Initiator Pharma

INITIATOR PHARMA: H1 2019 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 (2019-04-01 – 2019-06-30)
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -3,404 (-3,294)
• Earnings per share was DKK –0.15 (-0.19)

First Six Months of the Year (2019-01-01 – 2019-06-30)
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -4,867 (-6,404)
• Earnings per share was DKK –0.21 (-0.51)
• Cash and bank: TDKK 11,501 (10,025)
• Solidity: 82% (93%)

Group earnings per share: period result divided by a number of 23 157 178 shares (on 2019-06-30).
Solidity: equity divided by assets.

Business highlights in Q2 2019

- On April 29th we called for the Annual General Assembly that was held on May 23rd and released our annual report for 2018.
- On June 10th we announced that we had successfully completed the Phase 1 for IPED2015. The preliminary readout from the phase 1 has demonstrated that IPED2015 in general is safe and well tolerated at expected clinically relevant doses.
- On June 25th we announded the start of dosing of IPED2015 in the Phase 2a proof-of-concept clinical trial in erectile dysfunction patients.

Significant events after this reporting period

- On July 5th we announced that the incentive program in Initiator Pharma, approved by the AGM on May 23rd had been fully subscribed. If all warrants are exercised the company will issue a total of 434.197 new shares, representing 1.9% of issued shares, with par value of DKK 0.105 and with an exercise price of SEK 8,40.
- On Aug 13th we provided a status update on the ongoing Phase 2a study in patients with Erectile Dysfunction. The study is progressing well although recruitment of patients is taking slightly longer than planned. The reason for the slower recruitment is due to the aim of only including the correct medically qualified and motivated patients for the trial. This delay will alter the date for the final dosing of patients in the Phase 2a, and our current best estimate for releasing draft data from the study is early Q4.
- On Aug 13th we announced that the company has secured bridge financing of SEK 5 million with the aim of preparing the company's other candidate drug IP2018 for the start of a clinical phase 2a trial. With this bridge financing, the company is able to conduct activities for added value before seeking more long-term funding. The clinical phase 2a trial regarding IP2018 is expected to begin in early 2020.

Comments from the CEO

The first half of 2019 has been very eventful, and full of activities for Initiator Pharma. To begin with, we have reported the successful completion of the Phase 1 clinical trial in healthy subjects in June 2019. Accordingly, IPED2015 has now been advanced to the Proof-of-Concept Phase 2 clinical stage. We aim to complete the dosing of patients shortly and subsequently to progress with data analysis to have the final read-out report in early Q4. Furthermore, we have completed our preclinical evaluation

of IP2018 for which we have an option agreement in place with Saniona. We plan to exercise this option, and with the recently announed bridge financing we are proceeding with the preparatory activities for filing a CTA for a Phase 2a study before year-end.

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 and has about 3.500 shareholders. Read more at www.initiatorpharma.com.

Letter from the CEO

The first half-year of 2019 has been a transformational period for Initiator Pharma. Through the successful progression of the development program for IPED2015 and the planned inlicensing of IP2018 we now have two phase 2 ready drug candidates in our pipeline, both based on the same technology platform and addressing areas of significant unmet medical needs and commercial potential.

During the first half of the year we successfully completed the clinical phase I study and have advanced IPED2015 to the Proof-of-Concept generating clinical Phase 2a trial. Our goal is to complete the dosing in clinical phase 2a Proof-of-Concept very shortly, and we anticipate to the draft data ready early Q4. With a positive clinical phase 2a, we expect to have a compelling data package for IPED2015 that will allow us to continue our interaction with potential pharmaceutical partners and enable us to strike a deal by either sale, out-licensing or partnership of the IPED2015.

"We remain on track to achieve a clinical phase 2a Proof of Concept in 2019, and we are now gearing up the business development activities to identify and strike the optimal deal for the benefit of the company and its shareholders."

