ANNUAL REPORT

Initiator Pharma A/S

Initiator Pharma

2022

Initiator Pharma - a life science company dedicated to the development of paradigm changing drugs for CNS-disorders with significant unmet medical needs

Pharma A/S (publ)
CVR No. 37663808

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Initiator Pharma A/S

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Initiator Pharma

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.

Initiator Pharma is a pharmaceutical company based in Copenhagen, Denmark. Our shares are listed on Nasdaq First North Growth Market (INIT), and as of Dec 31, 2022 we had approx 4,000 shareholders.

Our current development portfolio contains two clinical stage assets; IP2015 and IP2018:

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. We are currently conducting a multi-center 120 patient Phase 2b trial in ED which is expected to read out in 2nd half 2023. During 2022 we reported positive efficacy data from a clinical Phase 1 proof of principel study that assessed pain-reducing effects in healthy male subjects challenged with the pain-inducing ingredient (capsaicin).

IP2018 is being developed for psychogenic Erectile Dysfunction (ED) and depression. IP2018 was in-lisenced in March 2020 from Saniona and is currently being examined in a 24 patient Phase 2a trial which is expected to read out in Q2 2023.

In addition to the two clinical stage assets, Initiator Pharma has two assets in preclinical development, targeting depression (IP2016) and pain (IP2017).

Significant events during the year and after year-end

Q1

- **In January** the Company announced the initiation of dosing in the IPTN2021 program Phase 1 to assess pain reducing effects in healthy volunteers.
- **In March** it was announced that the inclusion of test subjects in the IPTN2021 Phase 1 study had been completed.

Q2

- **In April** the Company announced that it has signed an option agreement for a Phase 2/3 ready drug asset for an undisclosed pain indication.
- **In April** 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.
- **In May** the Company announced positive efficacy outcome of the IPTN2021 program Phase 1 study to assess pain-reducing effects.
- **In June** the Company announced issuance of shares, share buyback and sale of shares in connection with long term incentive program for 2021.

Q3

- **In July** the Company announced the outcome of the fully guaranteeed rights issue of MSEK 41. Approximately 42.3% of the share issue was subscribed for, with the rest covered by underwriting commitments.
- **In July** the Company announced that it had carried out a directed share issue of MSEK 2.5 at a share price of SEK 7.50 to a strategic advisor to the company.
- **In July** the Company announced that it had completed a share buy back program of 24,000 shares in connection with the long-term incentive program LTI2021.
- **In September** the Company announced that the final study report from the Phase 1 study in the IPTN2021 program confirmed the statistically significant effects on pain measures that were reported after the first data read-out in May.

Q4

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

Q1 2023

- **In March** the Company announced the completion of dosing of all 24 patients in the Phase 2a clinical trial with IP2018.

Financial highlights and milestones

Key Figures

Income Statement, KDKK	2022	2021	2020
Operating profit/loss	-41 740	-23 072	-10 531
Profit/loss before tax	-44 132	-24 244	-10 240
Profit/loss for the year	**-38 455**	**-21 064**	**-8 697**

Balance Sheet, KDKK	2022	2021	2020
Fixed assets	17	-	11
Current receivables	9 216	19 355	2 088
Cash and cash equivalents	39 112	34 346	13 504
Total assets	**48 345**	**53 701**	**15 603**
Equity	34 023	34 994	14 409
Long-term liabilities	12 577	13 290	-
Current liabilities	1 745	5 417	1 194
Total equity and liabilities	**48 345**	**53 701**	**15 603**

Cash flow, KDKK	2022	2021	2020
Cash flow from operating activities	-32 702	-34 097	-8 064
Cash flow for the year	**4 766**	**20 841**	**5 943**

Key figures, %	2022	2021	2020
Liquidity ratio	337%	287%	1 306%
Equity ratio	70%	65%	92%

Share data, DKK	2022	2021	2020
Earnings per share before and after dilution	-0,80	-0,60	-0,35
Equity per share	0,65	0,80	0,52
Dividend	-	-	-
Cash flow per share	0,09	0,48	0,21

Share data, #	2022	2021	2020
Shares outstanding	52 361 887	43 772 462	27 705 728
Diluted shares outstanding	56 947 554	48 165 325	28 574 121
Weighted average number of shares	48 325 346	35 088 333	24 752 173

Liquidity ratio: Current assets/Current liabilities
Equity ratio: Equity/Total assets

Milestones

Milestones achieved during 2022

- [x] Strengthened the Company´s clinical development capabilities through the recruitement of Christina Gulberg.
- [x] Reported postive efficacy data outcome in a Phase 1 clinical trial to assess pain-reducing effects of IP2015
- [x] Raised approx SEKM 61 through a combination of direct and preferential rights issue of shares.
- [x] Initiated a Phase 1 pharmacokinetic study with new oral solid dose formulations of IP2015 enabling a bridging between previous data sets into new future clinical studies with IP2015.
- [x] Concluded not to in-license a Phase II/III ready asset targeting an undisclosed pain indication following a through review of its clinical and commercial opportunities.

Upcoming milestones during 2023

- [ ] Complete the ongoing Phase 2a proof of concept trial with IP2018 in psychogenic Erectile Dysfunction patients.
- [ ] Complete the ongoing Phase 1 pharmacokinetic study with new oral solid dose formulations of IP2015.
- [ ] Complete the ongoing Phase 2b trial with IP2015 in organic ED.
- [ ] Conclude on business development plans and clinical development plans for both IP2015 and IP2018.

Letter from the CEO

2022 was yet another eventful year for Initiator Pharma. We managed to increase the recruitment rate in our two ongoing Phase II studies in erectile dysfunction, resulting in the completion of the recruitment and dosing of the IP2018 study in March 2023.

We presented positive efficacy data from our Phase I study in neuropathic pain within the IPTN2021 program, and just before year-end we announced the initiation of a pharmacokinetic study in order to evaluate new oral solid dosage forms of IP2015. Thanks to a successful capitalization of the company during the summer 2022, the financing of all Initiator's currently planned activities are now secured to the end of 2024 allowing us to continue the advancement of all our ongoing clinical programs. I am truly grateful for the efforts and commitment our team has put in during the past year and I am convinced that we look forward to a very exciting 2023.

> **"There is a clear unmet medical need within psychogenic ED, and hopefully, IP2018 can become an effective drug for these patients. Data analysis is now in process, and we expect to be able to present first draft results end of Q2 2023."**

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. During 2022 we have seen a need to increase activities in order to optimize patient recruitment and have taken multiple measures to address this. 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 have seen an increased enrolment rate during the last couple of months and our goal to complete the dosing part of the trial in the first half of 2023 remains.

Dosing completed in the IP2018 Phase IIa study – results expected end of Q2

In our November portfolio update, we reported that the patient recruitment had been more challenging than anticipated in our Phase IIa study with the monoamine reuptake inhibitor IP2018, where we for the first time target depressed ED patients. Thus, we were very pleased to announce in the beginning of March 2023 that we had completed the study with the planned number of eligible patients and assessments despite the recruitment complications we previously experienced due to COVID-19. There is a clear unmet medical need within psychogenic ED, and hopefully, IP2018 can become an effective drug for these patients. Data analysis is now in process, and we expect to be able to present first draft results end of Q2 2023.

