Q3
2023

INTERIM REPORT | January - September

Initiator Pharma

BUSINESS HIGHLIGHTS

Business highlights in Q3 2023

- In July the company announced that it has obtained positive data from a Phase I drug formulation and pharmacokinetics study in healthy subjects evaluating optimized oral solid dosage forms of pudafensine (IP2015), enabling a smooth and efficient bridging between previous data sets into new future clinical studies for pudafensine.
- In August the company announced that the European Patent Office ("EPO") has granted the company's patent application for the product candidate IP2018, targeting monoamine reuptake transporters.
- In September the company announced that the drug candidates, pudafensine and IP2018, have shown significant efficacy in preclinical models for Female Sexual Dysfunction (FSD). Based on the findings, the company is reviewing the potential to extend the clinical indications for the drug candidates to include FSD.

Business highlights after this reporting period

- In October the company announced positive results from its Phase IIb clinical trial with pudafensine (IP2015) for the treatment of erectile dysfunction (ED). The study data analysis has demonstrated statistically significant and clinically relevant efficacy in ED-related endpoints and no observations of critical adverse events. 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.

Financial Highlights

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

As disclosed in the Q1:2022 report Initiator Pharma publishes its interim reports in English only.

Financial review

KDKK	Q3:2023	Q3:2022	9M:2023	9M:2022	2022
Net sales	-	-	-	-	-
Total operating expenses	-5 191	-6 689	-22 750	-35 263	-41 740
Operating profit/loss	-5 191	-6 689	-22 750	-35 263	-41 740
Net result	-4 614	-6 789	-24 303	-35 495	-38 455
Earnings per share before and after dilution (DKK	-0,09	-0,13	-0,46	-0,68	-0,73
Cash flow from operating activities	-6 749	-7 988	-19 937	-25 048	-32 701

	3Q:2023	3Q:2022	9M:2023	9M:2022	31.12.2022
Cash and cash equivalents	21 781	46 768	21 781	46 768	39 112
Equity	9 733	36 986	9 733	36 986	34 023
Total equity and liabilities	27 298	53 081	27 298	53 081	47 488
Equity ratio, %	36%	70%	36%	70%	72%
Number of shares outstanding	*52 471 887*	*52 361 887*	*52 471 887*	*52 361 887*	*52 361 887*
Number of shares, diluted	*56 947 554*	*57 480 750*	*56 947 554*	*57 480 750*	*56 947 554*
Average number of shares outstanding	*52 371 054*	*51 878 824*	*52 366 470*	*46 979 832*	*48 325 346*
Average number of shares, diluted	*56 947 554*	*56 997 687*	*56 947 554*	*51 898 695*	*53 225 959*

LETTER FROM THE CEO

2023 has so far been an exciting and stimulating year for Initiator Pharma, where we have achieved multiple important milestones across our development pipeline. Our most important milestone, the positive statistically significant and clinically relevant efficacy data with pudafensine from the completed Phase IIb trial in psychogenic ED, was announced just after the end of the period. The results highlight the potential of pudafensine as a novel treatment for patients who do not respond to or do not tolerate the currently marketed drugs. In June we reported statistically significant efficacy data in psychogenic erectile dysfunction (ED) with IP2018 from the Phase IIa trial, and in the beginning of this quarter we reported positive results from the Phase I pharmacokinetic trial with the new oral formulations of pudafensine. Furthermore, based on promising preclinical data for both IP2018 and pudafensine, we announced a possible indication expansion into female sexual dysfunction, an area with very large unmet clinical needs.

Statistically significant and clinically relevant Phase IIb pudafensine efficacy data in organic ED

The aim of our leading drug candidate, pudafensine, within ED is to improve the quality of life for a large number of patients who do not respond to or cannot be treated with currently marketed drugs. There is a massive medical need for more effective treatments, with about 150 million men worldwide suffering from ED. Of these, 30-40 percent will not respond to the currently available treatments. It was therefore with satisfaction that we on October 6 reported study data from the Phase IIb clinical trial with pudafensine. This study demonstrated statistically significant and clinically relevant efficacy in ED-related endpoints with no observations of critical adverse events.

