Q3
2022

INTERIM REPORT | January - September

Initiator Pharma

BUSINESS HIGHLIGHTS

Business highlights in Q3 2022

- On July 5th the Company announced the outcome of the fully guaranteeed rights issue of MSEK 41. Approximately 42.3% of the share issue was subscribed for, with the rest covered by underwriting commitments.
- On July 5th the Company announced that it had carried out a directed share issue of MSEK 2.5 at a share price of SEK 7.50 to a strategic advisor to the company.
- On July 22nd the Company announced that it had completed a share buy back program of 24,000 shares in connection with the long-term incentive program LTI2021.
- On September 21st the Company announced that the final study report from the Phase 1 study in the IPTN2021 program confirmed the statistically significant effects on pain measures that were reported after the first data read-out in May.

Business highlights after this reporting period

- On October 4th the Company announced the outcome of the LTI2022 incentive programs to management and leading employees and to board members.
- On November 4th the Company provided an update on its clinical programs.

Financial Highlights

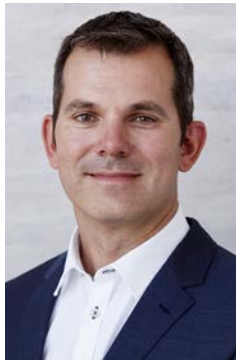
Initiator Pharma A/S is a Danish registered company, and is reporting its financial situation in Danish kroner (DKK).

Financial review

TDKK	3Q:2022	3Q:2021	9M:2022	9M:2021	2021
Net sales	-	-	-	-	-
Total operating expenses	-6 689	-9 056	-35 263	-15 792	-23 072
Operating profit/loss	-6 689	-9 056	-35 263	-15 792	-23 072
Net result	-6 789	-9 141	-35 495	-16 330	-21 064
Earnings per share before and after dilution (DKK)	-0,13	-0,24	-0,68	-0,51	-0,60
Cash flow from operating activities	-7 988	-22 340	-25 048	-26 780	-34 097

	30.09.2022	30.09.2021	31.12.2021
Cash and cash equivalents	46 768	41 394	34 346
Equity	36 986	39 728	34 994
Total equity and liabilities	53 081	55 013	53 701
Equity ratio, %	70%	92%	92%
Number of shares outstanding	*52 361 887*	*43 772 462*	*43 772 462*
Number of shares, diluted	*57 480 750*	*45 540 855*	*48 165 325*
Average number of shares outstanding	*51 878 824*	*38 466 710*	*35 088 333*
Average number of shares, diluted	*56 997 687*	*40 235 103*	*39 685 393*

LETTER FROM THE CEO



Thanks to a successful capitalization of the company via directed share issues and a fully guaranteed rights issue at the end of June, we entered the third quarter with secured financing well into 2024 allowing us to continue the advancement of all our clinical programs according to our overall plans and priorities.

Confirmative final results in the IPTN2021 program trial

At the end of the third quarter Initiator announced that the final dataset and study report analysis had been obtained from the IPTN2021 program clinical Phase I study, carried out in 24 healthy male subjects dosed with the drug IP2015 and challenged with a pain-inducing substance (capsaicin). We were very pleased to report that the final data analysis confirmed our previous observations from the study, that IP2015 shows promising and clinically relevant efficacy on pain. As previously there were only side effects of mild severity observed in the study.

The results are very encouraging, not only for Initiator as a company but also for the patients suffering from neuropathic pain. Many current available treatments for neuropathic pain are linked to limited efficacy and severe side-effects. Thus, the need for a new efficacious, tolerable and safe treatment is exceptionally high. Initiator is now one step closer to develop a new first-line treatment for these patients.

New Phase I pharmacokinetic (PK) study in neuropathic pain

The results observed in the completed clinical Phase I proof of principle study strengthen our conviction of IP2015's potential as a new treatment for neuropathic pain and provide us with supportive data that will help guide the continued development and design of the IPTN2021 program. As a first step for the clinical development program in neuropathic pain, we are now initiating a Phase I pharmacokinetic study in healthy subjects, testing new oral solid dosage forms which will bridge previous data sets into new future clinical studies for IP2015. We aim to have the first patient enrolled shortly and expect to provide interim data during the first quarter next year.

