



# 2024

## ANNUAL REPORT

Initiator Pharma A/S CVR No. 37663808

**Initiator** Pharma

**Address:** Ole Maaloes vej 3, 2200 Copenhagen, Denmark

Initiator Pharma  
developing innovative  
drugs that target key  
unmet medical needs  
within the central  
and peripheral  
nervous system

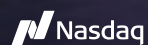
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The Initiator Pharma shares are listed on Nasdaq First North Growth Market (INIT), and as of Dec 31, 2024 the company had approx. 3,700 shareholders.

### Initiator Pharma A/S

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# Initiator Pharma

Initiator Pharma’s vision is to become a leading emerging pharma company developing novel therapeutics within the field of mono-amine reuptake transporters targeting CNS-disorders with significant unmet medical needs.

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

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

Initiator Pharma is a pharmaceutical company based in Copenhagen, Denmark. The shares are listed on Nasdaq First North Growth Market (INIT), and as of Dec 31, 2024 we had approx 3,700 shareholders.



### PROJECT PUDAFENSINE

Pudafensine, our most advanced asset, is a monoamine reuptake inhibitor primarily targeting the dopamine system. Pudafensine is being developed for both treatment resistant *organic* **Erectile Dysfunction (ED)** 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 I proof of principle study that assessed pain-reducing effects in healthy male subjects challenged with the pain-inducing ingredient (capsaicin).

### PROJECT 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 was in-licensed 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.





## Significant events

# 2024

Q1 JAN FEB MAR

- **In January** the company announced that the company will expand to a broader Sexual Health Franchise including both male Erectile Dysfunction (ED) and Female Sexual Dysfunction (FSD) indications
- **In January** 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 2021 ("LTI2021-program") and to conduct a directed buyback of shares in order to sell shares to the board of directors under the LTI2021-program
- **In February** the company announced the decision to carry out a capital increase directed at MAC Clinical Research Finance Ltd ("MAC") in connection with MAC's conversion notice regarding conversion of outstanding receivable on February 20th

Q2 APR MAY JUN

- **In April** the company announced the publication of pudafensine preclinical pharmacology results in the British Journal of Pharmacology

Q3 JUL AUG SEP

- **In July** the company announced the publication of the international patent application regarding pudafensine's dosage regime for the treatment of erectile dysfunction

Q4 OCT NOV DEC

- **In October** the Company completed the capital increase of 108,500 shares directed to members of executive management and key management under the LTI2023 incentive program, as well as the share-buy back of 23,000 treasury shares and subsequent re-sale of those shares to board members under the same incentive program

### Significant events after the end of the period

- None.

# Financial highlights and milestones

## Key Figures

Income Statement, TDKK	2024	2023	2022
Operating profit/loss	-14,502	-27,029	-41,740
Profit/loss before tax	-14,836	-27,706	-44,132
<b>Profit/loss for the year</b>	<b>-12,932</b>	<b>-22,872</b>	<b>-38,455</b>
<b>Balance Sheet, TDKK</b>	<b>2024</b>	<b>2023</b>	<b>2022</b>
<b>Fixed assets</b>	<b>17</b>	<b>17</b>	<b>17</b>
Current receivables	2,447	5,433	9,216
Cash and cash equivalents	13,371	24,336	39,112
<b>Total assets</b>	<b>15,835</b>	<b>29,786</b>	<b>48,345</b>
Equity	14,782	11,162	34,023
Long-term liabilities	0	15,437	12,577
Current liabilities	1,053	18,624	14,322
<b>Total equity and liabilities</b>	<b>15,835</b>	<b>29,786</b>	<b>48,345</b>
<b>Cash flow, TDKK</b>	<b>2024</b>	<b>2023</b>	<b>2022</b>
Cash flow from operating activities	-12,080	-17,647	-32,701
<b>Cash flow for the year</b>	<b>-10,965</b>	<b>-14,776</b>	<b>4,766</b>

Key figures, %	2024	2023	2022
Liquidity ratio	1,502%	160%	337%
Equity ratio	93%	37%	70%
<b>Share data, DKK</b>	<b>2024</b>	<b>2023</b>	<b>2022</b>
Diluted earnings per share	-0,23	-0,44	-0,80
Equity per share	0,26	0,21	0,65
Dividend	0	0	0
Cash flow per share	-0,20	-0,28	0,09
<b>Share data, #</b>	<b>2024</b>	<b>2023</b>	<b>2022</b>
Shares outstanding	56,158,361	52,471,887	52,361,887
Diluted shares outstanding	56,815,861	57,250,894	56,947,554
Weighted average number of shares	55,624,734	52,419,179	48,325,346

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

## Milestones

### Milestones achieved during 2024

- ☒ Initiated multiple business development processes.
- ☒ Resolved on clinical clinical development plans for pudafensine and IP2018.
- ☒ Advance sexual health franchise.

### Upcoming milestones

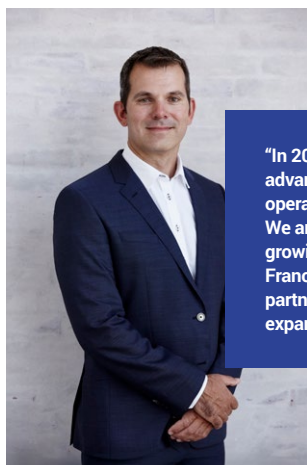
- ☐ Seal strategic business development deals.
- ☐ Lock in clinical roadmaps for Pudafensine and IP2018.
- ☐ Drive momentum in the women's health franchise.

