Q2
2023

INTERIM REPORT | January - June

Initiator Pharma

BUSINESS HIGHLIGHTS

Business highlights in Q2 2023

- In May the company announced that WHO had selected the International Nonproprietary Name (INN) pudafensine as the official generic name for the company's patented candidate drug IP2015, which is in clinical development in erectile dysfunction and neuropathic pain.
- In June the company announced positive, statistically significant, and dose-dependent clinical observations related to efficacy in psychogenic erectile dysfunction (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.
- In June the company announced the decision to carry out a capital increase directed at members of executive management and key management under the long term incentive program for 2022 ("LTI2022-program") and to conduct a buyback of shares in order to sell shares to the board of directors under the LTI2022-program.
- In June the company announced that it had completed recruitment of all planned patients for its Phase IIb clinical trial with pudafensine (IP2015). Topline results are expected in Q4 2023.

Business highlights after this reporting period

- In July the company announced 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") had granted the company's patent application for the product candidate IP2018, targeting monoamine reuptake transporters.

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	Q2:2023	Q2:2022	H1:2023	H1:2022	2022
Net sales	-	-	-	-	-
Total operating expenses	-8 882	-13 499	-17 559	-28 574	-41 740
Operating profit/loss	-8 882	-13 499	-17 559	-28 574	-41 740
Net result	-10 422	-13 554	-19 689	-28 706	-38 455
Earnings per share (DKK)	-0,20	-0,29	-0,38	-0,62	-0,73
Earnings per share, fully diluted (DKK)	-0,20	-0,29	-0,38	-0,62	-0,73
Cash flow from operating activities	-7 795	-9 066	-13 188	-17 060	-32 701

	2Q:2023	2Q:2022	H1:2023	H1:2022	31.12.2022
Cash and cash equivalents	25 935	31 099	39 112	31 099	39 112
Equity	14 347	29 255	34 023	29 255	34 023
Total equity and liabilities	31 538	32 975	47 488	32 975	47 488
Equity ratio, %	45%	89%	72%	89%	72%
Number of shares outstanding	*52 471 887*	*46 565 128*	*52 471 887*	*46 565 128*	*52 361 887*
Number of shares, diluted	*56 947 554*	*51 793 991*	*56 947 554*	*51 793 991*	*56 947 554*
Average number of shares outstanding	*52 371 054*	*45 288 212*	*52 366 470*	*44 530 337*	*48 325 346*
Average number of shares, diluted	*56 947 554*	*50 533 075*	*56 947 554*	*49 349 200*	*53 225 959*

LETTER FROM THE CEO

The positive momentum for Initiator Pharma has continued during the second quarter, with several key milestones reached, including the announcement of statistically significant efficacy data for IP2018 and completion of patient recruitment in the Phase IIb trial with IP2015, now referred to as its INN name, pudafensine. After the end of the period, we also announced positive results from the Phase I pharmacokinetic trial with new oral formulations of pudafensine.

Positive Phase IIa results support further development of IP2018

In 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, have treated patients with depression, mood disorder, and erectile dysfunction. The study was initiated in 2020 and was conducted on 24 young, depressed, erectile dysfunction patients at the MAC Phase I unit in Manchester, UK. It was very encouraging to observe a significant effect linked to administration, including an apparent dose-response effect, and the results support further development of IP2018 in this patient population. With the positive impact of IP2018 on the erectile function of patients, we are now working on the plan for the future clinical development step for IP2018 in parallel to conducting our business development activities, where we are now continuing the dialog with interested parties.

IP2018 is developed to treat psychogenic erectile dysfunction (ED), which is the inability to achieve or maintain an erection during sexual intercourse due to psychological factors. There is still a significant unmet medical need within psychogenic ED. Almost 70 percent of patients undergoing treatment for depressive disorder also suffer from sexual dysfunction, for which only 5-30 percent is resolved with antidepressant treatment. IP2018 has the potential to help these patients and significantly increase their quality of life. Completing this study is a significant milestone for Initiator Pharma and a great leap forward in our commitment to developing effective and safe treatment options for erectile dysfunction.

