

Q3
2021



Initiator Pharma

BUSINESS HIGHLIGHTS

Business highlights in Q3 2021

- On July 2nd it was announced that the board had decided to execute on the previously communicated preferential rights issue
- On July 8th the prospectus for the preferential rights issue was published
- On July 12th the subscription period of the preferential rights issue began
- On July 29th it was announced that the rights issue was oversubscribed for a total of 227 percent
- On August 13th the final day of trading in BTA in connection with the rights issue was announced
- On September 17th a screening agreement with US National Institute on Drug Abuse to evaluate anti-addictive properties of the company's preclinical assets was announced
- On September 24th it was announced that the first patient in the IPED2015 Phase 2b trial was included

Business highlights after this reporting period

- On October 8th it was announced that the company had received conditional approval for listing of the company's shares at Nasdaq First North Growth Market in Stockholm
- On October 18th the Information Memorandum in connection with the change of listing to Nasdaq First North Growth Market was published
- On October 18th it was announced that the CTA for a Phase 1 proof of principle study in neuropathic pain had been submitted
- On October 22nd it was announced that the company had been ap-

proved for listing at Nasdaq First North Growth Market

- On October 25th it was announced that the trading of the company's shares started on October 25th

Financial Highlights

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

Financial review

TDKK	3Q:2021	3Q:2020	9M:2021	9M:2020	2020
Net sales	-	-	-	-	-
Total operating expenses	-9 056	-3 068	-15 792	-8 462	-10 531
Operating profit/loss	-9 056	-3 068	-15 792	-8 462	-10 531
Net result	-9 141	-3 057	-16 330	-8 528	-8 697
Earnings per share (DKK)	-0,21	-0,12	-0,64	-0,33	-0,32
Earnings per share, fully diluted (DKK)	-0,20	-0,10	-0,54	-0,28	-0,30
Cash flow from operating activities	-22 340	-4 432	-26 780	-5 575	-8 064

	3Q:2021	3Q:2020	30.09.2021	30.09.2020	31.12.2020
Cash and cash equivalents	41 394	8 174	41 394	8 174	13 504
Equity	39 728	7 567	39 728	7 567	14 409
Total equity and liabilities	55 013	8 265	55 013	8 265	15 603
Equity ratio, %	72%	92%	72%	92%	92%

<i>Number of shares outstanding</i>	43 772 462	25 567 336	43 772 462	25 567 336	27 705 728
<i>Number of shares, diluted</i>	45 540 855	30 225 026	45 540 855	30 225 026	28 574 121
<i>Average number of shares outstanding</i>	38 466 710	25 567 336	32 193 623	24 379 658	24 752 173
<i>Average number of shares, diluted</i>	40 235 103	30 225 026	33 655 349	26 511 151	27 375 419

LETTER FROM THE CEO



The third quarter started off with the successful capital raise that provided the resources required for expanding our portfolio with our IPTN2021 program for Trigeminal Neuralgia. The first step was the directed issue in May, which provided close to SEK 30 million, and on July 29 we could announce that the following rights issue had been heavily oversubscribed. The rights issue provided a further SEK 29.4 million to Initiator Pharma before issue costs. I am truly impressed by and grateful for the confidence in Initiator Pharma shown by investors, led by long-term investors Linc AB and Adrigo Asset Management AB.

The successful financing meant that we could start the preparations for the clinical development of the IPTN2021 program in our new Orphan Drug indication Trigeminal Neuralgia. We are now financed to complete the ongoing clinical Phase 2a with IP2018 and clinical Phase 2b with IPED2015 for the treatment of erectile dysfunction of psychogenic and organic origin, respectively.

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.

IP2018 - Phase 2a

For our ongoing Phase 2a study with our monoamine reuptake inhibitor IP2018 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. The amendment has enabled us to cover an even broader portion of the Psychogenic ED patient segment which will provide unique guidance for the future positioning of IP2018. We are looking forward to recruiting the remaining patients into this trial, but we are focused on only enrolling the appropriate patients for the study to maximize the value of the trial and its results.

IPED2015 - Phase 2b initiated in September

IP2018, Initiator On September 24 we could announce that the first patient had been dosed in the Phase 2b study in Erectile Dysfunction (ED) patients in our IPED2015 program. The study is carried out in collaboration with MAC Clinical Research, UK, at multiple centers across UK. Results from our earlier Phase 2a Proof-of-Concept study support the goal of further developing an oral formulation of IP2015 for the treatment of moderate and severe erectile dysfunction in patients who do not respond to current therapies.