Positive efficacy data in IPTN2021 program Phase I study

Within the IPTN2021 program, targeting neuropathic pain, we initiated a clinical Phase I proof of principle study in the beginning of 2022 evaluating 24 healthy subjects dosed with IP2015 and challenged with a pain-inducing ingredient (capsaicin). In September we were happy to present the final study report from the trial, confirming the statistically significant effects on pain measures that were reported after the first data read-out in May.

The demonstrated effects on pain correlates well with and confirms our findings in previous preclinical pain models and support our planning of future clinical studies, particularly in relation to the most relevant patient segments within neuropathic pain e.g. Trigeminal Neuralgia.

Testing new oral solid dosage forms of IP2015 in Phase I

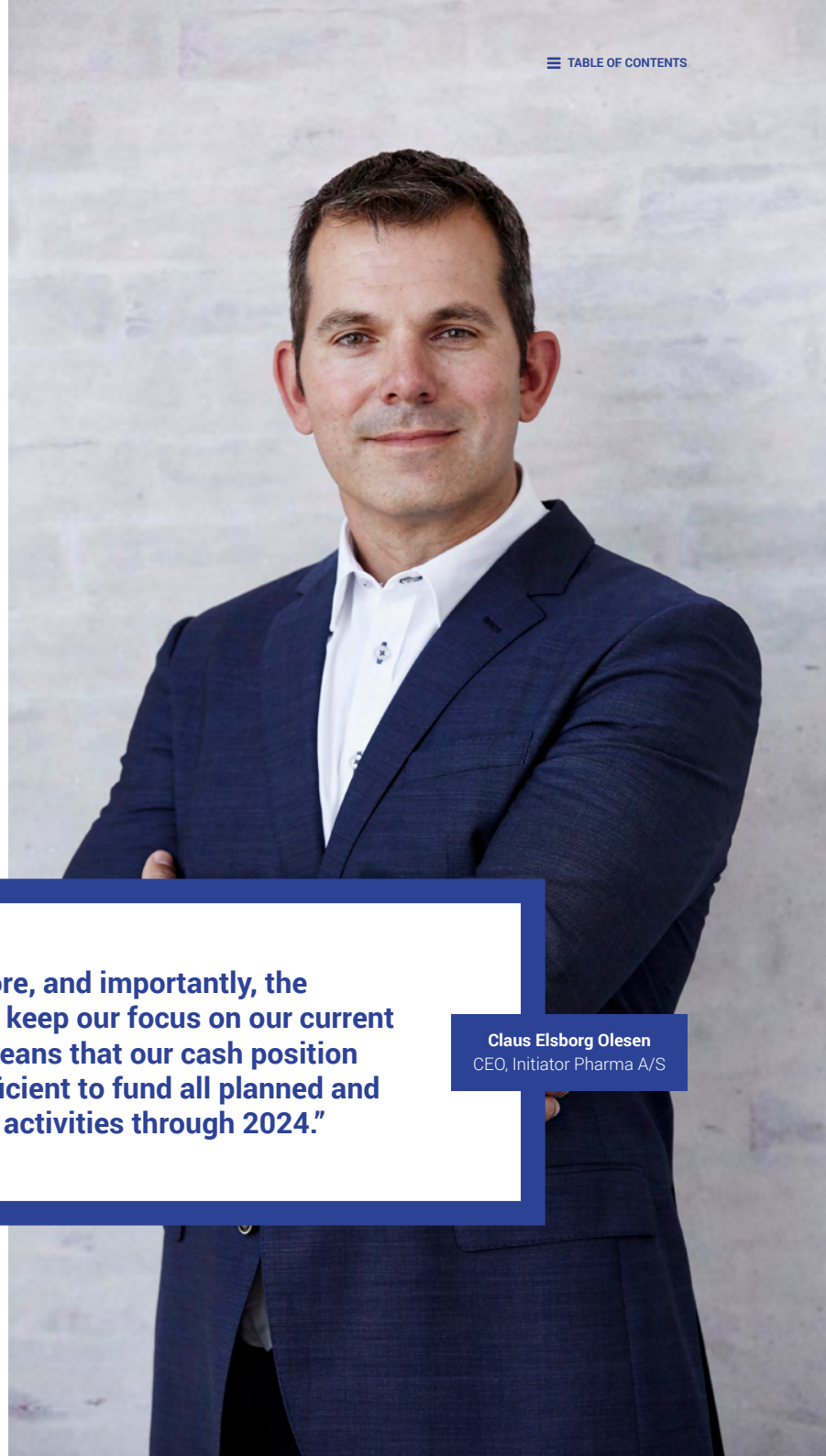
Due to the very encouraging results demonstrated in the IPTN2021 program Phase I study, we have initiated a Phase I pharmacokinetic study in healthy subjects testing new oral solid dosage forms of IP2015, which will bridge previous data sets into new future clinical studies for IP2015. The study is under way and is expected to 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 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.

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

Claus Elsborg Olesen
CEO



> **“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.”**

Claus Elsborg Olesen
CEO, Initiator Pharma A/S

Goals

Initiator Pharma's goal is to progress novel drug candidates toward the market in a cost and time effective way, for the benefit of both patients in need of improved medical therapies and for our shareholders.

Strategy

Initiator Pharma's strategy is to identify promising drug candidates focused on CNS disorders with significant unmet medical needs that are in late preclinical and early clinical development, and rapidly progress these candidates through clinical Proof-of-Concept studies to the point where we expect to enter partnerships for late-stage clinical development.

Business model

Initiator Pharma aims to commercialize its research efforts through internal development of selected programs through the early phases of clinical drug development, before out-licensing to pharmaceutical companies who will take over the further development of Initiator Pharma's programs and typical with upfront and development milestone payments as well as royalty payments on product sales.

The company aims to progress our portfolio of drug candidates to key value inflection points, where we anticipate significant partnering interest from international pharma industry for the further development of our drug candidates.

The company is employing a virtual organization model in order to maximize speed and flexibility while minimizing costs. During 2022 the organization was expanded with two employees, providing us with key capabilities within both preclinical and clinical development. The bulk of the drug development and the regulatory work will be outsourced via contracts with Contract Research Organizations (CROs). The work is conducted under the direction and supervision of Initiator Pharma.

Project portfolio

Initiator Pharma currently has a portfolio of five projects with four drug candidates, of which three are in clinical development and two are in preclinical development.

