Q4
2022

INTERIM REPORT | January - December

Initiator Pharma

BUSINESS HIGHLIGHTS

Business highlights in Q4 2022

- On October 4th the Company announced the outcome of the incentive program 'LTI2022' approved by the AGM on May 24th 2022.
- On November 4th the Company provided an update on its clinical programs.
- On December 20th the Company started a Phase 1 pharmaco-kinetics study for new IP2015 formulations.
- On December 23rd the Company announced that it had decided not to exercise the option for an undisclosed pain asset.

Business highlights after this reporting period

- Nothing to report.

Financial Highlights

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

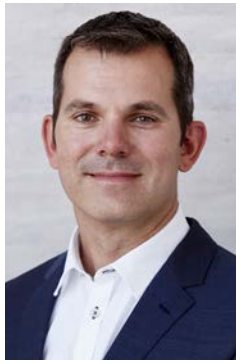
As disclosed in the Q1:2022 report Initiator Pharma publishes its interim reports in English only.

Financial review

TDKK	4Q:2022	4Q:2021	2022	2021
Net sales	-	-	-	-
Total operating expenses	-6 477	-7 280	-41 740	-23 072
Operating profit/loss	-6 477	-7 280	-41 740	-23 072
Net result	-2 960	-4 734	-38 455	-21 064
Earnings per share before and after dilution (DKK)	-0.06	-0.11	-0.73	-0.60
Cash flow from operating activities	-7 654	-7 317	-32 702	-34 097

	31.12.2022	31.12.2021	31.12.2022	31.12.2021
Cash and cash equivalents	39 112	34 346	39 112	34 346
Equity	34 023	34 994	34 023	34 994
Total equity and liabilities	47 488	53 701	47 488	53 701
Equity ratio, %	72%	92%	72%	92%
Number of shares outstanding	*52 361 887*	*43 772 462*	*52 361 887*	*43 772 462*
Number of shares, diluted	*56 947 554*	*48 165 325*	*56 947 554*	*48 165 325*
Average number of shares outstanding	*52 361 887*	*43 772 462*	*52 361 887*	*35 088 333*
Average number of shares, diluted	*57 381 750*	*48 599 522*	*56 947 554*	*39 685 393*

LETTER FROM THE CEO



The fourth quarter was the end of an eventful year for Initiator Pharma. Our neuropathic pain proof of principle study was completed with promising results. We initiated a pharmacokinetic study in order to evaluate new oral solid dosage forms. And we have managed to increase the recruitment rate in our two ongoing phase II studies in erectile dysfunction. I am truly grateful for the efforts and commitment our team has put in and I am convinced that we look forward to a very exciting year.

Accelerating patient inclusion in the IP2015 phase IIb program

IP2015 is Initiator Pharma's most advanced development program for the treatment of patients suffering from organic ED, not optimally treated and/or not responding to the currently marketed drugs in the PDE5i class (e.g. Viagra®, Cialis®, Levitra®). The ongoing clinical Phase IIb study in 120 healthy organic ED patients is conducted by MAC Clinical Research MAC Clinical Research. We have seen a need to increase activities in order to optimize patient recruitment and have taken measures in order to optimize patient recruitment. Some of the measures have already been fruitful. Furthermore, an amended clinical study protocol is in the approval process at the British Health Authorities and Ethics Committee. The amended protocol contains some revised inclusion criteria and an increase of the patient's stipend – all improvements will support a faster and higher recruitment rate without changing the deliverables or the quality of trial. We are optimistic that we will see an increased enrolment rate and we still aim for completion of the dosing part in the first half of 2023.

Waiting for the last patients in the IP2018 Phase IIa study

In our November portfolio update, we reported that the patient recruitment had been more challenging than anticipated in our Phase 2a study with the monoamine reuptake inhibitor IP2018, where we for the first time target depressed ED patients. Read-outs of the trial are still expected in Q2 2023. Although we made some adjustments to the protocol to accelerate the patient recruitment, we have kept the main inclusion criteria and original study design. It is important that all key inclusion criteria in the trial are fulfilled and the full inclusion on all patients is achieved to generate high quality of the data set on efficacy measures in this trial, as this is the first trial to be conducted in patients with psychogenic erectile dysfunction. Therefore, we prefer to have a small delay in the trial rather than risk compromising the data quality.

