Q3

Initiator Pharma

INTERIM REPORT JANUARY - SEPTEMBER

2025

BUSINESS HIGHLIGHTS

Business highlights in Q3 2025

- In July the Company announced the outcome of the Company's rights issue of up to 14,039,590 shares for which the subscription period ended on 26 June 2025. In the Rights Issue, 6,133,159 shares, corresponding to around 43.7 percent of the Rights Issue were subscribed through subscription rights. Additionally, 277,458 shares, corresponding to around 2.0 percent of the Rights Issue were subscribed without subscription rights. 5,670,164 shares, corresponding to around 40.4 percent of the Rights Issue were subscribed through guarantee undertakings. The Rights Issue will provide the Company with proceeds of approximately SEK 48.3 million before deduction of costs related to the Rights Issue.
- In September the Company announced the submission of a clinical trial application (CTA) to the UK's Medicines and Healthcare products Regulatory Agency (MHRA), and local ethics committee in the UK for the approval to conduct a Phase IIa clinical proof-of-concept study in women suffering from vulvodynia, a severe chronic pain condition affecting approximately 10 percent of women worldwide. The study will be conducted together with MAC Clinical Research in the UK.

Business highlights after this reporting period

- In November the Company announced that its Clinical Trial Application (CTA) for the planned Phase IIa clinical proof-of-concept study in women with vulvodynia has been approved by the UK Medicines and Healthcare products Regulatory Agency (MHRA) and a local ethics committee. First patients are expected to be enrolled in Q4 2025.

Financial Highlights

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

TDKK	Q3-2025	Q3-2024	9M-2025	9M-2024	FY-2024
Net sales	-	-	-	-	-
Total operating expenses	-4,318	-3,233	-10,815	-11,801	-14,502
Operating profit/loss	-4,318	-3,233	-10,815	-11,801	-14,502
Net result	-4,250	-3,172	-10,767	-12,081	-12,932
Earnings per share before and after dilution (DKK)	-0.06	-0.06	-0.16	-0.22	-0.23
Cash flow from operating activities	-4,431	-2,508	-15,337	-13,583	-12,080

TDKK	Q3-2025	Q3-2024	30.09.2025	30.09.2024	31.12.2024
Cash and cash equivalents	28,674	11,979	28,674	11,979	13,371
Equity	32,466	15,744	32,466	15,744	14,782
Total equity and liabilities	36,836	17,201	36,836	17,201	15,292
Equity ratio, %	88 %	92 %	88 %	92 %	97 %
Number of shares outstanding	*68,452,892*	*56,049,861*	*68,452,892*	*56,049,861*	*56,158,361*
Number of shares, diluted	*69,110,392*	*57,250,894*	*69,110,392*	*57,250,894*	*56,815,861*
Average number of shares outstanding	*68,417,267*	*56,049,861*	*60,244,663*	*55,460,923*	*55,624,734*
Average number of shares, diluted	*69,074,767*	*57,250,894*	*60,902,163*	*57,250,894*	*57,267,470*

LETTER FROM THE CEO

In the third quarter of 2025, following our successful capital raise during the summer, Initiator Pharma focused on preparing our planned randomized, placebo-controlled Phase IIa proof-of-concept study in 24 women with vulvodynia – a debilitating condition with no approved therapies and a significant unmet medical need. The clinical study which will be conducted in the UK received regulatory approval in early November. We have now initiated patient enrolment and aim to dose the first participants before the end of the year, with study completion anticipated by the end of 2026.

Advancing the vulvodynia Phase IIa study

We remain convinced of the potential of our portfolio and are committed to delivering strong clinical data in areas where our products can provide true patient benefit — with a particular focus on pain and sexual health in both men and women.

Our lead compound, pudafensine, is a unique dopamine modulator with a dual mechanism of action. Pudafensine increases dopamine levels centrally to relieve pain, while also addressing sexual dysfunction. No other compound in development matches pudafensine's pharmacological profile. Furthermore, and most importantly, pudafensine has been shown to have a benign safety profile in over 100 patients dosed in our clinical trials in erectile dysfunction.

