

# Q2

Initiator Pharma

# 2025

# BUSINESS HIGHLIGHTS

## Business highlights in Q2 2025

- In May the Company announced that the board of directors of Initiator Pharma A/S had resolved on a rights issue amounting to SEK 56 million, if fully subscribed. In total 85% of the share issue was covered by presubscriptions and guarantees.
- In May the Company announced the expansion of the FSD program to target vulvodynia, and that the company had signed a financing agreement with MAC Clinical Research worth up to GBP 2.5 million for partial financing of a Phase IIa clinical trial in vulvodynia with Pudafensine.

## Business highlights after this reporting period

- In July the Company announced the outcome of the rights issue. In total 45.7% of the rights issue was subscribed for with or without subscription rights, and another 40,4 percent subscribed through guarantee undertakings, in total ca 86% of the rights issue, providing the Company with proceeds of approximately SEK 48.3 million before deduction of costs related to the rights issue.

## Financial Highlights

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

TDKK	Q2-2025	Q2-2024	H1-2025	H1-2024	FY-2024
Net sales	-	-	-	-	-
Total operating expenses	-3 844	-4 991	-6 497	-8 568	-14 502
Operating profit/loss	-3 844	-4 991	-6 497	-8 568	-14 502
Net result	-3 864	-4 786	-6 517	-8 909	-12 932
Earnings per share before and after dilution (DKK)	-0.07	-0.09	-0.12	-0.16	-0.23
Cash flow from operating activities	-8 271	-4 273	-10 860	-11 075	-12 080

TDKK	Q2-2025	Q2-2024	30.06.2025	30.06.2024	31.12.2024
Cash and cash equivalents	4 700	14 487	4 700	14 487	13 371
Equity	8 266	18 916	8 266	18 916	14 782
Total equity and liabilities	13 773	20 228	13 773	20 228	15 292
Equity ratio, %	60 %	94 %	60 %	94 %	97 %

Number of shares outstanding	56 158 361	56 049 861	56 158 361	56 049 861	56 158 361
Number of shares, diluted	56 815 861	57 250 894	56 815 861	57 250 894	56 815 861
Average number of shares outstanding	56 158 361	56 049 861	56 158 361	55 166 454	55 624 734
Average number of shares, diluted	56 815 861	57 250 894	56 815 861	57 250 894	57 267 470

## LETTER FROM THE CEO



*The second quarter of 2025 was a pivotal period for Initiator Pharma as we executed key strategic steps to reinforce our position as a leading pharmaceutical company in sexual health and pain. With a clear focus on unlocking the full potential of pudafensine, we decided to advance our most mature clinical asset in vulvodynia, a severe neuropathic pain indication with significant unmet medical needs. In addition we also have data showing that pudafensine, when combined with PDE5 inhibitors, could offer additional benefit to*

*patients who do not respond adequately to standard treatments for erectile dysfunction. Hence, we have decided to develop this combination further and create a platform opportunity for a future partner within erectile dysfunction.*

We are convinced in the prospects of our portfolio and committed in delivering strong clinical data in segments where our products can make a true difference and create patient benefit in men and women, with a priority on both pain and sexual health. Hence, we are grateful for the continued support from our specialist investors Linc as well as from MAC, which both increased their ownership in Initiator Pharma in this capital raise, despite a challenging capital market environment. We are reassured that this financing is key building block to create substantial value to our shareholders. It sets the foundation for partnership ahead of late clinical development and launch of our assets in both neuropathic pain and sexual dysfunction, in men as well as in women.

Our lead drug candidate, pudafensine, has previously demonstrated

strong monotherapy efficacy in a Phase IIb trial in organic erectile dysfunction (ED), laying the foundation for a future late stage clinical program. In addition, we also have preclinical data showing that pudafensine, when combined with PDE5 inhibitors, could offer additional benefit to patients who do not respond adequately to standard treatments. As a consequence, we have decided to explore this opportunity with high priority. Additionally, IP2018, our second clinical-stage asset, has previously shown positive, statistically significant, and dose-dependent clinical observations related to efficacy in psychogenic ED. Finally, in our portfolio we have a follow-up preclinical assets (IP2016) targeting neuropathic pain. Given the huge issues with opioids and the unmet medical needs in this segment, there is great interest from big pharma for clinical as well as pre-clinical stage assets of relevance and IP2016 with its unique profile and strong patent position is just that.