The Phase 2b IPED2015 study is a randomized, double-blind, parallel group, repeat single oral dose study of IP2015 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 (also used in the first Phase IIa study) and a lower dose of IP2015 and

LETTER FROM THE CEO

placebo, respectively, and treatment for 4 weeks with frequent assessments of erectile dysfunction, safety and pharmacokinetics. The aim is to report results from the study in H2 2022.

IPTN2021 – getting closer to clinical development

Trigeminal Neuralgia is a rare disease with a prevalence of 10-20 per 100,000. It is a debilitating orofacial pain condition characterized by sudden onset of an extreme, short-duration yet debilitating pain, often described as suicidal pain. The only available FDA-approved treatment for Trigeminal Neuralgia, Carbamazepine, 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 the Trigeminal Neuralgia patients.

Following thorough preparations, we filed our Clinical Trials Application (CTA) on October 19 to the British regulatory agency, MHRA, for the planned Phase I study in our IPTN2021 program against Trigeminal Neuralgia with the drug substance IP2015 in healthy subjects challenged with pain inducing ingredient (capsaicin). The study will provide supportive pain related efficacy, biomarker and safety information to the planned clinical development of IP2015 into relevant pain indications. The program is based on the IP2015 asset that has already been proven safe and tolerable in the IPED2015 clinical trials. When the Phase I study is completed, and given positive results, we intend to follow up with a Phase 2 trial including Trigeminal Neuralgia patients. The interaction with the regulatory authorities will provide valuable guidance for both

the design of the first IPTN2021 trial in patients and for the potential subsequent registration trial. We also intend to apply for Orphan Drug Designation and subsequent Fast Track designation or conditional approval by the FDA or EMA, respectively.

NIDA-agreement on preclinical assets

Initiator Pharma targets CNS disorders with significant unmet medical needs and I am very proud of the quality and attractiveness of our clinical portfolio. And aside from our progress in our clinical programs, we could also announce in September the signing of a screening agreement with the National Institute on Drug Abuse (NIDA) in the USA in order to investigate the potential benefits of Initiator Pharma's preclinical assets IPDP2015 and IPNP2015 for improved treatment of addiction. In this prestigious collaboration, NIDA will perform the studies at no cost to the company while Initiator Pharma will maintain all rights to the assets and to use of the data. We do also see this as yet an important validation of our assets' broad potential in the CNS field.

Initiator Pharma – now on Nasdaq First North Growth Market

We were approved and could carry out the planned move from Spotlight Stock Market in the end of the quarter and since October 25, 2021, the Initiator Pharma share is now listed and traded on Nasdaq First North Growth Market. In connection with the change of listing venue we also launched our new and updated website. We do hope that investors will appreciate the potential of the improved visibility and increased access to the capital markets that that we expect from our new listing.

Finally, I would once more express my thanks both to old and new investors for your confidence in Initiator Pharma, highlighted by the successful capital raise in the beginning of this quarter. 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. As always, I look forward to keeping you informed on the clinical development of our portfolio.

Copenhagen, November 19, 2021

Claus Elsborg Olesen

CEO

ABOUT INITIATOR PHARMA

Initiator Pharma 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 Nasdaq First North Growth Market Stockholm (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:

