

# **Initiator** Pharma

# Business highlights in Q1 2021

• On January 14th the EGM approved the proposed convertible financing agreement with MAC Clinical Research, covering up to SEK 23 million (approx. DKK 17 million) of the clinical trial costs for the planned Phase 2b trial with IPED2015 in Erectile Dysfunction.

# Significant events after this reporting period

- On April 13th it was announced a proposal for a directed issue and fully guaranteed preferential rights issue of total SEK 60 million to expand into new orphan drug indication, led by longterm investors Linc AB and Adrigo Asset Management AB.
- On April 15th the summons for an extra-ordinary general meeting to approve the directed and fully guaranteed preferential rights issue was published.
- On April 20th it was announced today that it has filed a Clinical Trials Application for its planned Phase II study with IPED2105 in organic Erectile Dysfunction patients.
- On May 2nd the annual report for 2020 was published.
- On May 4th the summons for the annual general meeting to be held on May 28th was published.
- On May 11th the EGM approved the directed and fully guaranteed preferential rights issue.

# **Financial Highlights**

Initiator Pharma A/S is a Danish registered company, and is reporting its financial situation in Danish kroner (DKK).

#### **Financial review**

1Q:2021	1Q:2020	2020
-	-	-
-1 792	-2 392	-10 531
-1 792	-2 392	-10 531
-1 807	-2 484	-8 697
-0,07	-0,11	-0,32
-2 217	-480	-8 064
	-1 792 -1 792 -1 807 -0,07	-1792 -2392 -1792 -2392 -1807 -2484 -0,07 -0,11

	31.03.2021	31.03.2020	31.12.2020
Cash and cash equivalents	11 287	7 082	13 504
Equity	12 603	7 424	14 409
Total equity and liabilities	13 029	9 095	15 603
Equity ratio, %	97%	82%	92%
Number of shares outstanding	27 705 728	23 591 375	27 705 728

**Initiator Pharma's** fourth quarter was focused on the continued development of our two main assets, IPED2015 and IP2018, both clinical phase drug candidates in the field of erectile dysfunction (ED). IPED2015 is our most advanced candidate intended for patients suffering from organic ED, and IP2018 is being developed as a combined treatment for both depression and ED. Both represent First in Class treatments within their indication and are expected to improve the quality of life for a growing number of patients who are not responding to, or cannot be treated with, existing drugs on the market. The medical need for a new effective treatment for ED is massive, expected to affect more than 300 million men worldwide by 2025. And furthermore, just after the end of the quarter, we expanded our clinical portfolio and received financing from respected long-term investors.

# Progressing our two main assets in clinical phase 2

In early December last year, the first patient was dosed in the ongoing Phase 2a clinical trial with IP2018 to treat psychogenic sexual dysfunction. IP2018 is a unique drug candidate that targets a clear unmet medical need as it is differentiated from all existing anti-depressants and drugs for psychogenic ED. Up to 68 percent of patients with major depressive disorder suffer from sexual dysfunction, highlighting a significant unmet medical need.

The Phase 2a trial is a randomized, double-blind, placebo-controlled, 3-way crossover trial studying the efficacy and safety of IP2018 in young, depressed patients with ED. The primary objective of the trial is to investigate the effects of IP2018 on penile rigidity and tumescence using a visual sexual stimulation test. The trial is conducted on 24 patients at the MAC Phase I unit in Manchester, UK by MAC Clinical Research. We have experienced delays in patient recruitment due to the covid-19 pandemic, but we remain hopeful that the trial can be completed mid-year.

Our most advanced ED candidate, IPED2015, has potential to become a new treatment method for the large group of patients that do not respond to the currently marketed drugs in the PDE5i class, such as Viagra and Cialis. IPED2015 has successfully been through a Phase 2a Proof-of-Concept study and the next step is the planned IPED2015 clinical Phase 2b intercourse study.

