Q3

Initiator Pharma

INTERIM REPORT JANUARY - SEPTEMBER

2024

BUSINESS HIGHLIGHTS

Business highlights in Q3 2024

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

Business highlights after this reporting period

- Nothing to report

Financial Highlights

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

KDKK	Q3-2024	Q3-2023	9M-2024	9M-2023	FY-2023
Net sales	-	-	-	-	-
Total operating expenses	-3 233	-5 191	-11 801	-22 750	-27 029
Operating profit/loss	-3 233	-5 191	-11 801	-22 750	-27 029
Net result	-3 172	-4 614	-12 081	-24 303	-27 706
Earnings per share before and after dilution (DKK)	-0.06	-0.09	-0.22	-0.46	-0.53
Cash flow from operating activities	-2 508	-6 749	-13 583	-19 937	-17 647

KDKK	Q3-2024	Q3-2023	30.09.24	30.09.23	31.12.2023
Cash and cash equivalents	11 979	21 781	11 979	21 781	24 336
Equity	15 744	9 733	15 744	9 733	11 162
Total equity and liabilities	17 201	27 298	17 201	27 298	29 786
Equity ratio, %	92%	36%	92%	36%	37%
Number of shares outstanding	*56 049 861*	*52 471 887*	*56 049 861*	*52 471 887*	*52 471 887*
Number of shares, diluted	*57 250 894*	*56 947 554*	*57 250 894*	*56 947 554*	*57 250 894*
Average number of shares outstanding	*56 049 861*	*52 371 054*	*55 460 923*	*52 366 470*	*52 419 179*
Average number of shares, diluted	*57 250 894*	*56 947 554*	*57 250 894*	*56 947 554*	*57 269 804*

LETTER FROM THE CEO

I am pleased to share an update on Initiator Pharma's progress during the third quarter of 2024. We have focused on two main objectives; our business development efforts for our programs in erectile dysfunction (ED), and our expansion into pain and female sexual dysfunction (FSD). As previously communicated, FSD complements the company's strong position within ED, and our most advanced asset, pudafensine is a clinical de-risked candidate with a novel mode of action modulating dopamine in pain while strengthening the natural sexual response. Our pre-clinical data in FSD, combined with our pre-clinical and clinical results in pain and ED strongly support pudafensine's potential in the indication.

Early in the quarter our international patent application concerning the dosage regime for our leading drug candidate pudafensine in the treatment of ED was published as WO2024/146892. This patent application provides a strong foundation for pudafensine, extending its protection until 2044 with possibilities for further extension. The revitalization of the patent portfolio continues as we progress in exploring pudafensine's potential as a standalone therapy or in combination with existing treatments to enhance efficacy due to its unique mechanism of action.

Erectile dysfunction is a significant medical condition affecting millions of men's lives globally. Our goal in advancing pudafensine for the treatment of ED is to provide an effective, well-tolerated therapy that can make a meaningful difference in patients' lives. The unique ability of pudafensine to increase central dopamine and peripheral nitric oxide release offers a new pathway for initiating and maintaining erection, setting it apart from current PDE5 inhibitors. A randomized double-blind study of 130 patients with moderate-to-severe ED with organic origin, showed statistically and clinically relevant efficacy Phase IIb data for our leading drug candidate pudafensine, clearly highlighting its potential to address a significant unmet medical need, and provides strong support for pudafensine's further development towards market authorization.

Phase III studies are required for the registration and marketing of pudafensine for the treatment of erectile dysfunction. As shown in our Phase IIb study with four weeks treatment, the effect of pudafensine was more pronounced with time. Phase III studies are typically longer, with treatment times of 12 weeks; therefore, we are excited to anticipate that pudafensine will have an even more significant effect in forthcoming studies of longer duration.

The further clinical development program for pudafensine also includes an optimized solid oral dosage form, for which we obtained positive data in 2023 demonstrating that the oral solid dosing formulations provide relevant drug bioavailability and pharmacokinetic drug release profiles.

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 in a Phase IIa clinical trial in 24 patients with mild to moderate ED.

We are encouraged by the interest in our Sexual Health Franchise from both regional and global partners. The growing interest in the Female

LETTER FROM THE CEO

Sexual Dysfunction (FSD) space, combined with the strong data we continue to generate with our assets in this area, position us well for potential collaborations that can further accelerate our growth and expand our reach.

