

INITIATOR PHARMA: 1 QUARTER 2019

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.

First Quarter (2019-01-01 – 2019-03-31)
• Net revenues were TDKK 0 (0)
• EBIT was TDKK -1,463 (-3,111)
• Earnings per share was DKK -0.06 (-0.38)
• Cash and bank: TDKK 13,346 (14,491 as of 2018.12.31)
• Solidity: 94%

Group earnings per share: period result divided by 23 157 178 shares (on 2019-03-31).

Solidity: equity divided by total assets.

Business highlights in Q1 2019

- None

Significant events after this reporting period

- None

Update on the ongoing Phase 1 trial for IPED2015

The Phase 1 trial is progressing well, and we expect to complete the trial shortly with supportive data for continuing with the Phase 2a trial. We still expect to report phase 1 data during H1:2019. If successful we plan to immediately progress the compound into a phase 2a clinical proof of concept trial, with headline data available mid-2019.

Comments from the CEO

"We are very pleased with the progress of the Phase 1 trial and satisfied with the general conductance of the trial by MAC Clinical research, including the continuing recruitment of healthy subjects. We are looking forward to completing the Phase I study and are now preparing for the upcoming Phase 2a trial. We appreciate the support from existing and new shareholders and look forward to reporting data from our Proof-of- Concept study around mid-year".

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

Q1 2019 REPORT FOR INITIATOR PHARMA A/S
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Initiator Pharma

Letter from the CEO

We have been fully focusing on the execution of the Phase 1 clinical trial for IPED2015, which we anticipate to conclude shortly. Once completed we plan to progress rapidly into the clinical Phase 2a PoC. We maintain our ambition to report headline results from the Phase 2a study mid-2019, roughly one year ahead of the original schedule. With a successful clinical Phase 2a study, we expect to have a data package for IPED2015 which will be interesting to potential pharmaceutical partners.

“We are pleased with the progress of the Phase 1 trial for IPED2015 and satisfied with the general conductance of the trial by MAC Clinical research, including the continuing recruitment of healthy subjects. We look forward to conclude the Phase 1 study in the next few weeks and are now preparing for the upcoming Phase 2a trial”

Besides the clinical development of IPED2015, we have been continuing the evaluation of AN788, the Phase 2 ready drug candidate that we have available through the previously announced option agreement with Saniona. This option agreement allows us to thoroughly evaluate the clinical and commercial potential of AN788 at a minimal cost for the company – and potentially allow us to expand and strengthen our pipeline with another clinical asset that matches and complements the current ongoing activities and our development pipeline. We have over the past six months generated a valuable data package that has increased our understanding of the drug candidate’s potential and we anticipate to make a decision to exercise the option shortly. If exercised we are planning to rapidly progress AN788 into clinical development in a yet undisclosed indication.

“With the potential in-licensing of another phase 2 ready drug candidate Initiator Pharma is in a position to build a strong portfolio of clinical stage drug candidates - based on the same technological platform – with significant potential for both patients and shareholders.”

2019 promises to be a transformational year for Initiator Pharma. Firstly, we have IPED2015 which until now has shown good efficacy and low toxicity in both preclinical and first-in-man studies which obviously bodes well for the continuing clinical development. We are addressing the treatment of Erectile Dysfunction, a major market where we expect to treat/help a large number of patients currently lacking effective treatment. Our time and cost effective development plan also means that we can achieve Proof-of-Concept for IPED2015 - the key value inflection point in our development program – during 2019. Also, we are exploring the opportunity of transforming Initiator Pharma from a single clinical asset, to having multiple clinical stage programs. This expansion of the clinical pipeline will not only increase the value of the company but also position Initiator Pharma as a recognized player in the monoamine reuptake inhibitor field for various CNS related indications.

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.