All planned patients recruited in the pudafensine Phase IIb program – results expected in Q4

The next key achievement during the quarter was the completion of patient recruitment in the Phase IIb trial with IP2015. IP2015 is now called pudanfensine since it obtained its International Nonproprietary Name (INN) from WHO earlier in May this year. Pudafensine is our most advanced asset and is under development for both organic erectile dysfunction and neuropathic pain. The multi-center Phase IIb study in 120 otherwise healthy organic erectile dysfunction patients is conducted together with MAC Clinical Research. The primary objective of the trial is to investigate the effects of repeat single oral doses of pudafensine on male subjects with severe or moderate organic erectile dysfunction on the ability to develop and maintain an erection, but also with readouts on overall satisfaction. We have strong faith in pudafensine's mechanism of action and look forward to seeing the top-line results later this year.

LETTER FROM THE CEO

The aim of pudafensine within erectile dysfunction is to improve the quality of life for a large number of patients and their partners who do not respond to or cannot be treated with currently marketed drugs (PDE5 inhibitors, e.g., Viagra®, Cialis®, Levitra®). It is estimated that the number of erectile dysfunction patients is about 150 million men worldwide, a number that is estimated to increase to more than 300 million by 2025 and that about 30-40 percent of these patients will not respond to the currently available treatments. We have high hopes and strongly believe that pudafensine can become an effective drug for these patients.

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 happy 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. Further, the reported adverse events in the study were of mild severity and only potentially related to treatment.

The results from this pharmacokinetic study will bridge previous data sets into new future clinical studies with pudafensine and are vital for the design and execution of the continuous clinical program. This optimized solid oral dosage form of the product represents a key deliverable for pudafensine in preparation for its future pivotal registration trials and is a significant milestone for Initiator Pharma.

An eventful second half of the year ahead

With the achievements we have made during the first part of the year, we are now looking forward to an exciting and busy second half of the year with the upcoming pudanfensine Phase IIb results as a major inflection point.

Thank you for following Initiator Pharma.

Copenhagen, August 25, 2023

Claus Elsborg Olesen
CEO

ABOUT INITIATOR PHARMA

Initiator Pharma A/S *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 is currently conducting a Phase IIb trial with pudafensine (IP2015) in erectile dysfunction of organic origin, and successfully completed a Phase I proof of principle trial in neuropathic pain in 2022. With IP2018 the company has reported positive, statistically significant, and dose-dependent clinical observations related to efficacy in psychogenic erectile dysfunction (ED) in a Phase IIa clinical trial of IP2018 in patients with mild to moderate ED.*

Vision

Initiator Pharma´s vision is to become a leading emerging pharma company developing novel therapeutics targeting CNS-disorders with significant unmet medical needs.