We see a clear rationale for pudafensine in FSD, especially since it addresses the most bothersome aspects of several FSD-conditions: pain and sexual dysfunction. Pudafensine is a clinical de-risked candidate with a novel mode of action modulating dopamine in pain while strengthening the natural sexual response. Our pre-clinical data in FSD, combined with our pre-clinical and clinical results in pain and ED strongly support pudafensine's potential. We are currently evaluating indications where, considering the number of affected women, the market potential for an approved treatment is truly massive.

Our main focus remains on patients with moderate to severe ED – a difficult-to-treat patient group that often finds current treatments inadequate – and this is where we concentrate our business development efforts for our ED assets.

As we are approaching the end of this year, we are in the midst of a season of important business development meetings such as BioEurope, Jefferies Healthcare conference in London and the JP Morgan-week in the US. The compelling datasets for our two drug candidates within ED, and also our efforts in FSD, has drawn quite a lot of attention in the market which makes us very excited about our prospects of generating substantial shareholder value.

We will move forward with the same rigour and dedication that has brought us to this point. We will maintain our focus on low costs in our operations and a focus on value creation.

We are grateful for the continued, strong support from our largest shareholders, Linc, Adrigo and MAC, our CRO-partner as well as a validating and committed investor and I sincerely thank all our shareholders, partners, employees, and the entire Initiator Pharma community for their continued support. Together, we are making significant strides towards transforming the treatment landscape for sexual dysfunction and beyond.

Copenhagen, November 29, 2024

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 last year 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.