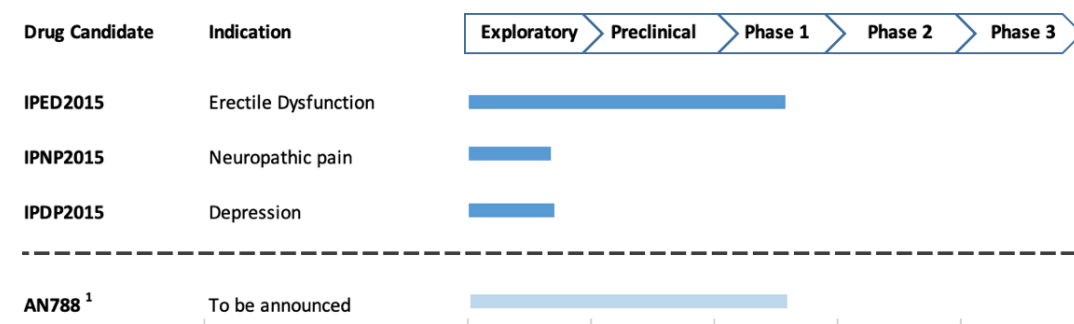
Business model

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 we expect to report phase 1 data during H1:2019. If successful we plan to immediately progress the compound into a phase 2a clinical proof of concept trial, with headline data available mid 2019.

In Q4:18 we announced that we had secured a 1 year exclusive option agreement for AN788, 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. Initiator Pharma intends to reposition the drug candidate based on our expertise with monoamine-reuptake inhibitors. The drug candidate has through the clinical studies already conducted been de-risked to a significant degree, and may therefore be assessed in a cost-effective Phase IIa, Clinical Proof of Concept study in a patient population with a high unmet medical need.

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 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.

Financial review

TDKK	1Q:2019	1Q:2018	2018
Net sales	0	0	0
Total operating expenses	-1 463	-3 111	-12 611
Operating profit/loss	-1 463	-3 111	-12 611
Cash flow from operating activities	-1 146	-4 906	-13 582
Operating margin, %	neg	neg	neg
Average number of employees, #	1	2	1
Earnings per share, DKK	-0,06	-0,38	-0,63
Diluted earnings per share, DKK	-0,06	-0,38	-0,63
	31.03.2019	31.03.2018	31.12.2018
Cash and cash equivalents	13 346	2 263	14 491
Equity	15 072	2 655	16 570
Total equity and liabilities	16 009	4 451	17 328
Equity ratio, %	94 %	60 %	96 %
<i>Number of shares outstanding</i>	23 157 178	8 683 943	23 157 178
<i>Number of shares, fully diluted</i>	24 025 572	8 683 943	24 025 572
<i>Weighted number of shares</i>	23 157 178	6 823 099	20 081 616

Revenues and result of the operation

Revenue

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

Operating profit/loss

The company recognized an operating loss of TDKK 1,463 for the first quarter of 2019 (-3,111). The decline in operating costs in the first quarter reflects the high preclinical and CMC activity during the first quarter of 2018.

External R&D costs in the first quarter amounted to TDKK 698, compared to 2,466 in the same period in 2018.

Financial position

The equity as of March 31, 2019 was TDKK 15,072. Cash and cash equivalents amounted to TDKK 13,346 as of March 31, 2019. Total assets as of March 31, 2019, were TDKK 16,009.

The company maintains its expectation that we have sufficient capital to fund the planned development activities through 2019 and the data read-out from the clinical phase 2 proof of concept trial. However, the existing capital base does not allow us to progress the development of our other pipeline assets.

Cash flow

In the first quarter of 2019 the total operating cash flow was TDKK -1,146, incl a positive change in working capital of TDKK 331. Cash flow from investment activities was TDKK -0. Cash flow from financing activities was TDKK 0.

The share, share capital and ownership structure

At March 31, 2019, the number of shares outstanding amounted to 23,157,178. The company has as of March 31 a total of 868,394 outstanding warrants, representing 3.7% of the number of issued shares.

