Q2 2021

Initiator Pharma

BUSINESS HIGHLIGHTS

Business highlights in Q2 2021

- 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 long-term 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 IPED2015 in organic Erectile Dysfunction patients.
- On May 4th 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.
- On June 2nd provided an update on the Phase 2a study with IP2018
- On June 28th it was announced that the CTA for a Phase 2b study with IP2015 was approved

Significant events after this reporting period

- On July 2nd it was announced that the board had decided on the execution of the previously communicated preferential rights issue
- On July 8th the prospectus prior to the preferential rights issue was published
- On July 29th it was announced that the rights issue was subscribed to a total of approx 227 percent

Financial Highlights

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

Financial review

TDKK	2Q:2021	2Q:2020	H1:2021	H1:2020	2020
Net sales	-	-		-	-
Total operating expenses	-4 944	-3 013	-6 736	-5 405	-10 531
Operating profit/loss	-4 944	-3 013	-6 736	-5 405	-10 531
Net result	-5 382	-2 998	-7 189	-5 482	-8 697
Earnings per share, fully diluted (DKK)	-0,14	-0,13	-0,19	-0,23	-0,32
Cash flow from operating activities	-2 223	-663	-4 440	-1 143	-8 064

	30.06.2021	30.06.2020	31.12.2020
Cash and cash equivalents	31 099	8 189	13 504
Equity	29 255	6 196	14 409
Total equity and liabilities	32 975	8 271	15 603
Equity ratio, %	89%	75%	92%
Number of shares outstanding	*35 813 834*	*24 146 930*	*27 705 728*
Number of shares, fully diluted	*38 002 227*	*25 449 521*	*28 574 121*

LETTER FROM THE CEO

The past quarter was truly exciting for Initiator Pharma. We could in early April announce a fully guaranteed financing to provide the resources required for expanding our portfolio with our candidate drug IPTN2021 for Trigeminal Neuralgia. This meant that we could start the preparations for the clinical development of IPTN2021. We received regulatory approval to start our upcoming Phase 2b study with IPED2015 in Erectile Dysfunction (ED) patients, which has, after the end of period, initiated patient recruiting. And in our ongoing Phase 2a study in depressed, ED patients, where the recruitment rate has been slow due to the Covid-19 pandemic, we received approval from the regulatory authorities to modify certain inclusion criteria in order to ensure a successful completion of the trial.

Initiator Pharma targets CNS disorders with significant unmet medical needs and I am very proud of the quality and attractiveness of our clinical portfolio. Our recent financing, where we in April could announce a directed share issue of SEK 30 million to be followed by a guaranteed preferential rights issue of SEK 29.4 million, shows that investors have a strong belief in our potential. End of July we could announce that the preferential rights issue had been oversubscribed with a subscription ratio of approximately 227 percent. The financing, which was led by long-term investors Linc and Adrigo, has given us muscles to initiate the clinical development of our new Orphan Drug indication Trigeminal Neuralgia and it has at the same time ensured continued operating and development costs of the ongoing and upcoming clinical trials with IP2018 and IPED2015 for the treatment of erectile dysfunction of psychogenic and organic origin, to a good bit into 2023.

The medical need for a new effective treatment for ED is massive, expected to affect more than 300 million men worldwide by 2025. Initiator Pharma's IPED2015 and IP2018 are both clinical phase drug candidates in the field of erectile dysfunction, and both candidates 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.

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Moving into Phase 2b with IPED 2015

IPED2015 is Initiator Pharma's most advanced ED candidate and has successfully been through a Phase 2a Proof-of-Concept study. 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.

