

# Q1

Initiator Pharma

# 2025

# BUSINESS HIGHLIGHTS

## Business highlights in Q1 2025

- In March the Company announced that Dr. Göran Ando, former Chairman of Novo Nordisk A/S, will be proposed for election to the company's Board of Directors at the 2025 AGM. Dr. Ando is also appointed as a Senior advisor, supporting the Board and management team, effective immediately.

## 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).

TDKK	Q1-2025	Q1-2024	FY-2024
Net sales	-	-	-
Total operating expenses	-2 653	-3 577	-14 502
Operating profit/loss	-2 653	-3 577	-14 502
Net result	-2 653	-4 123	-12 932
Earnings per share before and after dilution (DKK)	-0.05	-0.08	-0.23
Cash flow from operating activities	-2 589	-6 802	-12 080

TDKK	31.03.2025	31.03.2024	31.12.2024
Cash and cash equivalents	10 782	18 760	13 371
Equity	12 129	23 702	14 782
Total equity and liabilities	13 203	24 354	15 292
Equity ratio, %	92 %	97 %	97 %

<i>Number of shares outstanding</i>	56 158 361	56 049 861	56 158 361
<i>Number of shares, diluted</i>	56 815 861	57 250 894	56 815 861
<i>Average number of shares outstanding</i>	56 158 361	54 283 046	55 624 734
<i>Average number of shares, diluted</i>	56 815 861	57 250 894	57 267 470

## LETTER FROM THE CEO



*I'm pleased to share an update on Initiator Pharma's progress during the first quarter of 2025 — a period that saw continued momentum across our development programs, the expansion of our Sexual Health Franchise, and important additions to our leadership and advisory network. Building on a strong 2024, we maintained our focus in Q1 on business development, clinical planning, and pipeline growth. Our mission remains clear: to address unmet medical needs in male and female sexual health, as well as pain, with therapies that stand out through solid science and a practical approach to execution.*

Our lead program, pudafensine, continues to attract attention thanks to its novel mechanism and encouraging clinical profile. We're now preparing for the next clinical development step with the drug candidate in erectile dysfunction (ED), targeting men with moderate to severe symptoms — a large group not well served by current treatments. The statistically and clinically significant results from our prior Phase IIb trial provide a strong base for an upcoming Phase III program, which will further assess long-term benefits and durability of response, supporting future regulatory submissions. 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. Additionally, we're also planning to evaluate pudafensine in combination with PDE5 inhibitors. Early data suggests this could offer added benefit for patients who don't respond well to standard options.

At the same time, we're advancing our pipeline in female sexual dysfunction (FSD). Both pudafensine and IP2018 have shown promising effects in preclinical models for indications like hypoactive sexual desire disorder (HSDD) and vulvodynia. The data we've gathered so far gives us confidence to move forward, and commercial potential in this space remains significant. An external market analysis from Global Life Sciences estimates peak sales potential of up to USD 2 billion for an effective HSDD treatment — a figure that underlines the opportunity.

In March, we were proud to announce the proposed election of Dr. Göran Ando to our Board and his appointment as Senior Advisor. Dr. Ando brings decades of leadership experience, including time at Novo Nordisk and other top-tier pharma companies. His insights will be valuable as we deepen our business development and prepare for new partnerships.

Our participation in key industry and investor events is helping us build strong relationships and raise awareness of Initiator Pharma as a growing innovator in sexual health. 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.

## LETTER FROM THE CEO

Looking ahead, our priorities are to launch the next phase of pudafensine's clinical development in ED, push forward with our work in FSD and pain, and explore new strategic collaborations that can accelerate our progress. Our lean, focused organization remains a strength as we aim to deliver on both our clinical and business goals.

Finally, I want to thank our shareholders, partners, and employees for their continued trust and support. Together, we're working toward a future where people affected by sexual dysfunction and related conditions can access treatments that truly make a difference.

Copenhagen, May 9, 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).