Pudafensine and IP2018 offer therapeutic potential in both men and women. We see a compelling opportunity to broaden the scope for pudafensine to also include treatment of female sexual dysfunction and pain conditions in women. Preclinical models have shown promising effects in indications such as hypoactive sexual desire disorder (HSDD) and vulvodynia – a chronic and often debilitating condition affecting up to 10 percent of women globally. The data we have generated so far, together with the significant commercial potential, has strengthened our conviction to advance in this space.

In May, we announced the expansion of our Female Sexual Dysfunction (FSD) program to include vulvodynia.

## LETTER FROM THE CEO

Pudafensine's dual activity profile uniquely positions it to address both pain and sexual dysfunction, two key components of this underdiagnosed condition. A randomized, placebo-controlled Phase IIa proof-of-concept study in 24 women with vulvodynia, assessing the pain-relieving effects and safety of single oral doses of pudafensine, is planned to start in the second half of this year with first results expected by the end of 2026. This study builds on encouraging results from our earlier pain challenge trial and could position pudafensine as a first-in-class treatment in an area with no approved therapies to date.

The vulvodynia study will be conducted in collaboration with our UK-based partner and shareholder, MAC Clinical Research, and primarily financed through a convertible credit agreement worth up to GBP 2.5 million. Their commitment to fund the study, along with the right to convert the credit into shares at a premium, reflects strong belief in pudafensine's scientific and commercial promise and is a clear endorsement of our long-term strategy.

To further strengthen our financial position, improve our negotiation power in relation to business development discussions with partners, and ensure continuity across development programs, we launched a rights issue in June. The outcome, announced in early July, showed solid support from existing shareholders, including Linc and MAC, which both increase their ownership, and new investors. The issue was subscribed to approximately 86 percent and will provide net proceeds of SEK 43.3 million. These funds will enable us to advance pudafensine in vulvodynia, progress additional preclinical studies, further explore its use in combination with PDE5 inhibitors in ED, and to continue business development activities enabling new strategic collaborations

that can accelerate our progress – all while securing funding well into 2027. We are grateful for the continued support and confidence from our investors.

Our commitment to value-driven development remains firm. ED is a widespread medical issue affecting millions of men globally and I am encouraged by the advancements we are making as we prepare for the next phase of pudafensine's development in ED/FSD as well as in Vulvodynia/Pain. These opportunities are validated by a growing interest from potential partners and stakeholders. Looking ahead, our priorities for the second half of the year include the launch of the vulvodynia trial with MAC and accelerating business development activities. We enter this next phase with a solid scientific foundation, a strong financial position, and the backing of an engaged network of collaborators and investors.

I want to thank all our shareholders, employees, and partners for your continued trust and dedication. Together, we are working to bring forward meaningful, effective treatments to patients with unmet needs in sexual health and pain.

Copenhagen, August 22, 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. The company's pipeline includes two clinical-stage assets—pudafensine (IP2015) and IP2018—alongside one preclinical program. In late 2023, Initiator Pharma reported positive, statistically significant, and clinically meaningful results from a 130-patient Phase IIb trial of pudafensine in erectile dysfunction (ED) of organic origin. Pudafensine has also demonstrated proof-of-principle in neuropathic pain in a Phase I trial, and a Clinical Proof-of-Concept trial in vulvodynia is planned to start in 2025. For IP2018, the company has reported positive, statistically significant, and dose-dependent efficacy signals in a Phase IIa trial in patients with mild to moderate psychogenic ED. Both pudafensine and IP2018 are currently under investigation as potential treatments for female sexual dysfunction (FSD), further expanding their therapeutic potential.