Compunds	Profile	Indication	Discovery & Preclinical	Phase I	Phase Ib	Phase IIa	Phase IIb
IP2015	DAT (SERT/NET)	ED (Organic) *IPED2015*					
		Neuropathic *Pain IPTN2021*					
IP2018	DAT>SERT>NET	ED (Psychogenic)					
IP2016	DAT (SERT/NET)	Exploratory (Depression)					
IP2017	DAT (SERT/NET)	Exploratory (Pain)					

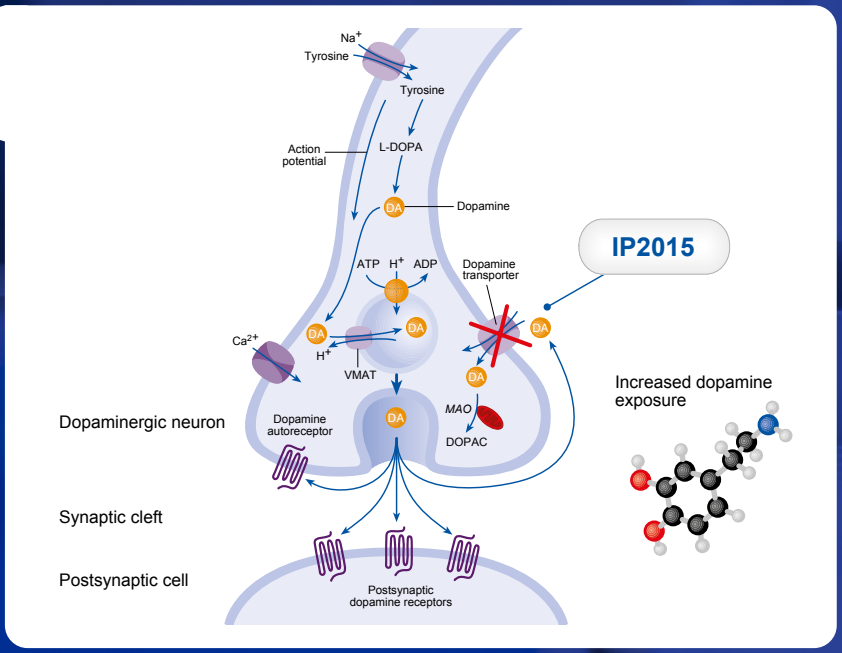
Partnership
MAC

DAT: *Dopamin*
SERT: *Serotonin*
NET: *Norepinephrine*

All four drug candidates belong to the drug class known as monoamine reuptake inhibitors (MRIs).

Molecules in this class act as a reuptake inhibitors of one or more of the three major monoamine neurotransmitters serotonin (SERT), norepinephrine (NET), and dopamine (DAT) by blocking the action of one or more of the respective monoamine transporters. This in turn results in an increase in the synaptic concentrations of one or more of these neurotransmitters and therefore an increase in monoaminergic neurotransmission.

The monoaminergic systems, i.e., the networks of neurons that use monoamine neurotransmitters, are involved in the regulation of processes such as emotion, arousal, and certain types of memory. The monoamines balance profiles have very differentiated effects and physiological impact.



IP2015 is an inhibitor of the Dopamine Re-uptake Transporter (DAT). IP2015 inhibition of DAT increases dopamine synaptic content, which improves sexual function and inhibits pathways transmitting pain.

IP2015, our most advanced asset, is being developed for both treatment resistant organic Erectile Dysfunction and neuropathic pain.

PROJECT IP2015

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 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 Pharma 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 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 (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.

Neuropathic pain/Trigeminal Neuralgia

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 estimate 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.[2]

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

PROJECT 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.

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.

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, GlaxoSmithKline, AstraZeneca and H Lundbeck A/S, 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.

4. 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.
5. 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
6. 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.
7. Reports and Data. "Anxiety Disorder and Depression Treatment Market By Therapies" (2020), https://www.reportsanddata.com/report-detail/anxiety-disorder-and-depression-treatment-market.

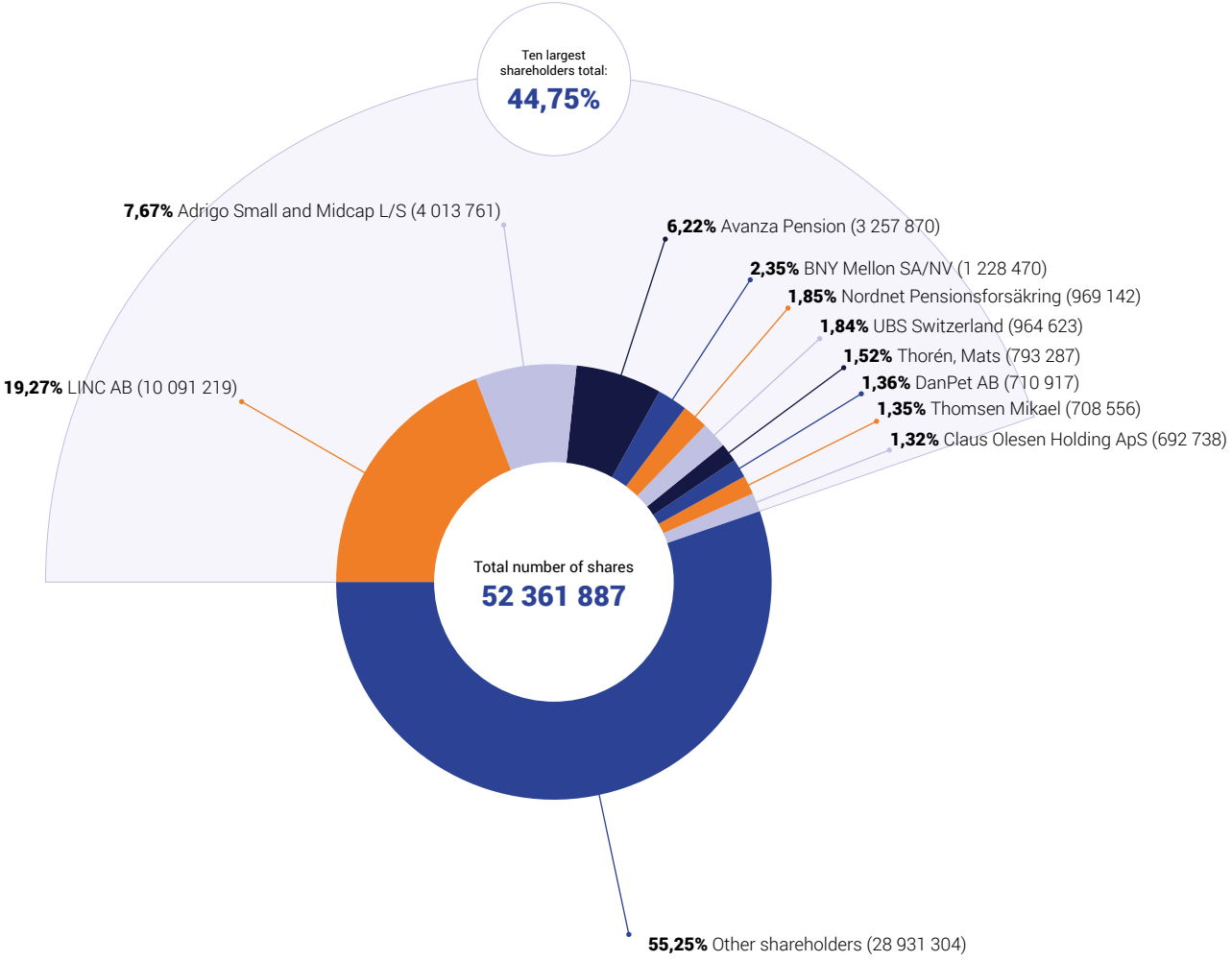
The Initiator Pharma share

The share and ownership structure

Initiator Pharma is listed on Nasdaq First North Growth Market Stockholm in Sweden, under the ticker code INIT. As of December 31, 2022, the number of shares outstanding totalled to 52,361,887 shares. The company has as of December 31 a total of 1,527,000 outstanding incentive warrants, representing 3.0% of the number of issued shares. In addition the company has entered a convertible credit agreement with MAC Clinical Research for part financing of the ongoing Phase 2b clinical trial with IP2015 that if fully utilized can result in a dilution of 3,058,667 shares, representing 5.8% of the number of issued shares.

