

**Q2**  
2022

# BUSINESS HIGHLIGHTS

## Business highlights in Q2 2022

- On April 5th the Company announced that it has signed an option agreement for a Phase 2/3 ready drug asset for an undisclosed pain indication.
- On April 13th the Board of Directors proposed a directed share issue and fully guaranteed rights issue of a total of approximately SEK 61 million to finance its clinical programs into the beginning of 2024. The directed share issue was approved by an EGM held on May 18th and on May 31st the board decided to execute the fully guaranteed rights issue.
- On May 23rd the Company announced positive efficacy outcome of the IPTN2021 program Phase 1 study to assess pain-reducing effects.
- On June 22nd the Company announced issuance of shares, share buyback and sale of shares in connection with long term incentive program for 2021

## Business highlights after this reporting period

- On July 5th the Company announced the outcome of the fully guaranteed rights issue of SEK 41. Approximately 42.3% of the share issue was subscribed for, with the rest covered by underwriting commitments.
- On July 5th the Company announced that it had carried out a directed share issue of SEK 2.5 at a share price of SEK 7.50 to a strategic advisor to the company.

- On July 22nd the Company announced that it had completed a share buy back program of 24,000 shares in connection with the long-term incentive program LT12021.

As disclosed in the Q1:2022 report Initiator Pharma publishes its interim reports in English only.

## Financial review

TDKK	2Q:2022	2Q:2021	H1:2022	H1:2021	2021
Net sales	-	-	-	-	-
Total operating expenses	-13 499	-4 944	-28 574	-6 736	-23 072
Operating profit/loss	-13 499	-4 944	-28 574	-6 736	-23 072
Net result	-13 554	-5 382	-28 706	-7 189	-21 064
Earnings per share (DKK)	-0,29	-0,15	-0,62	-0,20	-0,48
Earnings per share, fully diluted (DKK)	-0,26	-0,14	-0,55	-0,19	-0,44
Cash flow from operating activities	-9 066	-2 223	-17 060	-4 440	-34 097
	<b>30.06.2022</b>	<b>30.06.2021</b>	<b>31.12.2021</b>		
Cash and cash equivalents	29 468	31 099	34 346		
Equity	18 470	29 255	34 994		
Total equity and liabilities	35 458	32 975	53 701		
Equity ratio, %	52%	89%	92%		
<i>Number of shares outstanding</i>	46 565 128	35 813 834	43 772 462		
<i>Number of shares, diluted</i>	51 793 991	38 002 227	48 165 325		
<i>Average number of shares outstanding</i>	44 530 337	29 057 079	35 088 333		
<i>Average number of shares, diluted</i>	49 349 200	33 424 139	39 685 393		

## LETTER FROM THE CEO



The second quarter of 2022 has been intense for Initiator Pharma, with good progress in all our current clinical programs; IPED2015, IP2018 and IPTN2021. We have also received capitalization which secures the financing of our clinical programs and the runway for Initiator into the beginning of 2024.

### Positive top-line results in the IPTN2021 program trial

Our clinical Phase 1 study to assess pain-reducing effects, comprising 24 healthy male subjects challenged with the pain-inducing ingredient (capsaicin), was completed in April and we could report positive topline efficacy data a month later. The study was a randomized, double-blind, placebo-controlled study in 24 healthy male subjects, investigating the effects on pain measures (hyperalgesia, allodynia, and subjects' pain rating) of single doses of IP2015, pregabalin as active control, and placebo. IP2015 demonstrated a statistical significant effect on allodynia ( $p=0.049$ ) and showed a dose-dependent effect on the measured pain parameters. Pregabalin ( $p=0.083$ ) and IP2015 ( $p=0.051$ ) tended to reduce hyperalgesia, although the effects on hyperalgesia were not statistically significant compared to placebo-treated subjects. In addition, there were no observations of unexpected adverse events.

We are looking forward to completing the analysis of the entire data set over the coming months and are very enthusiastic about the first results, which support our conviction of IP2015 as a potential new treatment for Neuropathic pain. As the current standard of care for neuropathic pain patients often is linked to severe side-effects and

limited efficacy, there is a substantial unmet medical need for improved therapy. We are encouraged by the clinical data on pain relief we have seen in the top-line results, and very pleased that only side effects of mild severity were observed in the study. A final report is expected in the third quarter of 2022.