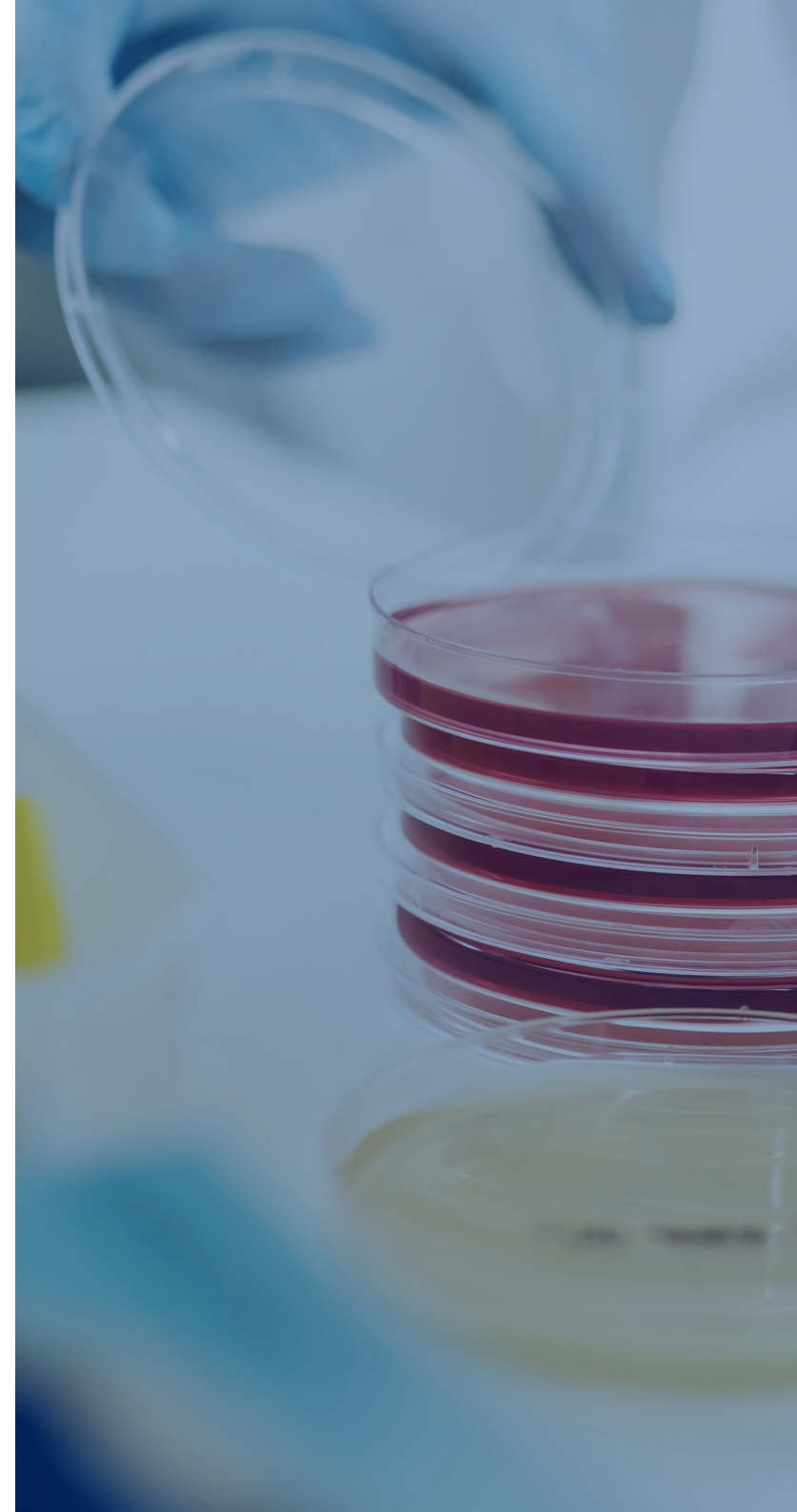
## Vision

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.

