Initiator Pharma

INITIATOR PHARMA: H1 2018 report

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.

Second Quarter (2018-04-01 – 2018-06-30)
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -3,294 (-2,023)
• Earnings per share was DKK –0.19 (-0.25)

First Six Months of the Year (2018-01-01 – 2018-06-30)
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -6,404 (-3,234)
• Earnings per share was DKK –0.51 (-0.48)
• Cash and bank: TDKK 10,025 (11,803)
• Solidity: 93% (88%)

Group earnings per share: period result divided by a number of 17 367 884 stocks (on 2018-06-30).
Solidity: equity divided by assets.

Business highlights in Q2 2018

- On April 5th we announced that the rights issue had been oversubscribed, raising SEK 19.1 million to the company before issuing costs and SEK 16.8 net of issuing costs.
- On May 3rd we called for the Annual General Meeting, to take place on May 25th, and published our Annual Report for 2017.
- On May 23rd we announced that we have filed a Clinical Trial Application, CTA for Drug candidate IPED2015 with the Medicines & Healthcare products Regulatory Agency, MHRA.UK.
- On June 4th we announced that we had selected MAC Clinical Research Unit as our collaborator for the upcoming clinical development of IPED2015
- On June 26th we announced that the Medicines & Healthcare products Regulatory Agency, MHRA.UK had approved our CTA for the Phase 1 for IPED2015.

Significant events after this reporting period

- On August 22nd we announced that we had started dosing of our first Phase 1 trial with IPED2015 at MAC Clinical Research, Manchester, UK. The general conduct and start of the study went well with no clinical adverse reactions recorded. However, 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 company and its connected experts are currently exploring this incidence, and resuming of dosing will await the full examination of this case.
- On August 23rd we announced that the warrant program 2018/2020, comprising a maximum of 434,197 warrants as resolved at the Annual General Meeting of 25 May 2018, 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 25 May, 2018.

Comments from the CEO

” With the successful completion of the preclinical development of IPED2015 in January, followed by the CTA filing in May and subsequent approval by MHRA in late June Initiator Pharma is now ready to become a clinical stage company. We have just announced that the dosing in our First-in-Man clinical trial with our Erectile dysfunction drug candidate was started in August, and we aim to conduct the Phase 2a PoC during first half of 2019”

Initiator Pharma

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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 3.400 shareholders. Read more at www.initiatorpharma.com.

Letter from the CEO

The first half year of 2018 has been full of actives in Initator Pharma. First, we completed the preclinical development of IPED2015 in January, ahead of the set schedule. The clinical trial application was filed in May and in June we received the approval by Medicines & Healthcare products Regulatory Agency, MHRA, UK. This allows us to start our first in man clinical trial. The fact that the non-clinical safety study package was completed ahead of schedule is driven by the very positive results from toxicology, genotoxicity and safety pharmacology studies in this non-cclinical part of development of IPED2015 and shows the commitment and expertise of our entire team.

We have just started dosing in clinical phase I study. The clinical phase IIa study will then commence as soon as possible after completion of phase 1. Our goal is to complete the 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.

"We are still on track to 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 could potentially allow for an exit option as early as 2019."

Besides the scientific activities we also successfully completed a preferential rights issue in March 2018, raising approximately 19 MSEK, and an additional 12 MSEK 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 the associated warrants are fully subscribed, is that no additional capital will be needed for the development of IPED2015 to reach the stage which we have had as our focal point since the start, the clinical phase 2a Proof-of-Concept.

"We are very pleased with the recent preferential rights issue as it has provided us with sufficient financial resources to archeive a major milestone, becoming a clinical stage Biotech with a Clinical Phase 2a PoC on the horizion. This will be a significant value inflection point and will create value for the shareholders and be a major advance for the many ED patients for whom there are no effectice 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 from the recent rights issue. Initiator Pharma will soon enter the clinic with a novel treatment of Erectile dysfunction and we look forward to report significant progress on our IPED2015 development program through the year.

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.

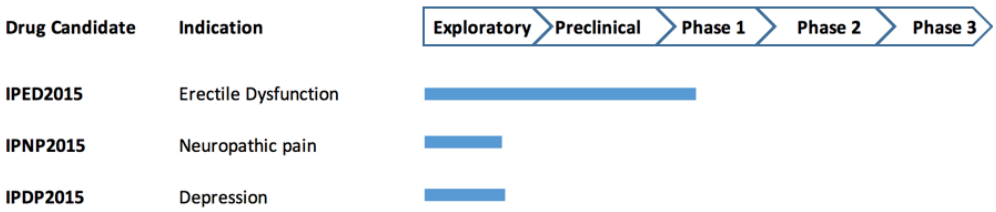
Business model

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. The clinical phase 1 for IPED 2015 is expected to start during Q3:2018.

