

# INITIATOR PHARMA: HALF-YEAR REPORT 2017

## 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 – 2016-06-30.

<b>Second Quarter (2017-04-01 – 2017-06-30)</b>
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -2,023 (-5)
• Earnings per share was DKK -0.25 (-0.00)

<b>First Six Months of the Year (2017-01-01 – 2017-06-30)</b>
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -3,234 (-5)
• Earnings per share was DKK -0.48 (-0.00)
• Cash and bank: TDKK 11,803 (0)
• Solidity: 88%

*Group earnings per share: period result divided by a number of 8 683 943 stocks (on 2017-06-30).*

*Solidity: equity divided by assets.*

## Business highlights in 2Q 2017

- Initiator Pharma has selected Syngene, India and Research Toxicology Centre, Italy (RTC) as contract research organizations (CROs) to conduct the pre-clinical development of the drug candidate IPED2015 for the treatment of ED
- Synthesis Route for IPED2015 selected
- The first exploratory toxicology and pharmacokinetic rat studies for IPED2015 for the treatment of Erectile dysfunction have been conducted at Syngene
- AGM (17 may 2017)
- Publication of the annual report for 2016.
- The AGM approves changes to article of association, incentive program and remuneration for the board members.

## Significant events after this reporting period

- None.

## Comments from the CEO

"In the second quarter of 2017 Initiator Pharma has fully focused on getting the regulatory animal toxicology and safety pharmacology studies up and running. We have received data from the first administration and the result have been encouraging. In combination with succesfull up-scaling of the API production we follow our timeline and are optimistic about the coming results from the continued safety and toxicology screening remain on track for initiating the initiate a first in man clinical phase I trial in 2018"

## 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 4.000 shareholders. Read more at [www.initiatorpharma.com](http://www.initiatorpharma.com).*

## Letter from the CEO

In the second quarter of 2017 our primary focus has been getting our drug candidate IPED2015 ready for the first dosing to rodents as part of the toxicology and safety pharmacology studies needed to be conducted as part of the regulatory approval package. In addition, the optimal synthesis route for our drug candidate IPED2015 was selected and up-scaled to produce the required quantities of the API (Active Pharmaceutical Ingredient) used in these and upcoming regulatory studies.

Our working relationship with Syngene, India and Research Toxicology Centre, Italy (RTC) under the direction and supervision by Initiator Pharma's CDO Mikael Thomsen and by Initiator Pharma's CTO Dan Peters has proved to be efficient and successful. The first positive data from the animal studies have been received and the results are very encouraging and provide a solid base for our continued work.

We are looking forward to Q3 where we will receive toxicology and safety data from the 14 days dosing in both rat and minipig. This leaves us and the program very much on the right trajectory to obtain a Regulatory Approval for initiating the first in man clinical Phase I trials in the summer/autumn 2018 for our drug candidate IPED2015.

Besides the regulatory development program for IPED2015 we continue with our efforts for the maturation of the other assets in our pipeline under the direction Initiator Pharma's CSO Ulf Simonsen at Aarhus University. Here, our focus is to identify strategically unmet and attractive medical indications supported by early stage proof-of-concepts in various models.

In conclusion, we are pleased with the progress of Development Program and look positively on the upcoming extended toxicology and safety Pharmacology studies. We are still very much on the right trajectory to obtain a Regulatory Approval for initiating the first in man clinical Phase I trials in the summer/autumn 2018 for our drug candidate IPED2015. I would finally like to say thank you to our existing and new shareholders for the support and trust in our company. Together we will build a stronger Initiator Pharma that will deliver paradigm changing medicine and delivery value for both patients and shareholders.

Claus Elsborg Olesen  
CEO, Initiator Pharma A/S

## About Initiator Pharma

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

## Vision

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

Drug Candidate	Indication	Exploratory	Preclinical	Phase 1	Phase 2	Phase 3
IPED2015	Erectile Dysfunction	█	█			
IPNP2015	Neuropathic pain	█				
IPDP2015	Depression	█				

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<sup>®</sup>, Cialis<sup>®</sup>, Levitra<sup>®</sup>). 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.

## 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. Because of this, comparing numbers refer to the time period 2016-05-02 – 2016-06-30.

