

Initiator Pharma

INITIATOR PHARMA: Q3 REPORT 2017

Initiator Pharma A/S, a Danish Biotech Company developing a novel treatment of Erectile Dysfunction.

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 – 2016-09-30.

Third Quarter (2017-07-01 – 2017-09-30)
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -2,456 (-164)
• Earnings per share was DKK -0.29 (-0.00)

First Nine Months of the Year (2017-01-01 – 2017-09-30)
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -5,698 (-168)
• Earnings per share was DKK -0.77 (-0.00)
• Cash and bank: TDKK 10,854 (145)
• Solidity: 75%

Group earnings per share: period result divided by a number of 8 683 943 stocks (on 2017-09-30).

Solidity: equity divided by assets.

Business highlights in Q3 2017

- The first exploratory toxicology and pharmacokinetic rat studies have been conducted at Syngene, India under the supervision of Initiator Pharma's CDO Mikael Thomsen. The data are promising and supports the next planned non-clinical safety studies for IPED2015
- The first maximum tolerated dose toxicology and toxicokinetic mini-pig studies have been conducted at RTC, Rome, Italy, under the supervision of Initiator Pharma's CDO Mikael Thomsen. The data are in line with what was observed in comparable rat studies already executed and supports the further development of IPED2015 with the aim to start clinical trials in 2018.
- The warrant program 2017/2020, comprising a maximum of 434,197 warrants as resolved at the Annual General Meeting of 16 May 2017, has been fully subscribed. Subscription of warrants have been submitted by employees, board members and key consultants, in total 7 persons, according to Appendix 2 to the AGM protocol from 16 May, 2017.

Significant events after this reporting period

- The company has initiated its first Good Laboratory Practice (GLP) toxicology and toxicokinetic rat study at Syngene, Bangalore, India.
- The company has received very positive preliminary results from its first Good Laboratory Practice (GLP) toxicology and toxicokinetic rat study at Syngene, Bangalore, India.

Comments from the CEO

"In Q3 Initiator Pharma obtained positive data from the maximum tolerated dose toxicology and toxicokinetic mini-pig study. On this basis we have recently proceed to the first 28 days Good Laboratory Practice (GLP) toxicology and toxicokinetic rat study. We expect to have the final report during Q4. The recent progress solidify our intend to initiate a first in man clinical phase I trial in early autumn 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.

Letter from the CEO

In the third 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..

The working relation with Syngene, India and Research Toxicology Centre, Italy remains very efficient and continuously provide high quality data at very attractive costs.

The recent first positive data from the animal studies have been received and the result are very encouraging and provide a solid base for our continued work. We are looking forward to Q4 where we will receive data from the GLP 28 days Good Laboratory Practice (GLP) toxicology and toxicokinetic in both rat and mini-pig.

On the Research and Discovery side of Initiator Pharma's CSO Ulf Simonsen, is working continuously on the maturation of our other assets and bring them to the stage where we can establish active partnerships that will ensure a continued value creating development for Initiator Pharma.

In conclusion, we are pleased with the progress of Development Program and look forward to all the exciting studies that are planend and that we provide data over the few months. Overall Initiator Pharma is still very much on the right trajectory to submit a clinical trial application druring the summer and obtaind the Regulatory Approval for initiating the first in man clinical Phase I trials in the late summer/autumn 2018 for our drug candidate IPED2015.

In conclusion we seen a nice progression in our quest to build a stronger Initiator Pharma that will deliver paradigm changing medicine and deliver 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.

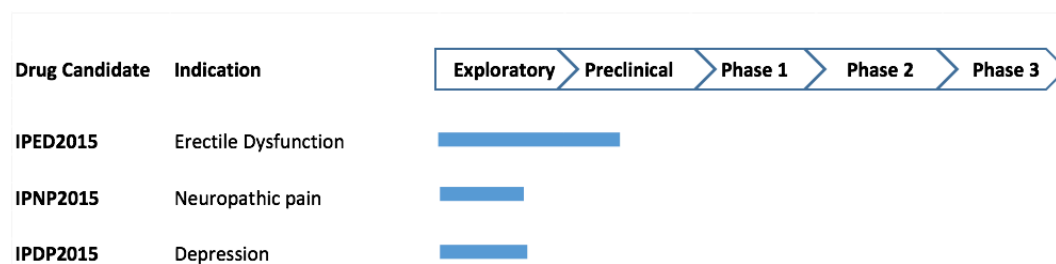
Business model

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:



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.

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 – 2016-09-30.

Financial review

TDKK	Q3:2017	Q3:2016	9M:2017	9M:2016	2016
Net sales	0	0	0	0	0
Total operating expenses	-2 456	-164	-5 698	-168	-887
Operating profit/loss	-2 456	-164	-5 698	-168	-887
Cash flow from operating activities	-1 111	-376	-4 099	-263	-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	-0,29	0,00	-0,77	0,00	-0,18
Diluted earnings per share, DKK	-0,29	0,00	-0,77	0,00	-0,18
	30.09.2017	30.09.2016			31.12.2016
Cash and cash equivalents	10 854	145			167
Equity	8 345	352			-371
Total equity and liabilities	11 179	307			563
Equity ratio, %	75 %	115 %			neg
<i>Number of shares outstanding</i>	<i>8 683 943</i>	<i>4 962 254</i>	<i>8 683 943</i>	<i>4 962 254</i>	<i>4 962 254</i>
<i>Number of shares, fully diluted</i>	<i>8 683 943</i>	<i>4 962 254</i>	<i>8 683 943</i>	<i>4 962 254</i>	<i>4 962 254</i>
<i>Weighted number of shares</i>	<i>8 683 943</i>	<i>4 962 254</i>	<i>7 753 521</i>	<i>4 962 254</i>	<i>4 937 210</i>

Revenues and result of the operation

Revenue

Initiator Pharma generated total revenues of TDKK 0 for the third quarter of 2017 (0) and TDKK 0 for the first nine months of 2017 (0).