The primary objective of the completed phase IIb study was to investigate the effects of pudafensine and placebo in 130 male patients with moderate or severe erectile dysfunction on the ability to develop and maintain an erection. The unique study design allowed the treatment of patients with moderate to severe ED in a home environment, and the evaluation of the sexual parameters of relevance for a future drug approval by the regulatory authorities. The clear efficacy results in moderate and severe ED provide support for pudafensine's further development towards market authorization.

Positive results in pharmacokinetic trial with new solid dosage forms of pudafensine

Our newly developed solid oral dosage form of pudafensine has been evaluated in a Phase I pharmacokinetic study in 12 healthy subjects. In July we were pleased to announce that we had obtained positive data demonstrating that the new oral solid dosing formulations provide relevant drug bioavailability and pharmacokinetic drug release profiles supporting the future treatment settings in Phase II and III trials. The reported adverse events in the study were of mild severity and only potentially related to treatment. The optimized solid oral dosage form supports an attractive product profile for pudafensine, with solid patent protection, and represents an important milestone in preparation for future pivotal registration trials.

LETTER FROM THE CEO

Dose-dependent significant efficacy data in psychogenic ED and strengthened IP for IP2018

At the beginning of June, we reported positive, statistically significant, and dose-dependent clinical observations related to efficacy in the Phase IIa clinical trial with the monoamine reuptake inhibitor IP2018, where we, for the first time, treated patients with depression, mood disorder, and erectile dysfunction. The study was conducted on 24 young, depressed, erectile dysfunction patients. With the positive impact of IP2018 on the erectile function of patients, we are currently working on the plan for the future clinical development step for IP2018 in parallel with our business development activities with interested parties.

In August, Initiator Pharma was granted a European patent by the EPO concerning IP2018 for the treatment of ED and depression. The granted patent confers protection in Europe until 2040, extending the protection for IP2018 and strengthening the exclusivity of our drug pipeline. We expect the European patent to play an essential role in the future commercialization strategy for IP2018.

Reviewing the potential to cover both female and male sexual dysfunction

During the last two years Initiator Pharma has investigated both pudafensine and IP2018 in preclinical models for Female Sexual Dysfunction (FSD) with auspicious results, as announced in September. Significant efficacy has been shown for both candidate drugs in the animal models tested for FSD. Despite the different pharmacological profiles of the two drugs, both show potential to be developed for treating female sexual dysfunction. The tested models are highly relevant and offer a way to predict efficacy in the clinical setting.

As current treatment options for women with FSD are minimal, there is a significant unmet medical need for new treatments in the field. We see great opportunities to broaden the scope and commercial potential of our clinical assets with an indication that could provide an important treatment option for millions of women worldwide, and that aligns very well with our current effort in men's sexual health. Consequently, we are currently reviewing the potential to extend the clinical indications for our drug candidates pudafensine and IP2018 to include FSD. It includes data generated to establish the best development plan, positioning, and commercialization strategy going forward. The review is conducted from both a commercial and clinical perspective to capture and optimize the large potential value offered by these two candidate drugs. This entails achieving significant value milestones while maintaining a conservative burn rate and remaining funded into 2025. We expect our strategic review to be completed by year-end and we are committed to harness the full potential of this unique opportunity.

With robust efficacy data for both our lead candidates in our hand, we are also increasing the intensity of our discussions with potential partners to optimize the value of our clinical assets where we now have both solid and successful phase IIb and phase IIa data, respectively. Recently, we participated at Bio-Europe 2023 in Munich and it was evident that our clinical progress in the last year, and the last couple of months in particular, has been noted by several stakeholders, big pharma companies included.

I am very confident about the future, proud of the achieved results so far, and excited about the potential for continued value creation going forward.