The Phase 2b study will be conducted at multiple sites in the UK, and together with MAC we have worked hard to utilize the learnings from our previous Phase 2a Proof-of-Concept study to design a robust and solid Phase 2b intercourse study. The final design of the study is still pending and requires approval from MHRA, but we hope to be able to initiate the study in within short, given that the Covid-19 situation allows for it. The study is expected to be completed in the second half of 2022. The clinical endpoints, besides safety and tolerability, will also include EIIRF-questionaries (International Index of **Erectile** Function (**IIEF**)).

We really appreciate the collaboration with MAC Clinical Research, the UK's largest independent clinical development organization. MAC has also through a convertible credit agreement that can be converted into Initiator Pharma shares provided a large part, around 70%, of the total funding for the IPED2015 Phase 2b study.

# Expanding and financing the clinical portfolio

A major step for Initiator Pharma was taken after the end of the first quarter when we in April announced the expansion of Initiator

Pharma's clinical pipeline with our proprietary clinical program – IPTN2021 – targeting an orphan drug indication in severe neuropathic pain, Trigeminal Neuralgia.

To finance this step and to provide additional funding for our ongoing phase 2 programs, the Board of Directors proposed a directed share issue of approximately SEK 30.0 million directed to long-term investors led by Linc AB and Adrigo Asset Management AB, and a fully guaranteed preferential rights issue of approximately SEK 29.4 million. The proposed share issues were approved by the EGM on May 11.

The major part of the capitalization will finance an expansion of Initiator's clinical pipeline with an additional indication. The new program will target the orphan neuropathic pain Indication Trigeminal Neuralgia, a rare disease with a prevalence of 10-20 per 100,000 where the female-to-male ratio is about 3:2 and the disease is more common above 50 years of age.

Trigeminal Neuralgia is a deliberating orofacial pain condition characterized by sudden onset of an extreme, short-duration yet debilitating pain, often referred to as suicidal pain. There is only one FDA-approved pharmacological treatment for Trigeminal Neuralgia available, Carbamazepine. The treatment only provides limited pain relief and is associated with a significant number of side effects. Therefore, the unmet need for a new efficacious, tolerable and safe treatment is exceptionally high. It is Initiator Pharma's ambition to develop a First-Line treatment for these patients.

IPTN2021 is based on Initiator Pharma's IPED2015 assets that already have proven safe and tolerable in clinical trials and have demonstrated efficacy for erectile dysfunction. The preclinical data package for IPED2015 also consists of substantial effects in animal pain models and provides the scientific rationale for expanding into the pain field. The intent is to start with a Proof-of-Principle Pain IPTN2021 trial in healthy volunteers with inflected pain and then follow up with a Phase 2 trial including Trigeminal Neuralgia patients.

A developmental benefit of Trigeminal Neuralgia is the opportunity to apply for Orphan Drug Designation and subsequent Fast Track designation or conditional approval by the FDA or EMA, respectively. The interaction with the regulatory authorities will provide valuable guidance for both the design of the first IPTN2021 trial in patients and for a potential subsequent registration trial.

When summarize the above, Initiator Pharma is in an extremely exciting phase now and for the coming couple of years. We now have a pipeline with three clinical-stage programs, all with upcoming key value inflection points in the form of Phase 2 data read-outs over the next couple of years. To support these clinical programs we have also recently strengthened our management team and will continue to do so over the next few months. I'm also very pleased that we now will have an investor base that includes specialized and longterm investors. I look forward to keeping you informed and update on our progress.

Aarhus May 25 2021

# Claus Elsborg Olesen

CEO

**Initiator Pharma** is a life science 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.

# Vision

Initiator Pharma's vision is to become a leading life science company developing novel therapeutics within the field of mono-amine reuptake transporters targeting CNS-disorders with significant unmet medical needs.

# **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 clinical 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.