With the upcoming Phase IIa study in vulvodynia, we aim to generate the first clinical proof-of-concept data in this neuropathic pain condition.

Assuming pudafensine reaches the market, it would become the first approved treatment for vulvodynia, thereby creating a new therapeutic category, offering potential blockbuster sales in vulvodynia as the first indication, but follow-up opportunities within a broad range of neuropathic pain indications over time.

The trial is conducted in collaboration with our UK-based partner and shareholder, MAC Clinical Research (MAC), and is primarily financed through a convertible credit agreement of up to GBP 2.5 million. This financing has several advantages; it shows MAC´s continued support as a validating and skilled shareholder, and their trust in our assets.

MAC is a large provider of CRO services, not only to biotech companies like us, but also to big pharma. MAC has operations in Northern Europe and in the US, and has true expertise in sexual health and pain, having executed a large number of clinical trials in these segments. Hence, MAC has the reach to relevant clinicians and, therefore, patient recruitment is expected to be very efficient. MAC is the largest, private CRO in northern Europe, so I am both proud and pleased that we have such strong support from MAC besides the great support we continue to receive from our largest shareholder, Linc, supporting us through an increased ownership during the capital raise this summer.

Strategic focus and portfolio progress

Our strategic focus remains, with intense business development activities to attract one or several partners for our assets. Pudafensine has already demonstrated strong efficacy as a monotherapy in a Phase IIb study in organic erectile dysfunction (ED).

LETTER FROM THE CEO

Preclinical data also indicate that pudafensine, when combined with PDE5 inhibitors, has a unique complementary profile which could benefit patients who do not respond adequately to existing ED therapies.

Having recently returned from BIO-EUROPE, which was held in Vienna during the first week of November, we are encouraged by the increased interest from both regional and global pharmaceutical companies in mid stage clinical assets. Hence, we are well poised for progressing and intensifying industry discussions for both our pudafensine and our IP2018/IP2016 franchises. Due to the potential in pain as well as in sexual health, we have broadened our industry discussions to cover companies with an interest in the pain segment as well, and we are very encouraged by the interest we obtain.

Advancing the vulvodynia Phase IIa study

Patient enrolment is now underway for our randomized, placebo-controlled Phase IIa study evaluating the pain-relieving effects and safety of single oral doses of pudafensine. The four-way crossover design allows each participant to receive both pudafensine and placebo during separate treatment periods, ensuring robust and comparative data.

We aim to initiate dosing before the end of 2025 and report topline results by late 2026. This study builds on the encouraging results from our previous pain challenge trial and could establish pudafensine as a first-in-class treatment in a field where patients currently have no approved therapeutic options.

Entering a new phase of growth

Initiator Pharma now enters a new and exciting phase with the launch of the vulvodynia study and acceleration and broadened scope of our partnering activities. We move forward with a solid scientific foundation, an attractive portfolio, a strong financial position, and the backing of an engaged network of collaborators and shareholders.

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

Copenhagen, November 21, 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.