Testing new oral solid dosage forms of IP2015 in phase I

The newly developed solid dosage form of IP2015 is now undergoing a Phase I pharmacokinetic study in healthy subjects, which will bridge previous data sets into new future clinical studies for IP2015. The study is now under way and will provide draft phamacokinetic data in Q2 2023. This pharmacokinetic study is vital for designing and executing future clinical development studies for IP2015. It will strengthen the intellectual property rights (IPR) portfolio for the entire IP2015 program, and the solid dosage formulation will bring us closer to having a final drug product that may be used in a potential future launch.

Keeping our focus

Towards the end of the year, we announced our decision not to exercise our exclusive option agreement for an undisclosed Phase II/III ready pharmaceutical asset. We performed an efficient and in-depth due

LETTER FROM THE CEO

diligence on the asset and after careful consideration, we concluded that the profile of the compound did not fulfill our evaluation cornerstone criteria, set to maximize clinical and commercial success within a reasonable timeline and investment. I remain confident that this was the correct decision. Furthermore, and importantly, the decision to keep our focus on our current portfolio means that our cash position will be sufficient to fund all planned and committed activities through 2024.

Going forward on a positive note

For my part, 2023 started by attending the JP Morgan week in San Francisco. We have a more encouraging environment where Pharma has an increased emphasis on clinical assets with clinical Proof-of-concept and a solid safety profile. My meetings with investors and potential partners were positive, and I look forward to follow up on these discussions.

I am looking forward to an exciting 2023 and to keeping our shareholders updated on the many upcoming inflection points in our clinical programs.

Copenhagen, November 4, 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 two clinical stage assets - the IP2018 and IP2015 – and two preclinical assets. The company is currently conducting a Phase 2b trial with IP2015 in erectile dysfunction of organic origin, and successfully completed a Phase 1 proof of principle trial in neuropathic pain in 2022. With IP2018 the company is conducting a Phase 2a trial for the treatment of erectile dysfunction of psychogenic origin.*

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

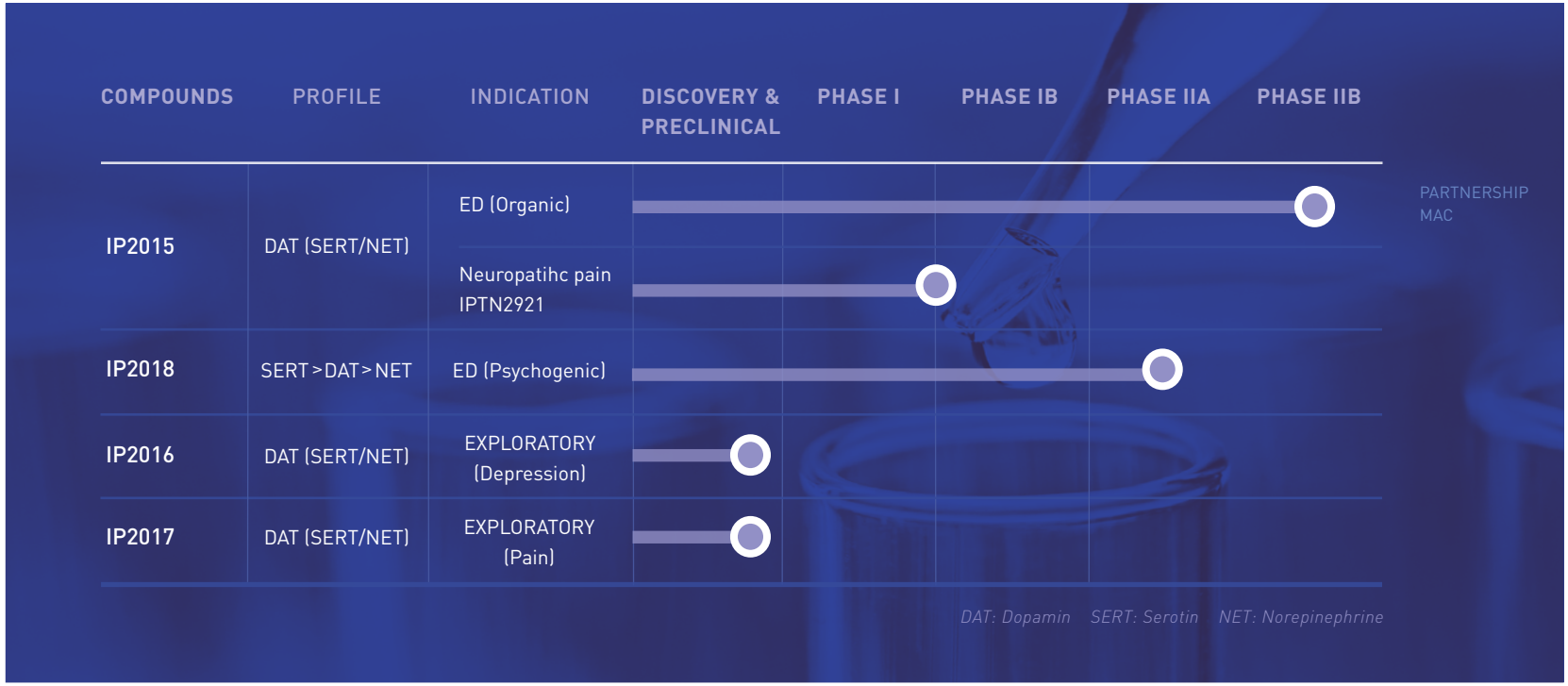
The company aims to commercialize its research efforts through the following 2 business models:

- 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, milestones and royalty payments.
- 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.

PROJECT PORTFOLIO

In 2016 Initiator Pharma acquired three potential drug candidates from Saniona (IP2015, IP2016 and IP2017). 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:



ERECTILE DYSFUNCTION

IPED2015: IP2015, our most advanced asset, is being developed for both organic Erectile Dysfunction (ED) that do not respond to the currently marketed drugs in the PDE5i class (e.g. Viagra®, Cialis®, Levitra®) and neuropathic pain.

Organic Erectile Dysfunction (IPED2015)

IP2015 is positioned as 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®). 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 clinical positioning of IP2015 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 [1]. 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 for IP2015. 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 IPED2015. Within the agreement, MAC Clinical Research (MAC) will take on the cost, up to 23 MSEK, for conducting a clinical Phase 2b inter-course 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 pharmaco-kinetics. 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. The current expectation is that the dosing part of the study will be completed in the first half of 2023.

ERECTILE DYSFUNCTION

Erectile Dysfunction (ED) Market

The current number of ED patients is estimated to about 150 million men worldwide and a number that is estimated to increase to more than 300 million 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 USD billion in sales and Initiator Pharma strongly believes that targeting the PDE5i non-responders will allow us to receive premium pricing for IP2015 and thereby generate substantial commercial value for Initiator Pharma.

[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.*

TRIGEMINAL NEURALGIA

Neuropathic pain/Trigeminal Neuralgia (IPTN2021)

Trigeminal neuralgia is a chronic neuropathic 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 event [2]. The IP2015 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.

Clinical development plans in Neuropathic Pain

On September 21st we announced the final 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.

Following a thorough review of the final dataset, the company has initiated a Phase I pharmacokinetic (PK) study in healthy subjects testing new oral solid dosage forms, bridging previous data sets into new future clinical studies for IP2015. The study was started in the beginning of 2023 and is expected to deliver draft phamacokinetic data in Q2 2023.

Neuropathic pain/Trigeminal Neuralgia Market

The neuropathic pain market is estimated to reach USD 9.8 billion annually by 2027 according to Garner market analysis, with an annual growth rate of 6.4% [3]. On average annual healthcare cost for painful neuropathic disorder is US 17,355 per patient. With a solid efficacy and safety data on IP2015 in neuropathic pain Initiator Pharma expect to target a commercial opportunity with the potential to reach high hundreds of USD million in annual sales.

[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.*

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 Neuropathic Pain

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.

As previously communicated the clinical trial is expected to be completed before the end of Q1 and draft data of the study in second quarter of 2023.

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 [4]. 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 [5]. About 13 percent of all Americans take antidepressant drugs, which means over 23 million prescriptions per year [6]. The global Anxiety Disorder and Depression Treatment Market is forecasted to grow at an annual rate of 2.4 percent from USD 15.8 billion in 2019 to USD 19.2 billion in 2027 [7]. The largest players are Pfizer, Eli Lilly, GSK, AstraZeneca and Lundbeck, accounting for more than 60% of antidepressants sold. 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.

[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.*

[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.*

PATENTS

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 pending in Australia, Brazil, Canada, China, Europe, Israel, Japan, Mexico, Singapore, South Korea and the USA; and has been granted in South Africa. The patent family can be kept in force until 2040.