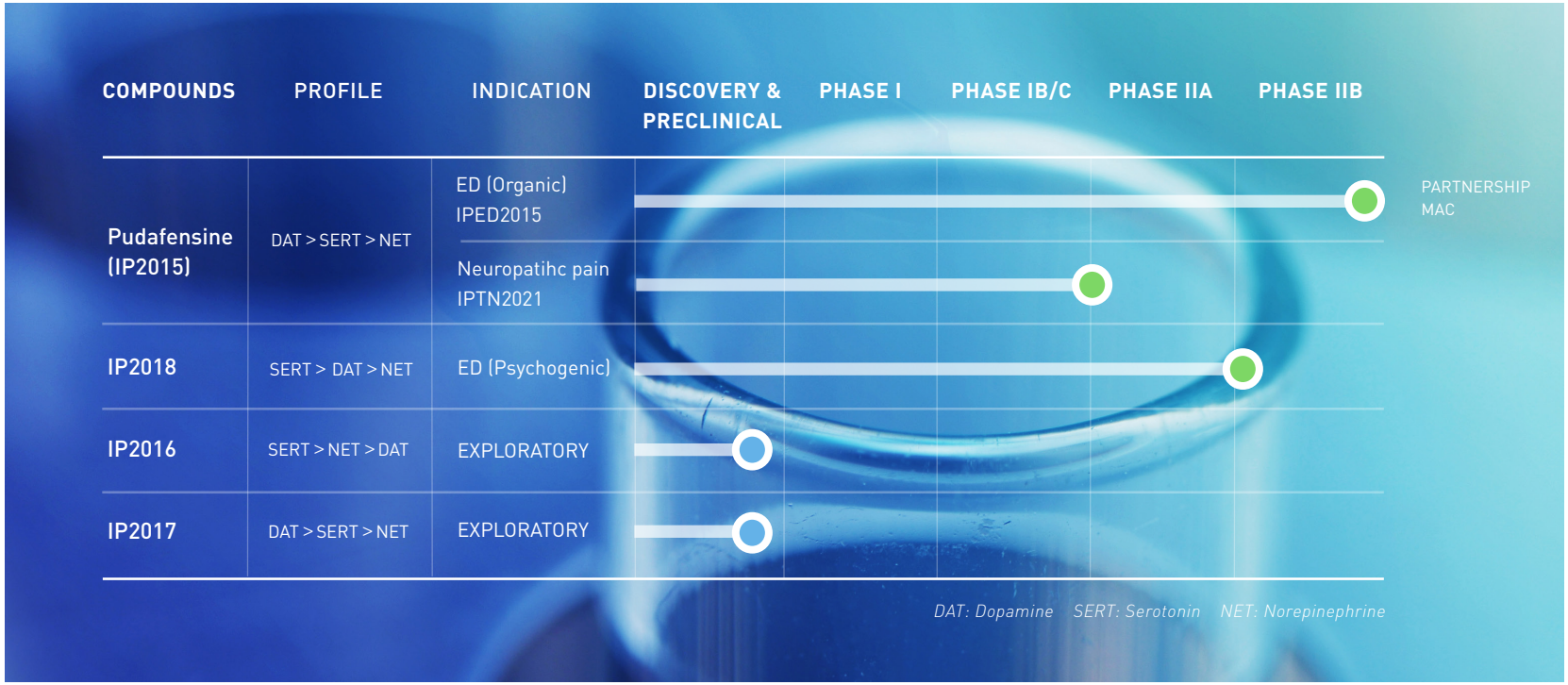
Business model

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 our portfolio of drug candidates to key value inflection points, where we anticipate significant partnering interest from international pharma industry for the further development of our 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 Initiator's most advanced asset, is being developed for both treatment resistant organic Erectile Dysfunction (ED) and neuropathic pain.

Organic Erectile Dysfunction (pudafensine/IP2015)

Pudafensine is positioned as a novel drug candidate for the treatment of patients suffering from organic Erectile Dysfunction (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 erectile dysfunction. 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 Pharma achieved successful Phase IIa results for pudafensine. The Phase IIa study was designed as an exploratory study and included twelve patients who had severe erectile dysfunction 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 erectile dysfunction in patients who do not respond to current therapies.

Clinical development plans in organic Erectile Dysfunction

On 25 November 2020 Initiator Pharma announced a financing agreement with MAC Clinical Research Ltd covering the continued development of pudafensine. Within the agreement, MAC Clinical Research (MAC) will take on the cost, up to 23 MSEK, for conducting a clinical Phase IIb intercourse study for pudafensine in patients suffering from organic erectile dysfunction, i.e. patients that is not responding to the currently marketed drugs in the PDE5i class. Upon the full completion of the study, MAC has the right to convert the accrued debt into Initiator shares at a share price of SEK 7.5.

The study is a randomized, double-blind, parallel-group, repeat single oral dose study of pudafensine or placebo in otherwise healthy organic Erectile Dysfunction patients. The study will enroll 120 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 erectile dysfunction, 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. During this quarter the Company announced the completion of the recruitement phase of the Phase IIb trial, and the current expectation is that the top-line results will be published sometime during Q4.

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.

PUDAFENSINE (IP2015)

About 30-40% of these patients will not respond to the current treatment and represent a significant unmeet medical need. This is exactly Initiator Pharma'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 us to receive premium pricing for pudafensine (IP2015) and thereby generate substantial commercial value for Initiator Pharma.

Neuropathic pain/Trigeminal Neuralgia (IPTN2021)

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 pudafensine (IP2015) 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 (IP2015), pregabalin as active control, and placebo. pudafensine (IP2015) 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 (IP2015) (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 a Phase I pharmacokinetic (PK) study in healthy subjects testing new oral solid dosage forms. The study was started in the beginning of 2023 and reported positive results from this study in July this year.