22 out of 24 patients enrolled in IP2018 Phase IIa study

In our Phase 2a study with the monoamine reuptake inhibitor IP2018, where we for the first time target depressed ED patients, the recruitment of the final few patients has proven more challenging than anticipated and two patients remain to be enrolled. However, the integrity and quality of patient inclusion are critical to answering the efficacy questions we are seeking in this trial, and although we made some adjustments to the protocol last summer, we have kept the main inclusion criteria and original study design. Given that the last two patients are successfully enrolled soon, the trial could still be completed before the end of the year, but it might run into the first quarter of 2023.

LETTER FROM THE CEO

Amended study protocol in IPED2015 Phase IIb study

The recruitment of qualified patients for the Phase IIb study in the IPED2015 clinical program, evaluating IP2015 in 120 healthy organic Erectile Dysfunction patients, has been more challenging than expected. In order to optimize and increase the recruitment rate, the clinical study protocol has been amended. The amendments are in the process of approval at the British Health Authorities and Ethics Committee and include some revised inclusion criteria as well as an increase of the patient's stipend. These improvements are expected to support a faster and higher recruitment rate and we now aim for a completion of the dosing part in the first half of 2023.

Evaluating a potential pipeline expansion

In April this year we announced our exclusive option agreement for a Phase 2/3 ready drug asset for an undisclosed pain indication. The potential asset matches and complements our current pipeline and ongoing clinical activities very well and could furthermore strengthen our ambition of targeting the CNS for a broad range of indications.

We are still evaluating the regulatory pathway and a clinical development plan that is time and cost-efficient and can fulfill the Target Product Profile for the undisclosed pain indication. I look forward to sharing further information after having completed the evaluation during the option period ending at year end 2022.

The two long-term incentive programs ("LTI2022"), one for Management and leading employees and one for board members, approved by the AGM on May 24, 2022 were used by participants to buy Investment Shares during the past quarter. The maximum total of 110.000 shares allocated to management and leading employees were purchased in the market by the end of the allowable investment period. The Board members had purchased 19.500 shares in the market by the end of the allowable investment period.

Initiator Pharma's business strategy builds on our ability to identify attractive but undervalued clinical-stage assets and to advance these through cost-efficient clinical trials to deliver key-value inflection points in indications with significant unmet medical needs. When summarizing our track-record this far, the progress of our clinical portfolio, our secured financing and our experienced and dedicated team, I remain confident about our future and look forward to keeping you updated on our progress.

Copenhagen, November 4, 2022

Claus Elsborg Olesen
CEO

ABOUT INITIATOR PHARMA

Initiator Pharma A/S is a Danish clinical stage life science company developing innovative drugs that target key unmet medical needs within the central and peripheral nervous system. Initiator Pharma's pipeline consists of three clinical programs - the IP2018 and IPED2015 programs for treatment of erectile dysfunction of psychogenic and organic origin, respectively, and the orphan drug program IPTN2021 developed for Trigeminal Neuralgia, a severe neuropathic pain condition. .

Vision

Initiator Pharma´s vision is to become a leading life science company developing novel therapeutics within the field of mono-amine reuptake transporters targeting CNS-disorders with significant unmet medical needs.

