

## INITIATOR PHARMA: Q3 report 2018

### 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>Third Quarter (2018-07-01 – 2018-09-30)</b>
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -3,699 (-2,464)
• Earnings per share was DKK -0.21 (-0.29)

  

<b>First Nine Months of the Year (2018-01-01 – 2018-09-30)</b>
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -10,103 (-5,968)
• Earnings per share was DKK -0.71 (-0.77)
• Cash and bank: TDKK 6,586 (10,854)
• Solidity: 91% (75%)

*Group earnings per share: period result divided by a number of 17 367 884 stocks (on 2018-09-30).  
Solidity: equity divided by assets.*

### Business highlights in Q3 2018

- On August 22<sup>nd</sup> we announced that we had started dosing of the first healthy subjects in the Phase 1 study with IPED2015 at MAC Clinical Trial Center in Manchester. A cardiovascular incident in one subject was observed, and the trial was put on pause while awaiting full examination of the case.
- On August 24<sup>th</sup> we reported that the incentive warrant program approved by the AGM had been fully subscribed for.
- On September 13<sup>th</sup> we announced that the examination of the cardiovascular incident in the Phase 1 study reported on August 22<sup>nd</sup> had been concluded, and that plans were to submit an amendment to the clinical trial protocol with the Medicines & Healthcare products Regulatory Agency, MHRA.UK.
- On September 21<sup>st</sup> we announced that the amendment to the clinical trial protocol for the Phase 1 study with IPED2015 had been submitted to the Medicines & Healthcare products Regulatory Agency, MHRA, UK.

### Significant events after this reporting period

- On October 3<sup>rd</sup> we reported that we received approval by MHRA in the UK to continue the Phase 1 trial for IPED2015.
- On October 11<sup>th</sup> we announced the start of the subscription period for the series TO1 warrants.
- On October 29<sup>th</sup> we announced that we are ready to resume dosing of IPED2015 in Phase 1 again, starting in the week of November 12<sup>th</sup>.
- On November 6<sup>th</sup> we announced the successful completion of the series TO1 warrant subscription period, raising a total of SEK 12.7 in gross proceeds to the company.
- On November 8<sup>th</sup> we announced that we had signed an option agreement with Saniona for a Phase 2 ready compound.
- On November 23<sup>rd</sup> we announced that we have re-started the Phase I with IPED2015.

### Comments from the CEO

"With the initiation of the Phase 1 trial of IPED2015 during Q3:18 Initiator Pharma has made the transformation into a clinical stage company. We have big expectations that IPED2015 will become a first in class oral treatment of Erectile Dysfunction for the large number of patients that do not respond to drugs in the PDE5i class. Contingent on a successful completion on the Phase 1 trial we remain

optimistic that we will be able to complete the clinical phase IIa Proof of Concept in the first half of 2019.

While maintaining full focus on the development program for IPED2015 we are also looking forward to leveraging the expertise within Initiator Pharma by expanding our pipeline with attractive assets that can provide value to the company and shareholders in addition to helping patients with unmet needs”

### **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

Q3 has been an eventful quarter for Initiator Pharma. The clinical phase 1 for IPED 2015 was initiated in August at MAC Clinical research, Manchester, UK. On August 22<sup>nd</sup> we reported that a cardiovascular incident in one subject was observed. There were no clinical symptoms but a technical abnormality on the readout of the cardiac function was observed. The subject was free of symptoms and felt fine all time during the dosing assessment period. The plasma levels of the drug were as expected much lower than what might cause any pharmacological effect based on the significant safety data package and safety index obtained from the preclinical data.



The company and its advisors in collaboration with MAC have examined the incidence in depth and on September 21<sup>st</sup> filed an amendment to the protocol with Medicines & Healthcare products Regulatory Agency, MHRA, UK as well as the Ethics Committee, EC which was subsequently approved.