At March 31, 2019 the company had around 3,500 shareholders. The 25 largest shareholders in the company on March 31 owned 49.8% of all outstanding shares:

Top 25 shareholders as of March 31, 2019		
Owners	Number of shares	Shares %
BNY Mellon SA/NV (Former BNY)	1 305 481	5,64 %
Försäkringsaktiebolaget, Avanza Pension	1 275 840	5,51 %
Nordnet Pensionsförsäkring AB	958 315	4,14 %
Ålandsbanken i ägares ställe	845 060	3,65 %
Claus Olesen Holding APS	692 738	2,99 %
UBS Switzerland AG	576 888	2,49 %
DanPet AB	537 438	2,32 %
Mikael Södergård Thomsen APS	505 946	2,18 %
Swedish Growth Fund AB	466 804	2,02 %
Lars Hendriksen A/S	452 711	1,95 %
Peters, Leif Anders Rudolf	451 511	1,95 %
Olofsson, Christian	380 000	1,64 %
Sv Handelsbanken Copenhagen branch	333 744	1,44 %
Olin, Lennart	330 001	1,43 %
Thauser Holding ApS	295 156	1,27 %
Härilin, Thomas	279 580	1,21 %
Feldthus, Thomas	267 143	1,15 %
Leif Andersen Consulting ApS	250 859	1,08 %
Clearstream Banking S.A, W8IMY	225 754	0,97 %
Coolmate ApS	213 416	0,92 %
Wall, Magnus	207 626	0,90 %
SEB Life - CJ Wachtmeister Consult	181 728	0,78 %
Müller, Christian Matthias	180 000	0,78 %
Hendriksen, Lars	170 353	0,74 %
Marnfeldt, Bengt	155 000	0,67 %
Other shareholders	11 618 086	50,17 %
Total	23 157 178	100,00 %

Personnel

As of March 31, 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.

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, May 23, 2019

Magnus Persson - Chairman

Henrik Moltke – Board member

Peter Holm – Board member

Claus Olesen – Board member and
CEO

Financial Statements

Statement of income

TDKK	1Q:2019	1Q:2018	2018
Gross loss	-1 255	-2 850	-11 437
Staff costs	-186	-239	-1 086
Depreciation and write-downs	-22	-22	-88
Operating profit/loss	-1 463	-3 111	-12 611
Other financial expenses	-36	-198	-93
Profit/loss	-1 499	-3 309	-12 704
Tax			2 406
Net profit for the period	-1 499	-3 309	-10 298

Statement of financial position

TDKK	1Q:2019	1Q:2018	2018
ASSETS			
Patents, acquired rights	50	73	56
Intangible assets	50	73	56
Other fixtures, fittings, tools and equipment	52	117	68
Property, plant and equipment	52	117	68
Fixed assets	102	190	124
Other receivables	155	8	307
Income tax receivables	2 406	1 735	2 406
Prepayments	0	255	0
Current receivables	2 561	1 998	2 713
Cash and cash equivalents	13 346	2 263	14 491
Current assets	15 907	4 261	17 204
Assets	16 009	4 451	17 328
EQUITY AND LIABILITIES			
Contributed capital	2 432	912	2 432
Retained earnings	12 640	1 743	14 138
Equity	15 072	2 655	16 570
Trade payables	469	783	239
Other payables	468	1 796	519
Current liabilities other than provisions	937	2 579	758
Liabilities other than provisions	937	1 796	758
Equity and liabilities	16 009	4 451	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	-1 499	-1 499
March 31, 2019	2 432	12 639	15 071

Statement of cash flow

TDKK	1Q:2019	1Q:2018	2018
Operating profit/loss	-1 463	-3 111	-12 611
Amortisation, depreciation and impairment losses	22	22	88
Changes in working capital	331	-1 619	-2 701
Cash flow from operating activities before financial items	-1 110	-4 708	-15 224
Other financial expenses	-36	-198	-93
Tax credit			1 735
Cash flow from operating activities	-1 146	-4 906	-13 582
Investing activities			
Investment in intangible assets			
Investments in tangible assets			
Cash flow from investing activities	0	0	0
Financing activities			
New share issue			20 760
Issue of warrants			144
Cash flow from financing activities	0	0	20 904
Increase/decrease in cash and cash equivalents	-1 145	-4 906	7 322
Cash and cash equivalents at the end of period	13 346	2 263	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