### Financial review

TDKK	Q2:2017	Q2:2016	1H:2017	1H:2016	2016
Net sales	0	0	0	0	0
Total operating expenses	-2 023	-5	-3 234	-5	-887
Operating profit/loss	-2 023	-5	-3 234	-5	-887
Cash flow from operating activities	-1 120		-2 984	112	-178
Operating margin, %	neg	neg	neg	neg	neg
Average number of employees, #	0,5	0,0	0,5	0,0	0,5
Earnings per share, DKK	-0,25	0,00	-0,48	0,00	-0,18
Diluted earnings per share, DKK	-0,25	0,00	-0,48	0,00	-0,18
	30.06.2017	30.06.2016			31.12.2016
Cash and cash equivalents	11 803	0			167
Equity	10 695	-5			-371
Total equity and liabilities	12 162	112			563
Equity ratio, %	88 %	neg			neg
<i>Number of shares outstanding</i>	8 683 943	4 962 254	8 683 943	4 962 254	4 962 254
<i>Number of shares, fully diluted</i>	8 683 943	4 962 254	8 683 943	4 962 254	4 962 254
<i>Weighted number of shares</i>	8 683 943	4 962 254	7 753 521	4 962 254	4 937 210

## Revenues and result of the operation

### Revenue

Initiator Pharma generated total revenues of TDKK 0 for the second quarter of 2017 (na) and TDKK 0 for the first half of 2017 (0).

### Operating profit/loss

The company recognized an operating loss of TDKK 2,023 for the second quarter of 2017 (na), and TDKK 3,234 for the first half of 2017 (-5). The increase in operating costs in the second quarter of 2017 and in the first half of 2017 reflects both increased administrative activity in the company as well as the start-up of the preclinical development program for IPED2015 that is required before the company can progress the drug candidate into clinical trials in the 2<sup>nd</sup> half of 2018.

### Financial position

The equity as of June 30, 2017 was TDKK 10,695. Cash and cash equivalents amounted to TDKK 11,803 as of June 30, 2017. Total assets as of June 30, 2017, were TDKK 12,162.

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 initiate the planned development activities into 1Q:2018.

### Cash flow

In the second quarter of 2017 the total operating cash flow was TDKK -1,120, incl a positive change in working capital of TDKK 1,044. Cash flow from investment activities was TDKK -0. Cash flow from financing activities was TDKK 0.

In the first half of 2017 the operating cash flow was TDKK -2,984, incl a positive change in working capital of TDKK 661. Cash flow from investment activities was TDKK -132 and cash flow from financing activities was TDKK 14,751.

## The share, share capital and ownership structure

At June 30, 2017, the number of shares outstanding amounted to 8,683,943. The company has as of June 30 no outstanding warrants.

At June 30, 2017 the company had around 4,000 shareholders. The 25 largest shareholders in the company on June 30 owned 63,15% of all outstanding shares:

Top 25 shareholders as of June 30, 2017		
Owners	Number of shares	Shares %
BNY Mellon SA/NV (Former BNY)	929 353	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	363 428	4,19 %
Handelsbanken Denmark	349 380	4,02 %
Olofsson, Christian	300 000	3,45 %
Swedish Growth Fund AB	272 724	3,14 %
Feldthus, Thomas	267 143	3,08 %
Nordnet Pensionsförsäkring AB	258 080	2,97 %
Hendriksen, Lars	133 165	1,53 %
Christophersen, Palle	117 143	1,35 %
Brästrup, Claus	105 100	1,21 %
JP Morgan Luxemburg	100 429	1,16 %
Larsen, Janus Schreiber	100 058	1,15 %
Clearstream Banking S.A, W8IMY	84 659	0,97 %
Peters, Leif Anders Rudolf	72 726	0,84 %
Bergh, Bjørn	72 569	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	60 000	0,69 %
Engstrand, Viktor	55 000	0,63 %
Other shareholders	3 199 984	36,85 %
<b>Total</b>	<b>8 683 943</b>	<b>100,00 %</b>

## Personnel

As of June 30, 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.



