

**Initiator** Pharma

# **BUSINESS HIGHLIGHTS**

#### Business highlights in October-December 2024

• 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

#### Business highlights after this reporting period

Nothing to report

#### **Financial Highlights**

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

KDKK	Q4-2024	Q4-2023	FY-2024	FY-2023
Net sales	-	-	-	-
Total operating expenses	-2 701	-4 279	-14 502	-27 029
Operating profit/loss	-2 701	-4 279	-14 502	-27 029
Net result	-851	1 429	-12 932	-22 872
Earnings per share before and after dilution (DKK)	-0.02	0.03	-0.23	-0.44
Cash flow from operating activities	1 503	2 290	-12 080	-17 647
KDKK	Q4-2024	Q4-2023	31.12.2024	31.12.2023
Cash and cash equivalents	13 371	24 336	13 371	24 336
Equity	14 782	11 162	14 782	11 162
Total equity and liabilities	15 292	29 786	15 292	29 786
Equity ratio, %	97%	37%	97%	37%
Number of shares outstanding	56 158 361	52 471 887	56 158 361	52 471 887
Number of shares outstanding Number of shares, diluted	56 158 361 56 815 861	52 471 887 57 250 894	56 158 361 56 815 861	52 471 887 57 250 894

# LETTER FROM THE CEO



I am pleased to share an update on Initiator Pharma's progress during the fourth quarter of 2024, a period marked by maintained focus on value creation and continued low operational costs. Building on the momentum of the previous quarters during the year, we have accelerated our efforts on business development and strategic partnerships based on our key programs in erectile dysfunction (ED), and our expansion into pain and female sexual dysfunction (FSD).

In the beginning of last year we announced the expansion of the company's position to a broader Sexual Health Franchise including both male ED and FSD indications. Both our lead drug candidates, pudafensine and IP2018, have shown significant efficacy in preclinical models for FSD, and we see a significant opportunity within the area as the commercial potential is considered to be very attractive with a substantial market growth for the coming years. An analysis of the FSD commercial opportunity, executed by Global Life Sciences in the UK, has conservatively concluded that a product for underserved women suffering from FSD/HSDD (Hypoactive sexual desire disorder) has the potential to reach peak sales of USD 2 billion.

The expansion of our pipeline in FSD remain a key focus when we enter into 2025 and we are currently evaluating indications where the market potential for an approved treatment is significant. Supporting the uniqueness of advancing pudafensine for FSD is the fact that many women with sexual dysfunctions very often suffer from vaginal pain,

generally or in connection with sexual activity. A rather common female-specific pain indication is vulvodynia – a severe chronic pain condition that affects the vulvar area and occurs without an identifiable cause. In a previous randomized, double-blind, placebo-controlled study, pudafensine had a positive effect on pain and showed the same effects as in preclinical studies, providing strong support for the unique positioning Pudafensine as a Novel and superior treatment for FSD.

One of the main reasons to expand the indications into the FSD area, is the significant interest we see from the industry and leading players. This has been evident when participating at key industry events during fourth quarter, such as BioEurope and the Jefferies Healthcare Conference, and the JP Morgan's annual Health Care Conference in the beginning of this year. These BD and investor focused events have resulted in productive engagements and several fruitful meetings. The growing recognition of our innovative approach in treating ED and FSD has led to increased interest from potential partners and investors, positioning us well for attractive collaborations and funding opportunities.

We remain poised to continue the development of pudafensine as a monotherapy for ED, but also see an attractive combination opportunity with PDE5i products. Our preclinical data very clearly demonstrates an additive effect of a combination, and this is also an important opportunity as such a product would enable poor PDE5i responders and has the potential is establish itself a premium product differentiating itself towards generic PDE5i products.

# LETTER FROM THE CEO

Our main focus remains on patients with moderate to severe ED – a significant medical condition affecting millions of men's lives globally – and we have continued to make advancements in our clinical programs as we prepare for the next phase of pudafensine's development, including refining our plans for Phase III studies in ED, which will be central for a future regulatory approval. Our previous Phase IIb study demonstrated both statistically and clinically relevant efficacy, reinforcing our confidence in pudafensine's potential as a novel treatment for ED. The prolonged treatment duration in Phase III studies is expected to further validate the drug's effectiveness and long-term benefits.