# Letter from the CEO

**I am pleased to reflect on our progress throughout 2024 — a year defined by our continued focus on value creation, disciplined operational execution, and strategic growth.**

Over the past year, we have accelerated our efforts in business development to form valuable strategic partnerships, building on our core programs in erectile dysfunction (ED), while also expanding into new therapeutic areas including pain and female sexual dysfunction (FSD).

In February, we were proud to welcome MAC Clinical Research as a new shareholder. Their deep engagement and support have been instrumental in driving our clinical development forward. This partnership also reinforces the growing recognition and validation of our innovative pipeline.



**“In 2025, we remain committed to advancing our clinical programs while operating with financial discipline. We are encouraged by the strong and growing interest in our Sexual Health Franchise and are actively exploring partnerships to support our growth and expand our global reach.”**

Our lead candidate drug pudafensine took a significant step forward in April with the publication of preclinical pharmacology data in the prestigious British Journal of Pharmacology. These findings validated its novel mechanism of action and bolstered our belief in its potential to serve patients who do not respond to or tolerate currently marketed ED treatments.

We also strengthened our intellectual property position for our leading drug candidate pudafensine in the treatment of ED with the publication of our international patent application (WO2024/146892) covering a novel dosage regimen for ED. This provides protection through 2044, with potential for further extension, forming a robust foundation as we evaluate pudafensine both as a monotherapy and in combination with current standard-of-care therapies.

In early 2024, we announced the expansion of our portfolio to encompass a broader Sexual Health Franchise, including both male ED and female sexual dysfunction indications. Our lead candidates have demonstrated promising efficacy in preclinical FSD models, and the commercial outlook is highly compelling. A market analysis conducted by Global Life Sciences (UK) suggests that a treatment for underserved women with FSD/HSDD (Hypoactive sexual desire disorder) could reach peak sales of up to USD 2 billion.

Looking ahead to 2025, we are evaluating additional FSD-related indications with strong market potential. Notably, many women with sexual dysfunction also experience pain, such as vulvodynia — a chronic condition that significantly impacts quality of life. In a prior randomized, double-blind, placebo-controlled study, pudafensine showed positive effects on pain, echoing results from preclinical studies and further supporting its promise as a unique and superior FSD treatment.

ED remains our core focus. Pudafensine, our leading candidate, targets a condition that affects millions of men worldwide. The strong efficacy data for pudafensine in organic ED is complemented by IP2018, which has shown positive, statistically significant,

and dose-dependent clinical observations related to efficacy in psychogenic ED. Our mission is to deliver an effective, well-tolerated therapy that addresses an unmet need. Notably, our participation in key industry events has confirmed strong interest from potential partners and global stakeholders, particularly in our differentiated approach across both ED and FSD.

We also see compelling potential for pudafensine in combination therapies with PDE5 inhibitors. Our preclinical data reveal an additive effect, presenting an opportunity to support patients with suboptimal response to current PDE5i treatments and to develop a premium product differentiated from generics.

We continue to prioritize patients with moderate to severe ED and have made important strides in clinical development. As we refine our Phase III study plans, we draw confidence from our prior Phase IIb trial, which demonstrated both statistically and clinically significant results. The upcoming Phase III program will further assess long-term benefits and durability of response, supporting future regulatory submissions.

In 2025, we remain committed to advancing our clinical programs while operating with financial discipline. We are encouraged by the strong and growing interest in our Sexual Health Franchise and are actively exploring partnerships to support our growth and expand our global reach.

In closing, I want to express my sincere gratitude to our shareholders and stakeholders for their continued support. Together, we are driving forward innovation and shaping the future of care in sexual health and beyond.

Warm regards,

**Claus Elsborg Olesen**  
Chief Executive Officer

# Goals, Strategy & Business model



## 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

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.



## Business model

The company 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.

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.

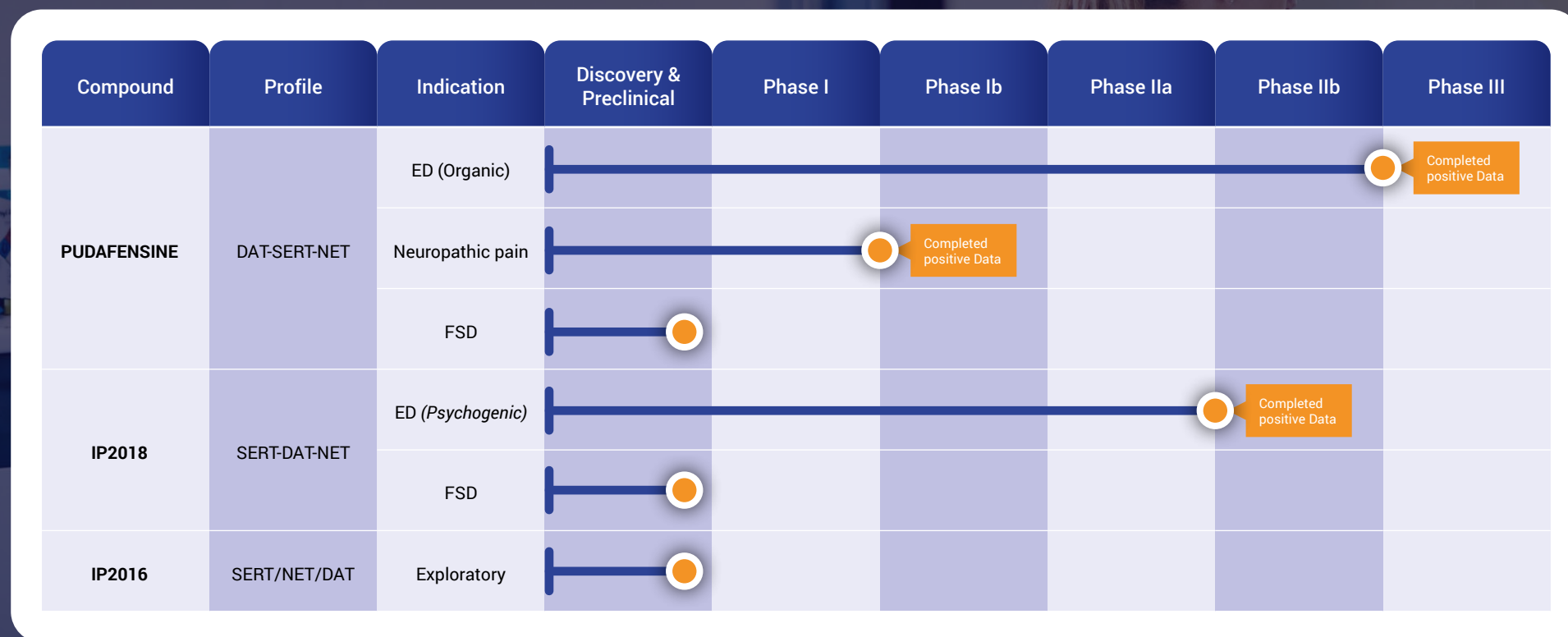
Initiator Pharma is employing a virtual organization model in order to maximize speed and flexibility while minimizing development costs. The bulk of the drug development and the regulatory work will be outsourced via contracts with Contract Research Organizations (CROs).