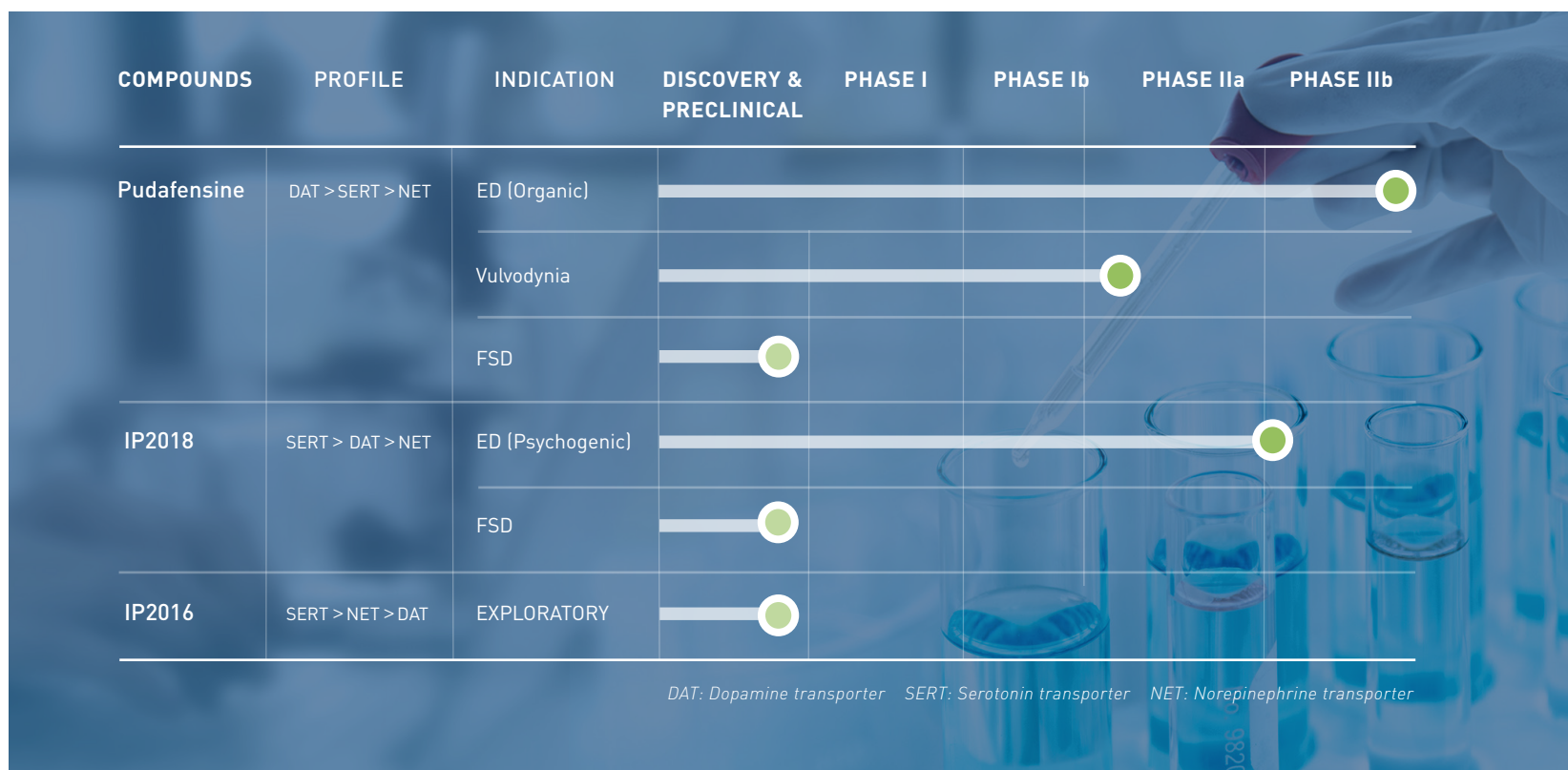
Initiator Pharma aims to progress its portfolio of drug candidates to key value inflection points, where the company anticipate significant partnering interest from international pharma industry for the further development of the company's drug candidates.



## 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. The company's current development pipeline:



# 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 the Neurppathic pain condition Vulvodynia.

## 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 150 million men worldwide and a number that is estimated to increase to more than 300 million by 2025. About 30-40% of these patients will not respond to the current treatment and represent a significant 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

# PUDAFENSINE

the PDE5i non-responders will allow for premium pricing for pudafensine and thereby generate substantial commercial value for Initiator Pharma.

## Vulvodynia/Neuropathic pain

Vulvodynia is pain in the vulva without a clear identifiable cause that lasts longer than 3 months and is considered a long-lasting, chronic pain condition (Bornstein 2016).

The pain of vulvodynia may be described as itching, burning, or stabbing and is often accompanied by dyspareunia (pain during intercourse) (Bornstein 2016).

Women living with vulvodynia experience excruciating pain during routine activities such as walking, sitting, or even wearing tight-fitting pants. Many are unable to use tampons or engage in sexual activities and intercourse, profoundly affecting their quality of life, intimacy, and relationships. Partners also tend to suffer from anxiety and depression symptoms as well as sexual dysfunction (Myrtveit & Stensrud 2023).

The two most important factors leading to the profoundly impaired quality of life in vulvodynia patients are the chronic pain in the vulva and impaired sexual function (Bohm-Starke 2024).