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. In 2018 the project portfolio was expanded through an option agreement to inlicense IP2018, which we exercised in March 2020. On April 13th we announced that we had further expanded our development pipeline with IPTN2021, aiming to develop the IPED2015 molecule for neurpathic pain, and specifically Trigeminal Neuralgia:

# Clinical Stage Pipeline

IPED2015 DAT (SERT/NET) ED (Organic)	Phase 2a Phase 2
FD	<b>—</b> 0
IP2018 SERT>DAT>NET (Psychogenic)	)
IPTN2021* DAT (SERT/NET) Trigeminal Neuralgia	

IPED2015, our most advanced drug candidate, is a novel drug candidate for the treatment of patients suffering from organic 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 ED in patients suffering from ED due to metabolic syndrome and diabetes.

IPED2015 is in clinical development. The goal is to improve the quality of life for a large number of patients (and their partners) who do not respond or cannot be treated with currently marketed drugs (PDE5 inhibitors) for sexual dysfunction. It is estimated that this represents 150 million men worldwide<sup>1</sup>. At the beginning of June 2019, Initiator announced that the Company had successfully completed a Phase 1 study regarding safety and tolerability with IPED2015, and in March 2020, Initiator achieved successful Phase 2a results for IPED2015. The Phase 2a study was designed as an exploratory study and included twelve patients who had severe erectile dysfunction with scores below 12 on the IIEF-5 scale, which meant that it was not possible to treat the condition with currently available treatment. Results from the study support the goal of further developing an oral formulation of IPED2015 for the treatment of moderate and severe erectile dysfunction in patients who do not respond to current therapies.

#### Clinical development plans for IPED2015

On 25 November 2020 Initiator announced a financing agreement with MAC Clinical Research Ltd covering the continued development of IPED2015. Within the agreement, MAC Clinical Research (MAC) will take on the cost, up to 23 MSEK, for conducting a clinical Phase 2b intercourse study for IPED2015 in patients suffering from organic erectile dysfunction, i.e. patients that is not responding to the currently marketed drugs in the PDE5i class. Upon the full completion of the study, MAC has the right to convert the accrued debt into Initiator shares at a share price of SEK 7.5.

The Phase 2b study will be conducted by MAC Clinical Research at multiple sites in the UK and is planned to be initiated in the first half of 2021, pending the development of the Covid-19 situation. The final design of the study is still pending and requires approval from MHRA. Initiator and MAC Clinical Research are utilising the learnings from the previous Phase 2a Proof-of-Concept study to design a Phase 2b intercourse study that also will have IIEF-questionares as clinical end point. The study is expected to be completed in the second half of 2022.

# 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 ED 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. **IPTN2021:** Trigeminal neuralgia is a chronic pain condition that affects the trigeminal nerve. The trigeminal nerve carries sensation from the face to the brain. In patients with trigeminal neuralgia, even mild stimulation of the face, such as brushing your teeth or putting on makeup, may trigger a jolt of excruciating pain. The disease is seriously invalidating. It is reported that worldwide 150,000 people are diagnosed with trigeminal neuralgia (TN) every year. Trigeminal neuralgia affects women more often than men, and it's more likely to occur in people who are older than 50. The causes of the disease include pressure on the nerve, aging, brain disease or is idiopathic. The treatment involves medications and surgery. Clinical guidelines recommend carbamazepine (the only drug FDA-approved for TN) and oxcarbazepine as first-line therapies, however the current medication is often found ineffective and with serious adverse events<sup>2</sup>. With our IPTN2021 program aim to address this significant unmet medical need<sup>3</sup>.

The IPTN2021 development plan aims for orphan drug registration for trigeminal neuralgia and the future ambition is to seek a fast track designation at the FDA and EMA to obtain regulatory support from the authorities and significantly reduce the lead time to product registration.

In the IPTN2021 program the Active Pharmaceutical ingredient is IPED2015. In preclinical studies, IPED2015 is effective and markedly inhibits neuralgic pain.

# Clinical development plans with IPTN2021

We aim in a Proof-of-Principle study to examine the effect of IPED2015 in subjects exposed to the sensory nerve stimulant capsaicin. The protocol is under development and conducted in collaboration with the MAC Clinical Research, Manchester, UK.

