Initiator Pharma

ANNUAL REPORT 2023

A clinical stage life science company developing **innovative drugs that target key unmet medical needs** within the central and peripheral nervous system.

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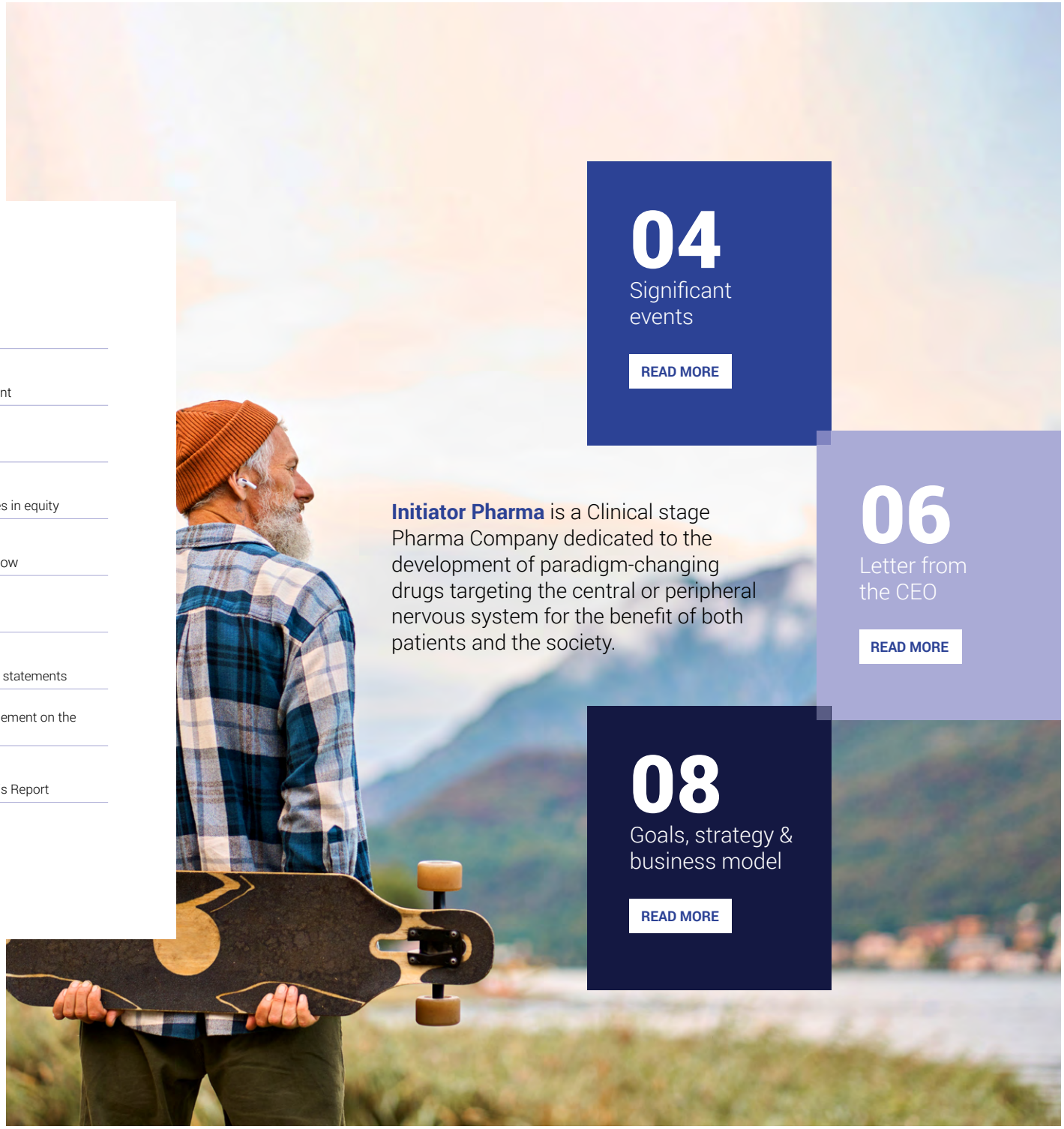
Table of contents



Initiator Pharma is a Clinical stage Pharma Company dedicated to the development of paradigm-changing drugs targeting the central or peripheral nervous system for the benefit of both patients and the society.

04 Significant events

READ MORE

06 Letter from the CEO

READ MORE

08 Goals, strategy & business model

READ MORE

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 that target key unmet medical needs within the central and peripheral nervous system.

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, 2023 we had approx 4,000 shareholders.

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

Pudafensine, 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. In the Fall 2023 we reported positive, statistically significant and clinically relevant efficacy results in a 130 patient Phase IIb trial with pudafensine in Erectile Dysfunction (ED) of organic origin. 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 in the Summer 2023 we reported positive, statistically significant, and dose-dependent clinical observations related to efficacy in psychogenic ED in a Phase IIa clinical trial in 24 patients with mild to moderate ED.

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

Significant events

Q1 2023

JAN FEB **MAR**

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

Q2 2023

APR **MAY JUN**

- **In May** the Company announced that WHO had selected the International Nonproprietary Name (INN) pudafensine as the official generic name for the company's patented candidate drug IP2015, which is in clinical development in erectile dysfunction and neuropathic pain.
- **In June** the Company announced positive, statistically significant, and dose-dependent clinical observations related to efficacy in psychogenic erectile dysfunction (ED) and no observations of serious or critical adverse events in the Phase IIa clinical trial of IP2018 in patients with mild to moderate ED.
- **In June** the Company announced the decision to carry out a capital increase directed at members of executive management and key management under the long term incentive program for 2022 ("LTI2022-program") and to conduct a buyback of shares in order to sell shares to the board of directors under the LTI2022-program.
- **In June** the Company announced that it had completed recruitment of all planned patients for its Phase IIb clinical trial with pudafensine (IP2015). Topline results are expected in Q4 2023.

Q3 2023

JUL AUG SEP

- **In July** the company announced that it has obtained positive data from a Phase I drug formulation and pharmacokinetics study in healthy subjects evaluating optimized oral solid dosage forms of pudafensine (IP2015), enabling a smooth and efficient bridging between previous data sets into new future clinical studies for pudafensine.
- **In August** the company announced that the European Patent Office ("EPO") has granted the company's patent application for the product candidate IP2018, targeting monoamine reuptake transporters.
- **In September** the company announced that the drug candidates, pudafensine and IP2018, have shown significant efficacy in preclinical models for Female Sexual Dysfunction (FSD). Based on the findings, the company is reviewing the potential to extend the clinical indications for the drug candidates to include FSD.

Q4 2023

OCT NOV DEC

- **In October** the company announced positive results from its Phase IIb clinical trial with pudafensine (IP2015) for the treatment of erectile dysfunction (ED). The study data analysis has demonstrated statistically significant and clinically relevant efficacy in ED-related endpoints and no observations of critical adverse events. The positive results, both regarding efficacy and safety, support further development of pudafensine aiming at registration and launch in this patient group with significant unmet medical need.

Q1 2024

JAN FEB MAR

- **In January** the company announced that it has expanded its position to a broader Sexual Health Franchise including both male Erectile Dysfunction (ED) and Female Sexual Dysfunction (FSD) indications and intensifies its business development efforts.
- **In January** the company announed the issuance of new shares and directed share buyback, as well as the sale of shares in connection with the long-term incentive program for 2021.
- **In February** the company announced that MAC Clinical Research has converted its convertible loan into shares in Initiator Pharma.