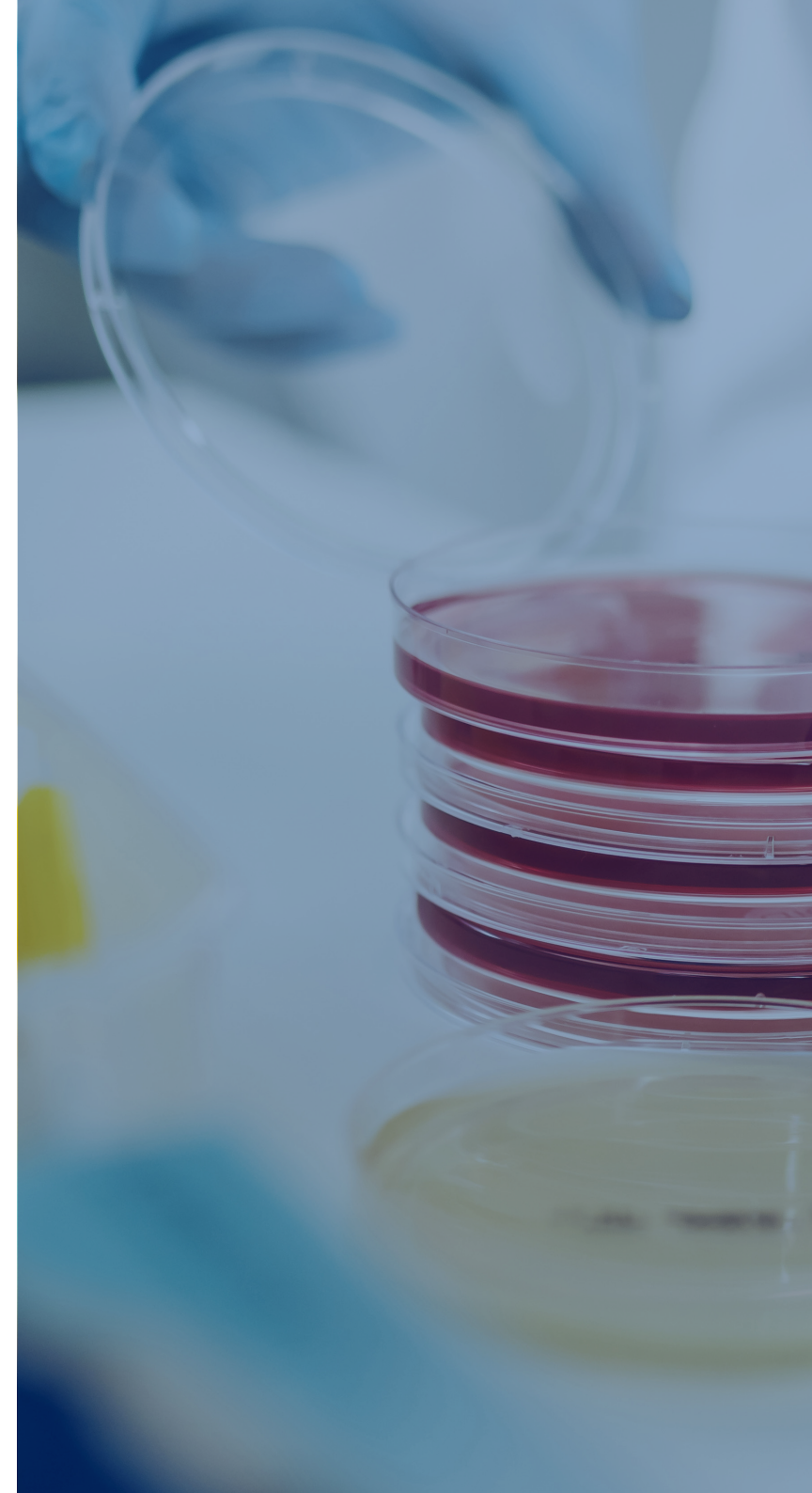
## Vision

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.