# **Trigeminal Neuralgia Market**

The neuropathic Pain Market to according to Garner a Valuation of US\$ 9860 Million by 2027<sup>4</sup>, at CAGR of 6.4 percent by the end of 2027. On average annual healthcare cost for painful neuropathic disorder is US\$ 17,355 per patient and with a solid efficacy and safety data on IPTN2021 Initiator Pharma expect to able to obtain premium pricing significantly strengthening the commercial opportunity with the potential to reach high hundreds of MUSD in sales.

<sup>1</sup> Alberson M, Orabi H, Lue T. Evaluation and treatment of erectile dysfunction in the aging male: a mini-review. Gerontology. 2012;58:3-14.

<sup>2</sup> Joanna M. Zakrzewska, Eastman Dental Hospital, London, United Kingdom Mark E. Linskey, University of California Irvine, Irvine, California Am Fam Physician. 2016 Jul 15;94(2):133-135.

- <sup>3</sup> Jones, M.R., Urits, I., Ehrhardt, K.P., Cefalu, J.N., Kendrick, J.B., Park, D.J., Cornett, E.M., Kaye, A.D. and Viswanath, O., 2019. A comprehensive review of trigeminal neuralgia. Current pain and headache reports, 23(10), pp.1-7.
- <sup>4</sup> Coherent Market Insights "Neuropathic Pain Market Analysis" (2020), https:// www.coherentmarketinsights.com/market-insight/neuropathic-pain-market-3656.

**IP2018** is a monoamine reuptake inhibitor for the treatment of psychogenic Erectile Dysfunction (mainly caused by anxiety and depression) mainly targeting the serotonin instead of the dopamine system. IP2018 is different from our frontrunner IPED2015 for organic erectile dysfunction (mainly caused by diabetes and age), primarily targeting the dopamine system.

- Due to the unique profile, IP2018 will, if successful, treat patients suffering major depressive disorder where the majority also suffer from comorbid sexual dysfunction or treatment-emergent sexual dysfunction.
- IP2018 has demonstrated an excellent safety profile in a single dose study and the proof of mechanism PET study, confirming the safety and the mechanism of action of our extensive package of preclinical data.
- IP2018 is efficacious in animal models of depression (forced swim and tail suspension tests) and erectile function (intraca-vernosal pressure to mean arterial pressure ratio) as well as in several mouse anxiety models.
- IP2018 is targeting a clear unmet medical need as up to 68% of patients with major depressive disorder suffer from sexual dysfunction, for which only 5% to 30% is resolved with antidepressant treatment.

IP2018 raises the serotonin levels in the brain, and in its preclinical trials, Initiator Pharma has shown that IP2018 has an effect on both depression and erectile function, which is a clear differentiation from

other antidepressants on the market today. In the planned clinical phase 2a trial, Initiator Pharma intends to primarily confirm the effect of IP2018 on the erectile function of patients and thereafter, if the outcome is positive, follow up with further clinical safety trials on multiple dosage parameters. The company intends to position IP2018 as a daily treatment for patients suffering from depression and sexual dysfunction and/or as a supplement to treat erectile dysfunction in patients with medically induced sexual dysfunction.

# Clinical development plans for IP2018

In June 2020 we announced that we had obtained approval from the Medicines and Healthcare products Regulatory Agency, MHRA, and the Ethical committee (EC) UK, for a Phase 2a clinical trial with its candidate drug IP2018. The Phase 2a trial is a randomized, double-blind, placebo-controlled, 3-way crossover trial studying the efficacy and safety of IP2018 in young, depressed, erectile dysfunction (ED) patients. The primary objective of this study is to investigate the effects of IP2018 on penile rigidity and tumescence using visual sexual stimulation test. The study will be conducted in 24 patients at the MAC Phase I unit in Manchester, UK.

On December 9th we announced that the dosing of the first patient enrolled in this trial had been completed. Pending the Covid-19 situation, the trial is planned to be executed within the first half of 2021, and top-line data from the trial is expected later this year.