Thank you for following Initiator Pharma.

Copenhagen, November 10, 2023

Claus Elsborg Olesen
CEO

ABOUT INITIATOR PHARMA

Initiator Pharma *is a Danish 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 two preclinical assets. The company recently reported positive, statistically significant and clinically relevant efficacy results in a 120 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 dose-dependent 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.*

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.

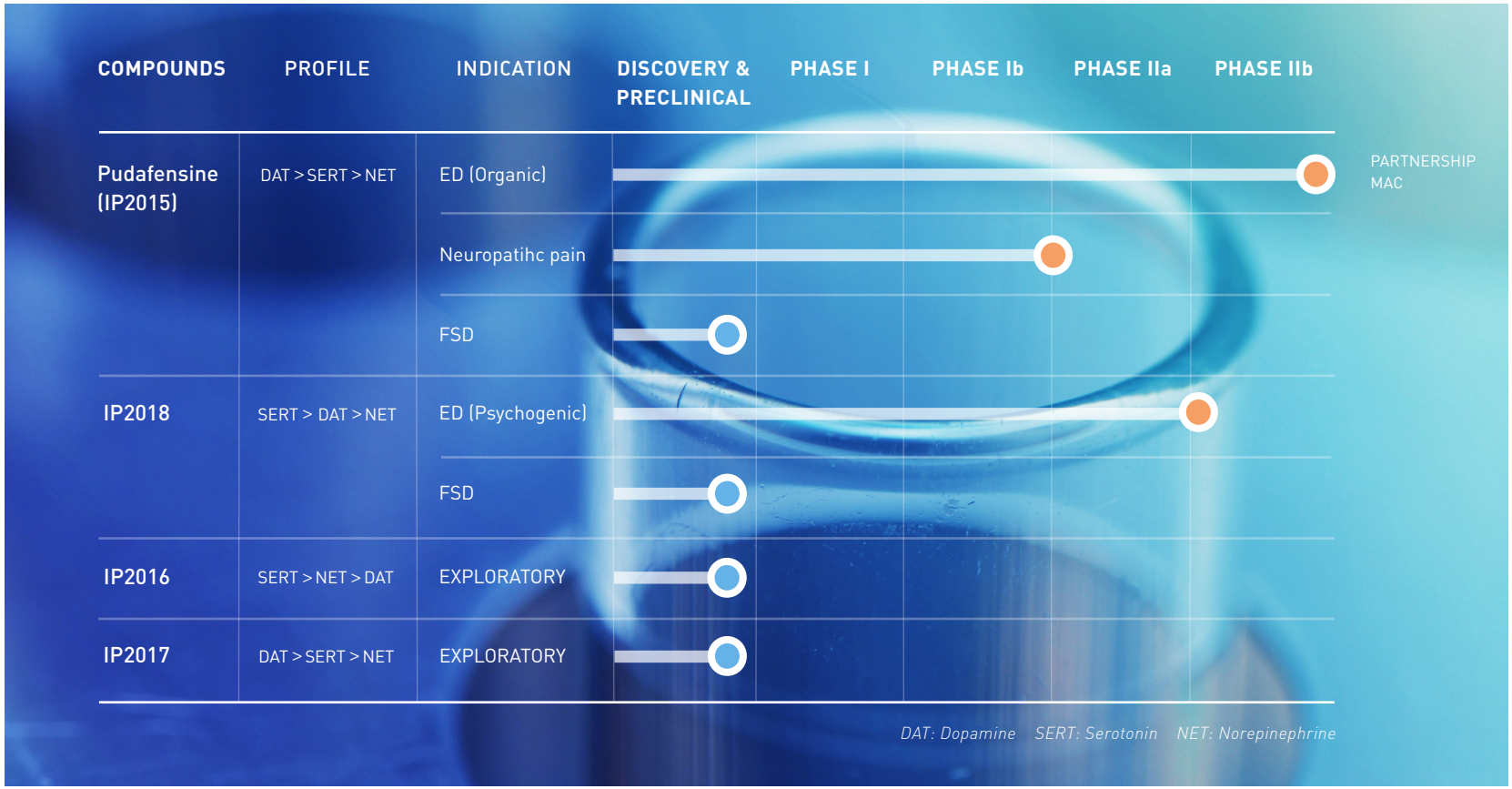
Business model

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 in-license IP2018, which we exercised in March 2020:



PUDAFENSINE (IP2015)

Pudafensine: Pudafensine, Initiators's most advanced asset, is being developed for both treatment resistant organic Erectile Dysfunction (ED) and neuropathic pain.

Organic Erectile Dysfunction

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.

Clinical development plans in organic Erectile Dysfunction

On October 6 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 is 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 comprises 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 Phase IIb trial received CTA approval from the MHRA in UK and the Ethics Committee in June 2021, and the first patient was dosed in September 2021. The study has been conducted at the MAC clinical sites in the UK.

Erectile Dysfunction 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 (IP2015)

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 us to receive premium pricing for pudafensine and thereby generate substantial commercial value for Initiator Pharma.

Neuropathic pain/Trigeminal Neuralgia

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 make-up, 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 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.

Clinical development plans in Neuropathic Pain

On September 21st last year 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 statistical 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 has 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 July 2023 Initiator reported positive results, enabling a smooth and efficient bridging between previous data sets into new future clinical studies for pudafensine.

PUDAFENSINE (IP2015)

Neuropathic pain/Trigeminal Neuralgia Market

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 different from the company's frontrunner pudafensine for organic ED (mainly caused by diabetes and age), primarily targeting the dopamine system.

- Due to the unique profile, IP2018 will, if successful, 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. 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.

Clinical development plans in psychogenic Erectile 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 is 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 is developed to treat 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.

IP2018

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 first-in-class treatments for psychogenic and organic ED, IP2018 and pudafensine, respectively.

Depression Market

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 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 [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 actional dysfunction.
- 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)

Clinical development plans in FSD

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.

Based on these promising findings, Initiator is reviewing the potential for extending the previous efforts in male ED also to include FSD.
In ED significant clinical efficacy has been shown in phase II trials, and Initiator Pharma is developing a strategy to tackle sexual health disorders covering both female and male sexual dysfunctions. The strategic review will include the data generated to establish the best development plan, positioning and commercialization strategy for these two assets going forward. The review will be executed in Q4, 2023, from both a commercial and clinical perspective, to best capture and optimize the large potential value offered by these two assets.

PATENTS

Patent protection

Intellectual Assets of Initiator Pharma includes patents conferring proprietary chemistry protection for pudafensine (IP2015) and IP2018 in the USA; and in the USA, Israel, Japan, the United Kingdom, Germany, France, and Switzerland, respectively.

The pudafensine patents expire in 2031, while the IP2018 patents expire in 2025 (2026 in the US due to patent term adjustment). Subject to Market Authorization prior to expiry of the patents, extensions by up to five years are available in key territories.

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, Israel, Japan, Mexico, Singapore, South Korea and the USA; and has been granted in Europe, Israel 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.

The preclinical program IP2017 previously known as IPNP2015 is protected by granted composition of matter claims in the USA, United Kingdom, Germany, France and Switzerland until 2030.

Initiator Pharma is pursuing an agressive 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 2023 (-).

Earnings

The company recognized an operating loss of KDKK 5,191 for the third quarter of 2023 (-6,689) and an operating loss of KDKK 22,750 for the first nine months (-35,263). The decrease in operating costs for the third quarter and first nine months of the year compared to last year reflects both the high level of clinical development activities as well as fundraising activities during first nine months of last year.

External R&D costs in the third quarter amounted to KDKK 3,194 compared to KDKK 3,344 in the same period in 2022. For the first nine months of the year external R&D costs amounted to KDKK 14,628, compared to KDKK 23,282 in the same period in 2022.