In addition to conducting the clinical program for IPED2015 we have been back in the laboratory generating a robust data package for IP2018 that now enables us to position the drug candidate for the treatment of men suffering from depression and erectile dysfunction. IP2018 is available to us through an option agreement with Saniona and the agreement has allowed us to conduct a thorough evaluation of this drug candidate in order to position it for the right indication, before advancing it to the clinic. We plan to exercise the option in the fall of 2019 in connection with the filing of our Clinical Trial Application (CTA) to the regulatory authorities.

"We are very pleased with the preclinical investigation and development of IP2018, and we strongly believe that we have identified a unique and the right indication for this drug candidate. We are looking forward to advancing this program to clinical testing in a Phase 2a study in early 2020, where we seek to demonstrate clinical efficacy in a patient group with high unmet medical need, offering what we believe is a significant commercial opportunities for a drug with the IP2018 profile."

I want to use this opportunity to thank the existing shareholders for your continuing support. Initiator Pharma will soon reach a significant value inflections points with the read-out of the Phase 2a for IPED2015. Besides, we have strengthened the pipeline, added considerable value and opportunity for success to Initiator Pharma by initiating the development of the unique IP2018 asset. These are vital steps in positioning Initiator Pharma as a capable and recognized player with a track record of adding significant value to drug candidates through well established POC clinical trials. We are looking forward to reporting significant progress on both IPED2015 and IP2018 programs in the near future.

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.

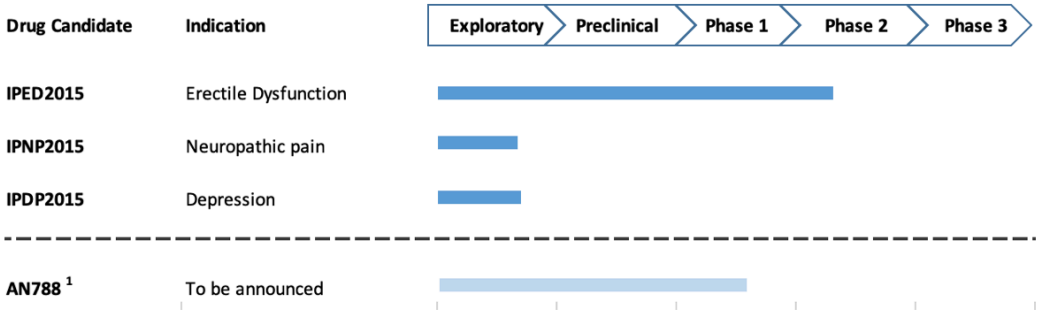
Business model

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:



[1] *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 in June 2019 we reported the successful completion of the phase 1 (single ascending dose) program. We immediately progressed IPED2015 into a carefully planned Phase 2a, and we expect to complete enrollment in this proof of concept study shortly, with headline data available Q4:19.

In Q4:18 we announced that we had secured a 1 year exclusive option agreement for AN788/IP2018, 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. During H1 we have undertaken a thourough preclinical evaluation of the drug candidate. Based on the results of this evaluation we now plan to exercise the option within the 12 month option period, and to pursue the clinical development of IP2018 for the treatment of men suffering from depression and erectile

dysfunction. With the recently announced bridge funding we have the financial flexibility to aggressively prepare for submitting a CTA for a Phase 2a study before year-end.

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 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	2Q:2019	2Q:2018	1H:2019	1H:2018	2018
Net sales	0	0	0	0	0
Total operating expenses	-3 404	-3 294	-4 867	-6 404	-12 611
Operating profit/loss	-3 404	-3 294	-4 867	-6 404	-12 611
Cash flow from operating activities	-1 845	-4 202	-2 991	-9 107	-13 582
Operating margin, %	neg	neg	neg	neg	neg
Average number of employees, #	1	2	1	2	1
Earnings per share, DKK	-0,15	-0,19	-0,21	-0,51	-0,63
Diluted earnings per share, DKK	-0,15	-0,19	-0,21	-0,51	-0,63
	30.06.2019	**30.06.2018**			**31.12.2018**
Cash and cash equivalents	11 501	10 025			14 491
Equity	11 669	11 334			16 570
Total equity and liabilities	14 149	12 163			17 328
Equity ratio, %	82 %	93 %			96 %
Number of shares outstanding	*23 157 178*	*17 367 884*	*23 157 178*	*17 367 884*	*23 157 178*
Number of shares, fully diluted	*24 025 572*	*17 802 081*	*24 025 572*	*17 802 081*	*24 025 572*
Weighted number of shares	*23 157 178*	*17 367 884*	*23 157 178*	*13 025 914*	*20 081 616*