With 2024 behind us, we remain committed to advancing our clinical programs while maintaining operational efficiency and a strong focus on value creation. We are encouraged by the interest in our Sexual Health Franchise from both regional and global partners, and we are well positioned for potential collaborations that can further accelerate our growth and expand our reach.

I extend my sincere gratitude to our shareholders and stakeholders for their unwavering confidence in Initiator Pharma. Together, we are driving innovation and transforming the treatment landscape for sexual dysfunction and beyond.

Copenhagen, February 28, 2025

Claus Elsborg Olesen CEO

# **ABOUT INITIATOR PHARMA**

Initiator Pharma is a clinical stage emerging pharma company developing innovative drugs that target key unmet medical needs within the central and peripheral nervous system. Initiator Pharma's pipeline consists of two clinical stage assets – pudafensine (IP2015) and IP2018 – and one preclinical asset. Late 2023 the company 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, and has previously completed a Phase I proof of principle trial in neuropathic pain. With IP2018 the company has reported positive, statistically significant, and dosedependent clinical observations related to efficacy in psychogenic ED in a Phase IIa clinical trial in patients with mild to moderate ED. Both pudafensine and IP2018 are currently being investigated as potential treatments of Female sexual dysfunction (FSD).

#### Vision

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.

#### **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.

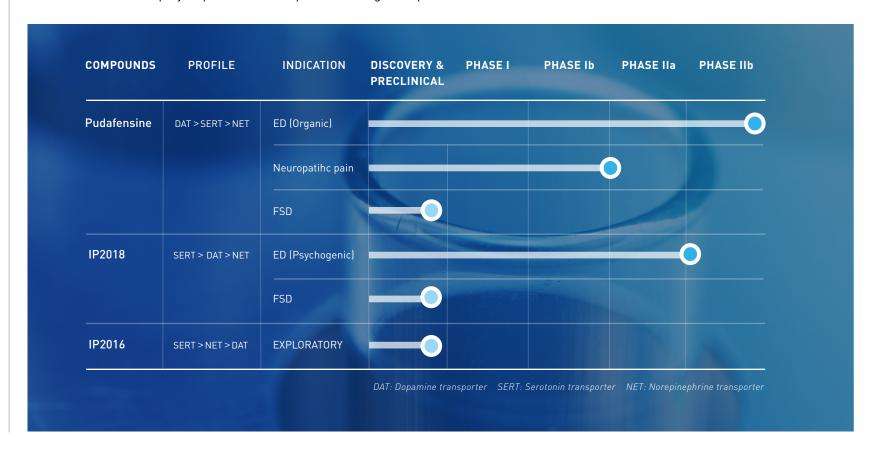
Initiator Pharma aims to progress its portfolio of drug candidates to key value inflection points, where the company anticipate significant partnering interest from international pharma industry for the further development of the company's drug candidates.



# 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:



# **PUDAFENSINE**

#### **Pudafensine:**

Pudafensine, Initiators'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 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.

In October 2023, Initiator reported statistically significant and clinically relevant efficacy in ED-related endpoints and no observations of critical adverse events from its Phase IIb 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 about 300 million men worldwide. About 30-40% of these patients do 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 for premium pricing for pudafensine and thereby generate substantial commercial value for Initiator Pharma.

# **PUDAFENSINE**

#### Neuropathic pain/Trigeminal Neuralgia

In Q3 2022 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 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 Q3 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.

# **IP2018**

**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 compa-

ny 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

# **IP2018**

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 forec asted 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.

- <sup>1</sup> Alberson M, Orabi H, Lue T. Evaluation and treatment of erectile dysfunction in the aging male: a mini-review. Gerontology. 2012;58:3-14.
- <sup>2</sup> Joanna M. Zakrzewska, Eastman Dental Hospital, London, United Kingdom Mark E. Linskey, University of California Irvine, Irvine, California Am Fam Physician. 2016 Jul 15;94(2):133-135.
- <sup>3</sup> Jones, M.R., Urits, I., Ehrhardt, K.P., Cefalu, J.N., Kendrick, J.B., Park, D.J., Cornett, E.M., Kaye, A.D. and Viswanath, 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.
- <sup>5</sup> Rosenberg, K. P., Bleiberg, K. L., Koscis, J., & Gross, C. (2003). A survey of sexual side effects among severely mentally ill patients taking psychotropic medications: impact on compliance. Journal of Sex &Marital Therapy, 29(4), 289-296.
- <sup>6</sup> Quilter M, Hodges L, von Hurst P, Borman B, Coad J. Male sexual function in New Zealand: a population-based cross-sectional survey of the prevalence of erectile dysfunction in men aged 40-70 years. J Sex Med. (2017) 14:928–36. doi: 10.1016/j.jsxm.2017.05.011
- <sup>7</sup> Pratt, L. A., Brody, D. J., & Gu, Q. (2017). Antidepressant Use among Persons Aged 12 and Over: United States, 2011-2014. NCHS Data Brief. Number 283. National Center for Health Statistics.
- 8 Reports and Data. "Anxiety Disorder and Depression Treatment Market By Therapies" (2020), https://www.reportsanddata.com/report-detail/anxiety-disorder-and-depression-treat-ment-market.