TABLE OF CONTENTS

Financial highlights and milestones

Key Figures

Income Statement, KDKK	2023	2022	2021
Operating loss	-27 029	-41 740	-23 072
Profit/loss before tax	-27 706	-44 132	-24 244
Profit/loss for the year	**-22 872**	**-38 455**	**-21 064**

Balance Sheet, KDKK	2023	2022	2021
Intangible assets	0	0	0
Deposits	17	17	0
Current receivables	5 433	9 216	19 355
Cash and cash equivalents	24 336	39 112	34 346
Total assets	**29 786**	**48 345**	**53 701**
Equity	11 162	34 023	34 994
Long-term liabilities	15 437	12 577	13 290
Current liabilities	3 187	1 745	5 417
Total equity and liabilities	**29 786**	**48 345**	**53 701**

Cash flow, KDKK	2023	2022	2021
Cash flow from operating activities	-17 647	-32 701	-34 097
Cash flow from investing activities	0	-17	0
Cash flow from financing activities	2 871	37 484	54 938
Cash flow for the year	**-14 776**	**4 766**	**20 841**

Key figures, %	2023	2022	2021
Liquidity ratio	160%	337%	287%
Equity ratio	37%	70%	65%

Share data, DKK	2023	2022	2021
Earnings per share before and after dilution	-0,44	-0,80	-0,35
Equity per share	0,21	0,65	0,80
Dividend	0	0	0
Cash flow per share	-0,28	0,09	0,48

Share data, #	2023	2022	2021
Shares outstanding	52 471 887	52 361 887	43 772 462
Warrants outstanding	4 779 007	4 585 667	4 392 863
Diluted shares outstanding	57 250 894	56 947 554	48 165 325
Weighted average number of shares	52 419 179	48 325 346	35 088 333

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

Milestones

Milestones achieved during 2023

- [x] Completed and reported positive data from the Phase 2a proof of concept trial with IP2018 in n=24 *psychogenic* Erectile Dysfunction patients.
- [x] Completed and reported positive data from the Phase 1 pharmacokinetic study with new oral solid dose formulations of IP2015.
- [x] Completed and reported positive data from the Phase 2b trial with IP2015 n=130 *organic* ED patients.
- [x] Prepared business development plans for both IP2015 and IP2018.

Upcoming milestones

- [ ] Conclude ongoing business development processes
- [ ] Resolve on clinical development plans for pudafensine and IP2018
- [ ] Advance sexual health franchise

TABLE OF CONTENTS

Letter from the CEO

2023 was a very busy and successful year for Initiator Pharma, where we achieved multiple important milestones across our development pipeline. All of our programs made significant progress, with the reported positive, statistically significant, and clinically relevant, efficacy Phase IIb data in erectile dysfunction (ED) with pudafensine as the standout achievement during year. The results highlight the potential of pudafensine as a novel treatment for patients who do not respond to or do not tolerate the currently marketed drugs.

Statistically significant and clinically relevant Phase IIb pudafensine efficacy data in organic ED reported in October

Our leading drug candidate is developed for patients with ED and pain indications. The aim of pudafensine within ED is to improve the quality of life for a large number of patients who do not respond to or cannot be treated with currently marketed drugs. There is a massive medical need for more effective treatments, with about 400 million men worldwide expected to be suffering from ED. Of these, 30-40 percent will not respond to the currently available treatments. It was therefore with great satisfaction that we in October reported positive study data from the Phase IIb clinical trial with pudafensine. This study demonstrated statistically significant and clinically relevant efficacy in ED-related endpoints with no observations of critical adverse events.

The primary objective of the Phase IIb study, which was completed in July 2023, was to investigate the effects of pudafensine and placebo in 130 male patients with moderate or severe erectile dysfunction on the ability to develop and maintain an erection. The unique study design allowed the patients with moderate to severe ED to observe the effect of pudafesnine in the home environment, and the evaluation of the sexual parameters of relevance for a future drug approval by the regulatory authorities. The clear efficacy results in moderate and severe ED provide support for pudafensine's further development towards market authorization.

Optimized solid dosage forms of pudafensine

Initiator is also developing a novel solid oral dosage form of pudafensine, which has been evaluated in a Phase I pharmacokinetic study in 12 healthy subjects. In the summer of 2023, we obtained positive data demonstrating that the oral solid dosing formulations provide relevant drug bioavailability and pharmacokinetic drug release profiles supporting the future treatment settings in Phase II and III trials. This optimized solid oral dosage form supports an attractive product profile for pudafensine and represents an important milestone in preparation for future pivotal registration trials.

Positive, dose-dependent, significant efficacy data in psychogenic ED reported for IP2018

The monoamine reuptake inhibitor IP2018 differs from our front-runner pudafensine as it, due to its unique profile, targets patients suffering from mild depression or low mood and ED. The goal is to position IP2018 as a treatment for patients suffering from depression and sexual dysfunction. It is estimated that up to 68% of patients with major depressive disorder also suffer from sexual dysfunction, for which only 5% to 30% is resolved with antidepressant treatment. With that in mind we were very pleased, in the summer of 2023, to announce positive, statistically significant, and dose-dependent clinical observations related to efficacy in our Phase IIa clinical trial with IP2018 in 24 mildly depressed or low mood, erectile dysfunction patients. This was the first time we treated patients with depression, mood disorder, and erectile dysfunction. During the year, we have also extended the IP protection for IP2018 in Europe, concerning the treatment of ED and depression, and thereby strengthened the exclusivity for our drug pipeline.

Sexual Health Franchise sets new direction

Based on promising preclinical data, where our drug candidates pudafensine and IP2018, have showed significant efficacy also in models for Female Sexual Dysfunction (FSD) we conducted a comprehensive strategic review of the FSD opportunity

"The broader sexual dysfunction effort will capture the FSD opportunity in a de-risked way and offers a great life cycle management opportunity with significant revenue and earnings potential."

during the fourth quarter. With the conclusions from the review, including a full commercial assessment, and the promising data obtained in the preclinical models, the management and board of directors decided to build on the strong data obtained from both our Phase II clinical studies with pudafensine and IP2018 and expand the position to a broader Sexual Health Franchise including both ED and FSD indications.

Female Sexual Dysfunction is a major opportunity

The broader sexual dysfunction effort will capture the FSD opportunity in a de-risked way and offers a great life cycle management opportunity with significant revenue and earnings potential. FSD includes a range of issues, such as hypoactive sexual desire disorder (HSDD, low libido), difficulty achieving arousal, pain during intercourse, and inability to reach orgasm. FSD can profoundly affect women's quality of life and relationships. There are medical treatment options for young women with FSD, but despite the current options, a large unmet need remains in restoring the desire for an intimate relationship with a partner. The commercial potential within the FSD area is considered very attractive. An analysis of the commercial assessment has concluded that a product for underserved women suffering from FSD/HSDD should have potential to reach peak sales of at least USD 2 billion. Initiator Pharma is initially exploring the opportunity with a priority on postmenopausal women with FSD, where there currently is no available treatment option. Both Pudafensine and IP2018 could offer the potential as first-line treatment options in the targeted market segments. Besides the apparent opportunity ahead within sexual dysfunction we maintain an interest in developing assets of relevance in severe neuropathic pain. We have previously executed a study in healthy volunteers with pudafensine, showing very encouraging data and supporting an effort within neuropathic pain. Our team has unique experience and skills which we are keen to harness and optimize in order to best capitalize on the possibilities in treating this underserved market segment with significant unmet medical needs and we expect to provide further details on this effort and the unique possibilities relating to a program in pain during 2024.