Initiator Pharma is continuously seeking discussions with potential pharma partners with the aim of entering partnerships for the company's development assets at the optimal timepoint, balancing development risks, costs and shareholder value.



# 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. In 2024 the Company decided to terminate the IP2017 program for commercial reasons. The company's current development pipeline:



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

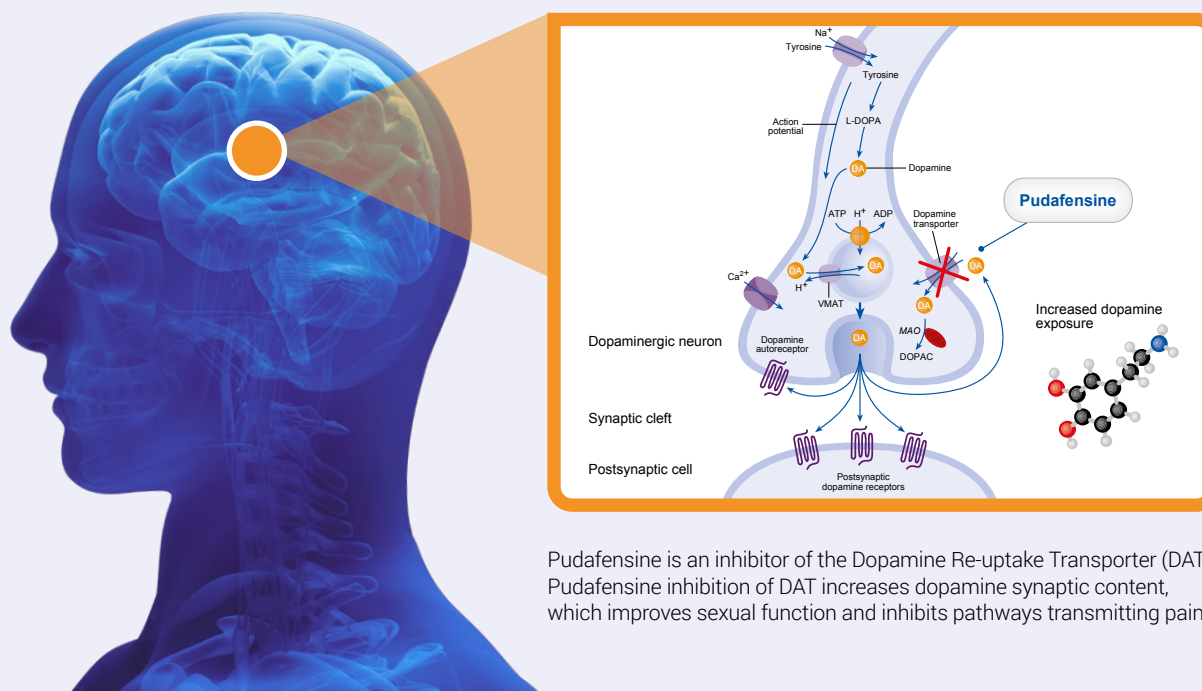


## All three drug candidates belong to the drug class known as monoamine reuptake inhibitors (MRIs).

Molecules in this class act as 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.

### MOA of Pudafensine



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

## Ongoing projects

### PROJECT Pudafensine

**Pudafensine, Initiator's most advanced asset, is a monoamine reuptake inhibitor primarily targeting the dopamine system. Pudafensine 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<sup>1</sup>.

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.

#### Erectile Dysfunction (ED) Market

The current number of ED patients is estimated to around 300 million. About 30-40% of these patients will not respond to the current treatment and represent a significant unmet medical need. This is exactly Initiator's primary target group and will clearly distinguish us from the PDE5i drugs, where patent expiry results in increasing price pressure from generics. In 2015 the ED market generated about 4 USD billion in sales, prior to patent expiry, 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.

<sup>1</sup>.Alberson M, Orabi H, Lue T. Evaluation and treatment of erectile dysfunction in the aging male: a mini-review. Gerontology. 2012;58:3-14.



## 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.<sup>2,3</sup>

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%<sup>4</sup>. 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>.





## PROJECT 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.





Up to 68% of patients undergoing treatment for depressive disorder also suffer from sexual dysfunction.