Vulvodynia represents a significant unmet medical need, affecting approximately 10% of females, equivalent to at least 18.5 million women over 18 years in the EU alone (Eurostat 2023, Patla 2023). Despite its high prevalence, there are currently no approved medical therapies.

The treatments used often carry unacceptable side effects and have poorly documented efficacy.

Women with vulvodynia endure severe physical pain, emotional distress, and societal stigma due to a lack of effective treatment options. Current therapies are mainly off-label, frequently inadequate, and often accompanied by undesirable side effects. As many as 73% of patients try multiple (off-label) therapies in their search for relief (Lamvy 2018). Despite multiple prescribed therapies, many patients (~70%) remain inadequately treated (Patla 2023). They are experiencing high pain scores, averaging 6.7 out of 10 (Schlaeger 2023), and as many as 64% report the worst quality of life score (Patla 2023). This chronic pain condition not only limits daily activities but also severely impairs sexual function, impacting the partners and incurring significant healthcare costs (Lua 2017, Xie 2012).

Clinicians confirm that existing treatments are mostly ineffective and often have significant side effects, creating a clear readiness to adopt innovative therapies like pudafensine. There is strong evidence of willingness to pay for a novel vulvodynia treatment, driven by a significant unmet medical need and the complete absence of approved or consistently effective therapies. A Commercial Assessment Report on pudafensine by Global Life Sciences highlights consistently positive feedback from prescribing clinicians, positioning pudafensine as a potential first-line therapy with blockbuster potential.



## PUDAFENSINE

The economic burden of vulvodynia is significant, with direct annual healthcare costs exceeding \$50 billion in the US alone. Informed by feedback from prospective prescribing clinicians, payer insights, and benchmarking against comparable conditions, we have modeled net annual pricing at approximately \$4,000 to \$4,500 in the U.S. and £900 to £1,000 in the EU4 and UK.

Even under conservative assumptions regarding pricing and market penetration, the base case scenario projects combined peak sales in the of \$1.6 to \$1.8 billion across US and EU4 + UK. In an upside scenario- with more effective market development and adoption—peak sales could exceed \$2.4 to \$3.5 billion.

Pudafensine's dual mechanism of action, targeting both central pain regulation and sexual function, makes it uniquely suited to fill this therapeutic gap and become the first truly effective treatment option.

# 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 company intends to position IP2018 as a daily treatment for patients suffering from depression and sexual dysfunction and/or as a supplement to treat ED in patients with medically induced sexual dysfunction.

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

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

# IP2018

## 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 second-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>2</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>3</sup>. About 13 percent of all Americans take antidepressant drugs, which means over 23 million prescriptions per year <sup>4</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>5</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> Rosenberg, K. P., Bleiberg, K. L., Koscis, J., & Gross, C. (2003). A survey of sexual side effects among severely mentally ill patients taking psychotropic medications: impact on compliance. *Journal of Sex & Marital Therapy*, 29(4), 289-296.5.

<sup>3</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>4</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>5</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 (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 second-line treatment options in postmenopausal generalized, acquired HSDD – where it would be positioned as the second 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 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 is pending in 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.

Additional protection for use of pudafensine is conferred by a specified dosage regime of pudafensine, for the treatment of erectile dysfunction via PCT application WO 2024/146892. National phase applications are pending in Canada, China, Europe, Japan, South Korea, Taiwan and the USA. When granted, this patent family can be kept in force until 2044.

Two PCT applications from Initiator Pharma published as WO 2024/261019 and WO 2024/261026 cover 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.

A PCT application directed to IP2018 for treatment of Female Sexual Dysfunction (FSD) is pending as WO2025/051846.



# PATENT PROTECTION

## IP2016

In addition to granted composition of matter patent for the IP2016 racemate in the US, Germany, France and the UK, a new PCT application from Initiator Pharma was published on 21 August 2025 as WO/2025/172422 and is protecting the pure active enantiomer of IP2016 as composition of matter. The European Patent Office acting as International Searching Authority has acknowledged patentability for all pending claims. When granted the patent can be kept in force until 2044..

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 second quarter or the six months of 2025.

## Earnings

The company recognized an operating loss of TDKK 3,844 for the second quarter of 2025 (-4,991). The decrease in operating costs for the second quarter compared to last year reflects limited resources spent on external development activities during the quarter.

