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## **BUSINESS HIGHLIGHTS**

#### Business highlights in Q1 2023

• In March the Company announced the completion of dosing of all 24 patients the the Phase IIa clinical trial with IP2018.

#### Business highlights after this reporting period

• Nothing to report.

#### **Financial Highlights**

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

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

#### **Financial review**

| КДКК   | Q1:2023    | Q1:2022    | Full Year 2022 |
|--|------------|------------|----------------|
| Net sales  | -          | -          | -              |
| Total operating expenses                           | -8 677     | -15 075    | -41 740        |
| Operating profit/loss                              | -8 677     | -15 075    | -41 740        |
| Net result   | -9 267     | -15 152    | -38 455        |
| Earnings per share before and after dilution (DKK) | -0,18      | -0,35      | -0,80          |
| Cash flow from operating activities                | -5 393     | -7 994     | -32 702        |
|  |            |            |                |
|  | 1Q:2023    | 1Q:2022    | 2022           |
| Cash and cash equivalents                          | 33 719     | 26 352     | 39 112         |
| Equity   | 24 757     | 19 412     | 34 023         |
| Total equity and liabilities                       | 39 557     | 37 275     | 47 488         |
| Equity ratio, %                                    | 63%        | 52%        | 72%            |
|  |            |            |                |
| Number of shares outstanding                       | 52 361 887 | 43 772 462 | 52 361 887     |
| Number of shares, diluted                          | 56 947 554 | 48 165 325 | 56 947 554     |
| Average number of shares outstanding               | 52 361 887 | 43 772 462 | 48 325 346     |
| Average number of shares, diluted                  | 56 947 554 | 48 165 325 | 53 225 959     |

# LETTER FROM THE CEO



2023 has started in the same positive spirit as we ended 2022. Our ongoing clinical programs are progressing according to plan and during the year we look forward to presenting results for both of our main clinical stage assets; IP2018 in development for psychogenic erectile dysfunction and depression and IP2015 in development for organic erectile dysfunction and neuropathic pain.

#### Results expected end of Q2 in the IP2018 Phase IIa program

The major event during the quarter was the completion of the recruitment and dosing in the beginning of March in the ongoing Phase IIa study with the monoamine reuptake inhibitor IP2018 for the treatment of psychogenic erectile dysfunction. The study was initiated in 2020 and is conducted in 24 young, depressed, erectile dysfunction patients at the MAC Phase I unit in Manchester, UK. As previously reported the patient recruitment was more challenging than anticipated, mainly due to COVID-19. Thus, we are very pleased that we have been able to complete the study with the planned number of eligible patients and assessments. The data analysis proceeds according to plan and we still expect to be able to present first draft results during the second quarter this year.

# Clear unmet medical need for more effective treatments within psychogenic ED

With the IP2018 Phase IIa study we target depressed ED patients for the first time. IP2018 is a unique substance that raises the serotonin levels in the brain and preclinical trials have 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 this study we hope 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. If the clinical development is successful we intend 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. With up to 68 percent of patients with major depressive disorder suffering from sexual dysfunction, for which only 5-30 percent is resolved with antidepressant treatment there is a clear unmet medical need within psychogenic ED. Hopefully IP2018 can become an effective drug for these patients.

# Patient recruitment soon to be completed in IP2015 Phase IIb program

IP2015 is our most advanced asset and is under development for both organic erectile dysfunction and for neuropathic pain. Within the erectile dysfunction indication we are currently conducting a multi-center Phase IIb study in 120 otherwise healthy organic Erectile dysfunction patients together with MAC Clinical Research. Even though the patient recruitment for the IP2015 study has been affected by Covid as well we have seen an increased enrolment rate since the end of 2022, we maintain our goal of completing the dosing part of the study in the first half of 2023.

## LETTER FROM THE CEO

The aim with IP2015 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, e.g. Viagra®, Cialis®, Levitra®) for erectile dysfunction. The medical need for this kind of treatment is significant. It is estimated that the number of ED patients is about 150 million men worldwide, a number that is estimated to increase to more than 300 million by 2025, and about 30-40% of these patients will not respond to the current available treatments.