Dosing in the Phase 1 study was resumed in the week commencing on November 12<sup>th</sup>. We are now looking forward to demonstrate the safety and tolerability of IPED2015 by reaching effective dose levels. Results from the Phase 1 will be reported upon conclusion of the study.

The plan is still to commence a clinical phase IIa study as soon as possible after completion of phase 1. Despite our slow start our aim is to complete the clinical phase 2a Proof of Concept in the first half of 2019.

*“We are still on track to achieve a clinical phase 2a 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 an attractive data package for a novel molecule with a unique positioning in the market”*

Besides the scientific activities we also successfully completed the TO1 warrant series associated to the preferential rights issue in March 2018, raising an additional 12 MSEK. This will provide us with sufficient funds to complete the phase 2a Proof-of-concept IPED2015 and necessary runway to complete an attractive deal for IPED2015.

*“We are very pleased with the strong support from the recent exercise of warrants, as it has provided us with sufficient financial resources to achieve a major milestone, becoming a clinical stage Biotech with a Clinical Phase 2a PoC on the horizon. This will be a significant value inflection point for our shareholders and be a major advance for the many ED patients for whom there are currently no effective treatment.”*

I want to use this opportunity to thank the existing shareholders for your continuing support and I would also like to welcome new investors that have obtained shares by buying and utilizing their warrants.

Claus Elsborg 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.

### Financial review

TDKK	3Q:2018	3Q:2017	9M:2018	9M:2017	2017
Net sales	0	0	0	0	0
Total operating expenses	-3 699	-2 464	-10 103	-5 698	-9 561
Operating profit/loss	-3 699	-2 464	-10 103	-5 698	-9 561
Cash flow from operating activities	-3 559	-1 119	-12 666	-4 099	-7 784
Operating margin, %	neg	neg			neg
Average number of employees, #	1	2	1	2	1
Earnings per share, DKK	-0,21	-0,29	-0,71	-0,77	-1,26
Diluted earnings per share, DKK	-0,15	-0,28	-0,43	-0,68	-1,14
	30.09.2018	30.09.2017			31.12.2017
Cash and cash equivalents	6 586	10 854			7 169
Equity	7 819	8 345			5 964
Total equity and liabilities	8 601	11 179			9 298
Equity ratio, %	91 %	75 %			64 %
<i>Number of shares outstanding</i>	<i>17 367 884</i>	<i>8 683 943</i>	<i>17 367 884</i>	<i>8 683 943</i>	<i>8 683 943</i>
<i>Number of shares, fully diluted</i>	<i>23 591 375</i>	<i>9 118 140</i>	<i>23 591 375</i>	<i>9 118 140</i>	<i>9 118 140</i>
<i>Weighted number of shares</i>	<i>17 367 884</i>	<i>8 683 943</i>	<i>14 473 237</i>	<i>8 063 662</i>	<i>8 218 732</i>

## Revenues and result of the operation

### Revenue

Initiator Pharma generated total revenues of TDKK 0 for the third quarter of 2018 (0) and TDKK 0 for the first nine months of 2018 (0).

### Operating profit/loss

The company recognized an operating loss of TDKK 3,699 for the third quarter of 2018 (-2,464). For the first nine months of the year the operating loss was TDKK 10,103 (-5,698). The increase in operating costs in the third quarter and for the first nine months of the year reflect the preparations for and start of the phase 1 clinical trial that was initiated in July 2018.

External R&D costs in the third quarter amounted to TDKK 2,588, compared to TDKK 1,477 in the same period in 2017. For the first nine months of the year external R&D costs totalled TDKK 7,138 compared to TDDK 2,843 in same period in 2017.

### Financial position

The equity as of September 30, 2018 was TDKK 7,819. Cash and cash equivalents amounted to TDKK 6,586 as of September 30, 2018 and total assets were TDKK 8,601.