MAC Clinical Research new shareholder in Initiator Pharma

February 2024, we could welcome MAC Clinical Research (MAC) as a new shareholder in the company. The background is the convertible loan agreement that was an important part of the financing of the pudafensine clinical Phase IIb study, which was carried out by MAC. The agreement gave MAC the right to convert the credit into Initiator shares up to approximately 23 MSEK at a share price of 7.5 SEK, equivalent to a premium of more than 70 percent compared to the share price at the day of signing the agreement, upon the full completion of the pudafensine Phase IIb study. MAC is av very trusted and important partner for Initiator Pharma and Mark Dale, MAC's CEO, has expressed that MAC looks forward to being a part of Initiator Pharma's promising future journey in the years ahead. We are glad to have MAC aboard as a shareholder.

Intensified business development efforts and funding into 2025

To optimize shareholder value, and with the strong support from our existing shareholders seeing the great potential in our assets, the discussions and negotiations with potential partners are of highest priority during 2024. We presented our new direction at business and investor meetings in connection with the 42nd Annual J.P. Morgan Healthcare Conference in San Francisco. With our extended opportunity, together with recent statistically significant and clinically relevant data from two strong drug candidates, the interest from potential partners was considerable.

I am also pleased to confirm that with the current priorities set, we have enough funding well into 2025 and no significant need to invest further in pudafensine or IP2018 during 2024.

Thank you for following Initiator Pharma.

Copenhagen, April 27, 2024

Claus Elsborg Olesen | CEO

Goals, Strategy and Business model

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.

Our 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.

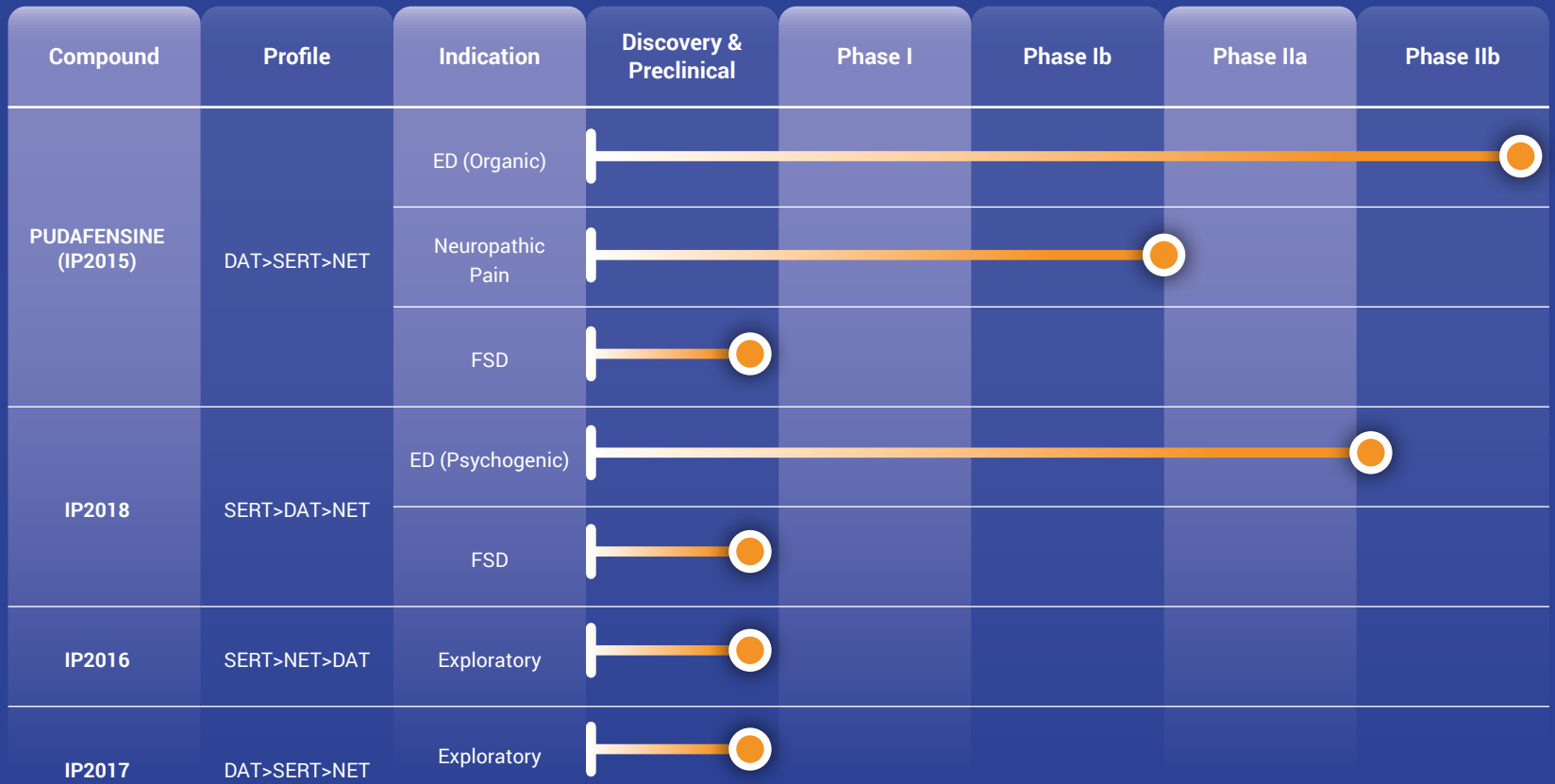
Initiator Pharma business model is to commercialize its research efforts through internal development of selected programs through the early phases of clinical drug development, before out-licensing to pharmaceutical companies who will take over the further development of Initiator Pharma's programs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

Initiator Pharma 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.

Initiator Pharma is employing a virtual organization model in order to maximize speed and flexibility while minimizing development costs. 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

In 2016 Initiator Pharma acquired three potential drug candidates from Saniona (pudafensine/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 the company exercised in March 2020:

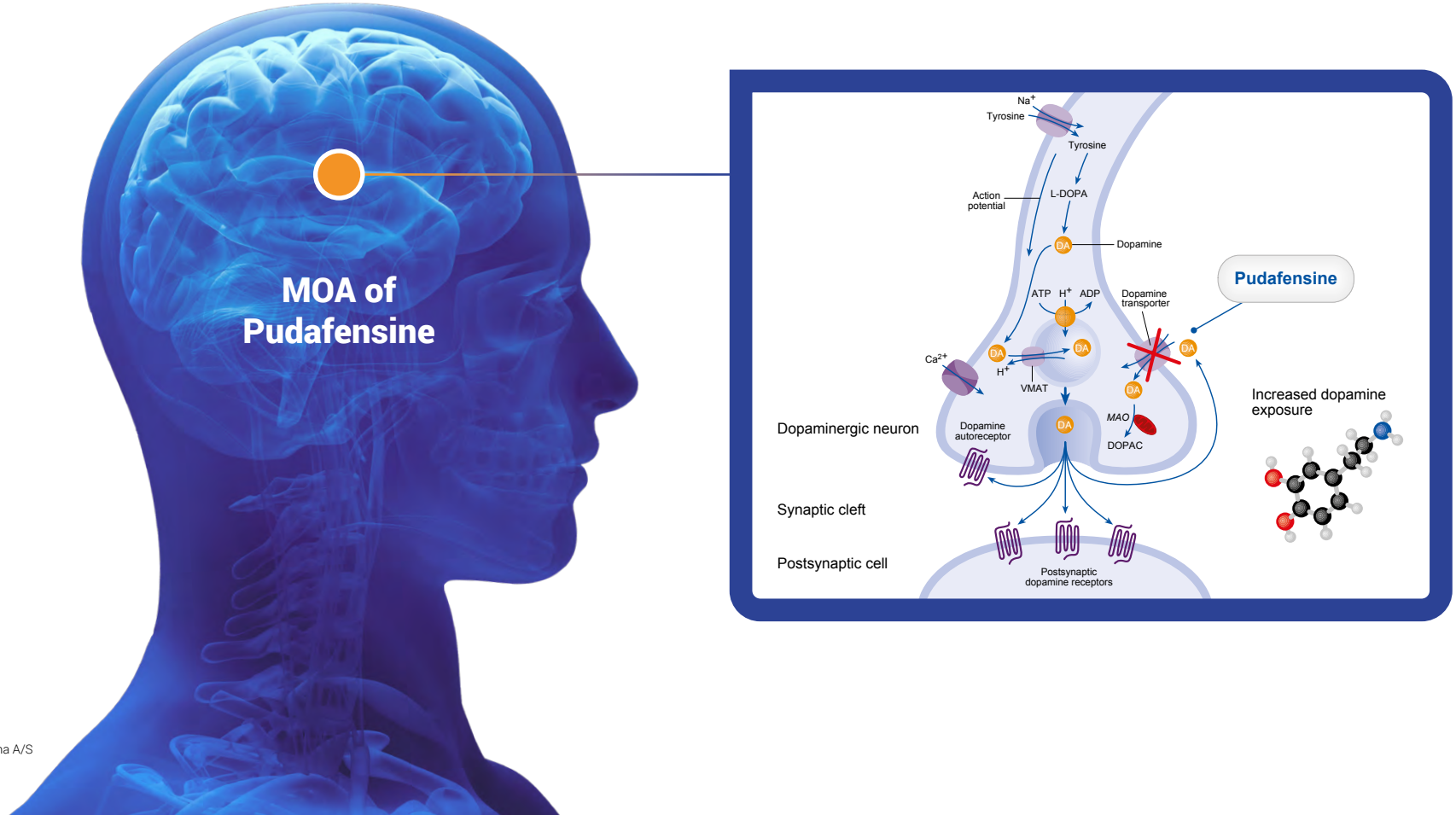


DAT: *Dopamin transporter* **SERT:** *Serotonin transporter* **NET:** *Norepinephrine transporter*

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 profile have very differentiated effects and physiological impact.



Ongoing projects

Pudafensine
(IP2015)

Pudafensine, Initiators's most advanced asset, is a monoamine reuptake inhibitor primarily targeting the dopamine system. Pudafensinve is being developed for both treatment resistant organic Erectile Dysfunction (ED) and neuropathic pain.

Organic Erectile Dysfunction (pudafensine)

Pudafensine is positioned as a novel drug candidate for the treatment of patients suffering from organic ED that do not respond to the currently marketed drugs in the PDE5i class (e.g. Viagra®, Cialis®, Levitra®). Pudafensine - 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 pudafensine 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 ED. 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 I study regarding safety and tolerability with pudafensine, and in March 2020, Initiator achieved successful Phase IIa results for pudafensine. The Phase IIa study was designed as an exploratory study and included twelve patients who had severe ED 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 pudafensine for the treatment of moderate and severe ED in patients who do not respond to current therapies.

On October 6 2023, Initiator reported statistically significant and clinically relevant efficacy in ED-related endpoints and no observations of critical adverse events from its Phase 2b clinical trial with pudafensine for the treatment of ED. The positive results, both regarding efficacy and safety, support further development of pudafensine aiming at registration and launch in this patient group with significant unmet medical need.

The Phase IIb trial was a randomized, double-blind, placebo-controlled, parallel-dosing group trial studying the efficacy and safety of high and low doses of pudafensine and placebo in otherwise healthy patients suffering from moderate to severe ED. The study comprised 130 patients divided into 3 parallel arms receiving a higher and a lower dose of pudafensine and placebo, respectively, with treatment duration of 4 weeks with frequent assessments of ED, safety and pharmacokinetics. The study was conducted at the MAC clinical sites in the UK.

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.

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 Initiator's 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 pudafensine and thereby generate substantial commercial value for Initiator Pharma.

Neuropathic pain/Trigeminal Neuralgia (IPTN2021)

On September 21st last year Initiator announced the final data from a clinical Phase I 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 pudafensine, pregabalin as active control, and placebo. Pudafensine demonstrated a statistically significant effect on allodynia (p=0.049) and showed a dose-dependent effect on the measured pain parameters. Pregabalin (p=0.083) and pudafensine (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 an open-labeled randomized Phase I drug formulation and pharmacokinetics (PK) study in 12 healthy subjects evaluating optimized oral solid dosage forms of pudafensine. The study was started in the beginning of 2023 and in July 2023 Initiator reported positive results, enabling a smooth and efficient bridging between previous data sets into new future clinical studies for pudafensine.

The pudafensine development plan aims for orphan drug designation 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.

Neuropathic pain/Trigeminal Neuralgia Market

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.[2,3]

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%[4]. On average annual healthcare cost for painful neuropathic disorder is US 17,355 per patient. With a solid efficacy and safety data on pudafensine 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. 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.

IP2018

IP2018 is a monoamine reuptake inhibitor for the treatment of psychogenic ED (mainly caused by anxiety and depression) mainly targeting the serotonin instead of the dopamine system. IP2018 is differentiated from the company's frontrunner pudafensine for organic ED (mainly caused by diabetes and age) that is primarily targeting the dopamine system:

- IP2018 is positioned to 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 the company's extensive package of preclinical data.
- IP2018 is efficacious in animal models of depression (forced swim and tail suspension tests) and ED (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 ED, which is a clear differentiation from other antidepressants on the market today. In the planned clinical Phase IIa trial, Initiator Pharma intends to primarily confirm the effect of IP2018 on the ED 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 ED in patients with medically induced sexual dysfunction.

In June 2023 Initiator announced positive, statistically significant, and dose-dependent clinical observations related to efficacy in psychogenic ED and no observations of serious or critical adverse events in the Phase IIa clinical trial of IP2018 in patients with mild to moderate ED.

The Phase IIa trial was a randomized, double-blind, placebo-controlled, 3-way crossover trial studying the efficacy and safety of a low and a high dose of IP2018 as well as a placebo in young, depressed patients who have ED. The primary objective of this study was to investigate the effects of IP2018 on penile rigidity and tumescence using a visual sexual stimulation test. Twenty-four patients with mild to moderate depression and ED completed the study. The high dose of IP2018 in single oral administration increased penile tumescence (p=0.04) and duration of rigidity (p=0.025) in a statistically significant way, sufficient for intercourse. The effect of IP2018 on ED was dose-dependent. The study demonstrated promising, clinically relevant efficacy data related to ED, supporting a new treatment paradigm for this patient segment. In addition, no safety observations of concern have been reported. Headache and gastrointestinal adverse events of mild character were the most common.

Depression Market

Psychogenic ED, which is the inability to achieve or maintain an erection during sexual intercourse due to psychological factors. Up to 68% of patients undergoing treatment for depressive disorder also suffer from sexual dysfunction. The patient segment thus represents a clear unmet medical need. IP2018 has the potential to help these patients and significantly increase their quality of life. In addition, IP2018 broadens the scope of Initiator Pharma pipeline, including first-in-class treatments for psychogenic and organic ED, IP2018 and pudafensine, respectively.

The main treatments for depression are drugs that selectively inhibit the uptake of serotonin (SSRIs) or serotonin and norepinephrine (SNRIs) or the breakdown of serotonin, norepinephrine and dopamine by inhibiting monoamine oxidase. Antidepressants such as SSRIs and SNRIs have a negative effect on male sexual function. Although the incidence of sexual dysfunction is lower with certain atypical antidepressants, such as bupropion, mirtazapine and vortioxetine, compared to SSRIs, it is nevertheless important to treat sexual dysfunction induced by antidepressant drugs (treatment-induced sexual dysfunction). In one study, it was observed that 41.7 percent of men discontinued psychiatric medication due to perceived sexual side effects.[5] Between 14 and 35 percent of young men have experience with ED, which may be due to performance anxiety, depression, schizophrenia, or other mental disorders.[6] About 13 percent of all Americans take antidepressant drugs, which means over 23 million prescriptions per year.[7] The global Anxiety Disorder and Depression Treatment Market is forecasted to grow at an annual rate of 2.4 percent from USD 15.8 billion in 2019 to USD 19.2 billion in 2027.[8] 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 ED to varying degrees, and this underlines the need to develop a better alternative.