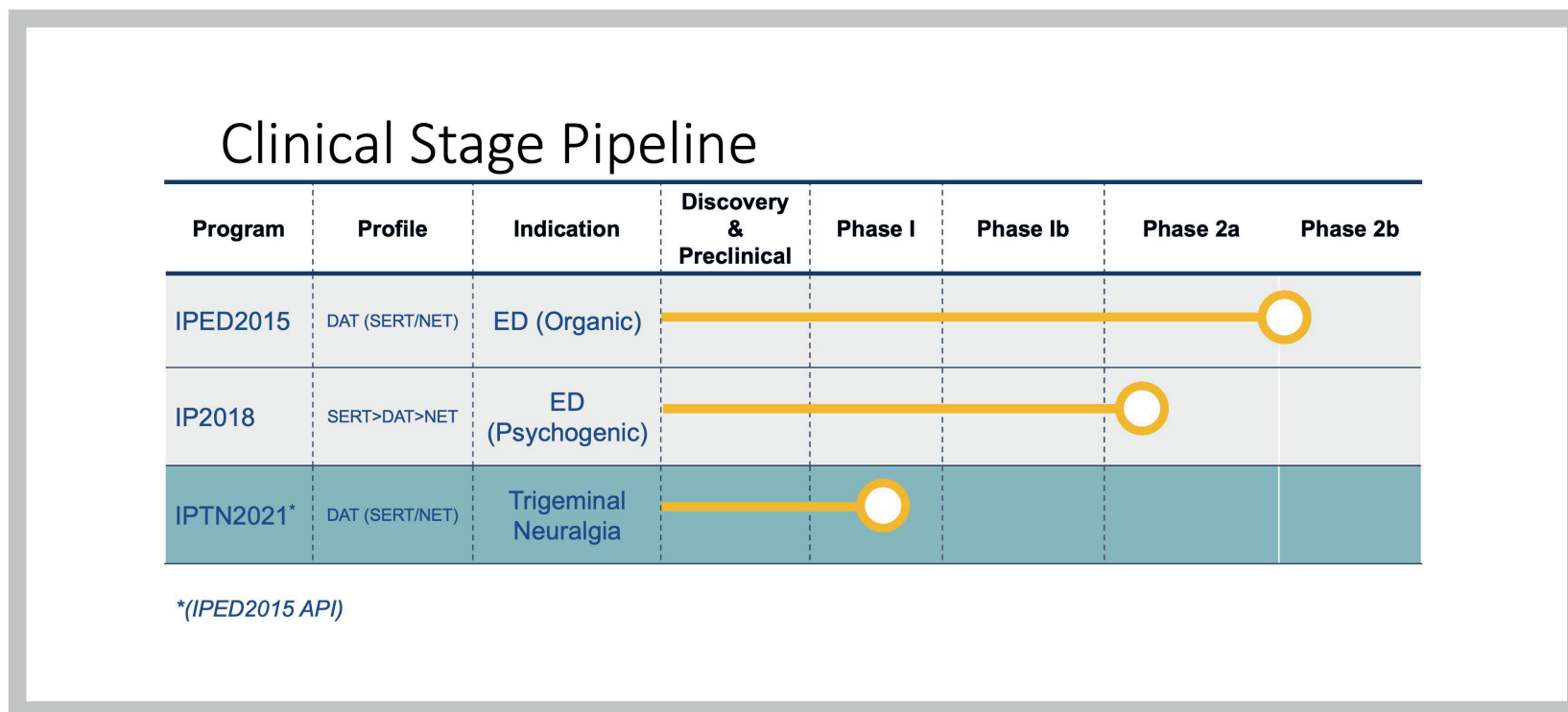
- By internal development of selected programs through the early phases of drug development before out-licensing to pharmaceutical companies who will take over the further clinical development of Initiator Pharma's programs and typical with upfront payments, milestone and royalty payments on product 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 neuropathic 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 study will enroll 120 patients 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, and on September 24th we announced the dosing of the first patient in the study.

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 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 IP2015 in

subjects exposed to the sensory nerve stimulant capsaicin. On October 18th we announced that we had filed the CTA for the planned Phase 1 proof of principle study, in which IP2015 will be evaluated for analgesic effects in healthy subjects challenged with capsaicin as a pain inducing agent. This is a well established pain model of neuropathic pain for early evaluation of analgesic effect, and if positive is planned to be followed by a Phase 2a study in patients suffering from Trigeminal Neuralgia.

Trigeminal Neuralgia Market

The neuropathic Pain Market according to Garner a Valuation of US\$ 9,862.3 Million by 2027 ⁴, 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 be able to obtain premium pricing significantly 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>.

Revenues and result of the operation

Revenue

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

Net

The company recognized an operating loss of TDKK 9,056 for the third quarter of 2021 (-3,068). The increase in operating costs during the third 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 nine months the operating loss was TDKK 15,792 (-8,462).

External R&D costs in the third quarter amounted to TDKK 4,342, compared to TDKK 1,731 in the same period in 2020. For the first nine months external R&D costs amounted to TDKK 7,796 (4,616).