# FEMALE SEXUAL DYSFUNCTION (FSD)

# Female sexual dysfunction Program (pudafensine and IP2018):

Female sexual dysfunction (FSD) includes a range of issues such as hypo-sexual desire disorder (HSDD; low libido), difficulty achieving arousal, pain during intercourse, and inability to reach orgasm. 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 a number of strategic markets based on the PCT application WO 2024/008808. An analogous national patent application is also pending in non-PCT country Taiwan. 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, via a pending PCT application published on 02 May 2024 as WO 2024/089247. The European Patent Office acting as International Searching Authority has acknowledged patentability of the claims. The PCT application will enter national phase in relevant major markets in Q2/2025. 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 W0 2024/261019 and W0 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.

#### 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.

# PATENT PROTECTION

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, extensions 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.

# FINANCIAL REVIEW

#### Revenue

Ilnitiator Pharma generated no revenues for the fourth quarter and for the full year 2024 (-).

#### **Earnings**

The company recognized an operating loss of KDKK 2,701 for the fourth quarter of 2024 (-4,279) and an operating loss of KDKK 14,502 for the full year 2024 (-27,029). The decrease in operating costs for the fourth quarter and the full year compared to last year reflects the high level of clinical development activities last year.

External R&D costs in the fourth quarter amounted to KDKK 65 compared to KDKK 661 in the same period in 2023. For the full year external R&D costs amounted to KDKK 1,778, compared to KDKK 15,296 in 2023.

Net financial costs in the fourth quarter amounted to KDKK 54, compared to net financial income of KDKK 874 in the same period in 2023. The net financial expenses in the fourth quarter is related to currency fluctuations during the quarter. For the full year the net financial expenses amounted to KDKK 334 compared to KDKK 677 in 2023.

The net loss before tax for the fourth quarter was KDKK 2,755 (-3,405). For the full year net loss before tax amounted to KDKK 14,836 (-27,706). The net loss after tax for the fourth quarter was KDKK 841 (1,429) and earnings per share totaled to DKK -0.02 (0.03). For the full year net loss after tax amounted to KDKK 12,932 (-22,872) and earnings per share DKK -0.23 (-0.44).

#### Financial position

The equity as of December 31, was KDKK 14,782 compared to KDKK 11,162 at year-end 2023, reflecting the conversion of the receivable held by MAC Clinical Research which co-financed the Phase IIb clinical trial with pudafensine. Cash and cash equivalents amounted to KDKK 13,371 as of December 31 compared to KDKK 24,336 at year-end 2023, and total assets were KDKK 15,292 compared to 29,786 at year-end 2023.

#### Cash flow

In the fourth quarter the cash flow from operating activities was KDKK 1,503 (2,290), reflecting the pay-out of KDKK 4,834 under the Danish tax credit system during forth quarter (5,500). Working capital during the fourth quarter increased by of KDKK 576 (-548), mainly related to reduced trade payables during the period. For the full year the cash flow from operating activities was KDKK -12,080 (-17,647), incl. a negative change in working capital of KDKK 2,078 (4,559).

The company had no cash flow from investment activities in the fourth quarter or during the full year.

The cash flow from financing activities in the fourth quarter was KDKK -111 (265). During the period the company issued 108,500 new shares to management and key employees under the LTI2023 incentive program as well as acquired 23,000 own shares at a price of SEK 7.24 per share which were subsequently sold to board members at a price of DKK 0.105 under the LTI2023 incentive program.