### IPED2015 and IP2018 clinical programs on track

Our most advanced program in erectile dysfunction (ED), IPED2015, is being evaluated in an ongoing Phase 2b trial conducted in the UK in collaboration with MAC Clinical Research. The patient recruitment rate is progressing as planned, and we expect that inclusion and dosing of the last of the 120 patients will be completed before year end.

The patient enrollment rate in our Phase 2a study with the monoamine reuptake inhibitor IP2018 in depressed ED patients, has increased significantly since we obtained approval from the regulatory authorities to modify certain inclusion criteria last summer. With the Covid-19 pandemic slowing down significantly we expect the inclusion and randomization of patients to be completed very soon.

### Potential pipeline expansion with a late-stage clinical asset

Early April, we announced the signing of an exclusive option agreement for a Phase 2/3 ready drug asset for an undisclosed pain indication. The drug candidate matches and complements Initiator's current pipeline and ongoing clinical activities very well, including our other pain program IPTN2021, and furthermore strengthens our ambition of targeting the CNS for a broad range of indications.

## LETTER FROM THE CEO

A major advantage with this late-stage asset is that it has already been de-risked to a high extent through previously conducted clinical studies, demonstrating exploratory clinical efficacy in the selected indication. We are currently evaluating the design of a regulatory and clinical development plan that is time and cost-efficient and can fulfill the Target Product Profile for the undisclosed pain indication. I look forward to sharing information about the asset, the indication and terms after having completed the evaluation during the option period ending at year end 2022.

### **Capitalization secures ongoing development and creates opportunities**

The directed share issues and the fully guaranteed rights issue that were successfully carried out in the end of, and completed just after the second quarter, provided Initiator with long-term financing of the company and ongoing programs to the early part of 2024. The financing allowed us to advance all our clinical programs according to set plans and priorities.

I am grateful to all investors that participated in the issues, particularly our anchor investors, Linc AB and Adrigo Asset Management AB, and I am very pleased that Annika Espander, our strategic advisor, has increased her investment in Initiator through a separate directed share issue. The confidence in our company shown by these experienced and skilled investors is a validation that is of immense value to us as management team and to all shareholders in the short as well as the long term.

I would also like to extend a warm welcome to Gunilla Ekström who was elected new board member at the AGM on May 24. She has extensive experience of managing advanced pre-clinical and clinical pharmaceutical development projects and organizations in the pharma industry, with companies such as Astra Zeneca, Orexo and Karolinska Development.

Initiator Pharma's track-record this far strongly supports our business strategy of identifying attractive but undervalued clinical-stage assets and advancing these through cost-efficient clinical trials to deliver key-value inflection points in indications with significant unmet medical needs. With secured financing, an attractive portfolio of clinical assets progressing according to plan, and an experienced and dedicated team, I see the future with confidence and look forward to keep you updated on our progress.

Copenhagen, August 26, 2022

**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 IP2018 and IPED2015 programs for treatment of erectile dysfunction of psychogenic and organic origin, respectively, and the orphan drug program IPTN2021 developed for Trigeminal Neuralgia, a severe neuropathic pain condition. .*