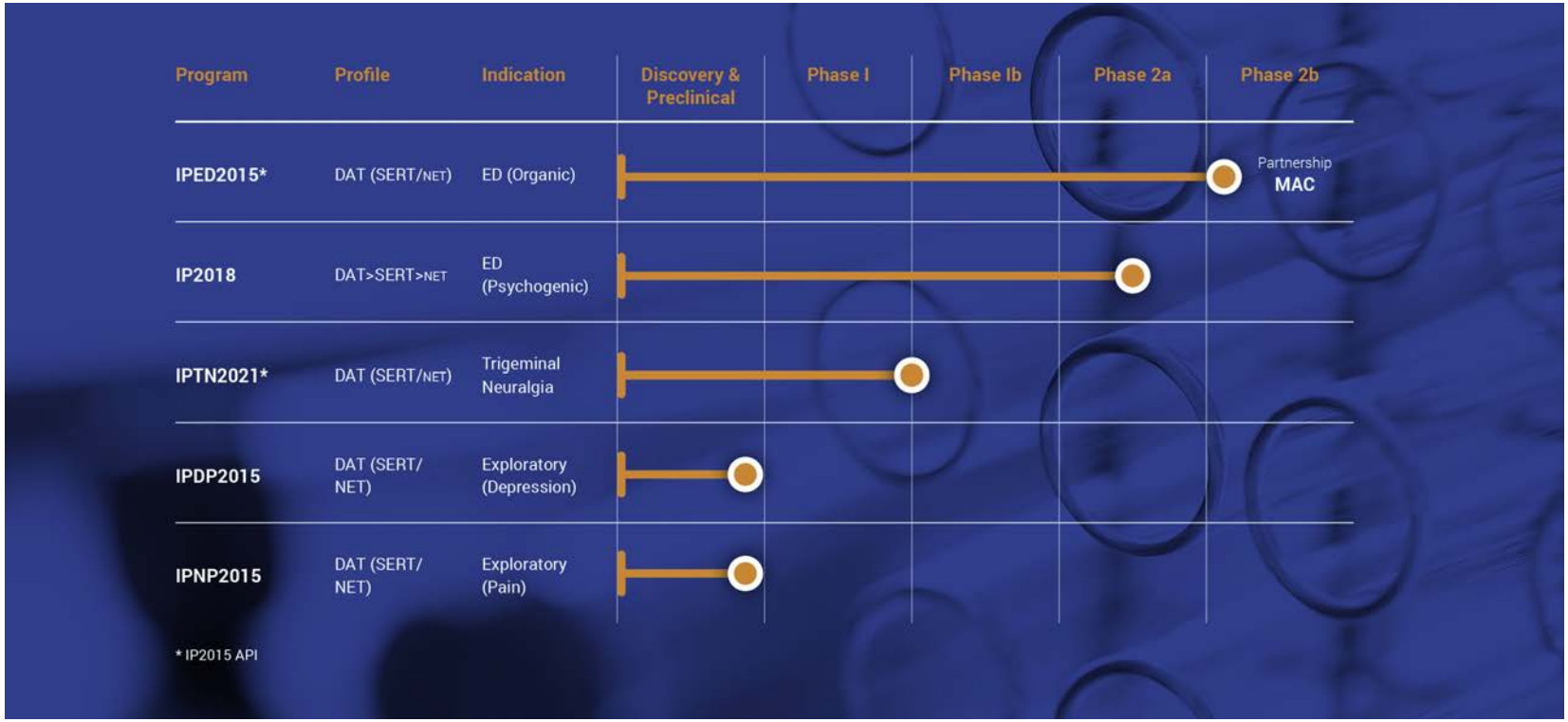
Business model

The company aims to commercialize its research efforts through the following 2 business models:

- By internal development of selected programs through the early phases of drug development before out-licensing to pharmaceutical companies who will take over the further clinical development of Initiator Pharma's programs and typical with upfront payments, milestone and royalty payments on product sales to Initiator Pharma.
- Through early stage research and development collaboration with pharmaceutical companies who will fund the research and development activities and pay upfront, milestones and royalty payments on product sales to Initiator Pharma.

PROJECT PORTFOLIO

In 2016 Initiator Pharma acquired three potential drug candidates from Saniona. 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 we exercised in March 2020. In 2021 we announced that we had further expanded our development pipeline with IPTN2021, aiming to develop the IP2015 molecule for neurpathic pain, and specifically Trigeminal Neuralgia:



On April 5th the Company announced that it had entered an option-to-acquire agreement for Phase 2/3 ready drug asset for an undisclosed pain indication. The Drug asset is currently being evaluated as to its clinical and regulatory pathway, and a decision to excersise the option or not is expected to be taken before year-end.

ERECTILE DYSFUNCTION

IPED2015: IPED2015 is our most advanced development program 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®). IP2015 - 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 Active Pharmaceutical ingredient in the IPED2015 program is IP2015.

The ambition with IPED2015 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 1 study regarding safety and tolerability with IP2015, and in March 2020, Initiator achieved successful Phase 2a results in the IPED2015 program. The Phase 2a 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 IP2015 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 announced a financing agreement with MAC Clinical Research Ltd covering the continued development of the IPED2015 program. Within the agreement, MAC Clinical Research (MAC) will take on the cost, up to 23 MSEK, for conducting a clinical Phase 2b intercourse study 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 IPED2015 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 IPED2015 and placebo respectively, with treatment duration of 4 weeks with frequent assessments of erectile dysfunction, safety and pharmacokinetics. The Phase 2b 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 current expectation is that the dosing part of the study will be completed in the first part of 2023, with topline data mid-2023.