#### Testing new oral solid dosage forms of IP2015 in phase I

Our newly developed solid dosage form of IP2015 is undergoing a Phase I pharmacokinetic study in healthy subjects, which will bridge previous data sets into new future clinical studies for IP2015. We expect that the study will report draft phamacokinetic data during Q2 2023. This pharmacokinetic study is vital for designing and executing future clinical development studies for IP2015. It will strengthen the intellectual property rights (IPR) portfolio for the entire IP2015 program, and the solid dosage formulation will bring us closer to having a final drug product that may be used in a potential future launch.

#### **Exciting times ahead**

The next couple of months look truly exciting. We will hopefully soon be able to present draft phamacokinetic data on the IP2015 solid dosage form Phase I study in healthy subjects. The draft results from the Phase IIa study with IP2018 for the treatment of psychogenic erectile dysfunction are scheduled to be provided end of Q2 2023. And we also hope to complete the dosing part of our Phase IIb study in organic erectile dysfunction patients in the first half of 2023. I am looking forward to update our shareholders on these coming inflection points in our clinical programs.

Copenhagen, May 5, 2023

**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 two clinical stage assets - the IP2018 and IP2015 – and two preclinical assets. The company is currently conducting a Phase IIb trial with 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 is conducting a Phase IIa trial for the treatment of erectile dysfunction of psychogenic origin.

#### 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 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.

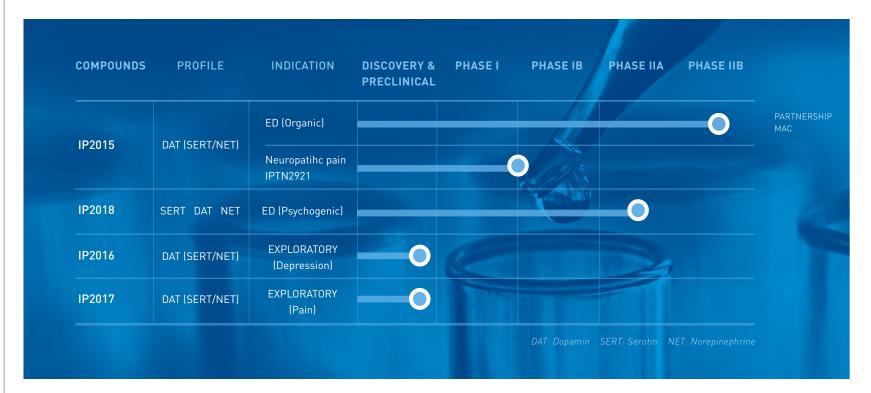
Initiator Pharma aims to progress our portfolio of drug candidates to key value inflection points, where we anticipate significant partnering interest from international pharma industry for the further development of our drug candidates.



## **PROJECT PORTFOLIO**

In 2016 Initiator Pharma acquired three potential drug candidates from Saniona (IP2015, IP2016 and IP2017). All three drug candidates belong to the drug class known as monoamine reuptake inhibitors. In 2018 the

project portfolio was expanded through an option agreement to inlicense IP2018, which we exercised in March 2020:



**IP2015:** IP2015, our most advanced asset, is being developed for both treatment resistant organic Erectile Dysfunction (ED) and neuropathic pain.

#### **Organic Erectile Dysfunction**

IP2015 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®). 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 clinical positioning of IP2015 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 <sup>1</sup>. At the beginning of June 2019, Initiator announced that the Company had successfully completed a Phase I study regarding safety and tolerability with IP2015, and in March 2020, Initiator achieved successful Phase IIa results for IP2015. 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 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 IP2015. 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 IP2015 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 IP2015 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 IP2015 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. The current expectation is that the dosing part of the study will be completed in the first half of 2023.