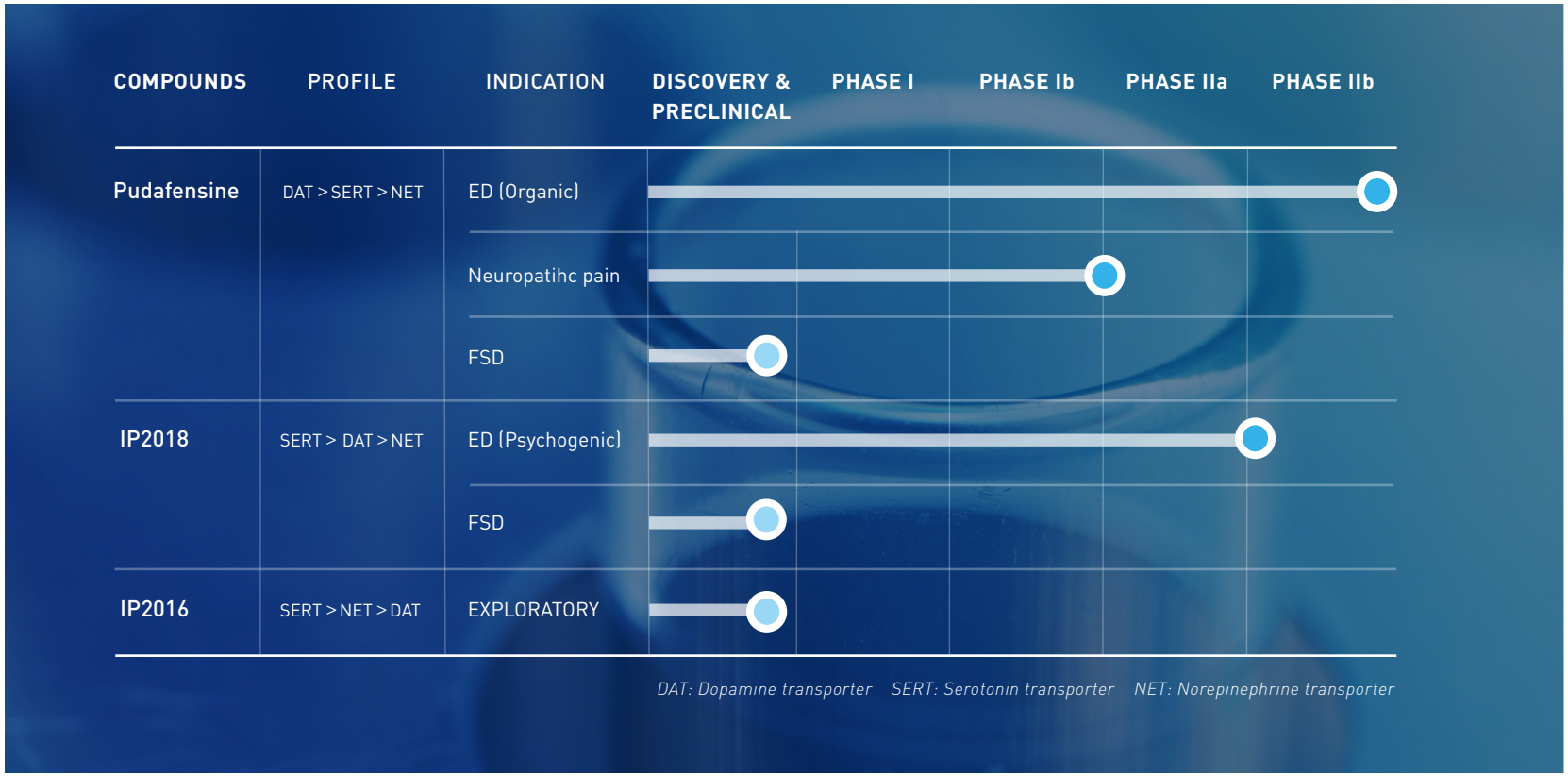
Business model

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 has decided to terminate the preclinical IP2017 program for commercial reasons:



PUDAFENSINE

Pudafensine: Pudafensine, Initiators's most advanced asset, is a monoamine reuptake inhibitor primarily targeting the dopamine system. Pudafensine is being developed for both treatment resistant organic Erectile Dysfunction (ED) and neuropathic pain.

Organic Erectile Dysfunction (pudafensine)

Pudafensine is positioned as a novel drug candidate for the treatment of patients suffering from organic ED that do not respond to the currently marketed drugs in the PDE5i class (e.g. Viagra®, Cialis®, Levitra®). Pudafensine - by having a dual action, both a central effect initiating erection and a peripheral effect potentiating erection through smooth muscle relaxation - is unique and aimed for treatment of ED in patients suffering from ED due to metabolic syndrome and diabetes.

The clinical positioning of pudafensine is to improve the quality of life for a large number of patients (and their partners) who do not respond or cannot be treated with currently marketed drugs (PDE5 inhibitors) for ED. It is estimated that this represents 150 million men worldwide [1].

At the beginning of June 2019, Initiator announced that the company had successfully completed a Phase I study regarding safety and tolerability with pudafensine, and in March 2020, Initiator achieved successful Phase IIa results for pudafensine. The Phase IIa study was designed as an exploratory study and included twelve patients who had severe ED with scores below 12 on the IIEF-5 scale, which meant that it was not possible to treat the condition with currently available treatment. Results from the study support the goal of further developing an oral formulation of pudafensine for the treatment of moderate and severe ED in patients who do not respond to current therapies.

In October 2023, Initiator reported statistically significant and clinically relevant efficacy in ED-related endpoints and no observations of critical adverse events from its Phase IIb clinical trial with pudafensine for the treatment of ED. The positive results, both regarding efficacy and safety, support further development of pudafensine aiming at registration and launch in this patient group with significant unmet medical need.

The Phase IIb trial was a randomized, double-blind, placebo-controlled, parallel-dosing group trial studying the efficacy and safety of high and low doses of pudafensine and placebo in otherwise healthy patients suffering from moderate to severe ED. The study comprised 130 patients divided into 3 parallel arms receiving a higher and a lower dose of pudafensine and placebo, respectively, with treatment duration of 4 weeks with frequent assessments of ED, safety and pharmacokinetics. The study was conducted at the MAC clinical sites in the UK.

Erectile Dysfunction (ED) Market

The current number of ED patients is estimated to about 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. In 2015 the ED market generated about 4 USD billion in sales and Initiator Pharma strongly believes that targeting the PDE5i non-responders will allow for premium pricing for pudafensine and thereby generate substantial commercial value for Initiator Pharma.