The company has a commitment from Innovation Fund Denmark to fund the trial with up to 3.8 MDKK through the Innobooster grant.

# **Depression Market**

The main treatments for depression are drugs that selectively inhibit the uptake of serotonin (SSRIs) or serotonin and norepinephrine (SNRIs) or the breakdown of serotonin, norepinephrine and dopamine by inhibiting monoamine oxidase. Antidepressants such as SSRIs and SNRIs have a negative effect on male sexual function. Although the incidence of sexual dysfunction is lower with certain atypical antidepressants, such as bupropion, mirtazapine and vortioxetine, compared to SSRIs, it is nevertheless important to treat sexual dysfunction induced by antidepressant drugs (treatment-induced sexual dysfunction). In one study, it was observed that 41.7 percent of men discontinued psychiatric medication due to perceived sexual side effects. Between 14 and 35 percent of young men have experience with erectile dysfunction, which may be due to performance anxiety, depression, schizophrenia, or other mental disorders. About 13 percent of all Americans take antidepressant drugs, which means over 23 million prescriptions per year. The global Anxiety Disorder and Depression Treatment Market is forecasted to grow at a rate of 2.4 percent from USD 15.85 billion in 2019 to USD 19.21 billion in 2027. The largest players, which account for more than 60 percent of antidepressants sold, are Pfizer, Eli Lilly, GlaxoSmithKline, AstraZeneca and H Lundbeck A/S. All are facing major patent expirations in the next few years, and generics and biosimilars are expected to hit revenues hard. All drugs currently on the market have been associated with erectile dysfunction to varying degrees, and this underlines the need to develop a better alternative.

# **Patent protection**

Intellectual Assets of Initiator Pharma includes patents conferring proprietary chemistry protection for IPED2015 and IP2018 in the USA; and in the USA, Israel, Japan, the United Kingdom, Germany, France, and Switzerland, respectively.

The IPED2015 patent expires in 2031, while the IP2018 patents expire in 2025 (2026 in the US due to patent term extension). Subject to Market Authorization prior to expiry of the patents, extensions by up to five years are available in key territories.

In addition to the composition of matter patent outlined above, patent protection for the use of IP2018 for the treatment of erectile dysfunction in depressive patients (psychogenic ED) is pending. This patent family is currently pending in the international phase, and will enter national phase in the Spring of 2022. The patent family is projected to expire in 2040.

<sup>5</sup> Rosenberg, K. P., Bleiberg, K. L., Koscis, J., & Gross, C. (2003). A survey of sexual side effects among severely mentally ill patients taking psychotropic medications: impact on compliance. Journal of Sex & Marital Therapy, 29(4), 289-296.

<sup>6</sup> Quilter M, Hodges L, von Hurst P, Borman B, Coad J. Male sexual function in New Zealand: a population-based cross-sectional survey of the prevalence of erectile dysfunction in men aged 40-70 years. J Sex Med. (2017) 14:928–36. doi: 10.1016/j.jsxm.2017.05.011

<sup>7</sup> Pratt, L. A., Brody, D. J., & Gu, Q. (2017). Antidepressant Use among Persons Aged 12 and Over: United States, 2011-2014. NCHS Data Brief. Number 283. National Center for Health Statistics.

8 Reports and Data. "Anxiety Disorder and Depression Treatment Market By Therapies" (2020), https://www.reportsanddata.com/report-detail/anxiety-disorder-and-depression-treatment-market.



# Revenues and result of the operation

# Revenue

Initiator Pharma generated total revenues of TDKK 0 for the first quarter of 2021 (0) and TDKK 0 for the full year (0).

### **Operating profit/loss**

The company recognized an operating loss of TDKK 1,792 for the first quarter of 2021 (-2,392). The decline in operating costs reflects the slow recruitment in the ongoing IP2018 proof of concept trial, due to Covid-19 in the UK.

External R&D costs in the first quarter amounted to TDKK 63, compared to TDKK 1,485 in the same period in 2020.