The closing share price on December 31 was SEK 6.06, down 25% for the year. The market capitalization of the company on December 31 was approx SEK 317 million. During 2022 the average daily trading volume was 49,706 shares, and for the full year the traded volume was 12.6 million shares or 24% of the issued shares at year-end.

At December 31, 2022 the company had around 4,000 shareholders, with the 10 largest shareholders holding 45% of all outstanding shares:



Shareholdings per size

Shareholding	Number of shareholders	Shareholding and votes	Shares (%)
1 - 500	1 819	270 288	0,52%
501 - 1,000	420	317 473	0,61%
1,001 - 5,000	953	2 278 043	4,35%
5,001 - 10,000	283	2 064 153	3,94%
10,001 - 15,000	129	1 591 560	3,04%
15,001 - 20,000	69	1 205 354	2,30%
20,001 -	264	44 635 016	85,24%
Total	**3 937**	**52 361 887**	**100,00%**

Shareholders by geography

Shareholders by country	Number of shareholders	Number of shares	Share of votes
Sweden	3 224	36 351 093	69,42%
Nordics, excl Sweden	657	7 180 491	13,71%
Europe, excl Nordics	42	8 242 253	15,74%
USA	3	312 253	0,60%
Other	11	196 399	0,38%
Total	**3 937**	**52 361 887**	**100,00%**

Report from the Board of Directors and the Chief Executive Officer

The Board of Directors and the Chief Executive Officer of Initiator Pharma A/S (publ), corporate identity number 37663808, hereby present the Annual Report for the calendar year 2022.

Initiator Pharma is a limited liability company registered and headquartered in Aarhus, Denmark. The address of the head office is Ole Maaloesvej 3, 2200 Copenhagen, Denmark. Initiator Pharma incorporated on May 2, 2016 and is listed on Nasdaq First North Growth Market Stockholm.

Financial development in 2022

Result

As a development company Initiator Pharma generated no revenues in the financial year 2022, unchanged from 2021. The company recognized an operating loss of KDKK 41,740 for the full year 2022, compared to KDKK 23,072 for 2021.

The increase in operating costs for the full year compared to the same period last year reflects increased development costs related to the ongoing Phase 2b trial with IP2015 in organic Erectile Dysfunction, the ongoing Phase 2a trial with IP2018 in psychogenic Erectile Dysfunction and the completion of the Phase 1 proof of principle study with IP2015 in neuropathic pain. In addition, the company has expanded its organization with key clinical development and research capabilities to support the company's development pipeline.

External R&D costs in 2022 amounted to to KDKK 26,342 compared to 11,807 in the same period in 2021. The external R&D costs are primarily CRO costs related to the running of the clinical trials as well as related activities on CMC (drug substance and drug product) and regulatory.

Net financial expenses in 2022 were KDKK 2,392 , compared to net financial income of KDKK 1,172 in the same period in 2021. The increase in net financial expenses for 2022 is mainly related to foreign currency movements in the period.

Financial position

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

During 2022 the Company raised a total of approx. MSEK 64 in new capital through a combination of directed and preferential rights issues, described in further detail under the section "The share, share capital and ownership structure below".

Cash flow

The operating cash flow for the financial year 2022 was KDKK -32,702 (-34,097), incl a positive change in working capital of KDKK 8,787 (-11,407). Cash flow from investment activities was KDKK -17 (0) and cash flow from financing activities was KDKK 37,484 (54,938) for the full year.

Share capital

At December 31, 2022, the number of shares outstanding totalled to 52,361,887 shares and on a fully diluted basis to 56,947,554, 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 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.

Potential financial impact of Covid-19

As of February 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.

Risks

Initiator Pharma is exposed to various kinds of risks that may impact the Company's results and financial position. The risks can be divided into operational risks and financial risks.

Operational risks

Financing needs and capital

Initiator Pharma´s research and development activities involve significant costs for the Company. Initiator Pharma is thus depending on that capital can be accessed to finance its planned activities. Any delays in product development could affect the cash flow negatively. There is a risk that the Company is unable to raise the additional capital needed. This may lead to the development being temporarily stopped or that Initiator Pharma is required to operate at a lower speed than wanted, which may affect the Company´s operations negatively. In case Initiator Pharma is unable to raise capital there is a risk that the Company cannot further develop its business. If the Company cannot finance the operations, there is a risk that Initiator Pharma´s drug development stops.

Suppliers

Initiator Pharma has entered an agreement with MAC Clinical Research regarding the conduct of the Phase 2b trial in IPED2015, the Phase 2a trial in IP2018 and the Phase 1 trial in IPTN2021. There is a risk that one or more of Initiator Pharma's suppliers choose to discontinue its cooperation with the Company, which could have a negative impact on the business. There is also a risk that Initiator Pharma's suppliers do not fully meet the quality standards set by the Company. There is also a risk that the establishment of new suppliers or replacement of existing suppliers becomes more costly and/or takes longer than the Company estimates, which may negatively affect the Company's results and financial position.

Key individuals and employees

Initiator Pharma's key individuals and employees have high competence and long experience in the Company's business. A loss of one or more key individuals or employees may have negative consequences for the Company's operations and results. It is not possible to fully protect against unauthorized disclosure of information, with the risk that competitors can gain access to and benefit from the know-how developed by Initiator Pharma, which could be detrimental to the Company. There is a risk that the loss of one or more key in- dividuals, employees and consultants leads to delays in the Company's work to develop drugs. Any delays can cause increased costs for the Company. Thus, there is also a risk that delays could negatively affect the Company's results.

Competitors

Initiator Pharma is a research and development company engaged in pharmaceutical development of drugs to be used for erectile dysfunction, depression and pain. Initiator Pharma's research is focused in the area of monoamine reuptake inhibitors. The Company's drug research will be conducted primarily through its own pharmaceutical development in the early phase and through potential cooperations with other major pharmaceutical companies. Some of the Company's competitors are multinational companies with large financial resources. A comprehensive investment and product development from a competitor may result in less favorable market conditions for Initiator Pharma. Furthermore, companies with global operations, which in the current situation are working in related areas, can also establish themselves within the Company's business. Increased competition could lead to could lead to negative sales and earnings effects for the Company in the future.

Economic development and currency risk

External factors such as inflation, currency and interest rate fluctuations, supply and demand as well as economic recessions and booms may have an impact on operating costs, sales prices and share valuations. A significant share of Initiator Pharma's development costs is in international currencies. Exchange rates can change substantially. There is a risk that Initiator Pharma's future operating costs, revenue and share valuation may be negatively affected by these factors, which are beyond the control of the Company.

Geopolitical risk

The Company, through its pharmaceutical development operates in a number of different countries and can therefore be affected by political and economic uncertainties in these countries. There is a risk that Initiator Pharma is negatively affected by changes in laws, taxes, duties, exchange rates and terms for foreign companies. The Company may also be negatively affected by any domestic policy decisions. The above could have negative consequences for the Company's research in pharmaceutical development and can thus affect the Company's future results and financial position.