PUDAFENSINE

Neuropathic pain/Trigeminal Neuralgia

In Q3 2022 Initiator announced the final data from a clinical Phase I study to assess pain-reducing effects, comprising 24 healthy male subjects challenged with the pain-inducing ingredient (capsaicin). The study was a randomized, double-blind, placebo-controlled study in 24 healthy male subjects, investigating the effects on pain measures (hyperalgesia, allodynia, and subjects' pain rating) of single doses of pudafensine, pregabalin as active control, and placebo. Pudafensine demonstrated a statistically significant effect on allodynia (p=0.049) and showed a dose-dependent effect on the measured pain parameters. Pregabalin (p=0.083) and pudafensine (p=0.051) tended to reduce hyperalgesia, although the effects on hyperalgesia were not statistically significant compared to placebo-treated subjects. In addition, there were no observations of unexpected adverse events.

Following a thorough review of the final dataset, the company initiated an open-labeled randomized Phase I drug formulation and pharmacokinetics (PK) study in 12 healthy subjects evaluating optimized oral solid dosage forms of pudafensine. The study was started in the beginning of 2023 and in Q3 2023 Initiator reported positive results, enabling a smooth and efficient bridging between previous data sets into new future clinical studies for pudafensine.

The pudafensine development plan aims for orphan drug designation for trigeminal neuralgia and the future ambition is to seek a fast track designation at the FDA and EMA to obtain regulatory support from the authorities and significantly reduce the lead time to product registration.

Neuropathic pain/Trigeminal Neuralgia Market

Trigeminal neuralgia is a chronic neuropathic pain condition that affects the trigeminal nerve. The trigeminal nerve carries sensation from the face to the brain. In patients with trigeminal neuralgia, even mild stimulation of the face, such as brushing your teeth or putting on makeup, may trigger a jolt of excruciating pain. The disease is seriously invalidating. US-based studies estimate that there are between 51,500 and 133,000 cases of Trigeminal Neuralgia in the US. Anecdotally, healthcare providers and health insurance plans in the US claim that 140,000 people suffer with Trigeminal Neuralgia in the US (Nguyen, 2010; Aetna, 2021).

Trigeminal neuralgia affects women more often than men, and it's more likely to occur in people who are older than 50. The causes of the disease include pressure on the nerve, aging, brain disease or is idiopathic. The treatment involves medications and surgery. Clinical guidelines recommend carbamazepine (the only drug FDA-approved for TN) and oxcarbazepine as first-line therapies, however the current medication is often found ineffective and with serious adverse events [2,3].

The neuropathic pain market is estimated to reach USD 9.8 billion annually by 2027 according to Garner market analysis, with an annual growth rate of 6.4% [4]. On average annual healthcare cost for painful neuropathic disorder is US 17,355 per patient. With a solid efficacy and safety data on pudafensine in neuropathic pain Initiator Pharma expect to target a commercial opportunity with the potential to reach high hundreds of USD million in annual sales.

IP2018

IP2018: IP2018 is a monoamine reuptake inhibitor for the treatment of psychogenic ED (mainly caused by anxiety and depression) mainly targeting the serotonin instead of the dopamine system. IP2018 is differentiated from the company's frontrunner pudafensine for organic ED (mainly caused by diabetes and age) that is primarily targeting the dopamine system:

- IP2018 is positioned to treat patients suffering major depressive disorder where the majority also suffer from comorbid sexual dysfunction or treatment-emergent sexual dysfunction.
- IP2018 has demonstrated an excellent safety profile in a single dose study and the proof of mechanism PET study, confirming the safety and the mechanism of action of the company's extensive package of preclinical data.
- IP2018 is efficacious in animal models of depression (forced swim and tail suspension tests) and ED (intracavernosal pressure to mean arterial pressure ratio) as well as in several mouse anxiety models.
- IP2018 is targeting a clear unmet medical need as up to 68% of patients with major depressive disorder suffer from sexual dysfunction, for which only 5% to 30% is resolved with antidepressant treatment

IP2018 raises the serotonin levels in the brain, and in its preclinical trials, Initiator Pharma has shown that IP2018 has an effect on both depression and ED, which is a clear differentiation from other antidepressants on the market today. In the planned clinical Phase IIa trial, Initiator Pharma intends to primarily confirm the effect of IP2018 on the ED of patients and thereafter, if the outcome is positive, follow up with further clinical safety trials on multiple dosage parameters. The 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.