Net financial items in the third quarter amounted to KDKK 577, compared to KDKK -100 in the same period in 2022. The net financial items in the third quarter is related to currency fluctuations during the quarter, impacting 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 items amounted to KDKK -1,553 compared to KDKK -232 for the same period last year.

The net loss after tax for the third quarter was KDKK 4,614 (-6,789) and earnings per share before and after dilution totaled to DKK -0.09 (-0.13). For the first nine months of the year net loss after tax amounted to KDKK 24,303 (-35,495) and earnings per share before and after dilution amounted to DKK -0.46 (-0.68).

Financial position

The equity as of September 30, was KDKK 9,733 compared to KDKK 34,023 at year-end 2022. Cash and cash equivalents amounted to KDKK 21,781 as of September 30 compared to KDKK 39,112 at year-end 2022, and total assets were KDKK 27,298 (47,488).

As of September 30 the balance of the convertible credit agreement with MAC covering part financing of the ongoing Phase IIb study with pudafensine was KDKK 15,525, an increase of KDKK 2 595 due to clinical trial activities during the quarter.

Cash flow

In the third quarter the cash flow from operating activities was KDKK -6,749 (-7,988), incl. a negative change in working capital of KDKK 2,135 (-1,199). The increase in working capital is related to previous pre-payments of costs of the Phase IIa clinical trial with IP2018 and the Phase IIb clinical trial with pudafensine.
For the first nine months the cash flow from operating activities was KDKK -19,937 (-25,048), incl a positive change in working capital of KDKK 4,011 (10,447).

The company had no cash flow from investment activities in the third quarter and the first nine months of the year (-).

The cash flow from financing activities in the third quarter was KDKK 2,595 (25,305), and for the first nine months KDKK 2,606 (37,487).

FINANCIAL REVIEW

Top 10 shareholders as of September 30, 2023		
Owners	**Number of shares**	**Shares %**
LINC AB	10 091 219	19,23%
Avanza Pension	3 628 155	6,91%
Adrigo Small and Midcap L/S	3 227 978	6,15%
BNY Mellon SA/NV	1 989 657	3,79%
UBS Switzerland	952 084	1,81%
Nordnet Pensionsforsäkring	917 972	1,75%
Thorén, Mats	766 901	1,46%
Thomsen Mikael	753 056	1,44%
DanPet AB	710 917	1,35%
Claus Olesen Holding ApS	692 738	1,32%
Ten largest shareholders	23 730 677	45,23%
Other shareholders	28 741 210	54,77%
Total	**52 471 887**	**100,00%**

The share, share capital and ownership structure

At September 30, 2023, the number of shares outstanding totalled to 52,471,887 shares and on a fully diluted basis 56,947,554, incl. both incentive warrants and potential dilution by the convertible credit agreement with MAC.

As of September 30 the company had around 4,000 shareholders. The 10 largest shareholders in the company on September 30 owned approx 45.2% 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 (2), of which 1 (1) were women. 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 2022.

Financial calendar

Year-end report 2023 (Q4)	23 February 2024
Interim Q3 2023 report	10 May 2024
Annual General Meeting 2024	24 May 2024

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

Audit review

This Interim Report has not been subject to review by the company´s auditor.

General information

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

Copenhagen, November 10, 2023

Magnus Persson *Chairman*	***Annette Colin*** *Board member*
Henrik Moltke *Board member*	***Gunilla Ekström*** *Board member*
Peter Holm *Board member*	***Claus Olesen*** *Board member and CEO*