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 (IP2015) 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 Erectile Dysfunction (mainly caused by anxiety and depression) mainly targeting the serotonin instead of the dopamine system. IP2018 is different from Initiator Pharma's frontrunner pudafensine (IP2015) for organic erectile dysfunction (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 Initiator Pharma's extensive package of preclinical data.
- IP2018 is efficacious in animal models of depression (forced swim and tail suspension tests) and erectile function (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 erectile function, 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 erectile function 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 erectile dysfunction in patients with medically induced sexual dysfunction.

Clinical development plans in psychogenic Erectile Dysfunction

In June 2023 Initiator Pharma's announced positive, statistically significant, and dose-dependent clinical observations related to efficacy in psychogenic erectile dysfunction (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 erectile dysfunction. 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 erectile dysfunction 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 erectile function 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

IP2018 is developed to treat psychogenic erectile dysfunction (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 first-in-class treatments for psychogenic and organic ED, IP2018 and pudafensine (IP2015), 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 erectile dysfunction, 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 erectile dysfunction to varying degrees, and this underlines the need to develop a better alternative.

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[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.*

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 (IP2015) 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 erectile dysfunction 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 second quarter and the first six months of 2023 (-).

Earnings

The company recognized an operating loss of KDKK 8,822 for the second quarter of 2023 (-13,499) and an operating loss of KDKK 17,559 for the first six months (-28,574). The decrease in operating costs for the second quarter and first six months of the year compared to last year reflects both the high level of clinical development activities as well as fundraising activities during first half of last year.

External R&D costs in the second quarter amounted to KDKK 5,586 compared to KDKK 6,044 in the same period in 2022. For the first six months of the year external R&D costs amounted to KDKK 11,434, compared to KDKK 18,622 in the same period in 2022.

Net financial expenses in the second quarter amounted to KDKK 1,540, compared to net financial expenses of KDKK 55 in the same period in 2022. The net financial expenses in the second quarter is related to currency fluctuations during the quarter, impacting both the conversion of funds held in SEK into DKK at the close of the quarter and the carrying value of the convertible debt to MAC Clinical Research. For the first six months of the year the net financial expenses amounted to KDKK 2,130 compared to KDKK 132 for the same period last year.

The net loss after tax for the second quarter was KDKK 10,422 (-13,554) and earnings per share before and after dilution totaled to DKK -0.20 (-0.29). For the first six months of the year net loss after tax amounted to KDKK 19,689 (-28,706) and earnings per share before and after dilution amounted to DKK -0.38 (-0.62).

Financial position

The equity as of June 30, was KDKK 14,347 compared to KDKK 34,023 at year-end 2022. Cash and cash equivalents amounted to KDKK 25,935 as of June 30 compared to KDKK 39,112 at year-end 2022, and total assets were KDKK 31,538 (47,488).

As of June 30 the balance of the convertible credit agreement with MAC covering part financing of the ongoing Phase IIb study with pudafensine (IP2015) was KDKK 12,930, an increase of KDKK 220 due to FX movements between GBP and DKK during the period and unchanged in GBP.

Cash flow

In the second quarter the cash flow from operating activities was KDKK -7,795 (-9,066), incl. a positive change in working capital of KDKK 2,421 (4,448). The reduction 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 (IP2015). For the first six months the cash flow from operating activities was KDKK -13,188 (-17,060), incl a positive change in working capital of KDKK 6,146 (11,646).

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

The cash flow from financing activities in the second quarter was KDKK 11 (12,182), and for the first six months KDKK 11 (12,182).

FINANCIAL REVIEW

Top 10 shareholders as of June 30, 2023		
Owners	**Number of shares**	**Shares %**
LINC AB	10 091 219	19,23%
Avanza Pension	3 462 069	6,60%
Adrigo Small and Midcap L/S	3 398 140	6,48%
BNY Mellon SA/NV	1 681 444	3,20%
UBS Switzerland	961 109	1,83%
Nordnet Pensionsforsäkring	897 234	1,71%
Thorén, Mats	766 901	1,46%
Thomsen Mikael	731 056	1,39%
DanPet AB	710 917	1,35%
Claus Olesen Holding ApS	692 738	1,32%
Ten largest shareholders	23 392 827	44,58%
Other shareholders	29 079 060	55,42%
Total	**52 471 887**	**100,00%**

The share, share capital and ownership structure

At June 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 June 30 the company had around 4,000 shareholders. The 10 largest shareholders in the company on June 30 owned approx 44.6% of all outstanding shares.