#### **Financial position**

The equity as of March 31, 2021 was TDKK 12,603 (7,424). Cash and cash equivalents amounted to TDKK 11,287 (7,082) as of March 31, 2021 and total assets were TDKK 13,029 (9,095).

#### **Cash flow**

In the first quarter of 2021 the total operating cash flow was TDKK -2 217 (TDKK -480), incl a negative change in working capital of TDKK 416 (TDKK 1,995). Cash flow from financing activities was TDKK 0 (TDKK 0).

### The share, share capital and ownership structure

At March 31, 2021, the number of shares outstanding amounted to 27,705,728 and 868,393 warrants, representing 3.1% of the number of issued shares.

On May 11th 2021 an extra-ordinary general meeting approved a capitalization of a total of SEK 60 million to finance the expansion of Initiator Pharma's clinical pipeline with its proprietary clinical program – IPTN2021 – targeting an orphan drug indication in severe neuropathic pain, Trigeminal Neuralgia. The capitalization consists of a directed share issue of approximately SEK 30.0 million and a fully guaranteed preferential rights issue of approximately SEK 29.4 million. The directed issue is directed to long-term investors led by Linc AB and Adrigo Asset Management AB. The terms for both issues include a subscription price of SEK 3.70 per new share, which corresponds to a discount of approximately 15 percent based on a VWAP counted five days back from the Board of Directors' decision on April 13th.

On May 20th the execution of the direct placement was announced, and the preferential rights issue will be executed as soon as the prospectus has been reviewed and approved by the Danish FSA. The preferential rights issue has been fully guaranteed by the new shareholders in the directed issue. The public is also given the opportunity to subscribe for new shares in the preferential rights issue. At March 31, 2020 the company had around 4,000 shareholders. The 10 largest shareholders in the company on December 31 owned approx 31% of all outstanding shares.

Owners	Number of shares	Shares %
Försäkringsaktiebolaget, Avanza Pension	1 604 071	5,79%
FormueNord Markedsneutral	1 146 781	4,14%
BNY Mellon SA/NV (Former BNY)	1 118 524	4,04%
Ålandsbanken i ågares ställe	899 191	3,25%
Nordnet Pensionsförsäkring AB	703 914	2,54%
Claus Olesen Holding APS	692 738	2,50%
UBS Switzerland AG	665 335	2,40%
Mikael Södergård Thomsen APS	636 056	2,30%
DanPet AB	619 622	2,24%
Peters, Dan	596 135	2,15%
Other shareholders	19 023 361	68,66%
Total	27 705 728	100,00%

### Personnel

As of March 31, 2021, the number of employees was 1 (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.

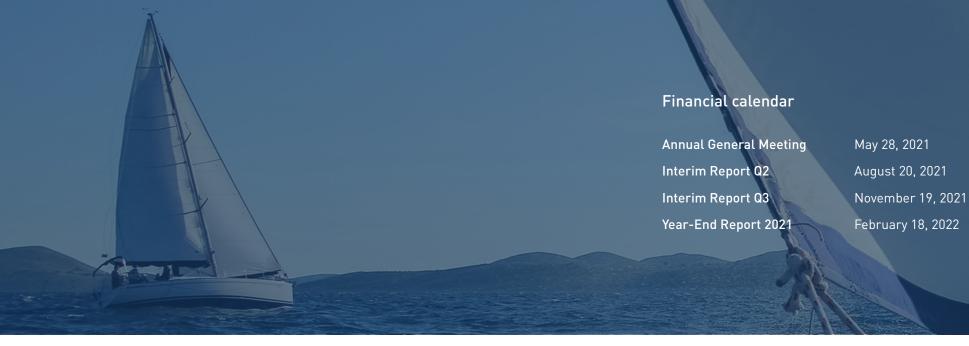
A more detailed description of the company's risk exposure and risk management is included in the memorandum published in May 2020.