Net financial expenses in the third quarter amounted to TDKK 85, compared to net financial income of TDKK 11 in the same period in 2020. For the first nine months net financial expenses were TDKK 538 (66). The increase in net financial expenses in the first nine months of 2021 is related to a combination of fees for the MSEK 10 loan facility that was entered into in April 2020 and that was terminated in the second quarter this year and foreign exchange movements.

Financial position

The equity as of September 30, was TDKK 39,728 (7,567). Cash and cash equivalents amounted to TDKK 41,394 (8,174) as of

September 30, and total assets were TDKK 55,013 (8,265). The increase in equity, cash and total assets is related to the completed share issues, described in further detail under the section "The share, share capital and ownership structure below".

Cash flow

In the third quarter the total operating cash flow was TDKK -22 340 (TDKK -4,432), incl a negative change in working capital of TDKK 13,199 (TDKK -1,395). The increase in working capital in the period is related to pre-payments for the ongoing Phase 2b study with IP2015. Cash flow from investment activities was TDKK 0 (TDKK 0). Cash flow from financing activities was TDKK 32,635 (TDKK 4,417). The cash flow from financing activities during Q3 includes:

- Preferential rights issue that was successfully completed during the quarter, raising TDKK 19,614 net of issuing costs (see below for further details)
- Increased lending of TDKK 13,021 under the convertible credit agreement with MAC covering part financing of the ongoing Phase 2b study.

For the first nine months the operating cash flow was TDKK -26,780 (TDKK -5,575), incl a negative change in working capital of TDKK 10,461 (TDKK 2,933). Cash flow from investment activities was TDKK 0 (TDKK 0) and cash flow from financing activities was TDKK 54,669 (TDKK 6,187). The cash flow from financing activities during the first 9 months includes:

- Directed issue that was successfully completed during Q2, raising TDKK 22,034 net of issuing costs (see below for further details)
- Preferential rights issue that was successfully completed during Q3, raising TDKK 19,614 net of issuing costs (see below for further details)
- Increased lending of TDKK 13,021 under the convertible credit agreement with MAC covering part financing of the ongoing Phase 2b study.

The share, share capital and ownership structure

At September 30, 2021, the number of shares outstanding totalled 43,772,462 shares and 1,768,393 warrants, representing 4.0% 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 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 was directed to long-term investors led by Linc AB and Adrigo Asset Management AB. The terms for both issues included a subscription price of SEK 3.70 per new share, which corresponded 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 million 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. On October 1st we announced that the board had decided to allocate a total of 152.000 shares under the program, and that 150.000 shares had been purchased under the program. Total number of outstanding warrants under the 2019, 2020 and 2021 incentive programs is maximum 1.768.393 warrants, representing a dilution of up to 4.0%.

At September 30, 2021 the company had around 4,000 shareholders. The 10 largest shareholders in the company on September 30 owned approx 39.5% of all outstanding shares.

On October 8th the company announced that the company had received conditional approval to change listing of its shares on to Nasdaq First North Growth Market in Stockholm, and the final approval was announced on October 22nd. Trading of Initiator Pharma's shares on Nasdaq First North Growth Market in Stockholm commenced on October 25th.

Top 10 shareholders as of September 30, 2021

Owners	Number of shares
LINC AB	5 780 781
Försäkringsaktiebolaget, Avanza Pension	2 672 597
Adrigo Small and Midcap L/S	2 330 852
BNY Mellon SA/NV	1 109 224
Thorén, Mats	1 086 224
Ålandsbanken i Ägares ställe	1 011 805
Nordnet Pensionsförsäkring	961 813
UBS Switzerland	821 516
Peters, Dan	759 805
DanPet AB	757 314
Ten largest shareholders	17 291 931
Other shareholders	26 480 531
Total	43 772 462

Personnel

As of September 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.

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 July 2021 and in the information memorandum published in October 2021 in connection with the change of listing to Nasdaq First North Growth Market.

Impact of COVID-19

As of November 2021 the clinical development programs of the company have been impacted by Covid-19. The company currently has two ongoing clinical trials – a Phase 2a clinical trial for IP2018 and a recently started Phase 2b clinical trial for IPED2015 – which is being conducted in England. Recruitment into the Phase 2a trial for IP2018 trial has been slower than anticipated and management attributes this to Covid-19. In addition to the impact on the two ongoing clinical trials, 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 1 proof of principle clinical trial for IPTN2021.