End of June we received CTA approval for our Phase 2b study with IPED2015 in ED patients and we have recently initiated the patient recruitment for the study, which is carried out in collaboration with MAC Clinical Research, UK, at multiple centers across UK. Depending on the Covid-19 pandemic

LETTER FROM THE CEO

Increasing the recruitment rate for IP2018

IP2018, Initiator Pharma's monoamine reuptake inhibitor for the treatment of psychogenic ED, is since end of last year being evaluated in a Phase 2a clinical trial in psychogenic sexual dysfunction. The recruitment rate to the study has been slow due to the ongoing Covid-19 pandemic and in order to mitigate the situation, and ensure a successful completion of the trial, Initiator Pharma has obtained approval from the regulatory authorities to modify certain inclusion criteria. The granted amendments to the protocol enable us to cover an even broader portion of the Psychogenic ED patient segment and this will provide unique guidance for the future positioning of IP2018. The recruitment rate is also expected to increase thanks to the high vaccination ratio and the reopening of the British society. As communicated earlier, we hope to enroll and complete the study later this year.

Initiating clinical development for Trigeminal Neuralgia

Our new IPTN2021 program is based on the IPED2015 asset that has already been proven safe and tolerable in clinical trials. IPTN2021 targets the orphan neuropathic pain indication Trigeminal Neuralgia, a rare disease with a prevalence of 10-20 per 100,000. 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 treatment for Trigeminal Neuralgia available, Carbamazepine, which 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. Our ambition is to develop a First-Line treatment for these patients. Our intention 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.

We also intend 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.

Finally, I would like to thank both old and new investors for your confidence in Initiator Pharma. All in all, the future looks very exciting and our three clinical-stage programs will all have upcoming key value inflection points in the form of Phase 2 data read-outs over the next couple of years. I look forward to keep you informed on the clinical development of our portfolio.

Aarhus, August 20, 2021

Claus Elsborg Olesen
CEO

ABOUT INITIATOR PHARMA

Initiator Pharma *A/S is a Danish clinical stage life science company developing innovative drugs that target key unmet medical needs within the central and peripheral nervous system. Initiator Pharma's pipeline consists of three clinical programs - the drug candidates IP2018 and IPED2015 for treatment of erectile dysfunction of psychogenic and organic origin, respectively, and the orphan drug candidate IPTN2021 developed for Trigeminal Neuralgia, a severe neuropathic pain condition. Initiator Pharma is listed on Spotlight Stockmarket (ticker: INIT).*

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.