## 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:

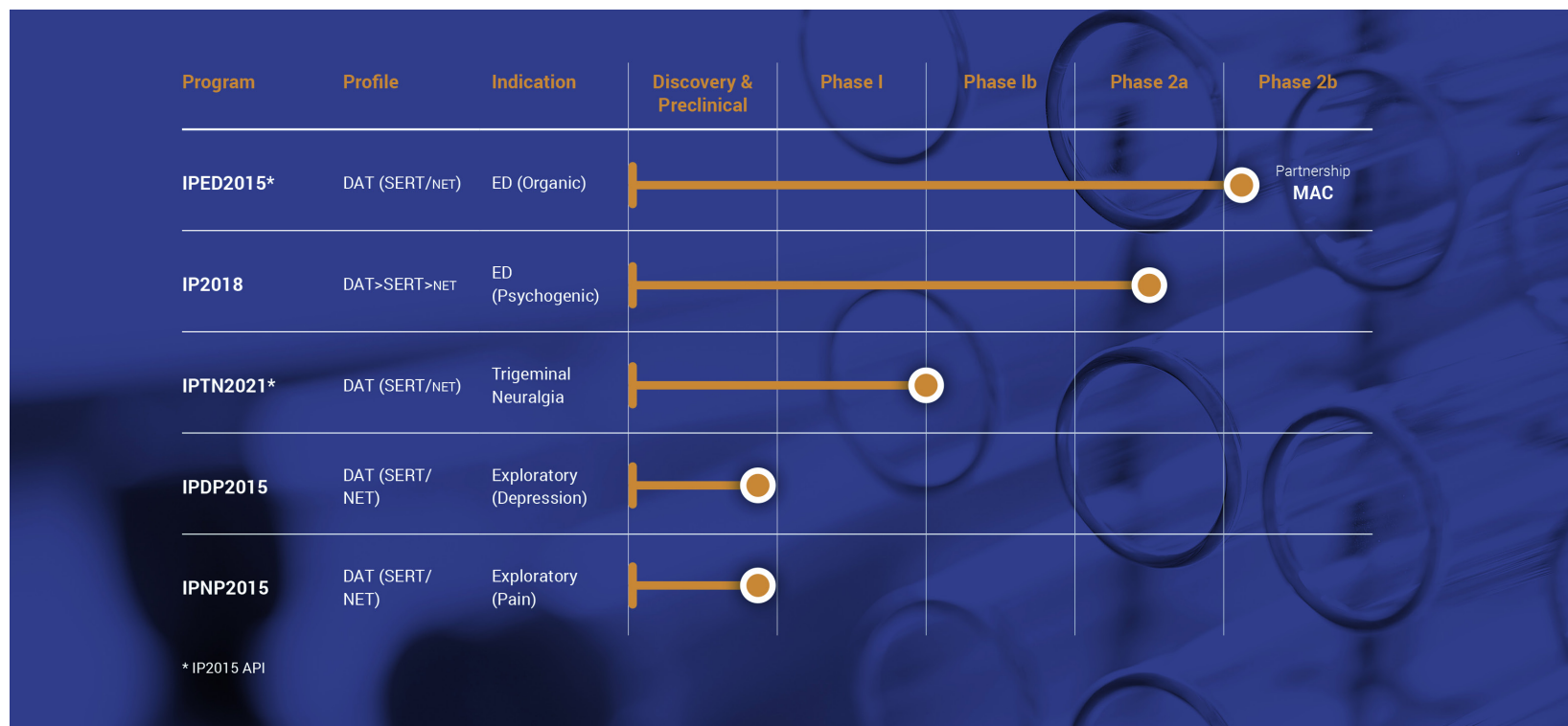
- By internal development of selected programs through the early phases of drug development before out-licensing to pharmaceutical companies who will take over the further clinical development of Initiator Pharma's programs and typical with upfront payments, milestone and royalty payments on product 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. In 2021 we announced that we had further expanded our development pipeline with IPTN2021, aiming to develop the IP2015 molecule for neuropathic pain, and specifically Trigeminal Neuralgia:



On April 5th the Company announced that it had entered an option-to-acquire agreement for Phase 2/3 ready drug asset for an undisclosed pain indication. The Drug asset is currently being evaluated as to its clinical and regulatory pathway, and a decision to exercise the option or not is expected to be taken before year-end.

# ERECTILE DYSFUNCTION

**IPED2015:** IPED2015 is our most advanced development program 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®). IP2015 - 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. The Active Pharmaceutical ingredient in the IPED2015 program is IP2015.

The ambition with IPED2015 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 erectile 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 IP2015, and in March 2020, Initiator achieved successful Phase 2a results in the IPED2015 program. 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 IP2015 for the treatment of moderate and severe erectile dysfunction in patients who do not respond to current therapies.

## Clinical development plans in organic Erectile Dysfunction

On 25 November 2020 Initiator announced a financing agreement with MAC Clinical Research Ltd covering the continued development of the IPED2015 program. Within the agreement, MAC Clinical Research

(MAC) will take on the cost, up to 23 MSEK, for conducting a clinical Phase 2b intercourse study 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 IP2015 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 Phase 2b trial received CTA approval from the MHRA in UK and the Ethics Committee in June 2021, and the first patient was dosed in September 2021. Inclusion and dosing of patients should be completed in H2 2022, pending the development of the Covid-19 pandemic.

## 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 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. US-based studies therefore suggest that there are between 51,500 and 133,000 cases of Trigeminal Neuralgia in the US. Anecdotally, healthcare providers and health insurance plans in the US claim that 140,000 people suffer with Trigeminal Neuralgia in the US (Nguyen, 2010; Aetna, 2021).