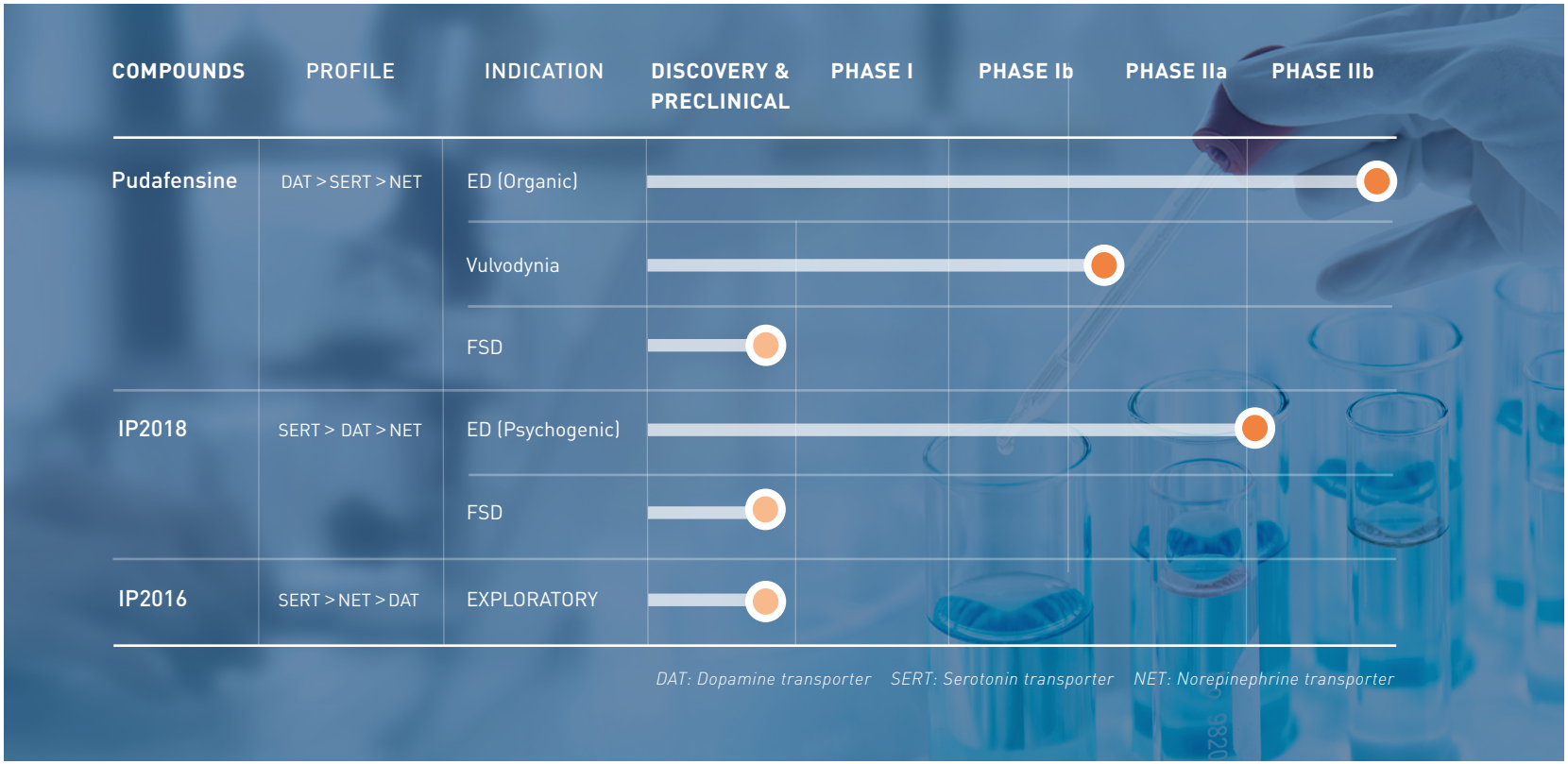
Business model

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 Neuropathic 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[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 150 million men worldwide and a number that is estimated to increase to more than 300 million by 2025. About 30-40% of these patients will not respond to the current treatment and represent a significant unmeet medical need. This is exactly Initiator's primary target group and will clearly distinguish us form the PDE5i drugs, where patent expiry results in increasing price pressure from generics.

PUDAFENSINE

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.

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 [2]. 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 [3]. About 13 percent of all Americans take antidepressant drugs, which means over 23 million prescriptions per year [4]. 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 [5]. 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.

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

[2] *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.*

[3] *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.*

[4] *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.*

[5] *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) including vulvodynia has entered national phase in Australia, Brazil, Canada, China, Europe, Israel, Japan, Mexico, Singapore, South Africa, South Korea, Taiwan, and the USA. A patent has granted in South Africa while applications are pending in the other jurisdictions. This patent family can be kept in force until 2043.

Further protection for medical use of pudafensine is conferred by a specified dosage regime of pudafensine, for the treatment of all types of pain, including vulvodynia, and 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 medical use of pudafensine is conferred by a specified dosage regime of pudafensine, for the treatment of erectile dysfunction. 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 include a patent conferring proprietary chemistry protection for IP2018 in the USA. The other patents in Israel, Japan, the United Kingdom, Germany, France, and Switzerland have expired in Q3/2025.