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.

Female sexual dysfunction Program
(pudafensine and IP2018)

Female sexual dysfunction (FSD) includes a range of issues such as hypo-sexual desire disorder (low libido), difficulty achieving arousal, pain during intercourse, and inability to reach orgasm. Female hypo-sexual desire disorder (HSDD) in the US occurs in 10% of women, independent of age. FSD can profoundly affect the individual's quality of life and relationships due to the distress, low self-esteem, and anxiety it causes. There are medical treatment options for young women with FSD, but despite the current options, a large unmet need is to restore the desire for an intimate relationship with the partner. Initiator will investigate the potential for its products with a priority on postmenopausal women with FSD, where there currently is no available treatment option.

Pudafensine and IP2018 offer the potential as first-line treatment options in postmenopausal generalized, acquired HSDD – where it would be positioned as the first approved therapy. Both products offer the potential of clear differentiation from current FSD drugs, with the key differentiators:

- Non-hormonal mechanism of action
- Clean safety/tolerability, no drug interaction or contraindication issues (as shown in completed trials in men with ED)
- Convenient, oral, on-demand dosing
- Potentially improved efficacy to Addyi and Vyleesi (currently only approved for use in HSDD in premenopausal women)

During the last two years, Initiator has internally investigated its phase II drug candidates, pudafensine and IP2018, currently developed in two types of male ED, in preclinical models for FSD. Significant efficacy has been shown for both pudafensine and IP2018 in the animal models tested for FSD. The tested models are highly relevant and offer a way to predict efficacy in the clinical setting.

The commercial potential within the FSD area is considered to be very attractive. An analysis of the commercial assessment has concluded that a product for underserved women suffering from FSD/HSDD should have potential to reach peak sales of at least USD 2 billion. Initiator Pharma is initially exploring the opportunity with a priority on postmenopausal women with FSD, where there currently is no available treatment option.

Patent protection

Intellectual Assets of Initiator Pharma includes patents conferring proprietary chemistry protection for pudafensine (IP2015) and IP2018 in the USA; and in the USA, Israel, Japan, the United Kingdom, Germany, France, and Switzerland, respectively.

The pudafensine 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 ED in depressive patients (psychogenic ED) is pending in Australia, Brazil, Canada, China, Europe, Japan, Mexico, Singapore, South Korea and the USA; and has been granted in Europe, Israel and 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.

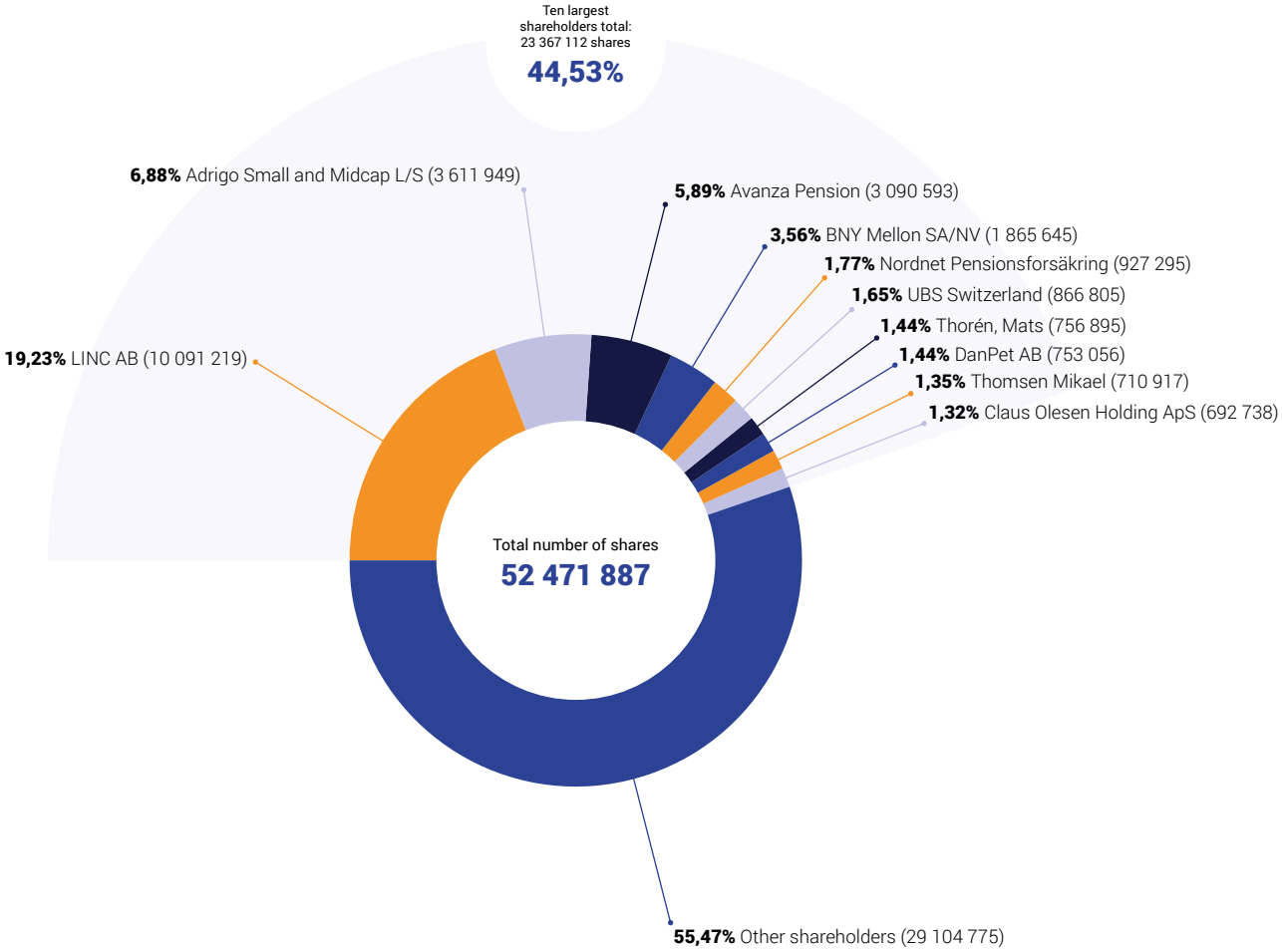
The Initiator Pharma share

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, 2023, the number of shares outstanding totalled to 52,471,887 shares. The company has as of December 31 a total of 2,054,722 outstanding incentive warrants, representing 3,9 % 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 9.24, up 49% for the year. The market capitalization of the company on December 31 was approx SEK 485 million. During 2023 the average daily trading volume was 49,072 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, 2023 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	1 882	274 101	0,52%
501 - 1,000	437	334 668	0,64%
1,001 - 5,000	922	2 232 659	4,25%
5,001 - 10,000	275	1 995 209	3,80%
10,001 - 15,000	121	1 492 204	2,84%
15,001 - 20,000	63	1 103 938	2,10%
20,001 -	278	44 966 129	85,70%
Total	**3 978**	**52 471 887**	**100,00%**

Shareholders by geography

Shareholders by country	Number of shareholders	Number of shares	Share of votes
Sweden	3 299	40 483 433	77,15%
Nordics, excl Sweden	624	6 804 939	12,97%
Europe, excl Nordics	39	4 477 992	8,53%
USA	6	437 253	0,83%
Other	10	195 291	0,37%
Total	**3 978**	**52 471 887**	**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 (publ), corporate identity number 37663808, hereby present the Annual Report for the calendar year 2023.