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 IP2015. In preclinical studies, IP2015 is effective and markedly inhibits neuralgic pain.

## Clinical development plans in Neuropathic Pain

On May 22nd we announced positive topline efficacy data from a clinical Phase 1 study to assess pain-reducing effects, comprising 24 healthy male subjects challenged with the pain-inducing ingredient (capsaicin). The study was a randomized, double-blind, placebo-controlled study in 24 healthy male subjects, investigating the effects on pain measures (hyperalgesia, allodynia, and subjects' pain rating) of single doses of IP2015, pregabalin as active control, and placebo. IP2015 demonstrated a statistical significant effect on allodynia ( $p=0.049$ ) and showed a dose-dependent effect on the measured pain parameters. Pregabalin ( $p=0.083$ ) and IP2015 ( $p=0.051$ ) tended to reduce hyperalgesia, although the effects on hyperalgesia were not statistically significant compared to placebo-treated subjects. In addition, there were no observations of unexpected adverse events.

The initial findings in this study are encouraging for further development of IP2015 in neuropathic pain. The full report from the study is expected during Q3 and following the full clinical study report management will elaborate on the future development priorities with IP2015, including potential future development of the compound in neuropathic pain.



# TRIGEMINAL NEURALGIA

## 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 <sup>4</sup>.

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, Q., 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>.

# 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 in psychogenic Erectile Dysfunction

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 is being conducted in 24 patients at the MAC Phase I unit in Manchester, UK.

The enrollment into this study has been significantly impacted by Covid-19. Late last year we announced that the patient recruitment rate in the ongoing Phase 2a study with the drug substance IP2018 had increased significantly since Initiator in July 2021 obtained approval from the regulatory authorities to modify certain inclusion criteria. We currently expect to complete the enrollment into the study during Q3.

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

# PSYCHOGENIC ERECTILE DYSFUNCTION

## 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 <sup>5</sup>. 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 <sup>6</sup>. About 13 percent of all Americans take antidepressant drugs, which means over 23 million prescriptions per year <sup>7</sup>. 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 <sup>8</sup>. 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 IP2015 and IP2018 in the USA; and in the USA, Israel, Japan, the United Kingdom, Germany, France, and Switzerland, respectively.

The IP2015 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 now pending in Australia, Brazil, Canada, China, Europe, Israel, Japan, Mexico, Singapore, South Korea and the USA, and recently granted in South Africa. The patent family can be kept in force until 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.*

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

## Revenue

Initiator Pharma generated total revenues of TDKK 0 for the second quarter of 2022 (0) and TDKK 0 for the first six months (0).

## Result

The company recognized an operating loss of TDKK 13,499 for the second quarter of 2022 (-4,944) and TDKK 28,574 for the first six months (-6,736). The increase in operating costs during the first half of the year reflects the three clinical trials that the company has ongoing, as well as increased corporate costs, including build-out of the organisation.

External R&D costs in the second quarter amounted to TDKK 7,360, compared to TDKK 3,185 in the same period in 2021. For the first six months of the year external R&D costs amounted to TDKK 19,938 (3,354).

Net financial expenses in the second quarter amounted to TDKK 55, compared to net financial expenses of TDKK 438 in the same period in 2021. For the first six months of the year net financial expenses amounted to TDKK 132 (453).

## Financial position

The equity as of June 30, was TDKK 18,470 compared to TDKK 34,994 at year-end 2021. Cash and cash equivalents amounted to TDKK 29,469 as of June 30 compared to TDKK 34,346 at year-end 2021, and total assets were TDKK 35,458 (53,701).

As of June 30 the balance of the convertible credit agreement with MAC covering part financing of the ongoing Phase 2b study was

TDKK 13,290, unchanged from year-end.

Following the close of the quarter the company completed the SEKM 41 rights issue and the SEKM 2.5 directed share issue to a strategic advisor to the company.

## Cash flow

In the second quarter the total operating cash flow was TDKK -9,066 (-2,223), incl. a positive change in working capital of TDKK 4,488 (3,154). The positive change in working capital is related to the reduction in pre-payments to MAC Clinical Research for the ongoing clinical trials. For the first six months the total operating cash flow was TDKK -17,060 (-4,440), incl. a positive change in working capital of TDKK 11,646 (2,738).

Cash flow from investment activities was TDKK 0 (0) in the second quarter and TDKK 0 (0) for the first six months.