Patents and other intellectual property

Currently Initiator Pharma holds 5 different patent families. There is a risk that any future patent applications will not be approved and there is also a risk that an approved patent will not constitute a total commercial protection in the future. Patents have a limited life. If the Company is forced to defend future patent rights against a competitor, this will involve considerable costs, which may negatively affect the Company's research, results and financial position. Furthermore, in the industry Initiator Pharma operates there is always the risk that the Company may or is alleged to infringe patent held by third parties. Other actors' patents may also limit the ability of one or more of the Company's future partners

to freely use the product or production method concerned. The risk associated with patent protection implies that the outcome of such disputes is difficult to predict. Negative outcome of litigation relating to intellectual property rights may lead to loss of protection, prohibition to continue to use the right or obligation to pay damages. In addition, the costs of litigation, even in case of a favorable outcome for Initiator Pharma, may be substantial, which could negatively affect the Company's results and financial position. The above could imply difficulties or delays in the commercialization of future products and thus also difficulties in generating revenue.

Development expenditure

Initiator Pharma will continue to develop drug candidates in its operating area. Time and cost aspects of drug development can be difficult to determine in advance with accuracy. This creates the risk of a planned product development program becoming more costly than planned, which may affect the Company's future results and financial position.

Financial risks

Financial risks relate to a potential negative impact on the financial position resulting from changes in the financial risk factors. The Board of Directors is ultimately responsible for the exposure, management and monitoring of the Company's financial risks. The Board of Directors sets the framework that applies to the exposure, management and monitoring of the financial risks and this framework is evaluated and revised yearly. The Board of Directors can decide on temporary departures from its predetermined framework. Below is a brief description of the financial risk factors that are deemed the most significant for Initiator Pharma.

Currency risks is the risk that the fair value of future cash flows fluctuate because of changed exchange rates. Exposure to currency risk is primarily sourced from payment flows in foreign currency and from the translation of balance sheet items in foreign currency.

Interest risk is the risk that fair value or future cash flows fluctuates as a result of changed market interest rates.

Liquidity risk is the risk that the Company encounters difficulties in satisfying commitments related to the Company's financial liabilities.

Credit risk is the risk that a counterparty in a transaction generates a loss for the Company by being unable to satisfy its contracted obligations. Credit risk may also arise if the Company's surplus liquidity is invested in various types of financial instrument.

Corporate governance

Initiator Pharma does not provide a Corporate Governance Report for 2022. The Board of Directors has adapted the following policies:

- Rules of Procedure for the Board of Directors
- Instructions for the CEO
- Information Policy
- Remuneration Policy

Organisation

As of December 31 2022, the number of employees was 3 of which 1 woman and 2 men. Of these employees, 2 were full-time employees and 1 was part-time.

In addition to its employees Initiator Pharma has a number of consultants who work with the Company on an ongoing basis.

Remuneration

The AGM resolves on remuneration to the Chair of the Board and other Board members. The AGM in 2021 approved a policy for remunerating the CEO and other senior executives. For more information on remuneration in the year, see note 1 as well as in the separately published Remuneration Report for 2022.

The Board of directors and Auditor

Magnus Persson (b. 1960)

Chairman and member of the Board of Directors since 2016

Education: Medical doctor and Ph.D. from the Karolinska Institute
No. of shares held*: 256 686
Warrants held: 65 000

Annette Colin (b. 1965)

Member of the Board of Directors since 2021

Education: Business administration from Lund University
No. of shares held: 17 000
Warrants held: 53 000

Henrik Moltke (b. 1958)

Member of the Board of Directors since 2016

Education: Master's degree in international economics and strategic management from the Copenhagen Business School
No. of shares held: 127 106
Warrants held: 77 000

Gunilla Ekström (b. 1958)

Member of the Board of Directors since 2022

Education: MD, PhD and associate professor from the Karolinska Institutet in Sweden
No. of shares held: 7 000
Warrants held: 42 000

Peter Holm (b. 1974)

Member of the Board of Directors since 2016

Education: Ph.D. in biochemistry from the Karolinska Institute and a Master's degree in chemistry from the University of Linköping
No. of shares held: 0
Warrants held: 0

Claus Olesen (b. 1974)

Member of the Board of Directors and CEO of Initiator Pharma since 2016 and co-founder of the company

Education: Ph.D. in Physiology and Biophysics from Aarhus University
No. of shares held*: 1 072 438
Warrants held: 510 000

Auditor: Deloitte Statsautoriseret Revisionspartnerselskab
Auditor in charge: Jens Sejer Pedersen
Address: Deloitte Statsautoriseret Revisionspartnerselskab, Weidekampsgade 6, 2300 Copenhagen S, Denmark

*No. of shares held includes shared held privately and held through holding companies

Management

Claus Olesen (b. 1974)

Member of the Board of Directors and CEO of Initiator Pharma since 2016 and co-founder of the company

Education: Ph.D. in Physiology and Biophysics from Aarhus University

No. of shares held*: 1 072 438

Warrants held: 510 000

Ulf Simonsen (b. 1963)

CMO of Initiator Pharma A/S since 2016 and co-founder of the company (consultant)

Education: Medical doctor (Aarhus University) and Ph.D. in Physiology (Complutense University, Madrid). Currently Professor of Pharmacology and head of Department of Pharmacology at Aarhus University.

No. of shares held*: 620 802

Warrants held: 110 000

Torgeir Vaage (b. 1964)

CFO of Initiator Pharma A/S since 2016 (consultant)

Education: Ph.D. in business administration from UC Berkeley and master's degree from the Norwegian School of Economics.

No. of shares held*: 327 448

Warrants held: 260 000

Mikael Thomsen (b. 1968)

CDO of Initiator Pharma A/S since 2016 and co-founder of the company (consultant)

Education: Ph.D. in Pharmacology and Toxicology (University of Copenhagen) and two M. Sc. degrees in Pharmacy and Human Biology (from University of Pharmaceutical Sciences, Copenhagen and University of Copenhagen, Medical Faculty).

No. of shares held*: 708 556

Warrants held: 260 000

*No. of shares held includes shared held privately and held through holding companies