Erectile Dysfunction (ED) Market

The current number of ED patients is estimated to about 150 mio men worldwide and a number that is estimated to increase to more than 300 mio 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 our 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 bn USD and Initiator Pharma strongly believes that targeting the PDE5i non-responders will allow us to receive premium pricing and thereby generate substantial commercial value for Initiator Pharma.

TRIGEMINAL NEURALGIA

IPTN2021: Trigeminal neuralgia is a chronic 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 therefore suggest 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]. With our IPTN2021 program aim to address this significant unmet medical need [3].

The IPTN2021 development plan aims for orphan drug registration 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.

In the IPTN2021 program the Active Pharmaceutical ingredient is IP2015. In preclinical studies, IP2015 is effective and markedly inhibits neuralgic pain.

Clinical development plans in Neuropathic Pain

On September 21st we announced the final data from a clinical Phase 1 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 IP2015, pregabalin as active control, and placebo. 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 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 decided to initiate a Phase I pharmacokinetic (PK) study in healthy subjects testing new oral solid dosage forms, bridging previous data sets into new future clinical studies for IP2015. The study is expected to start shortly and provide draft PK data in Q1 2023.

TRIGEMINAL NEURALGIA

Trigeminal Neuralgia Market

The neuropathic Pain Market to according to Garner a Valuation of US$ 9,862.3 Million by 2027, at CAGR of 6.4 percent by the end of 2027 [4].
On average annual healthcare cost for painful neuropathic disorder is US$ 17,355 per patient and with a solid efficacy and safety data on IPTN2021 Initiator Pharma expect to able to obtain premium pricing siginificantly strengthening the commercial opportunity with the potential to reach high hundreds of MUSD in sales.

[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.*

PSYCHOGENIC ERECTILE DYSFUNCTION

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 our frontrunner IPED2015 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 our 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 2a 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 2020 we announced that we had obtained approval from the Medicines and Healthcare products Regulatory Agency, MHRA, and the Ethical committee (EC) UK, for a Phase 2a clinical trial with its candidate drug IP2018. The Phase 2a trial is a randomized, double-blind, placebo-controlled, 3-way crossover trial studying the efficacy and safety of IP2018 in young, depressed, erectile dysfunction (ED) patients. The primary objective of this study is to investigate the effects of IP2018 on penile rigidity and tumescence using visual sexual stimulation test. The study is being conducted in 24 patients at the MAC Phase I unit in Manchester, UK.

22 out of 24 patients have now been enrolled in our Phase 2a study. The recruitment of the final few patients has proven more challenging than anticipated and two patients remain to be enrolled. Given that the last two patients are successfully enrolled soon, the trial could still be completed before the end of the year, but it might run into the first quarter of 2023.

The company has a commitment from Innovation Fund Denmark to fund the trial with up to 3.8 MDKK through the Innobooster grant.

PSYCHOGENIC ERECTILE DYSFUNCTION

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 a rate of 2.4 percent from USD 15.85 billion in 2019 to USD 19.21 billion in 2027 [8]. The largest players, which account for more than 60 percent of antidepressants sold, are Pfizer, Eli Lilly, GlaxoSmithKline, AstraZeneca and H Lundbeck A/S. 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.

Patent protection

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

The 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 now pending in Australia, Brazil, Canada, China, Europe, Israel, Japan, Mexico, Singapore, South Korea and the USA; and has been granted in South Africa. The patent family can be kept in force until 2040.

[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.*

FINANCIAL REVIEW

Revenue

Initiator Pharma generated total revenues of TDKK 0 for the third quarter (0) and TDKK 0 for the first nine months (0).

Earnings

The company recognized an operating loss of TDKK 6,689 for the third quarter (-9,056) and TDKK 35,263 for the first nine months (-15,792). The increase in operating costs during the first nine months of the year reflects the three clinical trials that has been ongoing, as well as increased corporate costs, including build-out of the organisation.

External R&D costs in the third quarter amounted to TDKK 3,344, compared to TDKK 4,698 in the same period in 2021. For the first nine months of the year external R&D costs amounted to TDKK 23,282 (8,052).