The preclinical program IP2016 previously known as IPDP2015 is protected by granted composition of matter claims in the USA until 2030, and in the United Kingdom, Germany, and France until 2029.

The preclinical program IP2017 previously known as IPNP2015 is protected by granted composition of matter claims in the USA, United Kingdom, Germany, France and Switzerland until 2030.

Initiator Pharma is pursuing an agressive patent strategy to capture value of developments in its clinical and preclinical programs, by filing new patent applications when possible.

FINANCIAL REVIEW

Revenue

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

Earnings

The company recognized an operating loss of TDKK 6,477 for the fourth quarter of 2022 (-7,280) and TDKK 41,740 for the full year (-23,072). The increase in operating costs for the full year reflects the three clinical trials that the company thas has been ongoing in 2022, as well as increased corporate costs, including build-out of the organisation.

External R&D costs in the fourth quarter amounted to TDKK 3,612, compared to TDKK 3,763 in the same period in 2021. For the full year external R&D costs amounted to TDKK 26,342 (11,807).

Net financial expenses in the fourth quarter amounted to TDKK 2,160, compared to net financial expenses of TDKK 634 in the same period in 2021. For the full year net financial exenses amounted to TDKK 2,392 (1,172). The net financial expenses in the fourth quarter is related to currency fluctuations during the quarter, impacting the conversion of funds held in SEK into DKK at year-end.

The net loss after tax for the full year was TDKK 38,632 (-21,064) and earnings per share totaled DKK -0.74 (-0.60).

Financial position

The equity as of December 31, was TDKK 34,023 compared to TDKK 34,994 at year-end 2021. Cash and cash equivalents amounted to TDKK 39,112 as of December 31 compared to TDKK 34,346 at year-end 2021, and total assets were TDKK 47,488 (53,701).

As of December 31 the balance of the convertible credit agreement with MAC covering part financing of the ongoing Phase 2b study was TDKK 12,577, down TDKK 713 due to FX movements between GBP and DKK during the period and unchanged in GBP.

Cash flow

In the fourth quarter the cash flow from operating activities was TDKK -7,654 (-7,317), incl. a negative change in working capital of TDKK 2,197 (-946). For the full year the total operating cash flow was TDKK -32,702 (-34,097), incl a positive change in working capital of TDKK 8,250 (-11,407).

Cash flow from investment activities was TDKK 0 (0) in the fourth quarter and TDKK -17 (0) for the full year.

Cash flow from financing activities in the fourth quarter was TDKK 0 (0) and TDKK 37,484 for the full year (54,938). During the year the company completed a directed issue of approx MSEK 20 in May, followed by a fully guaranteed rights issue of approx MSEK 41 in July, at a share price of SEK 7.50 per share. In July the company also announced a MSEK 2.5 directed issue to a strategic advisor to the company, also at SEK 7.50 per share.

The share, share capital and ownership structure

AAt December 31, 2022, the number of shares outstanding totalled to 52,361,887 shares and on a fully diluted basis 56,947,554, incl. both incentive warrants and potential dilution by the convertible credit agreement with MAC.

FINANCIAL REVIEW

Top 10 shareholders as of December 31, 2022		
Owners	**Number of shares**	**Shares %**
LINC AB	10 091 219	19,27%
Adrigo Small and Midcap L/S	4 013 761	7,67%
Avanza Pension	3 257 870	6,22%
BNY Mellon SA/NV	1 228 470	2,35%
Nordnet Pensionsforsäkring	969 142	1,85%
UBS Switzerland	964 623	1,84%
Thorén, Mats	793 287	1,52%
DanPet AB	710 917	1,36%
Thomsen Mikael	708 556	1,35%
Claus Olesen Holding ApS	692 738	1,32%
Ten largest shareholders	23 430 583	44,75%
Other shareholders	28 931 304	55,25%
Total	**52 361 887**	**100,00%**

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 July 5th the board of directors announced the completion of the fully guaranteed rights issue of 5,463,426 shares at a price of SEK 7.50 per share.

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.

On October 4th the company announced that a total of 129.500 shares had been bought in the market by board members, management and key employees under the LTI2022 program. Under this program the warrant holders may be entitled to subscribe for or purchase from the company a total of 777.000 shares at par value, representing a potential dilution of 1.5%.