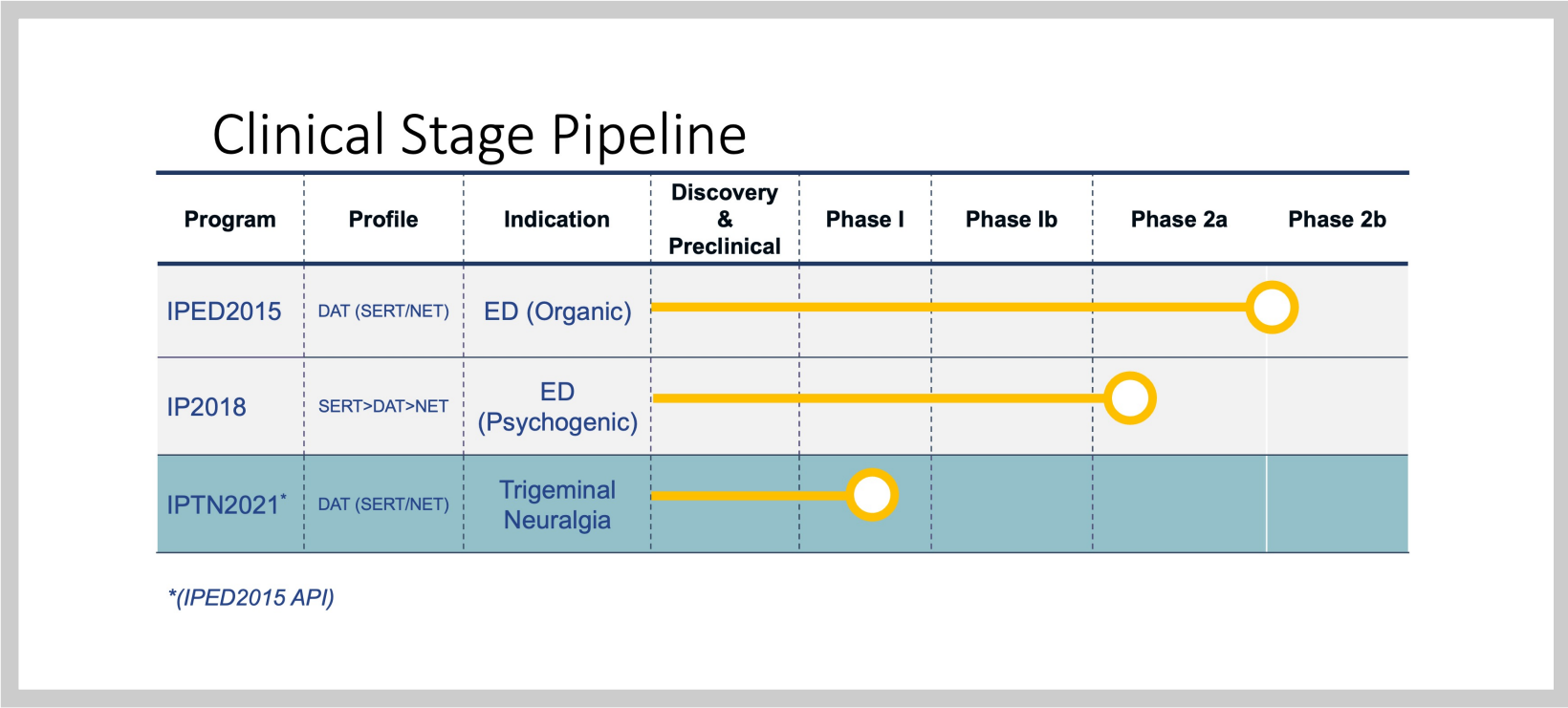
Business model

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.

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. 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:



ERECTILE DYSFUNCTION

IPED2015: 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 [1]. 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 study is a randomized, double-blind, parallel-group, repeat single oral dose study of IPED2015 or placebo in otherwise healthy organic Erectile Dysfunction patients. The plan is to include 120 patients in the study divided into 3 parallel arms receiving a higher and a lower dose of IPED2015 and placebo respectively, with treatment duration of 4 weeks with frequent assessments of erectile dysfunction, safety and pharmacokinetics. The Clinical Trial Application for the Phase 2b study was approved on June 28th, recruitement into the study is expected to start sometime during Q3 and 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.

TRIGEMINAL NEURALGIA

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 [2]. With our IPTN2021 program aim to address this significant unmet medical need [3] .

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 will be 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$ 9,862.3 Million by 2027, at CAGR of 6.4 percent by the end of 2027 [4]. 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 siginificantly strengthening the commercial opportunity with the potential to reach high hundreds of MUSD in sales.

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

[2] *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.*

[3] *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.*

[4] *Coherent Market Insights "Neuropathic Pain Market Analysis" (2020), https://www.coherentmarketinsights.com/market-insight/neuropathic-pain-market-3656.*

PSYCHOGENIC ERECTILE DYSFUNCTION

IP2018: 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 (intracavernosal 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. The enrollment into the study has been impacted by the Covid-19 situation. On June 2nd we announced that MHRA had approved an amendment to the protocol, modifying certain inclusion criteria. With the modified inclusion criteria and further helped by the reopening of the British society, the recruitment rate has increased.

PSYCHOGENIC ERECTILE DYSFUNCTION

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 [5]. 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 [6]. About 13 percent of all Americans take antidepressant drugs, which means over 23 million prescriptions per year [7]. 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 [8]. 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 patents expire in 2031, while the IP2018 patents expire in 2025 (2026 in the US due to patent term adjustment). 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.

[5] *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.*

[6] *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*

[7] *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.*

FINANCIAL REVIEW

Revenues and result of the operation

Revenue

Initiator Pharma generated total revenues of TDKK 0 for the second quarter of 2021 (0) and TDKK 0 for the first six months (0).