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.<sup>5</sup> 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.<sup>6</sup> About 13 percent of all Americans take antidepressant drugs, which means over 23 million prescriptions per year.<sup>7</sup> The global Anxiety Disorder and Depression Treatment Market is forecasted to grow at an annual rate of 2.4 percent from USD 15.8 billion in 2019 to USD 19.2 billion in 2027.<sup>8</sup> 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., Kosci, 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>.



## PROJECT

### 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

### Pudafensine

Intellectual Assets of Initiator Pharma includes patents conferring proprietary chemistry protection for pudafensine (IP2015) in the USA until 2031. In addition to the pudafensine (IP2015) composition of matter patent outlined above, protection for the use of pudafensine for the treatment of Female Sexual Dysfunction (FSD) has entered national phase in Australia, Brazil, Canada, China, Europe, Israel, Japan, Mexico, Singapore, South Africa, South Korea, Taiwan, and the USA and are all pending. When granted, this patent family can be kept in force until 2043.

Further protection for use of pudafensine is conferred by a specified dosage regime of pudafensine, for the treatment of all types of pain which has recently entered national phase and is pending in Australia, Brazil, Canada, China, Europe, Israel, Japan, Mexico, Singapore, South Africa, South Korea, Taiwan, and the USA and are all pending. When granted, this patent family can be kept in force until 2043.

Additional protection for use of pudafensine is conferred by a specified dosage regime of pudafensine, for the treatment of erectile dysfunction, via a pending PCT application published on 11 July 2024 as WO 2024/146892. The European Patent Office acting as International Searching Authority has acknowledged novelty of all the claims. The PCT application will enter national phase in relevant major markets in Q3/2025. When granted, this patent family can be kept in force until 2044.

On 26 December 2024 two PCT applications from Initiator Pharma were published as WO 2024/261019 and WO 2024/261026 covering an extended release formulation and an immediate release formulation respectively. The EPO has acknowledged patentability of both these patent families which provides possibility for extended composition of matter

protection for pudafensine in clinically and commercially relevant formulations until 2044. These two patent families are due for national phase in December 2025.

### IP2018

Intellectual Assets of Initiator Pharma further includes patents conferring proprietary chemistry protection for IP2018 in USA, Israel, Japan, the United Kingdom, Germany, France, and Switzerland. These IP2018 patents expire later in 2025, (2026 in the US due to patent term adjustment).

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 (divisional), South Korea and the USA; and has been granted in Europe (parent), Hong Kong (based on European grant), Israel, Japan, Mexico, Singapore and South Africa. The patent family can be kept in force until 2040.

On 13 March 2025, a PCT application directed to IP2018 for treatment of Female Sexual Dysfunction (FSD) was published as WO2025/051846.

### IP2016

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.

Subject to Market Authorization prior to expiry of a patent, extension by up to five years are available in key territories. As outlined above, Initiator Pharma is actively pursuing a vigorous patent strategy to capture value of developments in its clinical and preclinical programs, by filing new patent applications when possible.

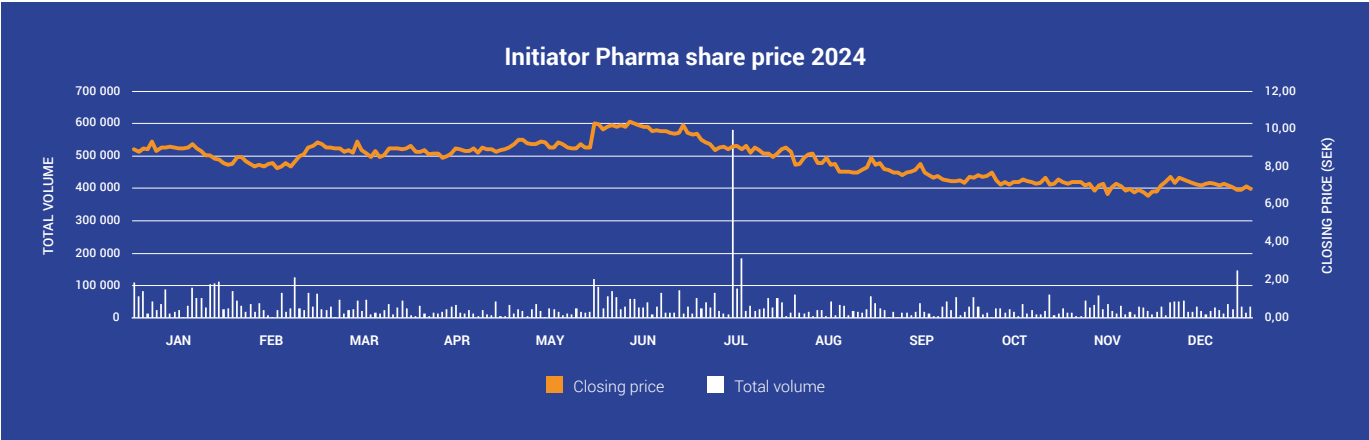
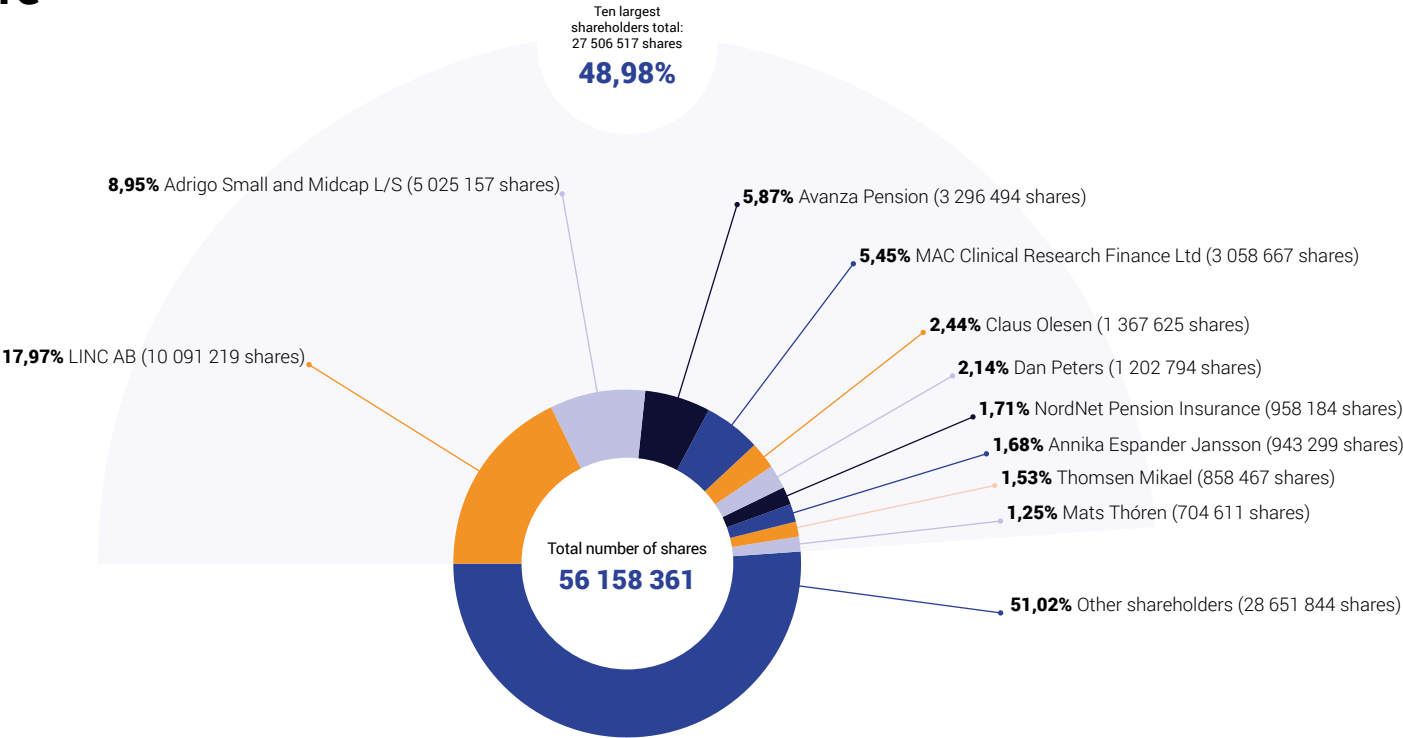
# The Initiator Pharma share