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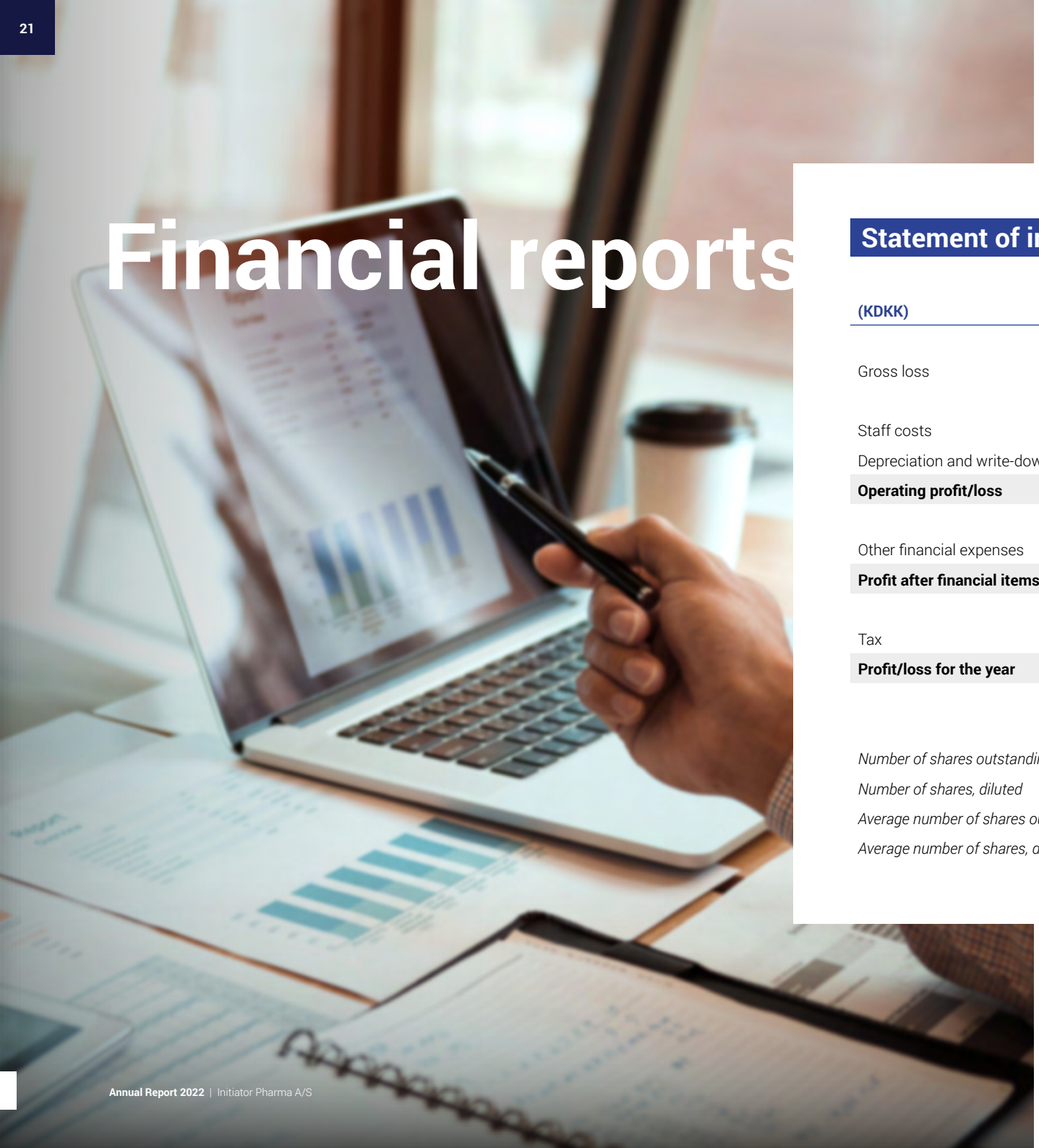


Financial reports

Statement of income

(KDKK)	Notes	2022	2021
Gross loss		-38 425	-21 626
Staff costs	1	-3 315	-1 435
Depreciation and write-downs	2	-	-11
Operating profit/loss		**-41 740**	**-23 072**
Other financial expenses		-2 392	-1 172
Profit after financial items		**-44 132**	**-24 244**
Tax	2	5 677	3 180
Profit/loss for the year	3	**-38 455**	**-21 064**
Number of shares outstanding		52 361 887	43 772 462
Number of shares, diluted		56 947 554	48 165 325
Average number of shares outstanding		48 325 346	35 088 333
Average number of shares, diluted		53 225 959	39 685 393

Balance Sheet

ASSETS

(KDKK)	Notes	2022	2021
Patents, acquired rights		-	-
Intangible assets	4	**-**	**-**
Deposit		17	-
Financial assets		**17**	**-**
Other receivables		1 706	945
Income Tax receivable		5 500	3 180
Prepayments	5	2 010	15 230
Current receivables		**9 216**	**19 355**
Cash and cash equivalents	6	**39 112**	**34 346**
Current assets		**48 328**	**53 701**
Assets		**48 345**	**53 701**

EQUITY AND LIABILITIES

(KDKK)	Notes	2022	2021
Contributed capital	7	5 498	4 596
Retained earnings		28 525	30 398
Equity		**34 023**	**34 994**
Convertible credit agreement	8	12 577	13 290
Long-term liabilities		**12 577**	**13 290**
Trade payables		801	4 800
Other payables		944	617
Current liabilities other than provisions		**1 745**	**5 417**
Liabilities other than provisions		**14 322**	**18 707**
Equity and liabilities		**48 345**	**53 701**

Statement of changes in equity

Statement of changes in equity for 2021

(KDKK)	Contributed capital	Retained earnings	Total
January 1, 2021	**2 909**	**11 501**	**14 410**
Increase of capital	1 687	41 809	43 496
Costs in connection with increase of capital	-	-1 848	-1 848
Profit/loss for the year	0	-21 064	-21 064
December 31, 2021	**4 596**	**30 398**	**34 994**

Statement of changes in equity for 2022

(KDKK)	Contributed capital	Retained earnings	Total
January 1, 2022	**4 596**	**30 398**	**34 994**
Increase of capital	902	43 797	44 699
Costs in connection with increase of capital	-	-7 215	-7 215
Profit/loss for the year	-	-38 455	-38 455
December 31, 2022	**5 498**	**28 525**	**34 023**

Statement of cash flow

(KDKK)	Notes	2022	2021
Profit/loss before tax		-44 132	-24 244
Amortisation, depreciation and impairment losses		-	11
Adjustment for non-cash transactions		-536	-
Profit/loss before tax, adj for non-cash transactions		**-44 668**	**-24 233**
Tax paid/received		3 180	1 543
Cash flow before change in working capital		**-41 488**	**-22 690**
Changes in working capital	9	8 787	-11 407
Cash flow from operating activities		**-32 701**	**-34 097**
Investing activities		-17	-
Cash flow from investing activities		**-17**	**-**
Financing activities			
New share issue		37 484	41 648
Issue of warrants		-	-
Credit agreement with MAC		-	13 290
Cash flow from financing activities		**37 484**	**54 938**
Cash flow for the reporting period		**4 766**	**20 841**
Cash and cash equivalents at the beginning of period		34 346	13 504
Cash and cash equivalents at the end of period		**39 112**	**34 346**

Accounting policies

Reporting class

This annual report has been presented in accordance with the provisions of the Danish Financial Statements Act governing reporting class B enterprises with addition of certain provisions for reporting class C.

The accounting policies applied to these financial statements are consistent with those applied last year.

Recognition and measurement

Assets are recognised in the balance sheet when it is probable as a result of a prior event that future economic benefits will flow to the Entity, and the value of the asset can be measured reliably.

Liabilities are recognised in the balance sheet when the Entity has a legal or constructive obligation as a result of a prior event, and it is probable that future economic benefits will flow out of the Entity, and the value of the liability can be measured reliably.

On initial recognition, assets and liabilities are measured at cost. Measurement subsequent to initial recognition is elected as described below for each financial statement item.

Anticipated risks and losses that arise before the time of presentation of the annual report and that confirm or invalidate affairs and conditions existing at the balance sheet date are considered at recognition and measurement.

Income is recognised in the income statement when earned, whereas costs are recognised by the amounts attributable to this financial year.