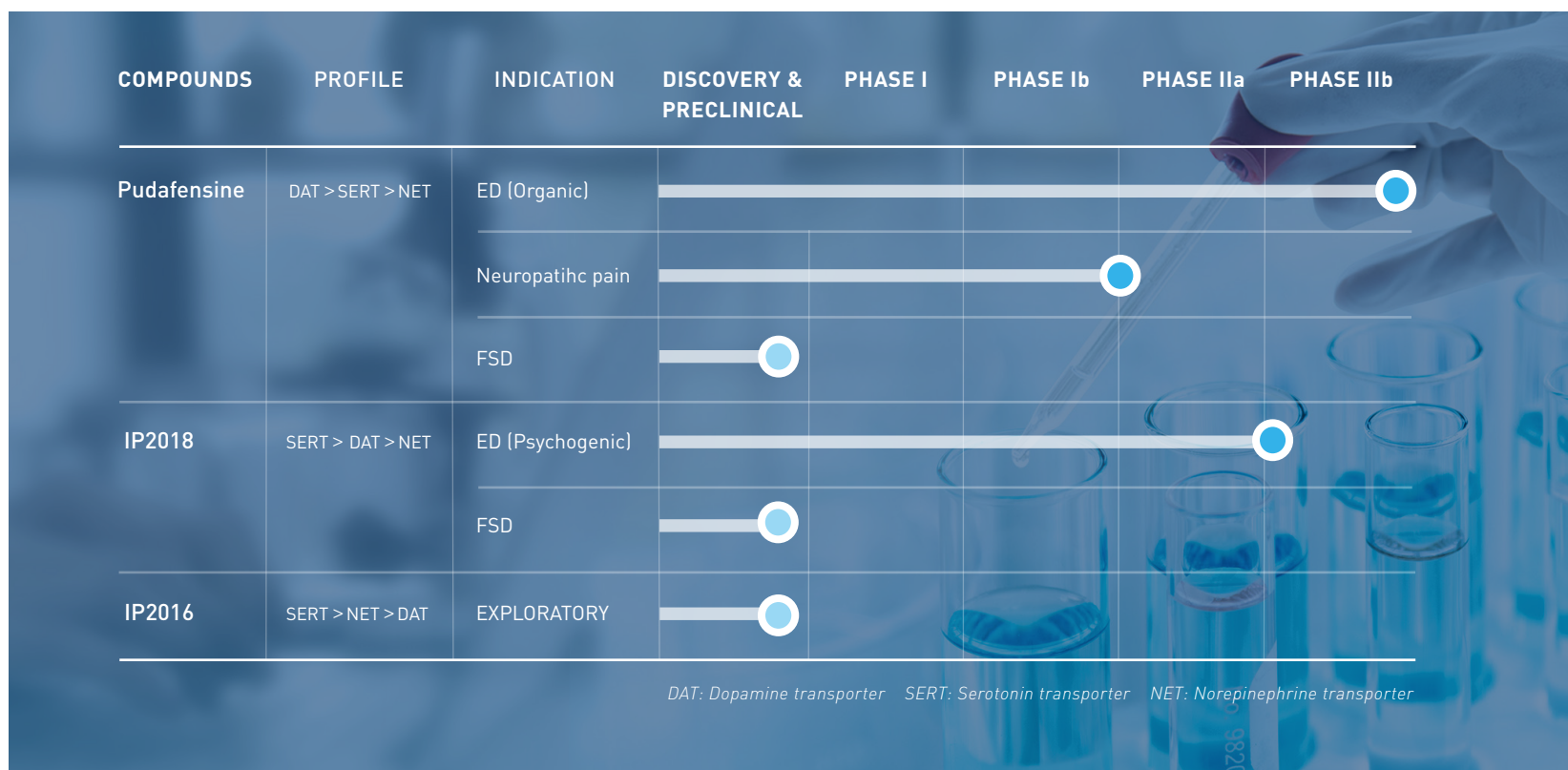




## PROJECT PORTFOLIO

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, 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.