In addition to the composition of matter patent in the USA outlined above, patent protection for the use of IP2018 for the treatment of ED in depressive patients (psychogenic ED) is pending in Brazil, Canada, China, Europe (divisional), South Korea and the USA; and has been granted in Australia, 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 WO 2025/051846.

PATENT PROTECTION

IP2016

A new PCT application from Initiator Pharma was published on 21 August 2025 as WO 2025/172422 and is protecting an entiopure composition 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 2045.

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 third quarter or the first nine months of 2025.

Earnings

The company recognized an operating loss of TDKK 4,318 for the third quarter of 2025 (-3,233). The increase in operating costs for the third quarter compared to last year reflects the start-up of the Phase IIa clinical trial in vulvodynia with pudafensine as well as fundraising efforts that were completed in early Q3.

External R&D costs in the third quarter amounted to TDKK 898 compared to TDKK 173 in the same period in 2024. For the first nine months of the year external R&D costs amounted to TDKK 1,316, compared to TDKK 1,713 in the same period in 2024.

Net financial income in the third quarter amounted to TDKK 68, compared to net financial income of TDKK 61 in the same period in 2024. The net financial income in the third 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 nine months of the year the net financial income amounted to TDKK 48 compared to net financial expenses of TDKK 280 for the same period last year.

The net loss after tax for the third quarter was TDKK 3,864 (-4,786) and earnings per share totaled to DKK -0.06 (-0.06). For the first nine months of the year net loss after tax amounted to TDKK 6,517 (-8,909) and earnings per share DKK -0.16 (-0.22).

Financial position

The equity as of September 30 was TDKK 32,466 compared to TDKK 14,782 at year-end 2024. Cash and cash equivalents amounted to TDKK 28,674 as of September 30 compared to TDKK 13,371 at year-end 2024, and total assets were TDKK 36,836 compared to 15,292 at year-end 2024.

Cash flow

In the third quarter the total operating cash flow was TDKK -4,431 (-2,508), incl. a negative change in working capital of TDKK 180 (664). 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 nine months the total operating cash flow was TDKK -15,337 (-13,583), incl a negative change in working capital of TDKK 4,524 (-1,502).

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

Cash flow from financing activities in the third quarter was TDKK 28,405 (-) and TDKK 30,640 for the first nine months (1,226) and relates to the share issue completed in July as well as financing of part of the Phase II clinical trial costs through the announced convertible financing agreement with MAC Clinical Research.

Cash flow for the third quarter totalled to TDKK 23,974 (-2,508) and TDKK 15,303 (-12,357) for the first nine months of the year.

Top 10 shareholders as of September 30, 2025		
Owners	**Number of shares**	**Shares %**
LINC AB	13,464,318	19.67 %
Adrigo Small and Midcap L/S	5,221,453	7.63 %
Avanza Pension	3,825,024	5.59 %
MAC Clinical Research Finance LTD	3,823,333	5.59 %
Håkan Kjellman	1,500,466	2.19 %
Nordnet Pension Insurance	1,465,389	2.14 %
Claus Elsborg Olesen	1,430,125	2.09 %
Dan Peters	1,346,544	1.97 %
Mats Thorén	986,473	1.44 %
Annika Espander Jansson	943,299	1.38 %
Ten largest shareholders	34,006,424	49.68 %
Other shareholders	34,446,468	50.32 %
Total	**68,452,892**	**100.00 %**

The share, share capital and ownership structure

As of September 30, 2025, the number of shares outstanding totalled to 68,452,892 shares and on a fully diluted basis 69,110,392, including warrants under the LTI2023 incentive program.

As of September 30 the company had around 3,700 shareholders. The 10 largest shareholders in the company on September 30 owned 49.7% of all outstanding shares.

On May 19 the company announced a planned rights issue totalling up to 14,039,590 shares (1:4 existing shares) at a subcription price of SEK 4,00 per share, in total up to SEKM 56. 85% or SEK 48 million 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 million 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.

Under the convertible credit agreement with MAC Clinical Research financing up to ca GBP 2.5 million 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 7.74.

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

Personnel

As of September 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.