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

Year-End Report 2021

February 18, 2022

Audit review

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

Aarhus, November 19, 2021

Magnus Persson
Chairman

Annette Colin
Board member

Henrik Moltke
Board member

Claus Olesen
Board member and CEO

Peter Holm
Board member

FINANCIAL STATEMENTS

Statement of income

TDKK	3Q:2021	3Q:2020	9M:2021	9M:2020	2020
Gross loss	-8 856	-2 553	-14 849	-7 346	-9 299
Staff costs	-200	-495	-932	-1 096	-1 206
Depreciation and write-downs	-	-9	-11	-20	-26
Operating profit/loss	-9 056	-3 068	-15 792	-8 462	-10 531
Other financial expenses	-85	11	-538	-66	291
Profit/loss	-9 141	-3 057	-16 330	-8 528	-10 240
Tax	-	-	-	-	1 543
Net profit for the period	-9 141	-3 057	-16 330	-8 528	-8 697

Statement of financial position

TDKK	Q3:2021	Q3:2020	2020
ASSETS			
Patents, acquired rights	-	17	11
Intangible assets	-	17	11
Other fixtures, fittings, tools and equipment	-	-	-
Property, plant and equipment	-	-	-
Fixed assets	-	17	11
Other receivables	196	74	487
Income tax receivables	1 543	-	1 543
Prepayments	11 880	-	58
Current receivables	13 619	74	2 088
Cash and cash equivalents	41 394	8 174	13 504
Current assets	55 013	8 248	15 592
Assets	55 013	8 265	15 603
EQUITY AND LIABILITIES			
Contributed capital	3 760	2 685	2 909
Retained earnings	35 968	4 882	11 500
Equity	39 728	7 567	14 409
Convertible credit agreement	13 021	-	-
Long-term liabilities	13 021	-	-
Trade payables	2 102	569	666
Other payables	162	129	528
Current liabilities other than provisions	2 264	698	1 194
Liabilities other than provisions	2 264	698	1 194
Equity and liabilities	55 013	8 265	15 603

Statement of changes in shareholder equity

TDKK	Contributed capital	Retained earnings	Total
January 1, 2020	2 477	7 431	9 908
Increase of capital	432	12 353	12 785
Other equity postings	-	414	414
Profit/loss for the period	-	-8 697	-8 697
December 31, 2020	2 909	11 501	14 410
January 1, 2020	2 477	7 431	9 908
Increase of capital	207	5 980	6 187
Profit/loss for the period	-	-8 528	-8 528
September 30, 2020	2 684	4 883	7 567
January 1, 2021	2 909	11 501	14 410
Increase of capital	851	40 797	41 648
Profit/loss for the period	-	-16 330	-16 330
September 30, 2021	3 760	35 968	39 728

FINANCIAL REVIEW

Statement of cash flow

TDKK	3Q:2021	3Q:2020	9M:2021	9M:2020	2020
Profit/loss before tax	-9 141	-3 057	-16 330	-8 528	-10 240
Adjustments for non-cash transactions	-	9	11	20	26
	-9 141	-3 048	-16 319	-8 508	-10 214
Tax paid/received	-	-	-	-	1 687
Cash flow before change in working capital	-9 141	-3 048	-16 319	-8 508	-8 527
Changes in working capital	-13 199	-1 384	-10 461	2 933	463
Cash flow from operating activities	-22 340	-4 432	-26 780	-5 575	-8 064
Investing activities	-	-	-	-	-
Cash flow from investing activities	-	-	-	-	-
Financing activities					
New share issue	19 614	4 003	41 648	5 773	13 593
Issue of warrants	-	414	-	414	414
Proceeds from loan	13 021	-	13 021	-	-
Cash flow from financing activities	32 635	4 417	54 669	6 187	14 007
Cash flow for the reporting period	10 295	-15	27 889	612	5 943
Cash and cash equivalents at the beginning of period	31 099	8 189	13 504	7 562	7 562
Cash and cash equivalents at the end of period	41 394	8 174	41 394	8 174	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

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



Q3
2 0 2 1

Initiator Pharma

www.initiatorpharma.com

Ole Maaloes vej 3, 2200 Copenhagen, DENMARK