Net income

The company recognized an operating loss of TDKK 4,944 for the second quarter of 2021 (-3,013). The increase in operating costs during the second quarter reflects the preparations for the start-up of the two new clinical programs, as well as the fundraising process during the quarter. For the first six months the operating loss was TDKK 6,736 (-5,405).

External R&D costs in the second quarter amounted to TDKK 3,254, compared to TDKK 1,381 in the same period in 2020. For the first six months external R&D costs amounted to TDKK 3,453 (2,865).

Net financial expenses in the second quarter amounted to TDKK 438, compared to net financial income of TDKK 15 in the same period in 2020. For the first six months net financial expenses were TDKK 543 (77). The increase in net financial expenses in the second quarter and first half 2021 is related to fees for the MSEK 10 loan facility that was entered into in April 2020 and that was terminated in the second quarter this year.

Financial position

The equity as of June 30, was TDKK 29,225 (6,196). Cash and cash equivalents amounted to TDKK 31,099 (8,189) as of June 30, and total assets were TDKK 32,975 (8,271). The increase in equity, cash and total assets is related the the completed directed share issue, described in further detail under the section "The share, share capital and ownership structure below".

Cash flow

In the second quarter the total operating cash flow was TDKK -2,223 (TDKK -663), incl a positive change in working capital of TDKK 3,154 (TDKK 2,333). Cash flow from investment activities was TDKK -0 (TDKK 0). Cash flow from financing activities was TDKK 22,034 (TDKK 1,770).

For the first half year the operating cash flow was TDKK -4,440 (TDKK -1,143), incl a positive change in working capital of TDKK 2,738 (TDKK 4,328). Cash flow from investment activities was TDKK -0 (TDKK 0) and cash flow from financing activities was TDKK 22,034 (TDKK 1,770).

The share, share capital and ownership structure

At June 30, 2021, the number of shares outstanding totalled 35,813,834 shares and 868,393 warrants, representing 3.1% of the number of issued shares.

FINANCIAL REVIEW

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 consisted 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 July 29th we announced that the rights issue was subscribed to a total of approx 227 percent, raising SEK 29.4 million gross and SEK 26.4 millon net of transaction costs.

The AGM held on May 28th approved a long-term incentive program to key personell. Under the approved program the board of directors is authorised to allocate up to 220.000 Investment Shares to individuals under the program, with each Investment Share carrying the right to subscribe for one share at par value at the AGM next year (Matching Share) and between 0 - 5 shares at part value at the end of 2023, depending on the development in the share price in Intitiator Pharma between May 28th 2021 and December 31, 2023 (Performance Shares). The Investment Shares need to be purchased in the market before September 30, 2021. If fully utilized the program represents a potential dilution of up to 1,320,000 shares.

At June 30, 2021 the company had around 4,000 shareholders. The 10 largest shareholders in the company on June 30 owned approx 46% of all outstanding shares.

Top 10 shareholders as of June 30, 2021 Owners	Number of shares	Shares %
LINC AB	4 729 729	13,21%
Diff för XDB i Ägares ställe	2 833 889	7,91%
Adrigo Small and Midcap L/S	2 162 162	6,04%
Försäkringsaktiebolaget, Avanza Pension	1 896 567	5,30%
BNY Mellon SA/NV	1 118 524	3,12%
Thorén, Mats	932 857	2,60%
Ålandsbanken i Ägares ställe	899 191	2,51%
Nordnet Pensionsförsäkring	734 657	2,05%
UBS Switzerland	635 787	1,78%
DanPet AB	619 622	1,73%
Other shareholders	19 250 849	53,75%
Total	**35 813 834**	**100,00%**

Personnel

As of June 30, 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 drug development and ensures the company the optimal balance of access to leading edge expertise, costs and flexibility.

FINANCIAL REVIEW

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 July 2021.

Impact of COVID-19

As of August 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. 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.