External R&D costs in the second quarter amounted to TDKK 377 compared to TDKK 890 in the same period in 2024. For the first six months of the year external R&D costs amounted to TDKK 418, compared to TDKK 1,931 in the same period in 2024.

Net financial expenses in the second quarter amounted to TDKK 20, compared to net financial income of TDKK 205 in the same period in 2024. The net financial expenses in the second quarter is related to currency fluctuations during the quarter, impacting both the conversion of funds held in SEK into DKK at the close of the quarter. For the first six months of the year the net financial expenses amounted to TDKK 20 compared to TDKK 341 for the same period last year.

The net loss after tax for the second quarter was TDKK 3,864 (-4,786) and earnings per share totaled to DKK -0.07 (-0.09). For the first six months of the year net loss after tax amounted to TDKK 6,517 (-8,909) and earnings per share DKK -0.12 (-0.16).

## 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 4,700 as of June 30 compared to TDKK 13,371 at year-end 2024, and total assets were TDKK 13,773 compared to 15,292 at year-end 2024.

## Cash flow

In the second quarter the total operating cash flow was TDKK -8,271 (-4,273), incl. a negative change in working capital of TDKK 4,408 (513). The negative change in working capital is related to pre-payments to MAC Clinical Research for the Phase IIa clinical trial in Vulvodynia with Pudafensine. For the first six months the total operating cash flow was TDKK -10,860 (-11,074), incl a negative change in working capital of TDKK 4,344 (-2,166).

Cash flow from investment activities was TDKK 0 (0) in the second quarter and TDKK 0 (0) for the first six months.

Cash flow from financing activities in the second quarter was TDKK 2,189 (-) and TDKK 2,189 for the first six months (1,226) and relates to the financing of part of the Phase II clinical trial costs through the announced convertible financing agreement with MAC Clinical Research.

Cash flow for the second quarter totalled to TDKK -6,082 (-4,273) and TDKK -8,671 (-9,848) for the first six months of the year.

# FINANCIAL REVIEW

## Top 10 shareholders as of June 30, 2025

Owners	Number of shares	Shares %
LINC AB	10 091 219	17,97 %
Adriego Small and Midcap L/S	5 200 196	9,26 %
Avanza Pension	3 377 145	6,01 %
MAC Clinical Research Finance LTD	3 058 667	5,45 %
Claus Elsborg Olesen	1 367 625	2,44 %
Dan Peters	1 202 794	2,14 %
Nordnet Pension Insurance	1 056 513	1,88 %
Annika Espander Jansson	943 299	1,68 %
Mikael Thomsen	858 467	1,53 %
Mats Thóren	727 662	1,30 %
Ten largest shareholders	27 883 587	49,65 %
Other shareholders	28 274 774	50,35 %
<b>Total</b>	<b>56 158 361</b>	<b>100,00 %</b>

## The share, share capital and ownership structure

As of June 30, 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 June 30 the company had around 3,700 shareholders. The 10 largest shareholders in the company on June 30 owned approx. 49% of all outstanding shares.

On May 19th the company announced a planned rights issue total-ling up to 14,039,590 shares (1:4 existing shares) at a subscription price of SEK 4,00 per share, in total up to SEK 56. 85% or SEK 48 were secured in the form of presubscriptions from leading shareholders as well as guarantee commitments. On July 1 the company announced the outcome of the rights issue, with a total

of 12,080,781 shares being subscribed for (86%), raising SEK 48.3 to the company before issuing costs. On July 15 the company announced the issuance of 213,750 shares to guarantors that elected to have their guarantee fee in whole or in part paid out in new shares.

Following these share issues the number of issued shares in the company will be 68,452,892 shares, and 69,110,392 including out-standing incentive warrants.

Under the convertible credit agreement with MAC Clinical Research financing up to ca GBPM 2.5 of the clinical trial costs associated with the Phase IIa clinical trial in vulvodynia with Pudafensine, MAC can convert the amount into shares at a pre-agreed share price of SEK 7.739.

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

## Personnel

As of June 30, 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.