## 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, 2024, the number of shares outstanding totalled to 56,158,361 shares. The company has as of December 31 a total of 657,500 outstanding incentive warrants, representing 1.2% of the number of issued shares.

The closing share price on December 31 was SEK 6.85, down 26% for the year. The market capitalization of the company on December 31 was approx SEK 385 million. During 2024 the average daily trading volume was 35,113 shares, and for the full year the traded volume was 8.8 million shares or 16% of the issued shares at year-end.

At December 31, 2024 the company had around 3,700 shareholders, with the 10 largest shareholders representing 49% of all outstanding shares.





# 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 2024.

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 2024

### Result

As a development Company Initiator Pharma generated no revenues in the financial year 2024, unchanged from 2023. The company recognized an operating loss of TDKK 14,502 for the full year 2024, compared to TDKK 27,029 for 2023.

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

External R&D costs in 2024 amounted to TDKK 1,778 compared to 15,296 in 2023. 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.

### Financial position

The equity as of December 31, was TDKK 14,782 compared to TDKK 11,162 at year-end 2023. Cash and cash equivalents amounted to TDKK 13,371 as of December 31 compared to TDKK 24,336 at year-end 2023, and total assets were TDKK 15,835 (29,786).

### Cash flow

The operating cash flow for the financial year 2024 was TDKK -12,080 (-17,647), incl a decrease in working capital of TDKK 2,078 (4,559). Cash flow from investment activities was TDKK 0 (0) and cash flow from financing activities was TDKK 1,115 (2,871) for the full year.

### Share capital

At December 31, 2024, the number of shares outstanding totalled to 56,158,361 shares and on a fully diluted basis 56,815,861, incl. incentive warrants.

On January 23rd the company issued 519,307 shares to management and key employees under the LTI2021 program at a price per share of DKK 0.105. Under the LTI2021 program management and key employees were entitled to subscribe for up to a maximum of 630,000 at a share price of DKK 0.105 per share, with the actual number depending on the performance of the Initiator Pharma share price between June 2021 and December 2023 ("Performance Shares"). Based on the actual share price performance in this period the number of Performance Shares to management and employees was calculated to 519,307 shares (82% of the maximum number), which were fully subscribed for.

On February 21st the company issued 3,058,667 shares to MAC Clinical Research through the conversion of the MAC receivable of TDKK 17,404. The conversion was conducted at the pre-agreed share price of SEK 7.50 per share.

On November 4th the company issued 108,500 shares to management and key employees under the LTI2023 program at a price per share of DKK 0.105 ("Matching Shares").

At the end of 2024 the LTI2022 program expired. Under this program the management and board could subscribe for up to 647,500 shares ("Performance shares"), depending on the share price performance in the period from the AGM 2022 to December 2024. The share price during December was below the share price threshold for triggering the right to subscribe for Performance Shares under this program. Consequently the number of outstanding warrants under the current incentive programs in the company was reduced from 1,305,000 to 657,500 as of year-end (see Note 6 for further details on the incentive programs in the company).