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 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 2023

Result

As a development Company Initiator Pharma generated no revenues in the financial year 2023, unchanged from 2022. The company recognized an operating loss of KDKK 27,029 for the full year 2023, compared to KDKK 41,740 for 2022.

The decrease in operating costs for the full year compared to the same period last year reflects the completion of both he Phase 2b trial with IP2015 in organic Erectile Dysfunction, and the Phase 2a trial with IP2018 in psychogenic Erectile Dysfunction during 2023.

External R&D costs in 2023 amounted to TDKK 15,296 compared to 26,342 in 2022. 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 2023 were TDKK 677, compared to net financial expenses of TDKK 2,392 in the same period in 2022. The reduction in net financial expenses for 2023 is mainly related to high negative foreign currency effects in 2022.

Financial position

The equity as of December 31, was TDKK 11,162 compared to TDKK 34,023 at year-end 2022. Cash and cash equivalents amounted to KDKK 24,336 as of December 31 compared to KDKK 39,112 at year-end 2022, and total assets were KDKK 29,786 (48,345).

Cash flow

The operating cash flow for the financial year 2023 was TDKK -17,647 (-32,071), incl a decrease in working capital of TDKK 4,559 (-8,787). Cash flow from investment activities was TDKK 0 (-17) and cash flow from financing activities was TDKK 2,872 (37,484) for the full year.

Share capital

At December 31, 2023, the number of shares outstanding totalled to 52,471,887 shares and on a fully diluted basis 57,250,894, incl. both incentive warrants and potential dilution by the convertible credit agreement with MAC.

On June 21st the Company announced the issuance of 110,000 new shares in connection with the long-term incentive program LTI2022. The new shares were subscribed for by executive management and key employees and consultants at a price of DKK 0.105 per share.

On September 25th the company announced that a total of 131.500 shares had been bought in the market by board members, management and key employees under the LTI2023 program. Under this program the warrant holders may be entitled to subscribe for or purchase from the company a total of 789.000 shares at par value, representing a potential dilution of 1.5%.

On December 31, 2023 the warrant program LTI2021 approved by the AGM in 2021 ended. Based on the share price performance (the "Performance Target") between the AGM and year-end 2023 the warrant holders were entitled to subscribe for Performance shares at a nominal value of DKK 0,105 per share. Based on the calculated Performance Target 4.12 Performance Shares per Investment Shares (82% of maximum), totalling 618 223 Performance Shares.

Own shares

During 2023 the company acquired a total of 19.500 own shares in the market (0.04% of issued shares), at an average share price of SEK 7,24. The shares were acquired as part of the LTI2022 incentive program, under which the members of the board had the right to acquire a total of 19.500 shares ("Matching Shares") from the company at a share price equal to the nominal value of DKK 0,105 per share. The subsequent sale of the own shares to the board members incurred a loss of DKKT 87 in 2023. As of year-end the company holds no own shares.

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 IPTN2022. 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.

Political 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 3 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.

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 2023. 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 2023, 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 2023 approved a policy for remunerating the CEO and other senior executives. For more information on remuneration in the year, see note 1 and the Remuneration Report for 2023.

The Board of directors and Auditor

Gunnar Magnus Severus Modee Persson

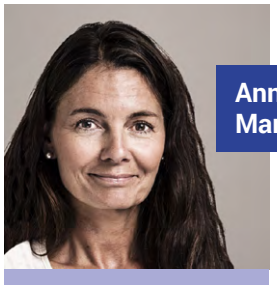
Chairman of the board since 2016

Born: 1960

Background: Magnus is medical doctor and PhD from the Karolinska Institute in Sweden and co-founder of the now publicly traded Aerocrine. He has been working as a clinical doctor and early in his career he was in charge of several clinical trial programs for Sanofi that resulted in blockbuster drugs. Magnus has a long history in the pharmaceutical industry and has built up investment funds both in Sweden and abroad with a focus on medical projects – particularly as Partner at HealthCap in Sweden from inception and later as Managing Partner in San Francisco based The Column Group. In these capacities Magnus helped found and develop many successful biotech companies.

Holdings in the company*: 267 186

Warrants: 101 715



Annette Ingegerd Marie Colin

Member of the Board of Directors since 2021

Born: 1965

Background: Annette has more than 30 years' experience from different functions within finance and management in executive positions as CEO, Group CFO, COO, Group Financial Controller and Tax Manager, including 20 years in Life Science. Annette has been part of fast-growing companies and organizations and has long experience in building strategic plans, building teams, streamlining infrastructure M&A, IPO and funding experience. She worked with both Venture Capital and Private Equity owners, however the majority in publicly listed companies. Most recent assignments include Boule Diagnostics AB (publ), Biotage AB (publ), Annexin Pharmaceuticals AB (publ) Observe Medical International (publ), Stille AB (publ), Lindab International AB (publ), Perbio Science AB (publ) and EY. Annette has her own consultant/advisory company since 2008. Besides from that she also has board assignments in Sozap AB (publ), ProstaLund AB (publ), NorrDia AB and Colinex Capital AB. Annette has education in Business Administration, from Lund University, Sweden.

Holdings in the company*: 25 000

Warrants: 73 850

Henrik Kristian Moltke

Member of the Board of Directors since 2016

Born: 1958

Background: Henrik has more than 25 years of experience as CFO and Senior Vice President within Life sciences and Health care. The primary focus in his career has been in Venture financing, IPO as well as follow on capital increases in the public market, Investor Relations and communication, finance and project management, Strategic development and business development with companies like Scandinavian Micro Biodevices ApS, Astion Pharma A/S, NeuroSearch A/S, Novo A/S, and Ferrosan A/S. Henrik has also a broad experience from several listed and unlisted companies as member of the Board. Today Henrik is Chairman of the board for "Werner Richter og Hustrus Legat" a charity foundation and is board member of Hartmanns A/S and chairman of the board of Valeos Pharma A/S. Henrik holds a master degree in International economics and strategic management from Copenhagen Business School, Denmark.

Holdings in the company*: 139 106

Warrants: 93 850

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

Ylva Gunilla Ekström

Member of the Board of Directors since 2022

Born: 1958

Background: Gunilla is medical doctor, PhD and associate professor from the Karolinska Institutet in Sweden and co-founder of Gesynta Pharma AB. Gunilla started her professional career in the pharma industry as scientist within drug metabolism. Later on, she moved on to project work and established cross functional, high-performance teams, responsible for a portfolio of projects for global development within analgesia, bringing compounds from discovery up to clinical phase 2. The role involved long term strategic plans, budgets, evaluation of in licensing opportunities and due diligence. As a member of an executive management team of a public company, she was involved in financing, prioritization of the portfolio, personnel and worked close to the board. Gunilla have experience from the entire R&D value chain (discovery to NDA) and from small, mid-sized and large pharma companies. She has held positions as CEO of virtual companies and is currently board member in Corline Biomedical AB, Emplicure AB, Disruptive Pharma AB and Strike Pharma AB in addition to Initiator Pharma.