Depression Market

Psychogenic ED, which is the inability to achieve or maintain an erection during sexual intercourse due to psychological factors. Up to 68% of patients undergoing treatment for depressive disorder also suffer from sexual dysfunction. The patient segment thus represents a clear unmet

IP2018

medical need. IP2018 has the potential to help these patients and significantly increase their quality of life. In addition, IP2018 broadens the scope of Initiator Pharma pipeline, including first-in-class treatments for psychogenic and organic ED, IP2018 and pudafensine, respectively.

The main treatments for depression are drugs that selectively inhibit the uptake of serotonin (SSRIs) or serotonin and norepinephrine (SNRIs) or the breakdown of serotonin, norepinephrine and dopamine by inhibiting monoamine oxidase. Antidepressants such as SSRIs and SNRIs have a negative effect on male sexual function. Although the incidence of sexual dysfunction is lower with certain atypical antidepressants, such as bupropion, mirtazapine and vortioxetine, compared to SSRIs, it is nevertheless important to treat sexual dysfunction induced by antidepressant drugs (treatment-induced sexual dysfunction). In one study, it was observed that 41.7 percent of men discontinued psychiatric medication due to perceived sexual side effects [5]. Between 14 and 35 percent of young men have experience with ED, which may be due to performance anxiety, depression, schizophrenia, or other mental disorders [6]. About 13 percent of all Americans take antidepressant drugs, which means over 23 million prescriptions per year [7]. The global Anxiety Disorder and Depression Treatment Market is forec asted to grow at an annual rate of 2.4 percent from USD 15.8 billion in 2019 to USD 19.2 billion in 2027 [8]. The largest players are Pfizer, Eli Lilly, GlaxoSmithKline, AstraZeneca and H Lundbeck A/S, accounting for more than 60% of antidepressants sold. All are facing major patent expirations in the next few years, and generics and biosimilars are expected to hit revenues hard. All drugs currently on the market have been associated with ED to varying degrees, and this underlines the need to develop a better alternative.

[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] *Joanna M. Zakrzewska, Eastman Dental Hospital, London, United Kingdom Mark E. Linskey, University of California Irvine, Irvine, California Am Fam Physician. 2016 Jul 15;94(2):133-135.*

[3] *Jones, M.R., Urits, I., Ehrhardt, K.P., Cefalu, J.N., Kendrick, J.B., Park, D.J., Cornett, E.M., Kaye, A.D. and Viswanath, O., 2019. A comprehensive review of trigeminal neuralgia. Current pain and headache reports, 23(10), pp.1-7.*

[4] *Coherent Market Insights "Neuropathic Pain Market Analysis" (2020), https://www.coherentmarketinsights.com/market-insight/neuropathic-pain-market-3656.*

[5] *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.*

[6] *Quilter M, Hodges L, von Hurst P, Borman B, Coad J. Male sexual function in New Zealand: a population-based cross-sectional survey of the prevalence of erectile dysfunction in men aged 40-70 years. J Sex Med. (2017) 14:928–36. doi: 10.1016/j.jsxm.2017.05.011*

[7] *Pratt, L. A., Brody, D. J., & Gu, Q. (2017). Antidepressant Use among Persons Aged 12 and Over: United States, 2011-2014. NCHS Data Brief. Number 283. National Center for Health Statistics.*

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

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 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 composition of matter patent outlined above, protection for the use of pudafensine for the treatment of Female Sexual Dysfunction (FSD) is pending as a PCT application and was published on 11 January 2024 as WO 2024/008808. The European Patent Office (EPO) acting as International Searching Authority has acknowledged patentability of these claims. The PCT application will enter national phase in relevant major markets in Q1/2025. An analogous national patent application is also pending in non-PCT country Taiwan. When granted, this patent family can be kept in force until 2043.

Further protection for use of pudafensine is conferred by a specified dosage regime of pudafensine, for the treatment of all types of pain, via a pending PCT application published on 02 May 2024 as WO 2024/089247. The European Patent Office acting as International Searching Authority has acknowledged patentability of the claims. The PCT application will enter national phase in relevant major markets in Q2/2025. When granted, this patent family can be kept in force until 2043.

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

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

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.