On April 5<sup>th</sup> the company successfully completed a preferential rights issue raising approximately MSEK 19.1 gross and MSEK 16.8 (MDKK 13.8 and MDKK 12.1 respectively) net of transaction related costs. In addition and in connection with the rights issue we issued 5 789 294 attached consideration-free share options of series TO1, each option allowing for the subscription of 1 new share at at subscription price of SEK 2.20 during the subscription period Oct 11 – Nov 1, 2018. On November 6<sup>th</sup> we announced the successful completion of the TO1 option program, raising an additional MSEK 12.7 gross (MDKK 9.2).

## Cash flow

In the third quarter of 2018 the total operating cash flow was TDKK -3,559 (TDKK -1,111), incl a positive change in working capital of TDKK 55 (TDKK 1,379). Cash flow from investment activities was TDKK -0 (TDKK 0). Cash flow from financing activities was TDKK 121 (TDKK 166) .

For the first nine months of 2018 the operating cash flow was TDKK -12,666 (TDKK -4,099), incl a negative change in working capital of TDKK -2,503 (TDKK 2,040). Cash flow from investment activities was TDKK -0 (TDKK -132) and cash flow from financing activities was TDKK 12,083 (TDKK 14,917).

## The share, share capital and ownership structure

At September 30, 2018, the number of shares outstanding amounted to 17,367,884. The company has as of September 30 a total of 868.394 outstanding warrants, representing 5.0% of the number of issued shares.

At September 30, 2018 the company had around 3,600 shareholders. The 25 largest shareholders in the company on September 30 owned 49,8% of all outstanding shares:

Top 25 shareholders as of September 30, 2018		
Owners	Number of shares	Shares %
BNY Mellon SA/NV (Former BNY)	1 006 519	5,80 %
Nordnet Pensionsforsikring AB	898 102	5,17 %
Försäkringsaktiebolaget, Avanza Pension	767 692	4,42 %
Claus Olesen Holding ApS	616 982	3,55 %
Swedish Growth Fund AB	545 448	3,14 %
DanPet AB	523 802	3,02 %
Mikael Söndergård Thomsen ApS	505 946	2,91 %
Olofsson, Christian	360 000	2,07 %
UBS Switzerland AG	327 010	1,88 %
SV Handelsbanken Copenhagen Branch, Clients ac	303 801	1,75 %
Peters, Leif Anders Rudolf	299 997	1,73 %
Feldthus, Thomas	267 143	1,54 %
Lars Hendriksen A/S	254 945	1,47 %
Leif Andersson Consulting ApS	250 859	1,44 %
JP Morgan Bank Luxembourg S.A	230 428	1,33 %
Thauser Holding ApS	228 490	1,32 %
Hendriksen, Lars	170 353	0,98 %
Clearstream Banking S.A.	169 316	0,97 %
Härlin, Tobias	163 841	0,94 %
Ålandsbanken i ägares ställe	151 589	0,87 %
SEB Life-CJ Wachtmeister Consult	136 296	0,78 %
Coolmate ApS	133 416	0,77 %
Christophersen, Palle	117 143	0,67 %
Brästrup, Claus	110 099	0,63 %
Weist Svensson, Ilona	108 750	0,63 %
Other shareholders	8 719 917	50,21 %
<b>Total</b>	<b>17 367 884</b>	<b>100,00 %</b>

## Personnel

As of September 30, 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

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, November 22, 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

### Statement of income

<b>TDKK</b>	<b>3Q:2018</b>	<b>Q3:2017</b>	<b>9M:2018</b>	<b>9M:2017</b>	<b>2017</b>
Gross loss	-3 428	-2 132	-9 230	-4 698	-8 180
Staff costs	-249	-310	-807	-938	-1 297
Depreciation and write-downs	-22	-22	-66	-62	-84
<b>Operating profit/loss</b>	<b>-3 699</b>	<b>-2 464</b>	<b>-10 103</b>	<b>-5 698</b>	<b>-9 561</b>
Other financial expenses	63	-56	-126	-503	-801
<b>Profit/loss</b>	<b>-3 636</b>	<b>-2 520</b>	<b>-10 229</b>	<b>-6 201</b>	<b>-10 362</b>
Tax					1 780
<b>Net profit for the period</b>	<b>-3 636</b>	<b>-2 520</b>	<b>-10 229</b>	<b>-6 201</b>	<b>-8 582</b>