FINANCIAL STATEMENTS

Statement of income

KDKK	Q3:2023	Q3:2022	9M:2023	9M:2022	2022
Gross loss	-4 504	-5 523	-20 720	-32 916	-38 425
Staff costs	-687	-1 166	-2 030	-2 347	-3 315
Depreciation and write-downs	-	-	-	-	-
Operating profit/loss	**-5 191**	**-6 689**	**-22 750**	**-35 263**	**-41 740**
Other financial items	577	-100	-1 553	-232	-2 392
Profit/loss before tax	**-4 614**	**-6 789**	**-24 303**	**-35 495**	**-44 132**
Tax	-	-	-	-	5 677
Net loss for the period	**-4 614**	**-6 789**	**-24 303**	**-35 495**	**-38 455**

FINANCIAL STATEMENTS

Statement of financial position

KDKK	Q3:2023	Q3:2022	Year End 2022
ASSETS			
Fixed assets	**17**	**17**	**17**
Other receivables	-	466	849
Income tax receivables	5 500	3 180	5 500
Prepayments	-	2 650	2 010
Current receivables	**5 500**	**6 296**	**8 359**
Cash and cash equivalents	**21 781**	**46 768**	**39 112**
Current assets	**27 281**	**53 064**	**47 471**
Assets	**27 298**	**53 081**	**47 488**
EQUITY AND LIABILITIES			
Contributed capital	5 509	5 498	5 498
Retained earnings	4 224	31 488	28 525
Equity	**9 733**	**36 986**	**34 023**
Convertible credit agreement	15 525	13 290	12 577
Long-term liabilities	**15 525**	**13 290**	**12 577**
Trade payables	437	1 903	701
Other payables	110	902	-654
Accrued expenses	1 493	-	841
Current liabilities other than provisions	**2 040**	**2 805**	**888**
Liabilities other than provisions	**2 040**	**16 095**	**13 465**
Equity and liabilities	**27 298**	**53 081**	**47 488**

FINANCIAL STATEMENTS

Statement of changes in shareholder equity

KDKK	Contributed capital	Retained earnings	Total
January 1, 2022	**4 596**	**30 398**	**34 994**
Share issue	902	36 582	37 484
Profit/loss for the period	-	-38 455	-38 455
December 31, 2022	**5 498**	**28 525**	**34 023**
January 1, 2022	**4 596**	**30 398**	**34 994**
Share issue	902	36 585	37 487
Profit/loss for the period	-	-35 495	-35 495
September 30, 2022	**5 498**	**31 488**	**36 986**
January 1, 2023	**5 498**	**28 525**	**34 023**
Share issue	11	-	11
Profit/loss for the period	-	-24 303	-24 303
September 30, 2023	**5 509**	**4 222**	**9 733**

FINANCIAL STATEMENTS

Statement of cash flow

KDKK	Q3:2023	Q3:2022	9M:2023	9M:2022	2022
Profit/loss before tax	-4 614	-6 789	-24 303	-35 495	-44 132
Adjustments for non-cash transactions	-	-	355	-	-536
Profit/loss before tax, adj for non-cash transactions	**-4 614**	**-6 789**	**-23 948**	**-35 495**	**-44 668**
Tax credit	-	-	-	-	3 180
Cash flow before change in working capital	**-4 614**	**-6 789**	**-23 948**	**-35 495**	**-41 488**
Changes in working capital	-2 135	-1 199	4 011	10 447	8 787
Cash flow from operating activities	**-6 749**	**-7 988**	**-19 937**	**-25 048**	**-32 701**
Investing activities	-	-17	-	-17	-17
Cash flow from investing activities	**-**	**-17**	**-**	**-17**	**-17**
Financing activities					
New share issue	-	25 305	11	37 487	37 484
Credit agreement with MAC	2 595	-	2 595	-	-
Cash flow from financing activities	**2 595**	**25 305**	**2 606**	**37 487**	**37 484**
Cash flow for the reporting period	**-4 154**	**17 300**	**-17 331**	**12 422**	**4 766**
Cash and cash equivalents at the beginning of period	25 935	29 468	39 112	34 346	34 346
Cash and cash equivalents at the end of period	**21 781**	**46 768**	**21 781**	**46 768**	**39 112**

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

Q3
2023

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