FINANCIAL REVIEW

Revenue

Initiator Pharma generated no revenues for the third quarter and the first nine months of 2024 (-).

Earnings

The company recognized an operating loss of KDKK 3,233 for the third quarter of 2024 (-5,191) and an operating loss of KDKK 11,801 for the first nine months (-22,750). The decrease in operating costs for the third quarter and the first nine months of the year compared to last year reflects the high level of clinical development activities during the first nine months of last year.

External R&D costs in the third quarter amounted to KDKK 173 compared to KDKK 3,194 in the same period in 2023. For the first nine months of the year external R&D costs amounted to KDKK 1,713, compared to KDKK 14,628 in the same period in 2023.

Net financial income in the third quarter amounted to KDKK 61, compared to net financial income of KDKK 577 in the same period in 2023. The net financial expenses in the third quarter is related to currency fluctuations during the quarter. For the first nine months of the year the net financial expenses amounted to KDKK 280 compared to KDKK 1,553 for the same period last year.

The net loss after tax for the third quarter was KDKK 3,172 (-4,614) and earnings per share totaled to DKK -0.06 (-0.09). For the first nine months of the year net loss after tax amounted to KDKK 12,081 (-24,303) and earnings per share DKK -0.22 (-0.46).

Financial position

The equity as of September 30, was KDKK 15,744 compared to KDKK 11,162 at year-end 2023, reflecting the conversion of the receivable held by MAC Clinical Research which co-financed the Phase IIb clinical trial with pudafensine. Cash and cash equivalents amounted to KDKK 11,979 as of September 30 compared to KDKK 24,336 at year-end 2023, and total assets were KDKK 17,201 and 29,786 at year-end 2023.

Cash flow

In the third quarter the cash flow from operating activities was KDKK -2,508 (-4,154), including a reduction in working capital of KDKK 664 (+2,135). The decrease in working capital is mainly related to payment of accrued expenses during the period. For the first nine months the cash flow from operating activities was KDKK -13,583 (-19,937), incl. a negative change in working capital of KDKK 1,502 (-4,011).

The company had no cash flow from investment activities in the third quarter or during the first nine months of the year.

The company had no cash flow from financing activities in the third quarter. For the first nine months of the year the cash flow from financing activities was KDKK 1,226 (-). During the first nine months the MAC receivable of DKK 17.4 million was converted into 3,058,667 shares in Initiator Pharma. During the first 9 months the company also issued 519,307 new shares to management and key

employees under the LTI2021 incentive program as well as acquired 98,915 own shares at a price of SEK 8.94 per share which were sold to board members at a price of DKK 0.105 under the LTI2021 incentive program. The incentive programs in Initiator Pharma are described in detail in the Annual Report for 2023.

Cash flow for the third quarter totalled to KDKK -2,508 (-4,154) and KDKK -12,357 for the first nine months of the year (-17,331).

The share, share capital and ownership structure

At September 30, 2024, the number of shares outstanding totalled to 56,049,861 shares and on a fully diluted basis 57,250,894, incl. warrants under the LTI2022 and LTI2023 incentive programs.

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

On February 21st the company issued 3,058,667 shares to MAC Clinical Research through the conversion of the MAC receivable of KDKK 17,404. The conversion was conducted at the pre-agreed share price of SEK 7,50 per share.

Top 10 shareholders as of September 30, 2024

Owners	Number of shares	Shares %
LINC AB	10 091 219	18,00%
Adrigo Small and Midcap L/S	4 354 207	7,77%
Avanza Pension	3 288 201	5,87%
MAC Clinical Research Finance LTD	3 058 667	5,46%
Claus Elsborg Olesen	1 337 625	2,39%
Dan Peters	1 202 794	2,15%
Nordnet Pension Insurance	957 536	1,71%
Annika Espander Jansson	943 299	1,68%
Mikael Thomsen	836 467	1,49%
Mats Thóren	757 634	1,35%
Ten largest shareholders	26 827 649	47,86%
Other shareholders	29 222 212	52,14%
Total	**56 049 861**	**100,00%**

As of September 30 the company had around 4,000 shareholders. The 10 largest shareholders in the company on September 30 owned approx. 47.9% of all outstanding shares.