### Own shares

During 2024 the company acquired a total of 121.915 own shares in the market (0.2% of issued shares), at an average share price of SEK 8,62. The shares were acquired as part of the LTI2021 and LTI2023 incentive programs. The subsequent sale of the own shares to the board members incurred a loss of DKK 677 in 2024. 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 relies on a number of key suppliers to support its development activities. 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 individuals, 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 and from the translation of balance sheet items in foreign currency, as well as upon the translation of foreign subsidiaries' income statements and balance sheets to the Company's reporting currency, which is DKK.

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 2024. 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 2024, the number of employees was 2 of which 1 woman and 1 man. Of these employees, 1 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.

#### Events after the balance sheet date

No events have occurred after the balance sheet date to this date, which would influence the evaluation of this annual report.

# The Board of directors and Auditor



**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\*:** 316 401

**Warrants:** 40 000

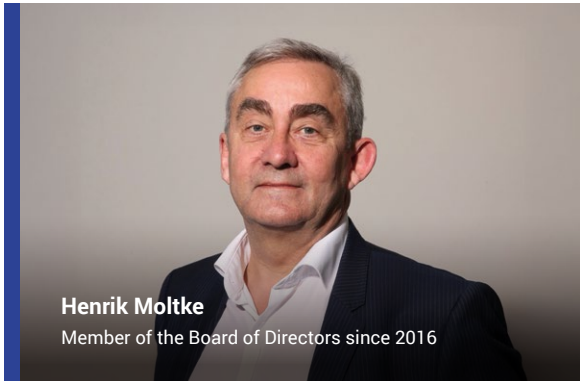


**Born:** 1965

**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 assignment in Colindex Capital AB. Annette has education in Business Administration, from Lund University, Sweden.

**Holdings in the company\*:** 37 654

**Warrants:** 25 000



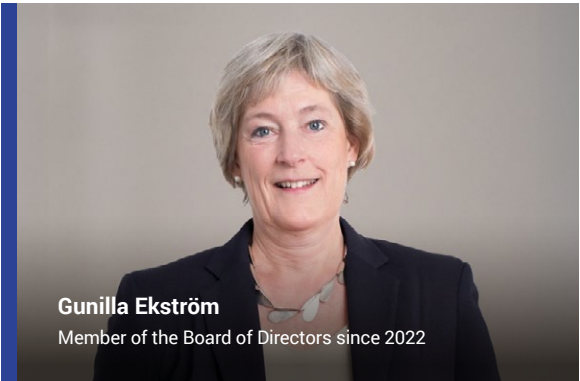
**Born:** 1958

**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 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\*:** 172 956

**Warrants:** 25 000



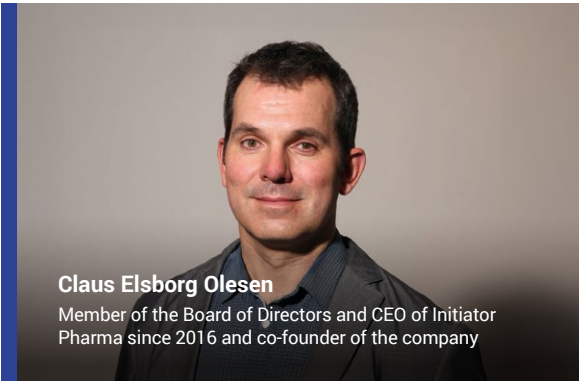


**Born:** 1958

**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, MyCural AB, Disruptive Pharma AB and Strike Pharma AB in addition to Initiator Pharma.

**Holdings in the company\*:** 24 000

**Warrants:** 25 000

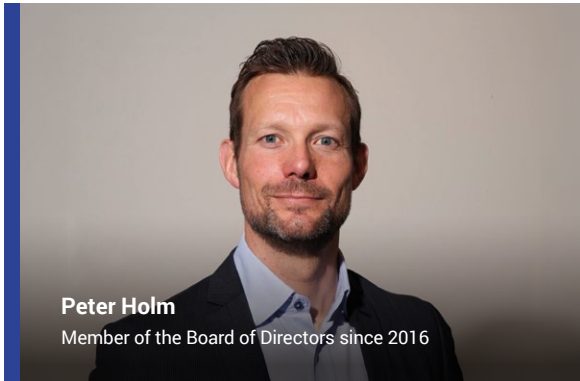


**Born:** 1974

**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\*:** 1 367 625

**Warrants:** 150 000



**Born:** 1974

**Background:** Peter has a PhD in biochemistry from Karolinska Institutet in Stockholm, and a Master's degree in chemistry from the University of Linköping. Holm is a partner, country manager Sweden and European Patent Attorney at the IP law firm HØIBERG. Holm has extensive experience in strategic IP counselling and commercialization organizations in the greater life science sector.

**Holdings in the company:** 0

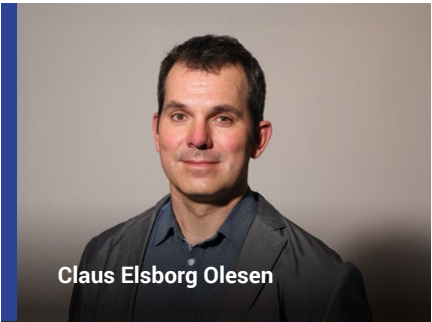
**Warrants:** 0

**Auditor**  
Deloitte Statsautoriseret Revisionspartnerselskab

Auditor in charge: Claus Jorch Andersen  
Address: Deloitte Statsautoriseret Revisionspartnerselskab, Weidekampsgade 6, 2300 Copenhagen S, Denmark



# Management



Claus Elsborg 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\*:** 1 367 625