Operating profit/loss

The company recognized an operating loss of TDKK 2,456 for the third quarter of 2017 (-164), and TDKK 5,698 for the first nine months of 2017 (-168). The increase in operating costs in the third quarter of 2017 and in the first 9 months of 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 2nd half of 2018, as well as increased administrative costs.

External R&D costs in the third quarter amounted to TDKK 1,477, compared to 0 in the same period in 2016. For the first nine months external R&D costs amounted to TDKK 2,843, compared to 0 in the same period in 2016.

Financial position

The equity as of September 30, 2017 was TDKK 8,345. Cash and cash equivalents amounted to TDKK 10,854 as of September 30, 2017. Total assets as of September 30, 2017, were TDKK 11,179.

On February 15th 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 6th 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 third quarter of 2017 the total operating cash flow was TDKK -1,111, incl a positive change in working capital of TDKK 1,379. Cash flow from investment activities was TDKK -0. Cash flow from financing activities was TDKK 166.

In the first nine months of 2017 the operating cash flow was TDKK -4,099, incl a positive change in working capital of TDKK 2,040. 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 September 30, 2017, the number of shares outstanding amounted to 8,683,943. The company has as of September 30 a total of 434.197 outstanding warrants, representing 5.0% of the number of issued shares.

At September 30, 2017 the company had around 3,600 shareholders. The 25 largest shareholders in the company on September 30 owned 62,86% of all outstanding shares:

Top 25 shareholders as of September 30, 2017		
Owners	Number of shares	Shares %
BNY Mellon SA/NV (Former BNY)	929 302	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	348 661	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	252 666	2,91 %
Leif Andersen Consulting ApS	250 859	2,89 %
Hendriksen, Lars	158 104	1,82 %
Sv Handelsbanken Copenhagen branch	126 176	1,45 %
Christophersen, Palle	117 143	1,35 %
Brästrup, Claus	105 100	1,21 %
JP Morgan Luxembourg	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	70 000	0,81 %
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 %
Marnfeldt, Bengt	60 000	0,69 %
Other shareholders	3 225 191	37,14 %
Total	8 683 943	100,00 %

Personnel

As of September 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, November 24, 2017

Magnus Persson - Chairman

Henrik Moltke – Board member

Peter Holm – Board member

Claus Olesen – Board member and
CEO

Financial Statements

Statement of income

TDKK	Q3:2017	Q3:2016	9M:2017	9M:2016	2016
Gross loss	-2 132	-164	-4 698	-165	-700
Staff costs	-310	0	-938	-3	-175
Depreciation and write-downs	-22	0	-62	0	-12
Operating profit/loss	-2 456	-164	-5 698	-168	-887
Other financial expenses	-56	0	-503	0	-5
Profit/loss	-2 512	-164	-6 201	-168	-892

Statement of financial position

TDKK	30.09.2017	30.09.2016	2016
ASSETS			
Patents	84	112	101
Intangible assets	84	112	101
Fixture, fittings, tools and equipment	150	0	64
Property, plant and equipment	150	0	64
Fixed assets	234	112	165
Other receivables	6	-35	32
Prepayments	85	85	199
Current receivables	91	50	231
Cash and cash equivalents	10 854	145	167
Current assets	10 945	195	398
Assets	11 179	307	563
EQUITY AND LIABILITIES			
Contributed capital	15 272	521	521
Retained earnings	-6 927	-169	-892
Equity	8 345	352	-371
Other payables	2 834	-45	934
Current liabilities other than provisions	2 834	-45	934
Liabilities other than provisions	2 834	-45	934
Equity and liabilities	11 179	307	563

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
Issue of warrants		166	166
Profit/loss for the period	0	-6 201	-6 201
September 30, 2017	15 272	-6 927	8 345

Statement of cash flow

TDKK	Q3:2017	Q3:2016	9M:2017	9M:2016	2016
Operating profit/loss	-2 456	-164	-5 698	-168	-887
Amortisation, depreciation and impairment losses	22	0	62	0	12
Changes in working capital	1 379	-212	2 040	-95	703
Cash flow from operating activities before financial items	-1 055	-376	-3 596	-263	-173
Interest income received	15	0	72	0	0
Interest expense paid	-71	0	-575	0	-5
Cash flow from operating activities	-1 111	-376	-4 099	-263	-178
Investing activities					
Investment in tangible assets	0	0	-132	0	-65
Investments in intangible assets	0	0	0	-112	-112
Investments in other financial assets	0	0	0	0	0
Cash flow from investing activities	0	0	-132	-112	-177
Financing activities					
New share issue	0	521	14 751	521	521
Issue of warrants	166	0	166	0	0
Cash flow from financing activities	166	521	14 917	521	521
Increase/decrease in cash and cash equivalents	-949	145	10 687	145	167
Cash and cash equivalents at the end of period	10 854	145	10 854	145	167

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