On December 31, 2022 the warrant program approved by the AGM in 2020 expired. The warrant program had an exercise price of SEK 6.52 compared to a share price of 6.06 on December 31. None of the warrants were exercised and hence 434,196 warrants expired, reducing the number of granted incentive warrants to 1,527,000, representing 2.9% of the number of issued shares.

As of December 31, 2022 the company had around 4,000 shareholders. The 10 largest shareholders in the company on December 31 owned approx 45.0% of all outstanding shares.

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

FINANCIAL REVIEW

Dividend
No dividend is proposed for 2022.

Personnel
As of December 31, the number of employees was 3 (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 June 2022 and in the Annual Report for 2021.

Impact of COVID-19
As of November 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 Q1 2023 report	5 May 2023
Annual Report 2022	1 May 2023
Annual General Meeting 2023	26 May 2023
Interim half year report 2023	25 August 2023
Interim Q3 2023 report	10 November 2023
Year-end report 2023 (Q4)	23 February 2024

The financial reports will be disclosed on www.initiatorpharma.com

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).

Copenhagen, February 17, 2023

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

FINANCIAL STATEMENTS

Statement of income

TDKK	4Q:2022	4Q:2021	2022	2021
Gross loss	-5 509	-6 777	-38 425	-21 626
Staff costs	-968	-503	-3 315	-1 435
Depreciation and write-downs	-	-	-	-11
Operating profit/loss	**-6 477**	**-7 280**	**-41 740**	**-23 072**
Other financial items	-2 160	-634	-2 392	-1 172
Profit/loss before tax	**-8 637**	**-7 914**	**-44 132**	**-24 244**
Tax	5 677	3 180	5 677	3 180
Net loss for the period	**-2 960**	**-4 734**	**-38 455**	**-21 064**

FINANCIAL STATEMENTS

Statement of financial position

TDKK	2022	2021
ASSETS		
Total non-current assets	**17**	**-**
Other receivables	849	945
Income tax receivables	5 500	3 180
Prepayments	2 010	15 230
Cash and cash equivalents	39 112	34 346
Total current assets	**47 471**	**53 701**
Total assets	**47 488**	**53 701**
EQUITY AND LIABILITIES		
Contributed capital	5 498	4 596
Retained earnings	28 525	30 398
Total equity	**34 023**	**34 994**
Convertible credit agreement	12 577	13 290
Total non-current liabilities	**12 577**	**13 290**
Trade payables	701	4 800
Other current liabilities	-654	-160
Accrued expenses	841	777
Total current liabilities	**888**	**5 417**
Total equity and liabilities	**47 488**	**53 701**

FINANCIAL STATEMENTS

Statement of changes in shareholder equity

TDKK	Contributed capital	Retained earnings	Total
January 1, 2021	**2 909**	**11 501**	**14 410**
Share issue	1 687	39 961	41 648
Profit/loss for the period	-	-21 064	-21 064
December 31, 2021	**4 596**	**30 398**	**34 994**
January 1, 2022	**4 596**	**30 398**	**34 994**
Share issue	902	36 582	37 484
Profit/loss for the period	-	-38 455	-38 455
December 31, 2022	**5 498**	**28 525**	**34 023**

FINANCIAL STATEMENTS

Statement of cash flow

TDKK	4Q:2022	4Q:2021	2022	2021
Profit/loss before tax	-8 637	-7 914	-44 132	-24 244
Adjustments for non-cash transactions	-	-	-	11
Profit/loss before tax, adj for non-cash transactions	**-8 637**	**-7 914**	**-44 132**	**-24 233**
Tax credit	3 180	1 543	3 180	1 543
Cash flow before change in working capital	**-5 457**	**-6 371**	**-40 952**	**-22 690**
Changes in working capital	-2 197	-946	8 250	-11 407
Cash flow from operating activities	**-7 654**	**-7 317**	**-32 702**	**-34 097**
Investing activities	-	-	-17	-
Cash flow from investing activities	**-**	**-**	**-17**	**-**
Financing activities				
New share issue	-	-	37 484	41 648
Credit agreement with MAC	-	269	-	13 290
Cash flow from financing activities	**-**	**269**	**37 484**	**54 938**
Cash flow for the reporting period	**-7 657**	**-7 048**	**4 765**	**20 841**
Cash and cash equivalents at the beginning of period	46 768	41 394	34 346	13 504
Cash and cash equivalents at the end of period	**39 112**	**34 346**	**39 112**	**34 346**

BUSINESS 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).

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

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

Q4
2022

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