# FINANCIAL REVIEW

## 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

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, August 22, 2025

**Magnus Persson**  
Chairman

**Annette Colin**  
Board member

**Peter Holm**  
Board member

**Gunilla Ekström**  
Board member

**Göran Ando**  
Board member

**Claus Elsborg Olesen**  
Board member and CEO



## FINANCIAL STATEMENTS

## Statement of income

TDKK	Q2-2025	Q2-2024	H1-2025	H1-2024	FY-2024
Gross loss	-2 721	-3 657	-4 822	-6 558	-11 073
Staff costs	-1 123	-1 334	-1 675	-2 010	-3 429
<b>Operating profit/loss</b>	<b>-3 844</b>	<b>-4 991</b>	<b>-6 497</b>	<b>-8 568</b>	<b>-14 502</b>
Net financial items	-20	205	-20	-341	-334
<b>Profit/loss before tax</b>	<b>-3 864</b>	<b>-4 786</b>	<b>-6 517</b>	<b>-8 909</b>	<b>-14 836</b>
Tax	-	-	-	-	1 904
<b>Net profit/loss for the period</b>	<b>-3 864</b>	<b>-4 786</b>	<b>-6 517</b>	<b>-8 909</b>	<b>-12 932</b>

## FINANCIAL STATEMENTS

## Statement of financial position

TDKK	June 30, 2025	Dec 31, 2024
<b>ASSETS</b>		
<b>Total non-current assets</b>	<b>17</b>	<b>17</b>
Other receivables	7 152	-
Income tax receivables	1 904	1 904
Cash and cash equivalents	4 700	13 371
<b>Total current assets</b>	<b>13 756</b>	<b>15 275</b>
<b>Total assets</b>	<b>13 773</b>	<b>15 292</b>
<b>EQUITY AND LIABILITIES</b>		
Contributed capital	5 897	5 897
Retained earnings	2 369	8 885
<b>Total equity</b>	<b>8 266</b>	<b>14 782</b>
Convertible credit agreement	2 189	-
<b>Total non-current liabilities</b>	<b>2 189</b>	<b>-</b>
Trade payables	2 794	366
Other current liabilities	155	-341
Accrued expenses	369	485
<b>Total current liabilities</b>	<b>3 318</b>	<b>510</b>
<b>Total equity and liabilities</b>	<b>13 773</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	-	-8 909	-8 909
<b>June 30, 2024</b>	<b>5 885</b>	<b>13 031</b>	<b>18 916</b>
<b>January 1, 2025</b>	<b>5 896</b>	<b>8 886</b>	<b>14 782</b>
Profit/loss for the period	-	-6 517	-6 517
<b>June 30, 2025</b>	<b>5 896</b>	<b>2 369</b>	<b>8 265</b>

## FINANCIAL STATEMENTS

## Statement of cash flow

TDKK	Q2-2025	Q2-2024	H1-2025	H1-2024	FY-2024
Operating profit/loss	-3 864	-4 991	-6 517	-8 568	-14 502
Adjustments for non-cash transactions	21	-	21	-	4 834
<b>Cash flow from operations before change in working capital</b>	<b>-3 843</b>	<b>-4 991</b>	<b>-6 496</b>	<b>-8 568</b>	<b>-9 668</b>
Interest received	32	244	55	347	499
Interest paid	-52	-39	-75	-687	-832
Changes in working capital	-4 408	513	-4 344	-2 166	-2 078
<b>Cash flow from operations</b>	<b>-8 271</b>	<b>-4 273</b>	<b>-10 860</b>	<b>-11 074</b>	<b>-12 079</b>
<b>Investing activities</b>	-	-	-	-	-
<b>Cash flow from investing activities</b>	-	-	-	-	-
<b>Financing activities</b>	-	-	-	-	-
Purchase of treasury shares	-	-	-	-580	-690
Sale of treasury shares	-	-	-	10	13
New share issue	-	-	-	17 233	1 792
Credit agreement with MAC	2 189	-	2 189	-15 437	-
<b>Cash flow from financing activities</b>	<b>2 189</b>	<b>-</b>	<b>2 189</b>	<b>1 226</b>	<b>1 115</b>
<b>Cash flow for the reporting period</b>	<b>-6 082</b>	<b>-4 273</b>	<b>-8 671</b>	<b>-9 848</b>	<b>-10 964</b>
Cash and cash equivalents at the beginning of period	10 782	18 760	13 371	24 336	24 336
<b>Cash and cash equivalents at the end of period</b>	<b>4 700</b>	<b>14 487</b>	<b>4 700</b>	<b>14 487</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

# Initiator Pharma

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

Initiator Pharma A/S

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# Q2

# 2025