Foreign currency translation

On initial recognition, foreign currency translations are translated applying the exchange rate at the transaction date. Receivables, payables and other monetary items dominated in foreign currencies that have not been settled at the balance sheet date are translated using the exchange rate at the balance sheet date. Exchange differences that arise between the rate at the transaction date and the rate in effect at the payment date, or the rate at the balance sheet date, are recognized in the income statement as financial income or financial expenses.

Income statement

Gross profit or loss

Gross profit or loss comprises revenue, other operating income, cost of raw materials and consumables and external expenses.

Other operating income

Other operating income comprises income of a secondary nature as viewed in relation to the Entity's primary activities.

Other external expenses

Other external expenses include expenses relating to the Entity's ordinary activities, including expenses for premises, stationery and office supplies, marketing costs, etc.

Staff costs

Staff costs comprise salaries and wages, and social security contributions, pension contributions, etc for entity staff.

Depreciation, amortisation and impairment losses

Depreciation, amortisation and impairment losses relating to property, plant and equipment and intangible assets comprise depreciation, amortisation and impairment losses for the financial year, and gains and losses from the sale of intangible assets as well as equipment.

Other financial income

Other financial income comprises interest income and exchange gains on payables and transactions in foreign currencies.

Other financial expenses

Other financial expenses comprise interest expenses, payables and transactions in foreign currencies etc.

Tax on profit/loss for the year

Tax for the year, which consists of current tax for the year and changes in deferred tax, is recognised in the income statement by the portion attributable to the profit for the year and recognised directly in equity by the portion attributable to entries directly in equity.

Balance sheet

Intellectual property rights etc

Intellectual property rights etc comprise acquired intellectual property rights and prepayments for intangible assets.

Intellectual property rights acquired are measured at cost less accumulated amortisation. Patents are amortised on a straight-line basis over their remaining duration, and licences are amortised over the term of the agreement.

Intellectual property rights etc are written down to the lower of recoverable amount and carrying amount.

Property, plant and equipment

Other fixtures and fittings, tools and equipment are measured at cost less accumulated depreciation and impairment losses.

Cost comprises the acquisition price, costs directly attributable to the acquisition and preparation costs of the asset until the time when it is ready to be put into operation.

The basis of depreciation is cost less estimated residual value after the end of useful life. Straight-line depreciation is made on the basis of the following estimated useful lives of the assets:

Other fixtures and fittings, tools and equipment: 3 years

Estimated useful lives and residual values are reassessed annually.

Items of property, plant and equipment are written down to the lower of recoverable amount and carrying amount.

Contributed capital in arrears consists

Contributed capital in arrears consists of capital subscribed, but not paid up, which is recognised as a separate amount receivable in assets and a separate reserve in equity (gross method). The amount receivable is measured at amortised cost.

Receivables

Receivables are measured at amortised cost, usually equalling nominal value less writedowns for bad and doubtful debts.

Tax payable or receivable

Current tax receivable is recognised in the balance sheet, stated as tax computed on this year's taxable income. The amount is compiled of tax credit under the Tax Assessment Act § 8x.

Prepayments

Prepayments comprise incurred costs relating to subsequent financial years. Prepayments are measured at cost.

Cash

Cash comprises cash in hand and bank deposits.

Other financial liabilities

Other financial liabilities are measured at amortised cost, which usually corresponds to nominal value.

Cash flow statement

The cash flow statement shows cash flows from operating, investing and financing activities, and cash and cash equivalents at the beginning and the end of the financial year.

Cash flows from operating activities are presented using the indirect method and calculated as the operating profit/loss adjusted for non-cash operating items, working capital changes and taxes paid.

Cash flows from investing activities comprise payments in connection with acquisition and divestment of enterprises, activities and fixed asset investments, and purchase, development, improvement and sale, etc of intangible assets and property, plant and equipment, including acquisition of assets held under finance leases.

Cash flows from financing activities comprise changes in the size or composition of the contributed capital and related costs, and the raising of loans, inception of finance leases, repayments of interest-bearing debt, purchase of treasury shares and payment of dividend.

Cash and cash equivalents comprise cash and short-term securities with an insignificant price risk.

Notes to the financial statements

NOTE 1 - Staff costs

	2022 (DKK)	2021 (DKK)
Wages and salaries	3 047 047	1 429 280
Pensions	225 000	-
Other social security costs	16 687	2 502
Other staff costs	26 760	2 951
Total staff	**3 315 494**	**1 434 733**
Average number of full-time employees	3	2

	Remuneration of management 2022 (DKK)	Remuneration of management 2021 (DKK)
Total amount for management categories	1 574 421	1 306 279
	1 574 421	**1 360 279**

NOTE 2 - Depreciation, amortisation and impairment losses

	2022 (DKK)	2021 (DKK)
Amortisation of intangible assets	-	11 184
Depreciation of property, plant and equipment	-	-
	-	**11 184**

NOTE 3 - Tax on profit/loss for the year

	2022 (DKK)	2021 (DKK)
Current tax	5 500 000	3 180 000
Adjustment concerning previous years	177 000	42
	5 677 000	**3 180 042**

NOTE 4 - Intangible assets

	Acquired rights (DKK)
Cost beginning of year	112 000
Cost end of year	**112 000**
Amortisation and impairment losses beginning of year	112 000
Amortisation for the year	-
Amortisation and impairment losses end of year	**112 000**
Carrying amount end of year	**-**

NOTE 5 - Prepayments

During 2022 the Company has been conducting several clinical trials which are performed by external suppliers, or clinical trial organizations ("CRO"). The invoicing by the CRO for the clinical trial services follow the payment plan established by the service agreements for each of the trials.

In order to account for the periodic costs of the clinical trials the company has developed a cost model that attempts to allocate the budgeted costs to the progress of the study.

Differences between invoiced costs from the CRO and the modelled costs is recognized as prepayments in the case where invoiced costs exceed the modelled costs, or as provisions in the case where invoiced costs are below modelled costs.

As of December 31, 2022 the invoiced clinical trial costs exceed the modelled costs, with KDKK 2,010 being recognized as prepayments.

NOTE 6 - Cash

Total cash funds amounts to KDKK 39,112, of which KDKK 200 is pledged as security for the guarantee provided by the Company's bank.

NOTE 7 - Share capital

	Number	Nominal value (DKK)
Shares	52,361,887	5,497,998
	52,361,887	**5,497,998**

The Company has two established warrant programs, approved by the AGM in 2021 and in 2022 respectively. The purpose of the warrant program is to align the long-term incentives of board members, Management and key consultants with those of our shareholders. The warrant programs currently outstanding have a ceiling of 1,527,000 warrants representing 2.9% of outstanding shares:

Year approved	Number of warrants	Subscription price	Pct of issued shares	Exercise price	Exercise deadline
AGM 2021	750 000	-	1.4%	DKK 0.105	Dec 31, 2023
AGM 2022	777 000	-	1.5%	DKK 0.105	Dec 31, 2024
Total	**1 527 000**		**2.9%**		

The AGM2021 Program ("LTI2021"):

Under this program the participants in the program have acquired 150,000 ordinary shares in the market at market price ("Investment Shares") in the period between May 28, 2021 and September 30, 2021, with each Investment Share carrying the right to subscribe for 1 new share at par value at the next AGM providing that the individual owning the Investment Share is still with the company at the time ("Matching Share"). After the AGM 2022 held on May 24, 2022 the participants in LTI2021 exercised their rights to acquire the full number of Matching Shares. Each Investment Share is also entitled to subscribe for between 0 and 5 new shares during 30 trading days after December 31, 2023, depending on the development of Initiator's share price in the period between May 28, 2021 and December 31, 2023. The maximum potential dilution under the program is 750,000 shares, representing approx. 1.4% of currently issued number of shares.