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

Financial calendar

Interim Report Q3	November 19, 2021
Year-End Report 2021	February 18, 2022

Audit review

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

Aarhus, August 20, 2021

Magnus Persson
Chairman

Claus Olesen
Board member and CEO

Henrik Moltk
Board member

Annette Colin
Board member

Peter Holm
Board member

FINANCIAL STATMENTS

Statement of income

TDKK	2Q:2021	2Q:2020	H1:2021	H1:2020	2020
Gross loss	-4 409	-2 578	-5 993	-4 793	-9 299
Staff costs	-530	-433	-732	-601	-1 206
Depreciation and write-downs	-5	-2	-11	-11	-26
Operating profit/loss	**-4 944**	**-3 013**	**-6 736**	**-5 405**	**-10 531**
Other financial expenses	-438	15	-453	-77	291
Profit/loss	**-5 382**	**-2 998**	**-7 189**	**-5 482**	**-10 240**
Tax	-	-		-	1 543
Net profit for the period	**-5 382**	**-2 998**	**-7 189**	**-5 482**	**-8 697**

FINANCIAL STATMENTS

Statement of financial position

TDKK	H1:2021	H1:2020	2020
ASSETS			
Patents, acquired rights	-	26	11
Intangible assets	**-**	**26**	**11**
Other fixtures, fittings, tools and equipment	-	-	-
Property, plant and equipment	**-**	**-**	**-**
Fixed assets	**-**	**26**	**11**
Other receivables	171	56	487
Income tax receivables	1 543	-	1 543
Prepayments	162	-	58
Current receivables	**1 876**	**56**	**2 088**
Cash and cash equivalents	**31 099**	**8 189**	**13 504**
Current assets	**32 975**	**8 245**	**15 592**
Assets	**32 975**	**8 271**	**15 603**
EQUITY AND LIABILITIES			
Contributed capital	3 760	2 535	2 909
Retained earnings	25 495	3 661	11 500
Equity	**29 255**	**6 196**	**14 409**
Trade payables	3 381	1 745	666
Other payables	339	330	528
Current liabilities other than provisions	**3 720**	**2 075**	**1 194**
Liabilities other than provisions	**3 720**	**2 075**	**1 194**
Equity and liabilities	**32 975**	**8 271**	**15 603**

FINANCIAL STATMENTS

Statement of changes in shareholder equity

TDKK	Contributed capital	Retained earnings	Total
January 1, 2021	**2 909**	**11 501**	**14 410**
Increase of capital	851	21 183	22 034
Profit/loss for the period	-	-7 189	-7 189
June 30, 2021	**3 760**	**25 495**	**29 255**

FINANCIAL REVIEW

Statement of cash flow

TDKK	2Q:2021	2Q:2020	H1:2021	H1:2020	2020
Profit/loss before tax	-5 382	-2 998	-7 189	-5 482	-10 240
Adjustments for non-cash transactions	5	2	11	11	26
	-5 377	**-2 996**	**-7 178**	**-5 471**	**-10 214**
Tax credit	-	-			1 687
Cash flow before change in working capital	**-5 377**	**-2 996**	**-7 178**	**-5 471**	**-8 527**
Changes in working capital	3 154	2 333	2 738	4 328	463
Cash flow from operating activities	**-2 223**	**-663**	**-4 440**	**-1 143**	**-8 064**
Investing activities	-	-	-	-	-
Cash flow from investing activities	**-**	**-**	**-**	**-**	**-**
Financing activities					
New share issue	22 034	1 770	22 034	1 770	13 593
Issue of warrants	-	-	-	-	414
Cash flow from financing activities	**22 034**	**1 770**	**22 034**	**1 770**	**14 007**
Increase/decrease in cash and cash equivalents	**19 811**	**1 107**	**17 594**	**627**	**5 943**
Cash and cash equivalents at the end of period	**31 099**	**8 189**	**31 099**	**8 189**	**13 504**

FINANCIAL TERMS

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

Financial Glossary

Earnings per share
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

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Initiator Pharma

www.initiatorpharma.com

Ole Maaloes vej 3, 2200 Copenhagen, DENMARK