**Warrants:** 150 000



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\*:** 477 395

**Warrants:** 110 000



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\*:** 708 166

**Warrants:** 110 000



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\*:** 858 503

**Warrants:** 110 000

# Financial information

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## Financial reports

### Statement of income

(TDKK)	Notes	2024	2023
Gross loss		-11,073	-23,413
Staff costs	1	-3,427	-3,617
<b>Operating profit/loss</b>		<b>-14,502</b>	<b>-27,030</b>
Other financial income	2	499	1,737
Other financial expenses	2	-832	-2,414
<b>Profit after financial items</b>		<b>-14,836</b>	<b>-27,707</b>
Tax	3	1,904	4,834
<b>Profit/loss for the year</b>		<b>-12,932</b>	<b>-22,873</b>
Distribution of profit/loss to retained earnings		-12,932	-22,873
<i>Number of shares outstanding</i>		56,158,361	52,471,887
<i>Number of shares, diluted</i>		56,815,861	57,250,894
<i>Average number of shares outstanding</i>		55,624,734	52,419,179
<i>Average number of shares, diluted</i>		57,267,470	57,269,804

## Balance Sheet

### ASSETS

(TDKK)	Notes	2024	2023
Patents, acquired rights		-	-
<b>Intangible assets</b>	4	-	-
Deposits		17	17
<b>Financial assets</b>		<b>17</b>	<b>17</b>
<b>Fixed assets</b>		<b>17</b>	<b>17</b>
Other receivables		543	599
Income Tax receivable		1,904	4,834
<b>Current receivables</b>		<b>2,447</b>	<b>5,433</b>
<b>Cash and cash equivalents</b>	5	<b>13,371</b>	<b>24,336</b>
<b>Current assets</b>		<b>15,818</b>	<b>29,769</b>
<b>Assets</b>		<b>15,835</b>	<b>29,786</b>

### EQUITY AND LIABILITIES

(TDKK)	Notes	2024	2023
Contributed capital	6	5,897	5,510
Retained earnings		8,885	5,652
<b>Equity</b>		<b>14,782</b>	<b>11,162</b>
Convertible credit agreement	7	0	15,437
<b>Long-term liabilities</b>		<b>0</b>	<b>15,437</b>
Trade payables		366	407
Other payables		202	246
Accrued expenses		485	2,534
<b>Current liabilities other than provisions</b>		<b>1,053</b>	<b>3,187</b>
<b>Liabilities other than provisions</b>		<b>1,053</b>	<b>18,624</b>
<b>Equity and liabilities</b>		<b>15,835</b>	<b>29,786</b>
Contingent asset	9		



## Statement of changes in equity

### Statement of changes in equity for 2023

(TDKK)	Contributed capital	Retained earnings	Total
<b>January 1, 2023</b>	<b>5,498</b>	<b>28,525</b>	<b>34,023</b>
Increase of capital	12	-	12
Profit/loss for the year	-	-22,873	-22,873
<b>December 31, 2023</b>	<b>5,510</b>	<b>5,652</b>	<b>11,162</b>

### Statement of changes in equity for 2024

(TDKK)	Contributed capital	Retained earnings	Total
<b>January 1, 2024</b>	<b>5,510</b>	<b>5,652</b>	<b>11,162</b>
Increase of capital	387	17,083	17,470
Costs in connection with increase of capital	-	-241	-241
Purchase of treasury shares	-	-690	-690
Sale of treasury shares	-	13	13
Profit/loss for the year	-	-12,932	-12,932
<b>December 31, 2024</b>	<b>5,896</b>	<b>8,886</b>	<b>14,782</b>

## Statement of cash flow

(TDKK)	Notes	2024	2023
<b>Cash flow from operations</b>			
Operating profit/loss		-14,502	-27,029
Corporate tax income received		4,834	5,500
<b>Cash flow from operations before change in working capital</b>		<b>-9,668</b>	<b>-21,529</b>
Interest received		499	1,737
Interest paid		-832	-2,414
Changes in working capital	8	-2,078	4,559
<b>Cash flow from operations</b>		<b>-12,079</b>	<b>-17,647</b>
Investing activities		0	0
<b>Cash flow from investing activities</b>		<b>0</b>	<b>0</b>
<b>Financing activities</b>			
Purchase of treasury shares		-690	0
Sale of treasury shares		13	0
New share issue		1,792	11
Credit agreement with MAC		0	2,860
<b>Cash flow from financing activities</b>		<b>1,115</b>	<b>2,871</b>
<b>Cash flow for the reporting period</b>		<b>-10,964</b>	<b>-14,776</b>
Cash and cash equivalents at the beginning of period		24,336	39,112
Cash and cash equivalents at the end of period		13,371	24,336

# 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 denominated 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 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 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.

According to the tax credit scheme the company has the opportunity to apply for a pay-out of an amount corresponding to the company tax (22 %) of the company's qualifying research and development costs, against a reduction of the remaining unused taxable losses.

## 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.

Corporate tax receivable recognized in the balance sheet relates to the application of the tax credit scheme under § 8X of the Tax Assessment Act, whereby the company can obtain the tax value of tax losses resulting from costs to Research and development.

Based on the examination of the criteria for the application of the scheme, management considers that the company is entitled to apply the scheme and the recognition has been based on this assessment. However, whether the criteria for applying the scheme are met are based on a discretionary assessment. As a result, there may be a risk that the tax authorities will judge that the criteria have not been met. If so, the receivable will have to be fully or partially reversed from the profit and loss account in subsequent financial years.

