, incl a negative change in working capital of TDKK 198. Cash flow from investment activities was TDKK -0. Cash flow from financing activities was TDKK 8,821.

For the full year 2018 the operating cash flow was TDKK -15,224, incl a negative change in working capital of TDKK 2,701. Cash flow from investment activities was TDKK 0 and cash flow from financing activities was TDKK 20,904.

## The share, share capital and ownership structure

At December 31, 2018, the number of shares outstanding amounted to 23,157,178. 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, 2018 the company had around 3,600 shareholders. The 25 largest shareholders in the company on December 31 owned 49,9% of all outstanding shares:

Top 25 shareholders as of December 31, 2018		
Owners	Number of shares	Shares %
BNY Mellon SA/NV (Former BNY)	1 380 078	5,96 %
Nordnet Pensionsförsäkring AB	1 356 617	5,86 %
Försäkringsaktiebolaget, Avanza Pension	1 317 828	5,69 %
Swedish Growth Fund AB	726 804	3,14 %
Claus Olesen Holding APS	692 738	2,99 %
UBS Switzerland AG	575 853	2,49 %
DanPet AB	537 438	2,32 %
Mikael Södergård Thomsen APS	505 946	2,18 %
Lars Henriksen A/S	452 711	1,95 %
Peters, Leif Anders Rudolf	451 511	1,95 %
Sv Handelsbanken Copenhagen branch	418 552	1,81 %
Olofsson, Christian	360 000	1,55 %
Thauser Holding ApS	295 156	1,27 %
Härilin, Thomas	279 580	1,21 %
Feldthus, Thomas	267 143	1,15 %
Leif Andersen Consulting ApS	250 859	1,08 %
Clearstream Banking S.A, W8IMY	225 754	0,97 %
Olin, Lennart	219 898	0,95 %
Ålandsbanken i ågares ställe	211 965	0,92 %
Muller, Christina Matthias	185 000	0,80 %
SEB Life - CJ Wachtmeister Consult	181 728	0,78 %
Coolmate ApS	173 416	0,75 %
Henriksen, Lars	170 353	0,74 %
Marnfeldt, Bengt	165 000	0,71 %
Trygg, Jonny Oscar	151 565	0,65 %
Other shareholders	11 603 685	50,11 %
<b>Total</b>	<b>23 157 178</b>	<b>100,00 %</b>

## Personnel

As of December 31, 2018, 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, February 22, 2019

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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

<b>TDKK</b>	<b>Q4:2018</b>	<b>Q4:2017</b>	<b>2018</b>	<b>2017</b>
Gross loss	-2 207	-3 482	-11 437	-8 180
Staff costs	-279	-359	-1 086	-1 297
Depreciation and write-downs	-22	-22	-88	-84
<b>Operating profit/loss</b>	<b>-2 508</b>	<b>-3 863</b>	<b>-12 611</b>	<b>-9 561</b>
Other financial expenses	33	-298	-93	-801
<b>Profit after financial items</b>	<b>-2 475</b>	<b>-4 161</b>	<b>-12 704</b>	<b>-10 362</b>
Tax	2 406	1 780	2 406	1 780
<b>Net profit for the period</b>	<b>-69</b>	<b>-2 381</b>	<b>-10 298</b>	<b>-8 582</b>

**Statement of financial position**

<b>TDKK</b>	<b>2018</b>	<b>2017</b>
<b>ASSETS</b>		
Patents	56	78
<b>Intangible assets</b>	<b>56</b>	<b>78</b>
Fixture, fittings, tools and equipment	68	134
<b>Property, plant and equipment</b>	<b>68</b>	<b>134</b>
<b>Fixed assets</b>	<b>124</b>	<b>212</b>
Other receivables	307	182
Tax credit	2 406	1 735
Prepayments	0	0
<b>Current receivables</b>	<b>2 713</b>	<b>1 917</b>
<b>Cash and cash equivalents</b>	<b>14 491</b>	<b>7 169</b>
<b>Current assets</b>	<b>17 204</b>	<b>9 086</b>
<b>Assets</b>	<b>17 328</b>	<b>9 298</b>
<b>EQUITY AND LIABILITIES</b>		
Contributed capital	2 432	912
Retained earnings	14 138	5 052
<b>Equity</b>	<b>16 570</b>	<b>5 964</b>
Other payables	758	3 334
<b>Current liabilities other than provisions</b>	<b>758</b>	<b>3 334</b>
<b>Liabilities other than provisions</b>	<b>758</b>	<b>3 334</b>
<b>Equity and liabilities</b>	<b>17 328</b>	<b>9 298</b>

**Statement of changes in shareholder equity**

TDKK	Contributed capital	Retained earnings	Total
<b>January 1, 2018</b>	<b>912</b>	<b>5 052</b>	<b>5 964</b>
Increase of capital	1 520	19 240	20 760
Issue of warrants		144	144
Profit/loss for the period		-10 298	-10 298
<b>December 31, 2018</b>	<b>2 432</b>	<b>14 138</b>	<b>16 570</b>

**Statement of cash flow**

TDKK	Q4:2018	Q4:2017	2018	2017
Operating profit/loss	-2 508	-3 863	-12 611	-9 561
Amortisation, depreciation and impairment losses	22	22	88	84
Changes in working capital	-198	409	-2 701	2 449
<b>Cash flow from operating activities before financial items</b>	<b>-2 684</b>	<b>-3 432</b>	<b>-15 224</b>	<b>-7 028</b>
Interest income received	45	45	238	118
Interest expense paid	-12	-343	-331	-919
Tax credit	1 735	45	1 735	45
<b>Cash flow from operating activities</b>	<b>-916</b>	<b>-3 685</b>	<b>-13 582</b>	<b>-7 784</b>
<b>Investing activities</b>				
Investment in tangible assets	0	0	0	0
Investments in intangible assets	0	0	0	-132
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>-132</b>
<b>Financing activities</b>				
New share issue	8 798	0	20 760	14 751
Issue of warrants	23	0	144	166
<b>Cash flow from financing activities</b>	<b>8 821</b>	<b>0</b>	<b>20 904</b>	<b>14 917</b>
<b>Increase/decrease in cash and cash equivalents</b>	<b>7 905</b>	<b>-3 685</b>	<b>7 322</b>	<b>7 002</b>
<b>Cash and cash equivalents at the end of period</b>	<b>14 491</b>	<b>7 169</b>	<b>14 491</b>	<b>7 169</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