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 unmeet medical need. This is exactly our primary target group and will clearly distinguish us form 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	Q2:2018	Q2:2017	H1:2018	H1:2017	2017
Net sales	0	0	0	0	0
Total operating expenses	-3 294	-2 023	-6 404	-3 234	-9 561
Operating profit/loss	-3 294	-2 023	-6 404	-3 234	-9 561
Cash flow from operating activities	-4 202	-1 119	-9 107	-2 984	-7 784
Operating margin, %	neg	neg	neg	neg	neg
Average number of employees, #	1	1	1	1	1
Earnings per share, DKK	-0,19	-0,25	-0,51	-0,48	-1,26
Diluted earnings per share, DKK	-0,19	-0,25	-0,51	-0,48	-1,26
	30.06.2018	**30.06.2017**			**31.12.2017**
Cash and cash equivalents	10 025	11 803			7 169
Equity	11 334	10 706			5 964
Total equity and liabilities	12 163	12 162			9 298
Equity ratio, %	93 %	88 %			64 %
Number of shares outstanding	*17 367 884*	*8 683 943*	*17 367 884*	*8 683 943*	*8 683 943*
Number of shares, fully diluted	*17 802 081*	*8 683 943*	*17 802 081*	*8 683 943*	*9 118 140*
Weighted number of shares	*17 367 884*	*8 683 943*	*13 025 914*	*7 753 521*	*8 218 732*

Revenues and result of the operation

Revenue

Initiator Pharma generated total revenues of TDKK 0 for the second quarter of 2018 (0) and TDKK 0 for the first half 2018 (0).

Operating profit/loss

The company recognized an operating loss of TDKK 3,294 for the second quarter of 2018 (-2,023). For the first half of the year the operating loss was TDKK 6,404 (-3,234). The increase in operating costs in the second quarter and for the first half of the year reflect the preparations for the phase 1 clinical trial that was initiated in July 2018.

External R&D costs in the second quarter amounted to TDKK 2,173, compared to TDKK 1,128 in the same period in 2017. For the first six months of the year external R&D costs totalled TDKK 4,550 compared to TDDK 1,366 in same period in 2017.

Financial position

The equity as of June 30, 2018 was TDKK 11,334. Cash and cash equivalents amounted to TDKK 10,025 as of June 30, 2018 and total assets were TDKK 12,163.

On April 5th 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. The TO1 option program, if fully subscribed, will raise an additional MSEK 12.1 gross (MDKK 8.7).

Cash flow

In the second quarter of 2018 the total operating cash flow was TDKK -4,202 (TDKK -1,119), incl a negative change in working capital of TDKK -939 (TDKK 1,044). Cash flow from investment activities was TDKK -0 (TDKK 0). Cash flow from financing activities was TDKK 11,962 (TDKK 0) .

For the first half 2018 the operating cash flow was TDKK -8,918 (TDKK -2,533), incl a negative change in working capital of TDKK -2,558 (TDKK 661). Cash flow from investment activities was TDKK -0 (TDKK -132) and cash flow from financing activities was TDKK 11,962 (TDKK 14,751).

The share, share capital and ownership structure
At June 30, 2018, the number of shares outstanding amounted to 17,367,884. The company has as of June 30 a total of 434.197 outstanding warrants, representing 2.5% of the number of issued shares. The Annual General Meeting on May 25th approved an incentive program, which if fully subscribed will increase the number of outstanding warrants by 434,197 to a total of 868,394, representing 5.0 of the number of issued shares.

At June 30, 2018 the company had around 3,400 shareholders. The 25 largest shareholders in the company on June 30 owned 56,5% of all outstanding shares:

Top 25 shareholders as of June 30, 2018 Owners	Number of shares	Shares %
NORDNET PENSIONSFORSAKRING	1 568 951	9,03 %
FORSAKRINGSAKTIEBOLAGET, AVANZA PENSION	1 439 998	8,29 %
BNY MELLON SA/NV (FORMER BNY), W8IMY	1 012 992	5,83 %
CLAUS OLESEN HOLDING APS	616 982	3,55 %
SWEDISH GROWTH FUND AB	545 448	3,14 %
DANPET AB	523 802	3,02 %
MIKAEL SONDERGARD THOMSEN APS	505 946	2,91 %
UBS SWITZERLAND AG-SPARNORD S.A.	308 580	1,78 %
OLOFSSON, CHRISTIAN	300 000	1,73 %
SV HANDELSBANKEN COPENHAGEN BRANCH, CLI	296 801	1,71 %
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	230 428	1,33 %
THA	228 490	1,32 %
HARLIN, TOBIAS	193 604	1,11 %
HENDRIKSEN LARS	170 353	0,98 %
CLEARSTREAM BANKING S.A., W8IMY	169 316	0,97 %
SEDERMERA FONDKOMMISSION BIFIRMA TILL A1	154 545	0,89 %
PETERS, LEIF ANDERS RUDOLF	145 452	0,84 %
WALL, MAGNUS	140 390	0,81 %
SEB LIFE-CJ WACHTMEISTER CONSULT	136 296	0,78 %
COOLMATE APS	119 416	0,69 %
CHRISTOPHERSEN, PALLE	117 143	0,67 %
BRASTRUP, CLAUS	110 099	0,63 %
OTHER SHAREHOLDERS	7 559 905	43,53 %
TOTAL	**17 367 884**	**100,00 %**

Personnel
As of June 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, August 23, 2018

Magnus Persson - Chairman	Henrik Moltke – Board member
Peter Holm – Board member	Claus Olesen – Board member and CEO

Financial Statements

Statement of income

TDKK	Q2:2018	Q2:2017	H1:2018	H1:2017	2017
Gross loss	-2 953	-1 684	-5 802	-2 566	-8 180
Staff costs	-319	-317	-559	-628	-1 297
Depreciation and write-downs	-22	-22	-44	-40	-84
Operating profit/loss	**-3 294**	**-2 023**	**-6 404**	**-3 234**	**-9 561**
Other financial expenses	9	-162	-189	-451	-801
Profit/loss	**-3 285**	**-2 185**	**-6 593**	**-3 685**	**-10 362**
Tax				0	1 780
Net profit for the period	**-3 285**	**-2 185**	**-6 593**	**-3 685**	**-8 582**

Statement of financial position

TDKK	30.06.2018	30.06.2017	2017
ASSETS			
Patents, acquired rights	67	90	78
Intangible assets	**67**	**90**	**78**
Other fixtures, fittings, tools and equipment	101	166	134
Property, plant and equipment	**101**	**166**	**134**
Fixed assets	**168**	**256**	**212**
Other receivables	236	18	182
Income tax receivables	1 735		1 735
Prepayments		85	
Current receivables	**1 971**	**103**	**1 917**
Cash and cash equivalents	**10 025**	**11 803**	**7 169**
Current assets	**11 995**	**11 906**	**9 086**
Assets	**12 163**	**12 162**	**9 298**
EQUITY AND LIABILITIES			
Contributed capital	1 824	912	912
Retained earnings	9 510	-4 577	5 052
Equity	**11 334**	**10 706**	**5 964**
Other payables	830	1 456	3 334
Current liabilities other than provisions	**830**	**1 456**	**3 334**
Liabilities other than provisions	**830**	**1 456**	**3 334**
Equity and liabilities	**12 163**	**12 162**	**9 298**

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		4 458	4 458
June 30, 2018	**1 824**	**9 510**	**11 334**

Statement of cash flow

TDKK	Q2:2018	Q2:2017	H1:2018	H1:2017	2017
Operating profit/loss	-3 294	-2 023	-6 404	-3 234	-9 561
Amortisation, depreciation and impairment losses	22	22	44	40	84
Changes in working capital	-939	1 044	-2 558	661	2 449
Cash flow from operating activities before financial items	**-4 211**	**-957**	**-8 918**	**-2 533**	**-7 028**
Other financial expenses	9	-162	-189	-451	-801
Tax credit					45
Cash flow from operating activities	**-4 202**	**-1 119**	**-9 107**	**-2 984**	**-7 784**
Investing activities					
Investment in intangible assets					-112
Investments in tangible assets				-132	-65
Cash flow from investing activities	**0**	**0**	**0**	**-132**	**-177**
Financing activities					
New share issue	11 962		11 962	14 751	14 751
Issue of warrants					166
Cash flow from financing activities	**11 962**	**0**	**11 962**	**14 751**	**14 917**
Increase/decrease in cash and cash equivalents	**7 761**	**-1 120**	**2 855**	**11 636**	**7 002**
Cash and cash equivalents at the end of period	**10 024**	**11 803**	**10 024**	**11 803**	**7 169**

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