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

Operational risks and uncertainties

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

The main risks and uncertainties which Initiator Pharma is exposed to are related to drug development, the company's collaboration agreements, competition, technology development, patent, regulatory requirements, capital requirements and currencies.

No new risks have arisen during the quarter. A more detailed description of the company's risk exposure and risk management is included in the Annual Report for 2023.

Prerequisites for continued operation

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

Audit review

This 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 2024 (Q4)	28 February 2025
Annual report 2024	Week of April 28, 2025
Interim Q1 2025 report	9 May 2025
Annual General Meeting 2025	23 May 2025
Interim Q2 2025 report	22 August 2025
Interim Q3 2025 report	21 November 2025

The financial reports will be disclosed on 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, November 29, 2024

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*

Statement of income

KDKK	Q3-2024	Q3-2023	9M-2024	9M-2023	FY-2023
Gross loss	-2 549	-4 504	-9 107	-20 720	-23 412
Staff costs	-684	-687	-2 694	-2 030	-3 617
Operating profit/loss	**-3 233**	**-5 191**	**-11 801**	**-22 750**	**-27 029**
Net financial items	61	577	-280	-1 553	-677
Profit/loss before tax	**-3 172**	**-4 614**	**-12 081**	**-24 303**	**-27 706**
Tax	-	-	-	-	-
Net profit/loss for the period	**-3 172**	**-4 614**	**-12 081**	**-24 303**	**-27 706**

Statement of financial position

KDKK	Sept 30, 2024	Sept 30, 2023	Dec 31, 2023
ASSETS			
Total non-current assets	**17**	**17**	**17**
Other receivables	371	-	599
Income tax receivables	4 834	5 500	4 834
Cash and cash equivalents	11 979	21 781	24 336
Total current assets	**17 184**	**27 281**	**29 769**
Total assets	**17 201**	**27 298**	**29 786**
EQUITY AND LIABILITIES			
Contributed capital	5 886	5 509	5 510
Retained earnings	9 858	4 224	5 652
Total equity	**15 744**	**9 733**	**11 162**
Convertible credit agreement	-	15 525	15 437
Total non-current liabilities	**-**	**15 525**	**15 437**
Trade payables	775	437	407
Other current liabilities	235	110	246
Accrued expenses	447	1 493	2 534
Total current liabilities	**1 457**	**2 040**	**3 187**
Total equity and liabilities	**17 201**	**27 298**	**29 786**

Statement of changes in shareholder equity

KDKK	Contributed capital	Retained earnings	Total
January 1, 2023	**5 498**	**28 525**	**34 023**
Share issue	11	-	11
Profit/loss for the period	-	-22 872	-22 872
December 31, 2023	**5 509**	**5 653**	**11 162**
January 1, 2023	**5 498**	**28 525**	**34 023**
Share issue	11	-	11
Profit/loss for the period	-	-19 689	-19 689
September 30, 2023	**5 509**	**8 836**	**14 347**
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**

Statement of cash flow

KDKK	Q3-2024	Q3-2023	9M-2024	9M-2023	FY-2023
Profit/loss before tax	-3 172	-4 614	-12 081	-24 303	-27 706
Adjustments for non-cash transactions	-	-	-	355	-
Profit/loss before tax, adj for non-cash transactions	**-3 172**	**-4 614**	**-12 081**	**-23 948**	**-27 706**
Tax credit	-	-	-	-	5 500
Cash flow before change in working capital	**-3 172**	**-4 614**	**-12 081**	**-23 948**	**-22 206**
Changes in working capital	664	-2 135	-1 502	4 011	4 559
Cash flow from operating activities	**-2 508**	**-6 749**	**-13 583**	**-19 937**	**-17 647**
Investing activities	-	-	-	-	-
Cash flow from investing activities	**-**	**-**	**-**	**-**	**-**
Financing activities					
Purchase of treasury shares	-	-	-580	-	
Sale of treasury shares	-	-	10	-	
New share issue	-	-	17 233	11	11
Credit agreement with MAC	-	2 595	-15 437	2 595	2 860
Cash flow from financing activities	**-**	**2 595**	**1 226**	**2 606**	**2 871**
Cash flow for the reporting period	**-2 508**	**-4 154**	**-12 357**	**-17 331**	**-14 776**
Cash and cash equivalents at the beginning of period	14 487	25 935	24 336	39 112	39 112
Cash and cash equivalents at the end of period	**11 979**	**21 781**	**11 979**	**21 781**	**24 336**

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

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.