# FINANCIAL REVIEW

For the full year the cash flow from financing activities was KDKK 1,115 (2,871). During 2024 the MAC receivable of DKK 17.4 million was converted into 3,058,667 shares in Initiator Pharma. During the year the company also issued a total of 627,807 new shares to management and key employees under the LTI2021 and LTI2023 incentive programs at par value of DKK 0.105. The company acquired a total of 121,915 own shares at a price of SEK 8.62 per share which were sold to board members at a price of DKK 0.105 under the LTI2021 LTI2023 incentive programs.

Cash flow for the fourth quarter totalled to KDKK 1,392 (2,555) and KDKK -10,965 for the full year (-14,776).

#### The share, share capital and ownership structure

As of December 31, 2024, the number of shares outstanding totalled to 56,158,361 shares and on a fully diluted basis 56,707,361, including warrants under the LTI2023 incentive program.

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 KDKK 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 treshhold 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. The incentive programs in Initiator Pharma are described in detail in the Annual Report for 2023.

As of December 31 the company had around 3,700 shareholders. The 10 largest shareholders in the company on December 31 owned approx. 49% of all outstanding shares.

Top 10 shareholders as of December 31, 2024				
Owners	Number of shares	Shares %		
LINC AB	10 091 219	17,97%		
Adrigo Small and Midcap L/S	5 025 157	8,95%		
Avanza Pension	3 296 494	5,87%		
MAC Clinical Research Finance Ltd	3 058 667	5,45%		
Claus Olesen	1 367 625	2,44%		
Dan Peters	1 202 794	2,14%		
NordNet Pension Insurance	958 184	1,71%		
Annika Espander Jansson	943 299	1,68%		
Thomsen Mikael	858 467	1,53%		
Mats Thóren	704 611	1,25%		
Ten largest shareholders	27 506 517	48,98%		
Other shareholders	28 651 844	51,02%		
Total	56 158 361	100,00%		

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

#### Personnel

As of December 31, the number of employees was 2 (3), of which 1 (1) was a woman. Initiator Pharma follows a strategy of using an extensive network of consultants to support the development activities in the company. Such a strategy is well established in drug development and ensures the company the optimal balance of access to leading edge expertise, costs and flexibility.

#### Operational risks and uncertainties

All business operations involve risk. Managed risk-taking is necessary to maintain good profitability. Risk may be due to events in the external environment and may affect a certain industry or market. Risk may also be specific to a certain company.

The main risks and uncertainties which Initiator Pharma is exposed to are related to drug development, the company's collaboration agreements, competition, technology development, patent, regulatory requirements, capital requirements and currencies. No new risks have arisen during the quarter. A more detailed description of the company's risk exposure and risk management is included in the Annual Report for 2023.

#### Prerequisites for continued operation

This financial information has been prepared under the assumption of continued operations. The company has historically reported losses. The company's ability to meet its future liquidity needs is highly dependent on securing external capital. The board continuously evaluates different financing possibilities to ensure the continued operation of the business. The management and the Board of Directors are aware that there are uncertainties in the estimation of future cash flows as well as uncertainties in the financing of operations, however the board and management's assessment are that the company is well positioned to secure the necessary financing when need arises.

#### **Audit review**

This year-end report has not been subject to review by the company's auditor.

#### **Certified Advisor**

As a business listed on Nasdaq First North Growth Market Stockholm, the Company is obliged to have a Certified Advisor. Initiator Pharna has appointed Redeye as its Certified Advisor.

#### Financial calendar

Annual report 2024 Week of April 28, 2025

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

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

The Board of Directors and the CEO certify that this Year-end report provides a true and fair view of the operations, financial position and earnings of the Company and describes the material risks and uncertainties faced by the Company.

Copenhagen, February 28, 2025

Magnus PerssonAnnette ColinChairmanBoard member

Henrik Moltke Gunilla Ekström Board member Board member

Peter HolmClaus Elsborg OlesenBoard memberBoard member and CEO

# Statement of income

KDKK	Q4-2024	Q4-2023	FY-2024	FY-2023
Gross loss	-1 966	-2 692	-11 073	-23 412
Staff costs	-735	-1 587	-3 429	-3 617
Operating profit/loss	-2 701	-4 279	-14 502	-27 029
Net financial items	-54	874	-334	-677
Profit/loss before tax	-2 755	-3 405	-14 836	-27 706
Tax	1 904	4 834	1 904	4 834
Net profit/loss for the period	-851	1 429	-12 932	-22 872