## Financial calendar

Annual General Meeting	May 16, 2017
Interim Report Q1	May 26, 2017
Interim Report Q2	August 24, 2017
Interim Report Q3	November 24, 2017
Year-End Report	February 21, 2018

Aarhus, August 24, 2017

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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>Q2:2017</b>	<b>Q2:2016</b>	<b>1H:2017</b>	<b>1H:2016</b>	<b>2016</b>
Gross loss	-1 684	-2	-2 566	-2	-700
Staff costs	-317	-3	-628	-3	-175
Depreciation and write-downs	-22	0	-40	0	-12
<b>Operating profit/loss</b>	<b>-2 023</b>	<b>-5</b>	<b>-3 234</b>	<b>-5</b>	<b>-887</b>
Other financial expenses	-162	0	-451	0	-5
<b>Profit/loss</b>	<b>-2 185</b>	<b>-5</b>	<b>-3 685</b>	<b>-5</b>	<b>-892</b>

**Statement of financial position**

<b>TDKK</b>	<b>30.06.2017</b>	<b>30.06.2016</b>	<b>2016</b>
<b>ASSETS</b>			
Patents	90	112	101
<b>Intangible assets</b>	<b>90</b>	<b>112</b>	<b>101</b>
Fixture, fittings, tools and equipment	166	0	64
<b>Property, plant and equipment</b>	<b>166</b>	<b>0</b>	<b>64</b>
<b>Fixed assets</b>	<b>256</b>	<b>112</b>	<b>165</b>
Other receivables	18	0	32
Prepayments	85	0	199
<b>Current receivables</b>	<b>103</b>	<b>0</b>	<b>231</b>
<b>Cash and cash equivalents</b>	<b>11 803</b>	<b>0</b>	<b>167</b>
<b>Current assets</b>	<b>11 906</b>	<b>0</b>	<b>398</b>
<b>Assets</b>	<b>12 162</b>	<b>112</b>	<b>563</b>
<b>EQUITY AND LIABILITIES</b>			
Contributed capital	15 272	0	521
Retained earnings	-4 577	-5	-892
<b>Equity</b>	<b>10 695</b>	<b>-5</b>	<b>-371</b>
Other payables	1 467	117	934
<b>Current liabilities other than provisions</b>	<b>1 467</b>	<b>117</b>	<b>934</b>
<b>Liabilities other than provisions</b>	<b>1 467</b>	<b>117</b>	<b>934</b>
<b>Equity and liabilities</b>	<b>12 162</b>	<b>112</b>	<b>563</b>

## Statement of changes in shareholder equity

TDKK	Contributed capital	Retained earnings	Total
January 1, 2017	521	-892	-371
Increase of capital	14 751	0	14 751
Profit/loss for the period	0	-3 685	-3 685
June 30, 2017	15 272	-4 577	10 695

## Statement of cash flow

TDKK	Q2:2017	Q2:2016	1H:2017	1H:2016	2016
Operating profit/loss	-2 023	-5	-3 234	-5	-887
Amortisation, depreciation and impairment losses	22	0	40	0	12
Changes in working capital	1 044	117	661	117	703
<b>Cash flow from operating activities before financial items</b>	<b>-958</b>	<b>112</b>	<b>-2 533</b>	<b>112</b>	<b>-173</b>
Interest income received	0	0	52	0	
Interest expense paid	-162	0	-503	0	-5
<b>Cash flow from operating activities</b>	<b>-1 120</b>	<b>112</b>	<b>-2 984</b>	<b>112</b>	<b>-178</b>
<b>Investing activities</b>					
Investment in tangible assets	0	0	-132	0	-65
Investments in intangible assets	0	-112	0	-112	-112
Investments in other financial assets	0	0	0	0	0
<b>Cash flow from investing activities</b>	<b>0</b>	<b>-112</b>	<b>-132</b>	<b>-112</b>	<b>-177</b>
<b>Financing activities</b>					
New share issue	0	0	14 751	0	521
<b>Cash flow from financing activities</b>	<b>0</b>	<b>0</b>	<b>14 751</b>	<b>0</b>	<b>521</b>
<b>Increase/decrease in cash and cash equivalents</b>	<b>-1 120</b>	<b>0</b>	<b>11 636</b>	<b>0</b>	<b>167</b>
<b>Cash and cash equivalents at the end of period</b>	<b>11 803</b>	<b>0</b>	<b>11 803</b>	<b>0</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