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

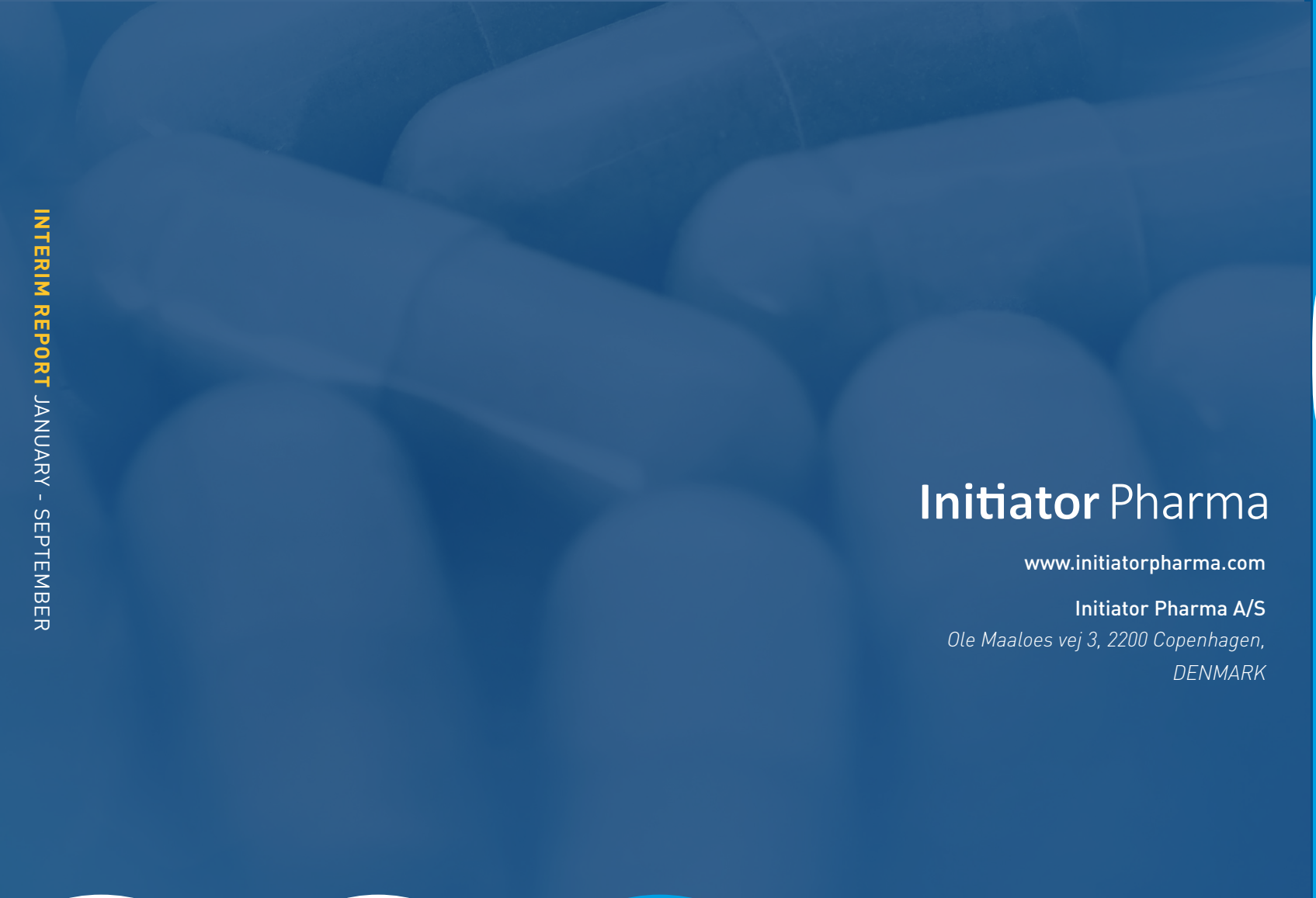
Earnings per share
Profit/loss for the period divided by the average number of shares outstanding at the end of the period

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

Q3

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2024