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 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 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, health-care 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.



# 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 <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.

<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.

<sup>4</sup> 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., 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.

<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.

<sup>8</sup> Reports and Data. "Anxiety Disorder and Depression Treatment Market By Therapies" (2020), <https://www.reportsanddata.com/report-detail/anxiety-disorder-and-depression-treatment-market>.

# FEMALE SEXUAL DYSFUNCTION (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 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 exten-

ded 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.

# PATENT PROTECTION

## 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.

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

Initiator Pharma generated no revenues for the first quarter of 2025.

## Earnings

The company recognized an operating loss of TDKK 2,653 for the first quarter of 2025 (-3,577). The decrease in operating costs for the first quarter compared to last year reflects limited resources spent on external development activities during the quarter.

External R&D costs in the fourth quarter amounted to TDKK 41 compared to TDKK 1,041 in the same period in 2024.

Net financial costs in the first quarter amounted to TDKK 0, compared to net financial expenses of TDKK 546 in the same period in 2024.

The net loss before and after tax for the first quarter was TDKK 2,653 (-4,123) and earnings per share totaled to DKK -0.05 (-0.08).

## Financial position

The equity as of March 31, was TDKK 12,129 compared to TDKK 14,782 at year-end 2024. Cash and cash equivalents amounted to TDKK 10,782 as of March 31 compared to TDKK 13,371 at year-end 2024, and total assets were TDKK 13,203 compared to 15,292 at year-end 2024.

## Cash flow

In the first quarter the cash flow from operating activities was TDKK -2,589 (-6,802), after changes in working capital of TDKK 64 (-2,679) during the quarter.

The company had no cash flow from investment activities in the first quarter (0).

The company had no cash flow from financing activities in the first quarter (1,226).

Cash flow for the first quarter totalled to TDKK -2,589 (-5,576).

## The share, share capital and ownership structure

As of March 31, 2025, 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.

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

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

# FINANCIAL REVIEW

## Top 10 shareholders as of March 31, 2025

Owners	Number of shares	Shares %
LINC AB	10 091 219	17,97 %
Adrigo Small and Midcap L/S	5 200 196	9,26 %
Avanza Pension	3 393 873	6,04 %
MAC Clinical Research Finance LTD	3 058 667	5,45 %
Claus Elsborg Olesen	1 337 625	2,38 %
Dan Peters	1 202 794	2,14 %
Annika Espander Jansson	943 299	1,68 %
Nordnet Pension Insurance	934 735	1,66 %
Mikael Thomsen	836 467	1,49 %
Mats Thören	683 611	1,22 %
Ten largest shareholders	27 682 486	49,29 %
Other shareholders	28 475 875	50,71 %
<b>Total</b>	<b>56 158 361</b>	<b>100,00 %</b>

## Personnel

As of March 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 2024.

## 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 interim 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 Pharma has appointed Redeye as its Certified Advisor.

## Financial calendar

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](http://www.initiatorpharma.com)*

The Board of Directors and the CEO certify that this interim 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, May 9, 2025

**Magnus Persson**  
Chairman

**Annette Colin**  
Board member

**Henrik Moltke**  
Board member

**Gunilla Ekström**  
Board member

**Peter Holm**  
Board member

**Claus Elsborg Olesen**  
Board member and CEO

## FINANCIAL STATEMENTS

## Statement of income

TDKK	Q1-2025	Q1-2024	FY-2024
Gross loss	-2 101	-2 901	-11 073
Staff costs	-552	-676	-3 429
<b>Operating profit/loss</b>	<b>-2 653</b>	<b>-3 577</b>	<b>-14 502</b>
Net financial items	-	-546	-334
<b>Profit/loss before tax</b>	<b>-2 653</b>	<b>-4 123</b>	<b>-14 836</b>
Tax	-	-	1 904
<b>Net profit/loss for the period</b>	<b>-2 653</b>	<b>-4 123</b>	<b>-12 932</b>