Net financial expenses in the third quarter amounted to TDKK 100, compared to net financial expenses of TDKK 85 in the same period in 2021. For the first nine months of the year net financial exenses amounted to TDKK 232 (538).

Financial position

The equity as of September 30, was TDKK 36,986 compared to TDKK 34,994 at year-end 2021. Cash and cash equivalents amounted to TDKK 46,768 as of September 30 compared to TDKK 34,346 at year-end 2021, and total assets were TDKK 53,081 (53,701).

As of September 30 the balance of the convertible credit agreement with MAC covering part financing of the ongoing Phase 2b study was TDKK 13,290, unchanged from year-end.

Cash flow

In the third quarter the total operating cash flow was TDKK -7,988 (-22,340), incl. a negative change in working capital of TDKK 1,199 (-13,199). For the first nine months the total operating cash flow was TDKK -25,048 (-26,780), incl a positive change in working capital of TDKK 10,447 (-10,461). The reduction in working capital during the first 9 months of the year is related to pre-payment to MAC Clinical Research for the ongoing Phase 2b study with IP2015 that was made in Q3 2021 in connection with the start-up of the study.

Cash flow from investment activities was TDKK -17 (0) in the third quarter and TDKK -17 (0) for the first nine months.

Cash flow from financing activities in the third quarter was TDKK 25,305 (32,635) and TDKK 37,487 for the first nine months (54,669). During the quarter the company completed a fully guaranteed rights issue of MSEK 41, at a share price of SEK 7.50 per share. During the quarter the company also announced a MSEK 2.5 directed issue to a strategic advisor to the company, also at SEK 7.50 per share.

The share, share capital and ownership structure

At September 30, 2022, the number of shares outstanding totalled to 52,361,887 shares and on a fully diluted basis 57,480,750, incl. both incentive warrants and potential dilution by the convertible credit agreement with MAC.

On April 13th the Company announced that the Board of Directors proposed a directed share issue and fully guaranteed rights issue of a total of approximately SEK 61 million at a share price

FINANCIAL REVIEW

Top 10 shareholders as of September 30, 2022		
Owners	**Number of shares**	**Shares %**
LINC AB	10 091 219	19,27%
Adrigo Small and Midcap L/S	3 703 351	7,07%
Avanza Pension	3 189 281	6,09%
BNY Mellon SA/NV	1 156 898	2,21%
Nordnet Pensionsforsäkring	1 036 852	1,98%
UBS Switzerland	965 337	1,84%
Thorén, Mats	803 287	1,53%
DanPet AB	710 917	1,36%
Thomsen Mikael	708 556	1,35%
Claus Olesen Holding ApS	692 738	1,32%
Ten largest shareholders	23 058 436	44,04%
Other shareholders	29 303 451	55,96%
Total	**52 361 887**	**100,00%**

of SEK 7.50 per share to finance its clinical programs into the beginning of 2024. The Extraordinary General Meeting on May 18 approved the proposal and the directed share issue to Linc AB and Adrigo Asset Management AB of 2,666,666 shares was executed shortly thereafter.

On June 22nd the Company announced the issuance of 126,000 new shares in connection with the long-term incentive program LTI2021. The new shares were subscribed for by executive management and key employees and consultants at a price of DKK 0.105 per share.

On May 31st the board of directors decided to execute the fully guaranteed rights issue of 5,463,426 shares, which was completed on July 5th.

On July 5th the board of directors announced a directed share issue to a strategic advisor of the company of 333,333 new shares at a price of SEK 7.50 per share.

After the close of the quarter the company announced that a total of 129.500 shares had been bought in the market by board members, management and key employees under the LTI2022 program. Under this program the warrant holders may be entitled to subscribe for or purchase from the company a total of 777.000 shares at par value, representing a potential dilution of 1.5%.

As of September 30, 2022 the company had around 4,300 shareholders. The 10 largest shareholders in the company on September 30 owned approx 44.0% 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 (1), of which 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.

FINANCIAL REVIEW

Operational risks and uncertainties

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

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

No new risks have arisen during 2022. A more detailed description of the company's risk exposure and risk management is included in the prospectus published in July 2021 and in the information memorandum published in October 2021 in connection with the change of listing to Nasdaq First North Growth Market.