Cash flow from financing activities in the second quarter was TDKK 12,182 (22,034) and TDKK 12,182 for the first six months (22,034). During the quarter the company announced the decision to carry out a directed share issue of SEKM 20 and a fully guaranteed rights issue of SEKM 41, both at a share price of SEK 7.50 per share. The directed share issue, directed towards Linc AB and Adrigo Asset Management AB, was completed during the quarter, while the rights issue was completed after the close of the quarter. After the close of the quarter the company also announced a SEKM 2.5 directed issue to a strategic advisor to the company, also at SEK 7.50 per share.

**Top 10 shareholders as of June 30, 2022**

Owners	Number of shares	Shares %
LINC AB	7 114 114	15,28%
Avanza Pension	3 119 936	6,70%
Adrigo Small and Midcap L/S	2 527 725	5,43%
BNY Mellon SA/NV	1 189 783	2,56%
UBS Switzerland	961 242	2,06%
Nordnet Pensionsförsäkring	930 146	2,00%
Thorén, Mats	732 153	1,57%
Ålandsbanken ABP	715 178	1,54%
DanPet AB	710 917	1,53%
Claus Olesen Holding ApS	692 738	1,49%
Ten largest shareholders	18 693 932	40,15%
Other shareholders	27 871 196	59,85%
<b>Total</b>	<b>46 565 128</b>	<b>100,00%</b>

**The share, share capital and ownership structure**

At June 30, 2022, the number of shares outstanding totalled to 46,565,128 shares and on a fully diluted basis 51,793,991, incl. both incentive warrants and potential dilution by the convertible credit agreement with MAC.

On April 13th the Company announced that the Board of Directors proposed a directed share issue and fully guaranteed rights issue of a total of approximately SEK 61 million at a share price of SEK 7.50 per share to finance its clinical programs into the beginning of 2024. An Extraordinary General Assembly ("EGM") on May 18 approved the proposal and the directed share issue to Linc AB and Adrigo Asset Management AB of 2,666,666 shares was executed shortly thereafter. On June 22nd the Company announced the issuance of 126,000 new shares in connection with the long-term

incentive program LTI2021. The new shares were subscribed for by executive management and key employees and consultants at a price of DKK 0.105 per share.

On May 31st the board of directors decided to execute the fully guaranteed rights issue of 5,463,426 shares, which was completed on July 5th and registered after the close of the quarter.

On July 5th the board of directors announced a directed share issue to a strategic advisor of the company of 333,333 new shares at a price of SEK 7.50 per share. The directed share issue was registered after the close of the quarter.

As of June 30, 2022 the company had around 4,300 shareholders. The 10 largest shareholders in the company on June 30 owned approx 40.2% of all outstanding shares.

The shares in Initiator Pharma are traded on Nasdaq First North Growth Market in Stockholm commenced.

**Personnel**

As of June 30, the number of employees was 2 (1), of which 1 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.

No new risks have arisen during 2022. 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 August 2022 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 in psychogenic erectile dysfunction (with IP2018)
- a Phase 2b clinical trial in organic erectile dysfunction (with IP2015)

All the ongoing clinical trials are being conducted in England. 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 Q3 2022 report 4 November 2022

Year-end report 2022 (Q4) 7 February 2023

### Audit review

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

### General information

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

Aarhus, August 26, 2022

**Magnus Persson**  
Chairman

**Annette Colin**  
Board member

**Henrik Moltke**  
Board member

**Gunilla Ekström**  
Board member

**Peter Holm**  
Board member

**Claus Olesen**  
Board member and CEO

## Statement of income

TDKK	2Q:2022	2Q:2021	H1:2022	H1:2021	2021
Gross loss	-12 824	-4 409	-27 393	-5 993	-21 626
Staff costs	-675	-530	-1 181	-732	-1 435
Depreciation and write-downs	-	-5	-	-11	-11
<b>Operating profit/loss</b>	<b>-13 499</b>	<b>-4 944</b>	<b>-28 574</b>	<b>-6 736</b>	<b>-23 072</b>
Other financial items	-55	-438	-132	-453	-1 172
<b>Profit/loss before tax</b>	<b>-13 554</b>	<b>-5 382</b>	<b>-28 706</b>	<b>-7 189</b>	<b>-24 244</b>
Tax	-	-	-	-	3 180
<b>Net loss for the period</b>	<b>-13 554</b>	<b>-5 382</b>	<b>-28 706</b>	<b>-7 189</b>	<b>-21 064</b>