### Impact of COVID-19

As of May 2021 the clinical development programs of the company have been impacted by Covid-19. The company has one ongoing clinical trial – a Phase 2a clinical trial for IP2018 – which is being conducted in England. Recruitement into this trial has been slower than anticipated and management attributes this to Covid-19 which has impacted England to a great extent over the last few months. In addition to the impact on the ongoing clinical trial, the board and management considers the following to be the key risk elements related to Covid-19 going forward:

- Potential delay in the start-up of the planned Phase 2b clinical trial for IPED2015.
- Potential risk that it will be difficult to secure additional funding on acceptable terms for the further development of the company and our projects.

The board and management will continue to carefully monitor the Covid-19 pandemic and its potential for impacting our operations and development plans.



# Audit review

This Interim Report has not been subject to review by the company's auditor.

Aarhus, May 25, 2021

**Magnus Persson** Chairman

**Henrik Moltk** Board member

**Peter Holm** Board member **Claus Olesen** Board member and CEO

Annette Colin Board member

# **Financial Statements**

# Statement of income

токк	1Q:2021	1Q:2020	2020
Gross loss	-1 584	-2 215	-9 299
Staff costs	-202	-168	-1 206
Depreciation and write-downs	-6	-9	-26
Operating profit/loss	-1 792	-2 392	-10 531
Other financial expenses	-15	-92	291
Profit/loss	-1 807	-2 484	-10 240
Тах	_	-	1 543
Net profit for the period	-1 807	-2 484	-8 697

# Statement of financial position

токк	1Q:2021	1Q:2020	202
ASSETS			
Patents, acquired rights	6	28	1
Intangible assets	6	28	1
Other fixtures, fittings, tools and equipment	-	-	-
Property, plant and equipment	-	-	-
Fixed assets	6	28	1
Other receivables	193	298	48
Income tax receivables	1 543	1 687	1 54
Prepayments	-	-	5
Current receivables	1 736	1 985	2 08
Cash and cash equivalents	11 287	7 082	13 50
Current assets	13 023	9 067	15 59
Assets	13 029	9 095	15 60
EQUITY AND LIABILITIES			
Contributed capital	2 909	2 477	2 90
Retained earnings	9 694	4 947	11 50
Equity	12 603	7 424	14 40
Trade payables	240	1 365	66
Other payables	186	306	52
Current liabilities other than provisions	426	1 671	1 19
Liabilities other than provisions	426	1 671	1 19
Equity and liabilities	13 029	9 095	15 60

# Statement of changes in shareholder equity

токк	Contributed capital	Retained earnings	Total
January 1, 2021	2 909	11 501	14 410
Increase of capital Profit/loss for the period	-	-1 807	-1 807
March 31, 2021	2 909	9 694	12 603

# Statement of cash flow

токк	1Q:2021	1Q:2020	2020
Operating profit/loss	-1 792	-2 392	-10 531
Amortisation, depreciation and impairment losses	6	9	26
Changes in working capital	-416	1 995	463
Cash flow from operating activities before financial	-2 202	-388	-10 042
items			
Other financial expenses	-15	-92	291
Tax credit	-	-	1 687
Cash flow from operating activities	-2 217	-480	-8 064
Investing activities Cash flow from investing activities	-	-	-
cash now from investing activities	-	-	-
Financing activities			
New share issue	-	-	13 593
Issue of warrants	-	-	414
Cash flow from financing activities	-	-	14 007
Increase/decrease in cash and cash equivalents	-2 217	-480	5 943
Cash and cash equivalents at the end of period	11 287	7 082	13 504

# 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©)

### IP2018

IP2018, currently in a on-going Phase 2a trial for psychogenic erectile dysfunction.

#### 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

FINANCIAL

GLOSSARY

Profit/loss for the period divided by the average number of shares outstanding at the end of the period

# Operating profit/loss, 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

# Earnings per share

Profit/loss for the period divided by the average number of shares outstanding at the end of the period



# Initiator Pharma

www.initiatorpharma.com Ole Maaloes vej 3, 2200 Copenhagen, DENMARK