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

Personnel

As of June 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 prospectus published in June 2022 and in the Annual Report for 2022.

Financial calendar

Interim Q3 2023 report	10 November 2023
Year-end report 2023 (Q4)	23 February 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, August 25, 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	Q2:2023	Q2:2022	H1:2023	H1:2022	Full Year 2022
Gross loss	-8 183	-12 824	-16 216	-27 393	-38 425
Staff costs	-699	-675	-1 343	-1 181	-3 315
Depreciation and write-downs	-	-	-	-	-
Operating profit/loss	**-8 882**	**-13 499**	**-17 559**	**-28 574**	**-41 740**
Other financial items	-1 540	-55	-2 130	-132	-2 392
Profit/loss before tax	**-10 422**	**-13 554**	**-19 689**	**-28 706**	**-44 132**
Tax	-	-	-	-	5 677
Net loss for the period	**-10 422**	**-13 554**	**-19 689**	**-28 706**	**-38 455**

FINANCIAL STATEMENTS

Statement of financial position

KDKK	H1:2023	H1:2022	Year End 2022
ASSETS			
Fixed assets	**17**	**-**	**17**
Other receivables	86	-	849
Income tax receivables	5 500	3 180	5 500
Prepayments	-	2 810	2 010
Current receivables	**5 586**	**5 990**	**8 359**
Cash and cash equivalents	**25 935**	**29 468**	**39 112**
Current assets	**31 521**	**35 458**	**47 471**
Assets	**31 538**	**35 458**	**47 488**
EQUITY AND LIABILITIES			
Contributed capital	5 509	4 596	5 498
Retained earnings	8 838	13 874	28 525
Equity	**14 347**	**18 470**	**34 023**
Convertible credit agreement	12 930	13 290	12 577
Long-term liabilities	**12 930**	**13 290**	**12 577**
Trade payables	2 683	1 643	701
Other payables	-	2 055	-654
Accrued expenses	1 578	-	841
Current liabilities other than provisions	**4 261**	**3 698**	**888**
Liabilities other than provisions	**4 261**	**16 988**	**13 465**
Equity and liabilities	**31 538**	**35 458**	**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	293	11 889	12 182
Profit/loss for the period	-	-28 706	-28 706
June 30, 2022	**4 889**	**13 581**	**18 470**
January 1, 2023	**5 498**	**28 525**	**34 023**
Share issue	11	-	11
Profit/loss for the period	-	-19 689	-19 689
June 30, 2023	**5 509**	**8 836**	**14 347**

FINANCIAL STATEMENTS

Statement of cash flow

KDKK	Q2:2023	Q2:2022	H1:2023	H1:2022	2022
Profit/loss before tax	-10 422	-13 554	-19 689	-28 706	-44 132
Adjustments for non-cash transactions	206	-	355	-	-536
Profit/loss before tax, adj for non-cash transactions	**-10 216**	**-13 554**	**-19 334**	**-28 706**	**-44 668**
Tax credit	-	-	-	-	3 180
Cash flow before change in working capital	**-10 216**	**-13 554**	**-19 334**	**-28 706**	**-41 488**
Changes in working capital	2 421	4 488	6 146	11 646	8 787
Cash flow from operating activities	**-7 795**	**-9 066**	**-13 188**	**-17 060**	**-32 701**
Investing activities	-	-	-	-	-17
Cash flow from investing activities	**-**	**-**	**-**	**-**	**-17**
Financing activities					
New share issue	11	12 182	11	12 182	37 484
Credit agreement with MAC	-	-	-	-	-
Cash flow from financing activities	**11**	**12 182**	**11**	**12 182**	**37 484**
Cash flow for the reporting period	**-7 784**	**3 116**	**-13 177**	**-4 878**	**4 766**
Cash and cash equivalents at the beginning of period	33 719	26 352	39 112	34 346	34 346
Cash and cash equivalents at the end of period	**25 935**	**29 468**	**25 935**	**29 468**	**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 (IP2015), Initiator Pharma'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 2a trial for psychogenic erectile dysfunction.

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 erectile 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

Q2
2023

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