Revenues and result of the operation

Revenue

Initiator Pharma generated total revenues of TDKK 0 for the second quarter of 2019 (0) and TDKK 0 for the first half 2019 (0).

Operating profit/loss

The company recognized an operating loss of TDKK 3,404 for the second quarter of 2019 (-3,294). For the first half of the year the operating loss was TDKK 4,867 (-6,404). The reduction in operating costs for the first half of the year compared to the same period last year reflects the high level of activity last year in preparations for the start of the clinical phase.

External R&D costs in the second quarter amounted to TDKK 2,336, compared to TDKK 2,173 in the same period in 2018. For the first six months of the year external R&D costs totalled TDKK 3,034 compared to TDDK 4,550 in same period in 2018.

Financial position

The equity as of June 30, 2019 was TDKK 11,669. Cash and cash equivalents amounted to TDKK 11,501 as of June 30, 2019 and total assets were TDKK 14,149.

Cash flow

In the second quarter of 2019 the total operating cash flow was TDKK -1,845 (TDKK -4,202), incl a positive change in working capital of TDKK 1,536 (TDKK -939). Cash flow from investment activities was TDKK -0 (TDKK 0). Cash flow from financing activities was TDKK 0 (TDKK 11,962).

For the first half 2019 the operating cash flow was TDKK -2,991 (TDKK -9,107), incl a positive change in working capital of TDKK 1,867 (TDKK -2,558). Cash flow from investment activities was TDKK -0 (TDKK 0) and cash flow from financing activities was TDKK 0 (TDKK 11,962).

The share, share capital and ownership structure

At June 30, 2019, the number of shares outstanding amounted to 23,157,178. The company has as of June 30 a total of 868,394 outstanding warrants, representing 3.7% of the number of issued shares.

The Annual General Meeting on May 23rd approved an incentive program, which if fully subscribed will increase the number of outstanding warrants by 434,197 to a total of 1,302,591, representing 5.6% of the number of issued shares.

At June 30, 2019 the company had around 3,500 shareholders. The 25 largest shareholders in the company on June 30 owned 47.0% of all outstanding shares:

Top 25 shareholders as of June 30, 2019 Owners	Number of shares	Shares %
Försäkringsaktiebolaget, Avanza Pension	1 247 505	5,39 %
BNY Mellon SA/NV (Former BNY)	1 067 518	4,61 %
Ålandsbanken i ågares ställe	910 778	3,93 %
Nordnet Pensionsförsäkring AB	823 872	3,56 %
Claus Olesen Holding APS	692 738	2,99 %
UBS Switzerland AG	612 896	2,65 %
DanPet AB	537 438	2,32 %
Mikael Södergård Thomsen APS	505 946	2,18 %
Lars Hendriksen A/S	466 096	2,01 %
Peters, Leif Anders Rudolf	451 511	1,95 %
Sv Handelsbanken Copenhagen branch	343 491	1,48 %
Olin, Lennart	324 606	1,40 %
Thauser Holding ApS	295 156	1,27 %
Härlin, Tobias	275 185	1,19 %
Feldthus, Thomas	251 143	1,08 %
Leif Andersen Consulting ApS	250 859	1,08 %
Olofsson, Christian	244 032	1,05 %
Pournouri, Milad	238 025	1,03 %
Clearstream Banking S.A, W8IMY	225 754	0,97 %
Coolmate ApS	225 416	0,97 %
Wall, Magnus	196 526	0,85 %
Müller, Christian Matthias	192 233	0,83 %
SEB Life International Assurance	181 728	0,78 %
Hendriksen, Lars	170 353	0,74 %
Kaae, Michael Nicolai Lägård	153 268	0,66 %
Other shareholders	12 273 105	53,00 %
Total	**23 157 178**	**100,00 %**