## 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

	2024 (TDKK)	2023 (TDKK)
Wages and salaries	2,995	3,196
Pensions	420	400
Other social security costs	12	17
Other staff costs	2	4
<b>Total staff</b>	<b>3,429</b>	<b>3,617</b>
Average number of full-time employees	2	2

	Remuneration of management 2024 (TDKK)	Remuneration of management 2023 (TDKK)
Total amount for management categories	1,745	1,711
	<b>1,745</b>	<b>1,711</b>

## NOTE 2 - Other financial items

	2024 (TDKK)	2023 (TDKK)
Interest income	285	206
Currency gain	214	1,531
<b>Other financial income</b>	<b>499</b>	<b>1,737</b>
Interest expense	-2	-88
Currency expense	-830	-2,326
<b>Other financial expenses</b>	<b>-832</b>	<b>-2,414</b>

## NOTE 3 - Tax on profit/loss for the year

	2024 (TDKK)	2023 (TDKK)
Current tax	(1,904)	(4,834)
	<b>(1,904)</b>	<b>(4,834)</b>

## NOTE 4 - Intangible assets

	Acquired rights (TDKK)
Cost beginning of year	112
<b>Cost end of year</b>	<b>112</b>
Amortisation and impairment losses beginning of year	(112)
Amortisation for the year	(0)
<b>Amortisation and impairment losses end of year</b>	<b>(112)</b>
Carrying amount end of year	0

## NOTE 5 - Cash

Total cash funds amounts to TDKK 13,371, of which TDKK 197 is pledged as security for the guarantee provided by the Company's bank.



**NOTE 6 - Share capital**

	Number	Nominal value (DKK)
Shares	56,158,361	5,896,628
<b>Total</b>	<b>56,158,361</b>	<b>5,896,628</b>

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, 2024 have a ceiling of 657,500 warrants representing 1.2% of outstanding shares:

Year approved	Number of warrants	Subscription price	Pct of issued shares	Exercise price	Exercise deadline	Performance baseline <sup>1</sup>
AGM 2022	-	-	-	DKK 0.105	Jan 31, 2025	SEK 7.27
AGM 2023	657 500	-	1.2%	DKK 0.105	Jan 31, 2026	SEK 7.28
<b>Total</b>	<b>657 500</b>		<b>1.2%</b>			

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

**The AGM2022 Program (“LT12022”):**

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 (“Performance Target”) in the period between May 24, 2022 and December 31, 2024. The maximum potential dilution under the program was 777,000 shares.

After the AGM 2023 held on May 26, 2023 the participants in LT12022 exercised their rights to acquire 129,500 shares, the full number of Matching Shares.

On December 31, 2024 the LT12022 program expired, with no vested Performance shares. The number of Performance shares was determined by the share price performance between 2022 and 2024, measured based on the volume weighted average share price 30 trading days immediately following the annual general meeting on 24 May 2022 (SEK 7.27) and 30 trading days immediately preceding 31 December 2024 (SEK 6.98). 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 0 Performance Shares vested on Dec 31, 2024 (0% of the maximum number).

As of December 31, 2024 there are no additional warrants remaining under the LT12022 program.

**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 was 789,000 shares.

After the AGM 2024 held on May 24, 2024 the participants in LTI2023 exercised their rights to acquire 131,500 shares, the full number of Matching Shares.

The remaining potential dilution under this program as of December 31, 2024 is 657,500, representing 1.2% of the issued shares in the company.

The warrant programs are subject to vesting conditions.

**NOTE 7 - Convertible and dividend-yielding debt instruments**

In 2021 the Company 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 gave 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.

In February 2024 the company announced that MAC had decided to convert the credit into Initiator shares, and as a consequence the company issued 3,058,667 shares at a debt conversion price of DKK 5.7 per share.

Following this conversion of debt into shares the credit arrangement with MAC has ended.

<b>NOTE 8 - Change in working capital</b>	<b>2024 (TDKK)</b>	<b>2023 (TDKK)</b>
Increase/decrease in receivables	56	2,260
Increase/decrease in trade payables etc	2,134	2,299
	<b>2,078</b>	<b>4,559</b>

**NOTE 9 - Contingent assets**

The company possesses a deferred tax asset valued at 15 million Danish Kroner (mDKK), which is related to tax loss carried forward. Due to recent assessments and projections, it has been determined that the company will not be able to utilise these tax losses in the foreseeable future. Consequently, the tax asset has been written down to reflect the reduced likelihood of its realisation.

# 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 01/01/2024 - 12/31/2024.

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 12/31/2024 and of the results of its operations and cash flows for the fiscal year 01/01/2024 - 12/31/2024.

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, 04-28-2025

## Executive Board



Claus Elsborg Olesen

## Board of Directors



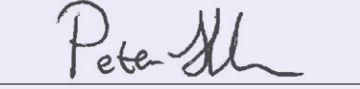
Gunnar Magnus Severus Modee Persson  
*Chairman*



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 01.01.2024 - 31.12.2024, 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 31.12.2024 and of the results of its operations and cash flows for the financial year 01.01.2024 - 31.12.2024 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, 28.04.2025

### **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

### Female Sexual Dysfunction

Female sexual dysfunction (FSD) includes a range of issues such as hypoactive sexual desire disorder (low libido), difficulty achieving arousal, pain during intercourse, and inability to reach orgasm.

### Hypoactive sexual desire disorder

Hypoactive Sexual Desire Disorder (HSDD) is the most common Female Sexual Dysfunction (FSD) affecting adult women of any age, including postmenopausal women. HSDD may have significant effects on the relationships and emotional balance of women and constitutes the most common form of FSD observed in clinical practice.

### 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

## FINANCIAL CALENDAR

Interim Q1 2025 report	9 May 2025
Annual General Meeting 2025	23 May 2025
Interim Q2 2025 report	22 August 2025
Interim Q3 2025 report	21 November 2025
Year-end report 2025 (Q4)	20 February 2026

## CONTACT INFORMATION

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