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

Year-end report 2025 (Q4)	20 February 2026
Annual report 2025	Week of April 27, 2026
Interim Q1 2026 report	8 May 2026
Annual General Meeting 2026	29 May 2026
Interim Q2 2026 report	21 August 2026
Interim Q3 2026 report	20 November 2026

The financial reports will be disclosed on https://www.initiatorpharma.com/en/investors/financial-reports/

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, November 21, 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	Q3-2025	Q3-2024	9M-2025	9M-2024	FY-2024
Gross loss	-3,840	-2,549	-8,662	-9,107	-11,073
Staff costs	-478	-684	-2,153	-2,694	-3,429
Operating profit/loss	**-4,318**	**-3,233**	**-10,815**	**-11,801**	**-14,502**
Net financial items	68	61	48	-280	-334
Profit/loss before tax	**-4,250**	**-3,172**	**-10,767**	**-12,081**	**-14,836**
Tax	-	-	-	-	1,904
Net profit/loss for the period	**-4,250**	**-3,172**	**-10,767**	**-12,081**	**-12,932**

FINANCIAL STATEMENTS

Statement of financial position

TDKK	September 30, 2025	Dec 31, 2024
ASSETS		
Total non-current assets	**17**	**17**
Other receivables	251	-
Income tax receivables	1,904	1,904
Prepayments	5,990	-
Cash and cash equivalents	28,674	13,371
Total current assets	**36,819**	**15,275**
Total assets	**36,836**	**15,292**
EQUITY AND LIABILITIES		
Contributed capital	7,187	5,897
Retained earnings	25,279	8,885
Total equity	**32,466**	**14,782**
Convertible credit agreement	2,143	-
Total non-current liabilities	**2,143**	**-**
Trade payables	2,414	366
Other current liabilities	-316	-341
Accrued expenses	129	485
Total current liabilities	**2,227**	**510**
Total equity and liabilities	**36,836**	**15,292**

FINANCIAL STATEMENTS

Statement of changes in shareholder equity

TDKK	Contributed capital	Retained earnings	Total
January 1, 2024	**5,498**	**28,525**	**34,023**
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**
January 1, 2024	**5,509**	**5,653**	**11,162**
Share issue	376	16,857	17,233
Purchase of treasury shares	-	-580	-580
Sale of treasury shares	-	10	10
Profit/loss for the period	-	-12,081	-12,081
September 30, 2024	**5,885**	**9,859**	**15,744**
January 1, 2025	**5,896**	**8,886**	**14,782**
Share issue	1,291	31,620	32,911
Costs in association with increase of capital		-4,460	-4,460
Profit/loss for the period		-10,767	-10,767
September 30, 2025	**7,187**	**25,279**	**32,466**

Statement of cash flow

TDKK	Q3-2025	Q3-2024	9M-2025	9M-2024	FY-2024
Operating profit/loss	-4,250	-3,172	-10,767	-12,081	-14,502
Adjustments for non-cash transactions	-69	-	-26	-	4,834
Cash flow from operations before change in working capital	**-4,319**	**-3,172**	**-10,793**	**-12,081**	**-9,668**
		-		-	
Interest received	131	-3,172	55	-12,081	499
Interest paid	-63		-75		-832
Changes in working capital	-180	664	-4,524	-1,502	-2,078
Cash flow from operations	**-4,431**	**-2,508**	**-15,337**	**-13,583**	**-12,079**
Investing activities	-	-	-	-	-
Cash flow from investing activities	**-**	**-**		**-**	**-**
Financing activities					
Purchase of treasury shares	-	-	-	-580	-690
Sale of treasury shares	-	-	-	10	13
New share issue	28,451	-	28,451	17,233	1,792
Credit agreement with MAC	-46	-	2,189	-15,437	-
Cash flow from financing activities	**28,405**	**-**	**30,640**	**1,226**	**1,115**
Cash flow for the reporting period	**23,974**	**-2,508**	**15,303**	**-12,357**	**-10,964**
Cash and cash equivalents at the beginning of period	4,700	14,487	13,371	24,336	24,336
Cash and cash equivalents at the end of period	**28,674**	**11,979**	**28,674**	**11,979**	**13,371**

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

INTERIM REPORT JANUARY - SEPTEMBER

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2025

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