## Statement of financial position

TDKK	H1:2022	H1:2021	2021
<b>ASSETS</b>			
<b>Fixed assets</b>	-	-	-
Other receivables	-	171	945
Income tax receivables	3 180	1 543	3 180
Prepayments	2 810	162	15 230
<b>Current receivables</b>	<b>5 990</b>	<b>1 876</b>	<b>19 355</b>
<b>Cash and cash equivalents</b>	<b>29 468</b>	<b>31 099</b>	<b>34 346</b>
<b>Current assets</b>	<b>35 458</b>	<b>32 975</b>	<b>53 701</b>
<b>Assets</b>	<b>35 458</b>	<b>32 975</b>	<b>53 701</b>
<b>EQUITY AND LIABILITIES</b>			
Contributed capital	4 596	3 760	4 596
Retained earnings	13 874	25 495	30 398
<b>Equity</b>	<b>18 470</b>	<b>29 255</b>	<b>34 994</b>
Convertible credit agreement	13 290	-	13 290
<b>Long-term liabilities</b>	<b>13 290</b>	<b>-</b>	<b>13 290</b>
Trade payables	1 643	3 381	4 800
Other payables	2 055	339	617
<b>Current liabilities other than provisions</b>	<b>3 698</b>	<b>3 720</b>	<b>5 417</b>
<b>Liabilities other than provisions</b>	<b>3 698</b>	<b>3 720</b>	<b>18 707</b>
<b>Equity and liabilities</b>	<b>35 458</b>	<b>32 975</b>	<b>53 701</b>

## Statement of changes in shareholder equity

TDKK	Contributed capital	Retained earnings	Total
<b>January 1, 2021</b>	<b>2 909</b>	<b>11 501</b>	<b>14 410</b>
Share issue	1 687	39 961	41 648
Profit/loss for the period	-	-21 064	-21 064
<b>December 31, 2021</b>	<b>4 596</b>	<b>30 398</b>	<b>34 994</b>
<b>January 1, 2021</b>	<b>2 909</b>	<b>11 501</b>	<b>14 410</b>
Share issue	851	21 183	22 034
Profit/loss for the period	-	-7 189	-7 189
<b>June 30, 2021</b>	<b>3 760</b>	<b>25 495</b>	<b>29 255</b>
<b>January 1, 2022</b>	<b>4 596</b>	<b>30 398</b>	<b>34 994</b>
Share issue	293	11 889	12 182
Profit/loss for the period	-	-28 706	-28 706
<b>June 30, 2022</b>	<b>4 889</b>	<b>13 581</b>	<b>18 470</b>

## Statement of cash flow

TDKK	2Q:2022	2Q:2021	H1:2022
Profit/loss before tax	-13 554	-5 382	-28 706
Adjustments for non-cash transactions	-	5	-
<b>Profit/loss before tax, adj for non-cash transactions</b>	<b>-13 554</b>	<b>-5 377</b>	<b>-28 706</b>
Tax credit	-	-	-
<b>Cash flow before change in working capital</b>	<b>-13 554</b>	<b>-5 377</b>	<b>-28 706</b>
Changes in working capital	4 488	3 154	11 646
<b>Cash flow from operating activities</b>	<b>-9 066</b>	<b>-2 223</b>	<b>-17 060</b>
<b>Investing activities</b>	-	-	-
<b>Cash flow from investing activities</b>	-	-	-
<b>Financing activities</b>	-	-	-
New share issue	12 182	22 034	12 182
Credit agreement with MAC	-	-	-
<b>Cash flow from financing activities</b>	<b>12 182</b>	<b>22 034</b>	<b>12 182</b>
<b>Cash flow for the reporting period</b>	<b>3 116</b>	<b>19 811</b>	<b>-4 878</b>
Cash and cash equivalents at the beginning of period	26 352	11 287	34 346
<b>Cash and cash equivalents at the end of period</b>	<b>29 468</b>	<b>31 099</b>	<b>29 468</b>

## 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).

### IP2015

IP2015, 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



**Q2**  
2022

**Initiator** Pharma

[www.initiatorpharma.com](http://www.initiatorpharma.com)

*Ole Maaloes vej 3, 2200 Copenhagen, DENMARK*