Holdings in the company*: 19 000

Warrants: 65 000

Claus Elsborg Olesen

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

Born: 1974

Background: Claus earned his PhD in Physiology and Biophysics from Aarhus University in 2008 and has been engaged in both basic and applied research with an emphasis on structural biology and function of membrane proteins ever since. Furthermore, Dr. Olesen has been in involved in numerous drug development projects in both academic and industrial collaborations with both soluble and membrane protein targets. He is the author of a number of articles including two first authorship articles in Science and Nature. He is the co-founder of Pcovery ApS (2009) an antifungal Biotech situated in Copenhagen and NMD Pharma (2015) a biotech company focused on the development of new treatments for neuromuscular disorders. He is the coordinator of the Business Research Manager program at the faculty of Health at Aarhus University aimed at establishing more collaboration between the research at the university and pharmaceutical industry. He is former professional sailor having competed in the Americas Cup for Sweden in 2003 and participating in two Olympics representing Denmark (2004 & 2012)

Holdings in the company*: 1 137 438

Warrants: 602 289

Peter Joakim Holm

Member of the Board of Directors since 2016

Born: 1974

Background: Peter has a PhD in biochemistry from the Karolinska in Stockholm, and a Master's degree in chemistry from the University of Linköping. Holm is a partner and European Patent Attorney at the Patent & Trademark Office Høiberg. Holm has extensive experience in strategic global IPR and commercialization advisory services to companies and organizations in the life science sector.

Holdings in the company: 0

Warrants: 0

Auditor
Deloitte Statsautoriseret Revisionspartnerselskab

Auditor in charge: Claus Jorch Andersen
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

Member of the Board of Directors and CEO since 2016. Co-founder of the company

Born: 1974

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

Holdings in the company*: 1 137 438

Warrants: 602 289

TORGEIR VAAGE

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

Born: 1964

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

Holdings in the company*: 371 948

Warrants: 347 537

ULF SIMONSEN

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

Born: 1963

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.

Holdings in the company*: 652 802

Warrants: 223 215

MIKAEL THOMSEN

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

Born: 1968

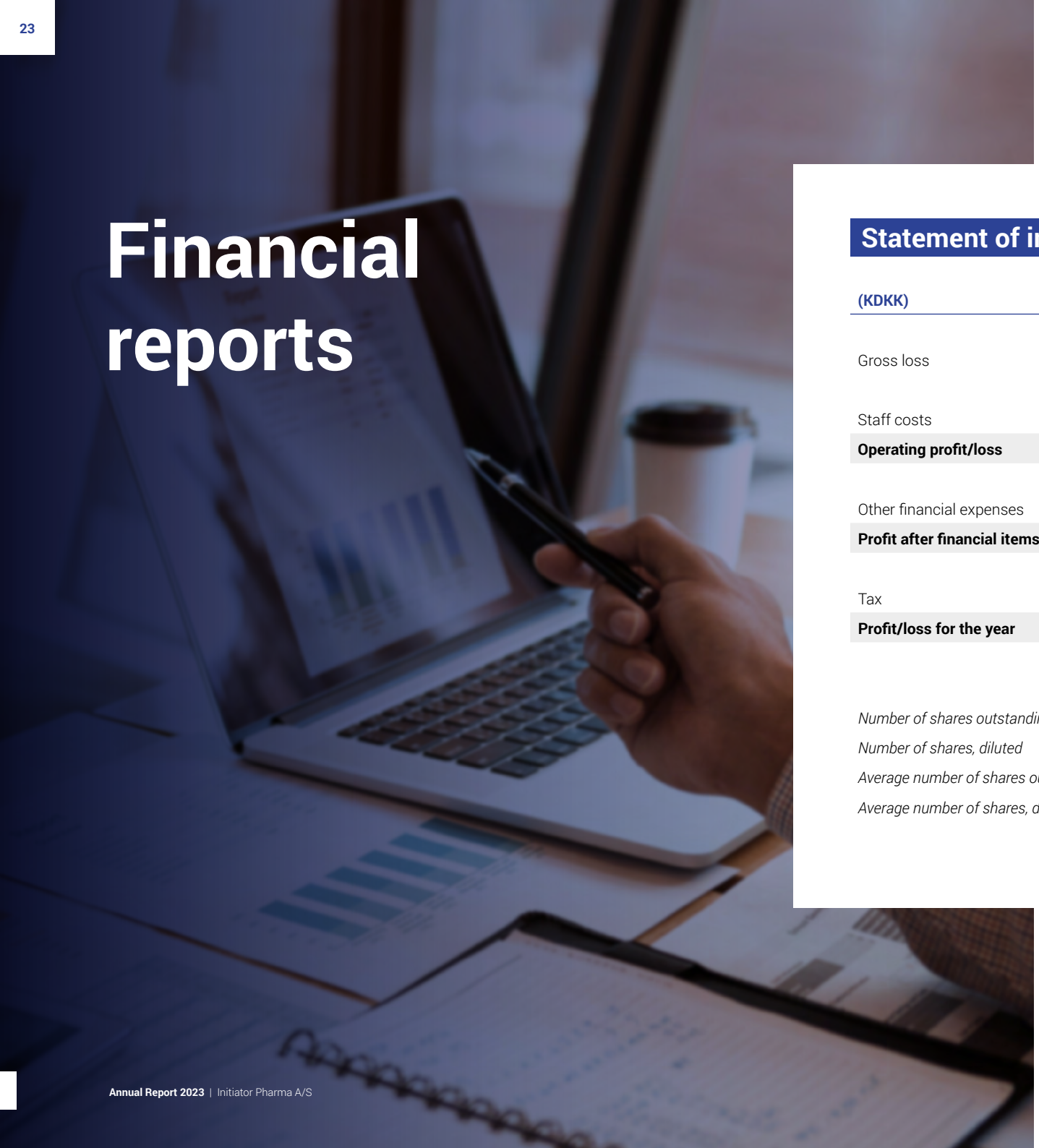
Education: Ph.D. in Pharmacology and Toxicology (University of Copenhagen) and two M. Sc. degrees in Pharmacy and Human Biology (from University of Pharmaceutical Sciences, Copenhagen and University of Copenhagen, Medical Faculty).

Holdings in the company*: 753 056

Warrants: 347 537

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

TABLE OF CONTENTS



Financial reports

Statement of income

(KDKK)	Notes	2023	2022
Gross loss		-23 413	-38 425
Staff costs	1	-3 617	-3 315
Operating profit/loss		**-27 030**	**-41 740**
Other financial expenses		-677	-2 392
Profit after financial items		**-27 707**	**-44 132**
Tax	2	4 834	5 677
Profit/loss for the year		**-22 873**	**-38 455**
Number of shares outstanding		52 471 887	52 361 887
Number of shares, diluted		57 250 894	56 947 554
Average number of shares outstanding		52 419 179	48 325 346
Average number of shares, diluted		57 269 804	53 225 959

Balance Sheet

ASSETS

(KDKK)	Notes	2023	2022
Patents, acquired rights		-	-
Intangible assets	3	**-**	**-**
Deposits		17	17
Financial assets		**17**	**17**
Fixed assets		**17**	**17**
Other receivables		599	1 706
Income Tax receivable		4 834	5 500
Prepayments	4	-	2 010
Current receivables		**5 433**	**9 216**
Cash and cash equivalents	5	**24 336**	**39 112**
Current assets		**29 769**	**48 328**
Assets		**29 786**	**48 345**

EQUITY AND LIABILITIES

(KDKK)	Notes	2023	2022
Contributed capital	6	5 510	5 498
Retained earnings		5 652	28 525
Equity		**11 162**	**34 023**
Convertible credit agreement	7	15 437	12 577
Long-term liabilities		**15 437**	**12 577**
Trade payables		407	801
Other payables		246	944
Accrued expenses	8	2 534	-
Current liabilities other than provisions		**3 187**	**1 745**
Liabilities other than provisions		**18 624**	**14 322**
Equity and liabilities		**29 786**	**48 345**

Statement of changes in equity

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 changes in equity for 2023

(KDKK)	Contributed capital	Retained earnings	Total
January 1, 2023	**5 498**	**28 525**	**34 023**
Increase of capital	12	-	12
Costs in connection with increase of capital	-	-	-
Profit/loss for the year	-	-22 873	-22 873
December 31, 2023	**5 510**	**5 652**	**11 162**

Statement of cash flow

(KDKK)	Notes	2023	2022
Profit/loss before tax		-27,707	-44 132
Adjustment for non-cash transactions		-	-536
Profit/loss before tax, adj for non-cash transactions		**-27 707**	**-44 668**
Tax paid/received		5 500	3 180
Cash flow before change in working capital		**-22 207**	**-41 488**
Changes in working capital	9	4 559	8 787
Cash flow from operating activities		**-17 648**	**-32 701**
Investing activities		-	-17
Cash flow from investing activities		**-**	**-17**
Financing activities			
New share issue		12	37 484
Issue of warrants		-	-
Credit agreement with MAC		2 860	-
Cash flow from financing activities		**2 871**	**37 484**
Cash flow for the reporting period		**-14 776**	**4 766**
Cash and cash equivalents at the beginning of period		39 112	34 346
Cash and cash equivalents at the end of period		**24 336**	**39 112**

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 effected 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.