The AGM2022 Program ("LTI2022"):

Under this program the participants in the program have acquired 129,500 ordinary shares in the market at market price ("Investment Shares") in the period between May 24, 2022 and September 30, 2022, with each Investment Share carrying the right to subscribe for 1 new share at par value at the next AGM providing that the individual owning the Investment Share is still with the company at the time ("Matching Share"). Each Investment Share is also entitled to subscribe for between 0 and 5 new shares during 30 trading days after December 31, 2024, depending on the development of Initiator's share price in the period between May 24, 2022 and December 31, 2023. The maximum potential dilution under the program is 777,000 shares, representing approx. 1.5% of currently issued number of shares.

The warrant programs are subject to vesting conditions.

NOTE 8 - Convertible and dividend-yielding debt instruments

The Company has entered a financing agreement with MAC Clinical Research through which MAC Clinical Research will cover up to SEK 23 mill of the clinical trial costs for a planned Phase 2b trial for IPED2015, the Company´s lead program, through a convertible credit agreement. The agreement gives MAC Clinical Research the right to convert the credit into Initiator Pharma shares up to approximately 23 MSEK at a share price of 7.5 SEK upon the full completion of a planned Phase 2b study.

If fully utilized the agreement gives MAC Clinical Research the right to convert the credit into 3,058,667 shares each of a nominal value of DKK 0.105, representing 5.8% of issued shares as of Dec 31, 2022 upon completion of the study.

If MAC Clinical Research decides not to convert the credit upon completion of the study, the credit is converted into long-term debt carrying 1% annual interest and payable in full 3 years after the completion of the study.

As of December 31, 2022 a total of KDKK 12,577 has been accrued under the convertible credit agreement, representing a potential dilution of approx. 1.7 million shares or 3.2% of number of issued shares on December 31, 2022.

NOTE 9 - Change in working capital

	2022 (DKK)	2021 (DKK)
Increase/decrease in receivables	(13 030 000)	15 630 000
Increase/decrease in trade payables etc	4 243 000	4 223 000
	8 787 000	**11 407 000**

Statement by management on the annual report

The Board of Directors and the Executive Board have today considered and approved the Annual Report of Initiator Pharma A/S for the fiscal year 01/01/2022 - 12/31/2022.

The annual report is presented in accordance with the Danish Financial Statements Act.

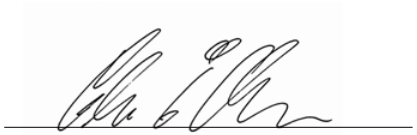
In our opinion, the financial statements give a true and fair view of the Entity's financial position at 12/31/2022 and of the results of its operations and cash flows for the fiscal year 01/01/2022 -12/31/2022.

We believe that the management commentary contains a fair review of the affairs and conditions referred to therein.

We recommend that the Annual Report with its accompanying financial statements be adopted at the Annual General Meeting.

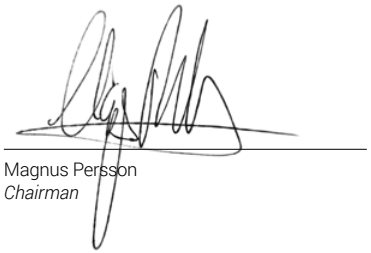
Copenhagen, 04-27-2023

Executive Board



Claus Olesen

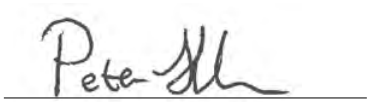
Board of Directors



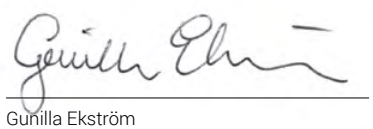
Magnus Persson
Chairman

Henrik Moltke

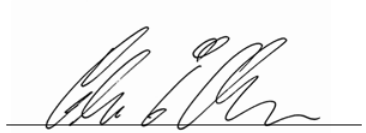
Annette Colin



Peter Holm



Gunilla Ekström



Claus Olesen

Independent auditor's report

To the shareholders of Initiator Pharma A/S

Opinion

We have audited the financial statements of Initiator Pharma A/S for the financial year 01.01.2022 - 31.12.2022, which comprise the income statement, balance sheet, statement of changes in equity, cash flow statement and notes, including a summary of significant accounting policies. The financial statements are prepared in accordance with the Danish Financial Statements Act.

In our opinion, the financial statements give a true and fair view of the Entity's financial position at 31.12.2022 and of the results of its operations and cash flows for the financial year 01.01.2022 - 31.12.2022 in accordance with the Danish Financial Statements Act.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs) and additional requirements applicable in Denmark. Our responsibilities under those standards and requirements are further described in the "Auditor's responsibilities for the audit of the financial statements" section of this auditor's report. We are independent of the Entity in accordance with the International Ethics Standards Board for Accountants' International Code of Ethics for Professional Accountants (IESBA Code) and the additional ethical requirements applicable in Denmark, and we have fulfilled our other ethical responsibilities in accordance with these requirements and the IESBA Code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Management's responsibilities for the financial statements

Management is responsible for the preparation of financial statements that give a true and fair view in accordance with the Danish Financial Statements Act, and for such internal control as Management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, Management is responsible for assessing the Entity's ability to continue as a going concern, for disclosing, as applicable, matters related to going concern, and for using the going concern basis of accounting in preparing the financial statements unless Management either intends to liquidate the Entity or to cease operations, or has no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Entity's internal control.

- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.

- Conclude on the appropriateness of Management's use of the going concern basis of accounting in preparing the financial statements, and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Entity's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Entity to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures in the notes, and whether the financial statements represent the underlying transactions and events in a manner that gives a true and fair view.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Statement on the management commentary

Management is responsible for the management commentary.

Our opinion on the financial statements does not cover the management commentary, and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the management commentary and, in doing so, consider whether the management commentary is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

Moreover, it is our responsibility to consider whether the management commentary provides the information required under the Danish Financial Statements Act.

Based on the work we have performed, we conclude that the management commentary is in accordance with the financial statements and has been prepared in accordance with the requirements of the Danish Financial Statements Act. We did not identify any material misstatement of the management commentary.

Copenhagen,

Deloitte
Statsautoriseret Revisionspartnerselskab
CVR No. 33963556

Jens Søjer Pedersen
State Authorised Public Accountant
Identification No (MNE) mne14986

Glossary

Business terms

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©)

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

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

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

Initiator Pharma

2022

FINANCIAL CALENDAR

Interim Q1 2023 report	5 May 2023
Annual General Meeting 2023	26 May 2023
Interim report 1st half 2023	25 August 2023
Interim Q3 2023 report	10 November 2023
Year-end report 2023 (Q4)	23 February 2024

CONTACT INFORMATION

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