Personnel

As of June 30, 2019, 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, August 22, 2019

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

Financial Statements

Statement of income

TDKK	2Q:2019	2Q:2018	1H:2019	1H:2018	2018
Gross loss	-2 943	-2 953	-4 198	-5 802	-11 437
Staff costs	-439	-319	-625	-559	-1 086
Depreciation and write-downs	-22	-22	-44	-44	-88
Operating profit/loss	**-3 404**	**-3 294**	**-4 867**	**-6 404**	**-12 611**
Other financial expenses	1	9	-35	-189	-93
Profit/loss	**-3 403**	**-3 285**	**-4 902**	**-6 593**	**-12 704**
Tax					2 406
Net profit for the period	**-3 403**	**-3 285**	**-4 902**	**-6 593**	**-10 298**

Statement of financial position

TDKK	30.06.2019	30.06.2018	2018
ASSETS			
Patents, acquired rights	45	67	56
Intangible assets	**45**	**67**	**56**
Other fixtures, fittings, tools and equipment	35	101	68
Property, plant and equipment	**35**	**101**	**68**
Fixed assets	**80**	**168**	**124**
Other receivables	162	236	307
Income tax receivables	2 406	1 735	2 406
Prepayments	0	0	0
Current receivables	**2 568**	**1 971**	**2 713**
Cash and cash equivalents	**11 501**	**10 025**	**14 491**
Current assets	**14 069**	**11 995**	**17 204**
Assets	**14 149**	**12 163**	**17 328**
EQUITY AND LIABILITIES			
Contributed capital	2 432	1 824	2 432
Retained earnings	9 237	9 510	14 138
Equity	**11 669**	**11 334**	**16 570**
Trade payables	1 841	563	239
Other payables	639	267	519
Current liabilities other than provisions	**2 480**	**830**	**758**
Liabilities other than provisions	**2 480**	**830**	**758**
Equity and liabilities	**14 149**	**12 163**	**17 328**

Statement of changes in shareholder equity

TDKK	Contributed capital	Retained earnings	Total
January 1, 2019	**2 432**	**14 138**	**16 570**
Increase of capital	0	0	0
Profit/loss for the period	0	-4 902	-4 902
June 30, 2019	**2 432**	**9 236**	**11 668**

Statement of cash flow

TDKK	2Q:2019	2Q:2018	1H:2019	1H:2018	2018
Operating profit/loss	-3 404	-3 294	-4 867	-6 404	-12 611
Amortisation, depreciation and impairment losses	22	22	44	44	88
Changes in working capital	1 536	-939	1 867	-2 558	-2 701
Cash flow from operating activities before financial items	**-1 846**	**-4 211**	**-2 956**	**-8 918**	**-15 224**
Other financial expenses	1	9	-35	-189	-93
Tax credit					1 735
Cash flow from operating activities	**-1 845**	**-4 202**	**-2 991**	**-9 107**	**-13 582**
Investing activities					
Investment in intangible assets					
Investments in tangible assets					
Cash flow from investing activities	**0**	**0**	**0**	**0**	**0**
Financing activities					
New share issue		11 962		11 962	20 760
Issue of warrants					144
Cash flow from financing activities	**0**	**11 962**	**0**	**11 962**	**20 904**
Increase/decrease in cash and cash equivalents	**-1 845**	**7 761**	**-2 990**	**2 855**	**7 322**
Cash and cash equivalents at the end of period	**11 501**	**10 025**	**11 501**	**10 025**	**14 491**

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