# Statement of financial position

KDKK	Dec 31, 2024	Dec 31, 2023	
ASSETS		•	
Total non-current assets	17	17	
Other receivables	-	599	
Income tax receivables	1 904	4 834	
Prepayments	-	-	
Cash and cash equivalents	13 371	24 336	
Total current assets	15 275	29 769	
Total assets	15 292	29 786	
EQUITY AND LIABILITIES			
Contributed capital	5 897	5 510	
Retained earnings	8 885	5 652	
Total equity	14 782	11 162	
Convertible credit agreement	-	15 437	
Total non-current liabilities	-	15 437	
Trade payables	366	407	
Other current liabilities	-341	246	
Accrued expenses	485	2 534	
Total current liabilities	510	3 187	
Total equity and liabilities	15 292	29 786	

# Statement of changes in shareholder equity

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 period	-	-22 873	-22 873
December 31, 2023	5 510	5 652	11 162
October 1, 2024	5 885	9 859	15 744
Increase of capital	11	-	11
Costs in connection with increase of capital	-	-15	-15
Purchase of treasury shares	-	-109	-109
Sale of treasury shares	-	2	2
Profit/loss for the period	-	-851	-851
December 31, 2024	5 896	8 886	14 782
January 1, 2024	5 509	5 653	11 162
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 period	-	-12 932	-12 932
December 31, 2024	5 896	8 886	14 782

# Statement of cash flow

KDKK	Q4-2024	Q4-2023	FY-2024	FY-2023
Profit/loss before tax	-2 755	-3 403	-14 836	-27 706
Adjustments for non-cash transactions	-	-355	-	-
Profit/loss before tax, adj for non-cash transactions	-2 755	-3 758	-14 836	-27 706
Tax credit	4 834	5 500	4 834	5 500
Cash flow before change in working capital	2 079	1 742	-10 002	-22 206
Changes in working capital	-576	548	-2 078	4 559
Cash flow from operating activities	1 503	2 290	-12 080	-17 647
Investing activities	-	=	-	-
Cash flow from investing activities	-	-	-	-
Financing activities				
Purchase of treasury shares	-109	-	-690	-
Sale of treasury shares	2	-	13	-
New share issue	-4	-	17 229	11
Credit agreement with MAC	-	265	-15 437	2 860
Cash flow from financing activities	-111	265	1 115	2 871
Cash flow for the reporting period	1 392	2 555	-10 965	-14 776
Cash and cash equivalents at the beginning of period	11 979	21 781	24 336	39 112
Cash and cash equivalents at the end of period	13 371	24 336	13 371	24 336

### Business terms - glossary

#### **CNS**

The Central Nervous System, a part of the nervous system consisting of the brain and spinal cord.

#### CTA

Clinical Trial Application which a pharmaceutical company file to EMA in order to obtain permission to ship and test an experimental drug in Europe before a marketing application for the drug has been approved. The approved application is called an Investigational New Drug (IND) in the US.

#### **EMA**

European Medicines Agency

#### **Erectile Dysfunction**

Erectile dysfunction (ED) or impotence is sexual dysfunction characterized by the inability to develop or maintain an erection of the penis during sexual activity in humans.

#### **FDA**

US Food and Drug Administration

#### 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 Investigational New Drug 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).

#### **PUDAFENSINE IP2015**

Pudafensine, Initiators's most advanced drug candidate, is a novel drug candidate for the treatment of patients suffering from Erectile Dysfunction (ED) that do not respond to the currently marketed drugs in the PDE5i class (e.g. Viagra©, Cialis©,Levitra©)

#### **IP2018**

IP2018, currently in a on-going Phase IIa trial for psychogenic ED.

### Business terms - glossary

#### 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 ED and were the first effective oral treatment available for the condition.

# Financial Glossary

#### Earnings per share

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

#### Operating profit/loss, EBIT

Earnings Before Interest and Taxes (Operating profit/loss)

#### **Equity ratio**

Shareholders' equity as a proportion of total assets

#### Diluted earnings per share

Profit/loss for the period divided by the average number of shares after dilution at the end of the period

#### Operating margin

EBIT as proportion of revenue

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# **Initiator** Pharma

www.initiatorpharma.com

Initiator Pharma A/S

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