Impact of COVID-19

As of November 2022 the clinical development programs of the company have been impacted by Covid-19. The company currently has two ongoing clinical trials

- a Phase 2a clinical trial in psychogenic erectile dysfunction (with IP2018)
- a Phase 2b clinical trial in organic erectile dysfunction (with IP2015)

All the ongoing clinical trials are being conducted in England. The board and management will continue to carefully monitor the Covid-19 pandemic and its potential for impacting our operations and development plans.

Financial calendar

Year-end report 2022 (Q4)	7 February 2023

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 4, 2022

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

TDKK	3Q:2022	3Q:2021	9M:2022	9M:2021	2021
Gross loss	-5 523	-8 856	-32 916	-14 849	-21 626
Staff costs	-1 166	-200	-2 347	-932	-1 435
Depreciation and write-downs	-	-	-	-11	-11
Operating profit/loss	**-6 689**	**-9 056**	**-35 263**	**-15 792**	**-23 072**
Other financial items	-100	-85	-232	-538	-1 172
Profit/loss before tax	**-6 789**	**-9 141**	**-35 495**	**-16 330**	**-24 244**
Tax	-	-	-	-	3 180
Net loss for the period	**-6 789**	**-9 141**	**-35 495**	**-16 330**	**-21 064**

FINANCIAL STATEMENTS

Statement of financial position

TDKK	9M:2022	9M:2021	2021
ASSETS			
Fixed assets	**17**	**-**	**-**
Other receivables	466	196	945
Income tax receivables	3 180	1 543	3 180
Prepayments	2 650	11 880	15 230
Current receivables	**6 296**	**13 619**	**19 355**
Cash and cash equivalents	**46 768**	**41 394**	**34 346**
Current assets	**53 064**	**55 013**	**53 701**
Assets	**53 081**	**55 013**	**53 701**
EQUITY AND LIABILITIES			
Contributed capital	5 498	3 760	4 596
Retained earnings	31 488	35 968	30 398
Equity	**36 986**	**39 728**	**34 994**
Convertible credit agreement	13 290	13 021	13 290
Long-term liabilities	**13 290**	**13 021**	**13 290**
Trade payables	1 903	2 102	4 800
Other payables	902	162	617
Current liabilities other than provisions	**2 805**	**2 264**	**5 417**
Liabilities other than provisions	**2 805**	**2 264**	**18 707**
Equity and liabilities	**53 081**	**55 013**	**53 701**

FINANCIAL STATEMENTS

Statement of changes in shareholder equity

TDKK	Contributed capital	Retained earnings	Total
January 1, 2021	**2 909**	**11 501**	**14 410**
Share issue	1 687	39 961	41 648
Profit/loss for the period	-	-21 064	-21 064
December 31, 2021	**4 596**	**30 398**	**34 994**
January 1, 2021	**2 909**	**11 501**	**14 410**
Share issue	851	40 797	41 648
Profit/loss for the period	-	-16 330	-16 330
September 30, 2021	**3 760**	**35 968**	**39 728**
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**

FINANCIAL STATEMENTS

Statement of cash flow

TDKK	3Q:2022	3Q:2021	9M:2022	9M:2021
Profit/loss before tax	-6 789	-9 141	-35 495	-16 330
Adjustments for non-cash transactions	-	-	-	11
Profit/loss before tax, adj for non-cash transactions	**-6 789**	**-9 141**	**-35 495**	**-16 319**
Tax credit	-	-	-	
Cash flow before change in working capital	**-6 789**	**-9 141**	**-35 495**	**-16 319**
Changes in working capital	-1 199	-13 199	10 447	-10 461
Cash flow from operating activities	**-7 988**	**-22 340**	**-25 048**	**-26 780**
Investing activities	-17	-	-17	-
Cash flow from investing activities	**-17**	**-**	**-17**	**-**
Financing activities				
New share issue	25 305	19 614	37 487	41 648
Credit agreement with MAC	-	13 021	-	13 021
Cash flow from financing activities	**25 305**	**32 635**	**37 487**	**54 669**
Cash flow for the reporting period	**17 300**	**10 295**	**12 422**	**27 889**
Cash and cash equivalents at the beginning of period	29 468	31 099	34 346	13 504
Cash and cash equivalents at the end of period	**46 768**	**41 394**	**46 768**	**41 394**

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).

IP2015
IP2015, our 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

Q3
2022

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