## FINANCIAL STATEMENTS

## Statement of financial position

TDKK	March 31, 2025	Dec 31, 2024
<b>ASSETS</b>		
<b>Total non-current assets</b>	<b>17</b>	<b>17</b>
Other receivables	500	-
Income tax receivables	1 904	1 904
Cash and cash equivalents	10 782	13 371
<b>Total current assets</b>	<b>13 186</b>	<b>15 275</b>
<b>Total assets</b>	<b>13 203</b>	<b>15 292</b>
<b>EQUITY AND LIABILITIES</b>		
Contributed capital	5 897	5 897
Retained earnings	6 232	8 885
<b>Total equity</b>	<b>12 129</b>	<b>14 782</b>
Trade payables	868	366
Other current liabilities	88	-341
Accrued expenses	118	485
<b>Total current liabilities</b>	<b>1 074</b>	<b>510</b>
<b>Total equity and liabilities</b>	<b>13 203</b>	<b>15 292</b>



## FINANCIAL STATEMENTS

## Statement of changes in shareholder equity

TDKK	Contributed capital	Retained earnings	Total
<b>January 1, 2024</b>	<b>5 498</b>	<b>28 525</b>	<b>34 023</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 period	-	-12 932	-12 932
<b>December 31, 2024</b>	<b>5 896</b>	<b>8 886</b>	<b>14 782</b>
<b>January 1, 2024</b>	<b>5 509</b>	<b>5 653</b>	<b>11 162</b>
Share issue	376	16 857	17 233
Purchase of treasury shares	-	-580	-580
Sale of treasury shares	-	10	10
Profit/loss for the period	-	-4 123	-4 123
<b>March 31, 2024</b>	<b>5 885</b>	<b>17 817</b>	<b>23 702</b>
<b>January 1, 2025</b>	<b>5 896</b>	<b>8 886</b>	<b>14 782</b>
Profit/loss for the period	-	-2 653	-2 653
<b>March 31, 2025</b>	<b>5 896</b>	<b>6 233</b>	<b>12 129</b>

## FINANCIAL STATEMENTS

## Statement of cash flow

TDKK	Q1-2025	Q1-2024	FY-2024
Operating profit/loss	-2 653	-3 577	-14 502
Adjustments for non-cash transactions	-	-	4 834
<b>Cash flow from operations before change in working capital</b>	<b>-2 653</b>	<b>-3 577</b>	<b>-9 668</b>
Interest received	22	103	499
Interest paid	-22	-648	-832
Changes in working capital	64	-2 679	-2 078
<b>Cash flow from operations</b>	<b>-2 589</b>	<b>-6 802</b>	<b>-12 079</b>
<b>Investing activities</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Cash flow from investing activities</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Financing activities</b>	<b>-</b>	<b>-</b>	<b>-</b>
Purchase of treasury shares	-	-580	-690
Sale of treasury shares	-	10	13
New share issue	-	17 233	1 792
Credit agreement with MAC	-	-15 437	-
<b>Cash flow from financing activities</b>	<b>-</b>	<b>1 226</b>	<b>1 115</b>
<b>Cash flow for the reporting period</b>	<b>-2 589</b>	<b>-5 576</b>	<b>-10 964</b>
Cash and cash equivalents at the beginning of period	13 371	24 336	24 336
<b>Cash and cash equivalents at the end of period</b>	<b>10 782</b>	<b>18 760</b>	<b>13 371</b>

# BUSINESS TERMS

## Business terms - glossary

### CNS

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

### CTA

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

### EMA

European Medicines Agency

### Erectile Dysfunction

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

### FDA

US Food and Drug Administration

### 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

## 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

## 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



# Q1

## Initiator Pharma

[www.initiatorpharma.com](http://www.initiatorpharma.com)

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# 2025