## Statement of financial position

<b>TDKK</b>	<b>30.09.2018</b>	<b>30.09.2017</b>	<b>2017</b>
<b>ASSETS</b>			
Patents, acquired rights	62	84	78
<b>Intangible assets</b>	<b>62</b>	<b>84</b>	<b>78</b>
Other fixtures, fittings, tools and equipment	85	150	134
<b>Property, plant and equipment</b>	<b>85</b>	<b>150</b>	<b>134</b>
<b>Fixed assets</b>	<b>147</b>	<b>234</b>	<b>212</b>
Other receivables	133	6	182
Income tax receivables	1 735		1 735
Prepayments	0	85	0
<b>Current receivables</b>	<b>1 868</b>	<b>91</b>	<b>1 917</b>
<b>Cash and cash equivalents</b>	<b>6 586</b>	<b>10 854</b>	<b>7 169</b>
<b>Current assets</b>	<b>8 454</b>	<b>10 945</b>	<b>9 086</b>
<b>Assets</b>	<b>8 601</b>	<b>11 179</b>	<b>9 298</b>
<b>EQUITY AND LIABILITIES</b>			
Contributed capital	1 824	15 272	912
Retained earnings	5 995	-6 927	5 052
<b>Equity</b>	<b>7 819</b>	<b>8 345</b>	<b>5 964</b>
Other payables	782	2 834	3 334
<b>Current liabilities other than provisions</b>	<b>782</b>	<b>2 834</b>	<b>3 334</b>
<b>Liabilities other than provisions</b>	<b>782</b>	<b>2 834</b>	<b>3 334</b>
<b>Equity and liabilities</b>	<b>8 601</b>	<b>11 179</b>	<b>9 298</b>

## Statement of changes in shareholder equity

TDKK	Contributed capital	Retained earnings	Total
January 1, 2018	912	5 052	5 964
Increase of capital	912		912
Profit/loss for the period		943	943
September 30, 2018	1 824	5 995	7 819

## Statement of cash flow

TDKK	3Q:2018	3Q:2017	9M:2018	9M:2017	2017
Operating profit/loss	-3 699	-2 464	-10 103	-5 698	-9 561
Amortisation, depreciation and impairment losses	22	22	66	62	84
Changes in working capital	55	1 379	-2 503	2 040	2 449
<b>Cash flow from operating activities before financial items</b>	<b>-3 622</b>	<b>-1 063</b>	<b>-12 540</b>	<b>-3 596</b>	<b>-7 028</b>
Other financial expenses	63	-56	-126	-503	-801
Tax credit					45
<b>Cash flow from operating activities</b>	<b>-3 559</b>	<b>-1 119</b>	<b>-12 666</b>	<b>-4 099</b>	<b>-7 784</b>
<b>Investing activities</b>					
Investment in intangible assets				-132	-112
Investments in tangible assets					-65
<b>Cash flow from investing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-132</b>	<b>-177</b>
<b>Financing activities</b>					
New share issue			11 962	14 751	14 751
Issue of warrants	121	166	121	166	166
<b>Cash flow from financing activities</b>	<b>121</b>	<b>166</b>	<b>12 083</b>	<b>14 917</b>	<b>14 917</b>
<b>Increase/decrease in cash and cash equivalents</b>	<b>-3 438</b>	<b>-949</b>	<b>-583</b>	<b>10 687</b>	<b>7 002</b>
<b>Cash and cash equivalents at the end of period</b>	<b>6 586</b>	<b>10 854</b>	<b>6 586</b>	<b>10 854</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