Other financial income

Other financial income comprises interest income 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 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.

Receivables

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

Tax payable or receivable

Current tax payable or receivable is recognised in the balance sheet, stated as tax computed on this year's taxable income, adjusted for prepaid tax.

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

	2023 (DKK)	2022 (DKK)
Wages and salaries	3,196,305	3,047,047
Pensions	400,000	225,000
Other social security costs	16,919	16,687
Other staff costs	3,796	26,760
Total staff	**3,617,020**	**3,315,494**
Average number of full-time employees	2	3

	Remuneration of management 2023 (DKK)	Remuneration of management 2022 (DKK)
Total amount for management categories	1,710,809	1,574 ,421
	1,710,809	**1,574,421**

NOTE 2 - Tax on profit/loss for the year

	2023 (DKK)	2022 (DKK)
Current tax	4,834,000	5,500,000
Adjustment concerning previous years	0	177,000
	4,834,000	**5,677,000**

NOTE 3 - 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	0
Amortisation and impairment losses end of year	**112,000**
Carrying amount end of year	**0**

NOTE 4 - Prepayments

During 2023 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 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.

During 2023 the recognized prepayments as of December 31, 2022 were reversed based on the applied cost model, and on December 31, 2023 the recognized amount as prepayments was TDKK 0 (TDKK 2,010). Based on the cost model, the company has made accruals for un-invoiced costs, see Note 9 below.

NOTE 5 - Cash

Total cash funds amounts to TDKK 24,336, of which TDKK 200 is pledged as security for the guarantee provided by the Company's bank.

NOTE 6 - Share capital

	Number	Nominal value (DKK)
Shares	52,471,887	5,509,548
Total	**52,471,887**	**5,509,548**

The Company has three established warrant programs, approved by the AGM in 2021, in 2022 and in 2023 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 outstanding as of December 31, 2023 have a ceiling of 2,054,722 warrants representing 3.9% of outstanding shares:

Year approved	Number of warrants	Subscription price	Pct of issued shares	Exercise price	Exercise deadline	Performance baseline[1]
AGM 2021	618 222	-	1.2%	DKK 0.105	Jan 31, 2024	SEK 4.98
AGM 2022	647 500	-	1.2%	DKK 0.105	Jan 31, 2025	SEK 7.27
AGM 2023	789 000	-	1.5%	DKK 0.105	Jan 31, 2026	SEK 7.28
Total	**2 054 722**		**3.9%**			

1. Performance baseline = volume weighted average share price in the 30 day period following the respective AGM date.

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 ("Performance Target") in the period between May 28, 2021 and December 31, 2023. The maximum potential dilution under the program is 750,000 shares, representing approx. 1.2% of currently issued number of shares.

The Performance Target is measured based on the volume weighted average share price 30 trading days immediately following the annual general meeting on 28 May 2021 (SEK 4.98) and 30 trading days immediately preceding 31 December 2023 (SEK 9.26). An increase in the share price with less than 20 per cent does not entitle to any vesting of any of the Performance Shares, an increase in the share price with 20 per cent entitles to vesting of 1 Performance Share per Investment Share and an increase in the share price with 100 per cent or more entitles to vesting of all the 5 Performance Shares per Investment Share. In the event of an increase in the share price of between 20 and 100 per cent, vesting of the

Performance Shares will occur linearly between 1 and 5. Based on the Performance Target, a total of 618,222 Performance Shares vested on Dec 31, 2024 (82% of the maximum number).

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"). After the AGM 2023 held on May 26, 2023 the participants in LTI2022 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, 2024, depending on the development of Initiator's share price ("Performance Target") in the period between May 24, 2022 and December 31, 2024. The maximum potential dilution under the program is 777,000 shares, representing approx. 1.2% of currently issued number of shares.

The AGM2023 Program ("LTI2023"):
Under this program the participants in the program have acquired 131,500 ordinary shares in the market at market price ("Investment Shares") in the period between May 26, 2023 and September 30, 2023, 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, 2025, depending on the development of Initiator's share price ("Performance Target") in the period between May 26, 2023 and December 31, 2025. 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 7 - 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, 2023 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, 2023 a total of KDKK 15,437 has been accrued under the convertible credit agreement, representing a potential dilution of approx. 3.1 million shares or 5,8% of number of issued shares on December 31, 2023.

NOTE 8 - Accrued expenses

During 2023 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 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, 2023 the company has TDKK 1,070 in accrued expenses, related to the expensing of the clinical studies in addition to accruals for other operating costs.

NOTE 9 - Change in working capital

	2023 (DKK)	2022 (DKK)
Increase/decrease in receivables	2,260,000	13,030,000
Increase/decrease in trade payables etc	2,299,000	4,243,000
	4,559,000	**8,787,000**

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 01/01/2023 - 12/31/2023.

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 12/31/2023 and of the results of its operations and cash flows for the fiscal year 01/01/2023 - 12/31/2023.

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

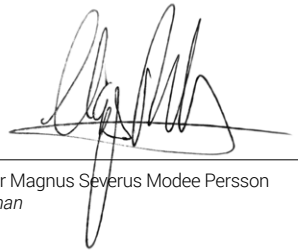
We recommend that the Annual Report with its accompanying financial statements be adopted at the Annual General Meeting.

Copenhagen, 04-26-2024

Executive Board

Claus Elsborg Olesen

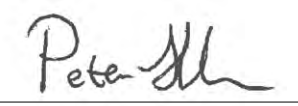
Board of Directors



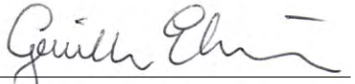
Gunnar Magnus Severus Modee Persson
Chairman

Henrik Kristian Moltke

Annette Ingegerd Marie Colin



Peter Joakim Holm



Ylva Gunilla Ekström

Claus Elsborg 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 01.01.2023 - 31.12.2023, 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 31.12.2023 and of the results of its operations and cash flows for the financial year 01.01.2023 - 31.12.2023 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 by relevant law and regulations.

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 in the relevant law and regulations. We did not identify any material misstatement of the management commentary.

Copenhagen, 04-26-2024

Deloitte
Statsautoriseret Revisionspartnerselskab CVR No. 33963556

Claus Jorch Andersen
State Authorised Public Accountant Identification No (MNE) mne33712

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.

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

Initiator Pharma

FINANCIAL CALENDAR

Interim Q1 2024 report	10 May 2024
Annual General Meeting 2024	24 May 2024
Interim Q2 2024 report	23 August 2024
Interim Q3 2024 report	15 November 2024
Year-end report 2024 (Q4)	28 February 2025

CONTACT INFORMATION

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