#### Erectile Dysfunction (ED) Market

The current number of ED patients is estimated to about 150 million men worldwide and a number that is estimated to increase to more than 300 million by 2025. About 30-40% of these patients will not respond to the current treatment and represent a significant unmeet medical need. This is exactly 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 USD billion in sales and Initiator Pharma strongly believes that targeting the PDE5i non-responders will allow us to receive premium pricing for IP2015 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 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 <sup>2,3</sup>.

The 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 we 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 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 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 is expected to deliver draft phamacokinetic data in Q2 2023.

#### 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% <sup>4</sup> . On average annual healthcare cost for painful neuropathic disorder is US 17,355 per patient. With a solid efficacy and safety data on 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 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 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 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 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 Neuropathic Pain

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 IIa clinical trial with its candidate drug IP2018. The Phase IIa 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.

As previously communicated we expect to report topline data from the clinical trial during the second quarter.

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

#### 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.

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

<sup>2</sup> 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.

<sup>3</sup> 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.

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

<sup>5</sup> 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.

<sup>6</sup> 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 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 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.

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.

#### Revenue

Initiator Pharma generated generated no revenues for the first quarter of 2023 (-).

#### Earnings

The company recognized an operating loss of KDKK 8,677 for the first quarter of 2023 (-15,075). The decrease in operating costs for the period compared to last year reflects the completion of phase I clinical proof of concept trial with IP2015 in Q2 2022.

External R&D costs in the first quarter amounted to KDKK 5,848, compared to KDKK 12,578 in the same period in 2022.

Net financial expenses in the first quarter amounted to KDKK 590, compared to net financial expenses of KDKK 77 in the same period in 2022. The net financial expenses in the first 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.

The net loss after tax for the first quarter was KDKK 9,267 (-15,152) and earnings per share totaled to DKK -0.18 (-0.35).

#### **Financial position**

The equity as of March 31, was KDKK 24,575 compared to KDKK 34,023 at year-end 2022. Cash and cash equivalents amounted to KDKK 33,719 as of March 31 compared to KDKK 39,112 at yearend 2022, and total assets were KDKK 39,557 (47,488).

As of March 31 the balance of the convertible credit agreement with MAC covering part financing of the ongoing Phase IIb study

was KDKK 12,708, an incrase of KDKK 131 due to FX movements between GBP and DKK during the period and unchanged in GBP.

#### Cash flow

In the first quarter the cash flow from operating activities was KDKK -5,393 (-7,994), incl. a positive change in working capital of KDKK 3,725 (7,158). The reduction in working capital is related to previous pre-payments of costs of the Phase 2a clinical trial with IP2018 and the Phase IIb clinical trial with IP2015.

The company had no cash flow from investment activities in the first quarter (-).

The company had no cash flow from financing activities in the first quarter (-).

#### The share, share capital and ownership structure

At March 31, 2023, the number of shares outstanding totalled to 52,361,887 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 March 31 the company had around 4,000 shareholders. The 10 largest shareholders in the company on March 31 owned approx 45.8% of all outstanding shares.

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

| Owners                      | Number of shares | Shares |
|-----------------------------|------------------|--------|
| LINC AB                     | 10 091 219       | 19,27  |
| Adrigo Small and Midcap L/S | 4 039 828        | 7,72   |
| Avanza Pension              | 3 362 657        | 6,42   |
| BNY Mellon SA/NV            | 1 671 444        | 3,19   |
| UBS Switzerland             | 961 109          | 1,84   |
| Nordnet Pensionsforsäkring  | 927 530          | 1,77   |
| Thorén, Mats                | 788 286          | 1,51   |
| DanPet AB                   | 710 917          | 1,36   |
| Thomsen Mikael              | 708 556          | 1,35   |
| Claus Olesen Holding ApS    | 692 738          | 1,32   |
| Ten largest shareholders    | 23 954 284       | 45,75  |
| Other shareholders          | 28 407 603       | 54,25  |

#### Personnel

As of March 31, the number of employees was 3 (1), of which 1 (0) 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

Annual General Meeting 2023 Interim half year report 2023 Interim Q3 2023 report Year-end report 2023 (Q4)

26 May 2023 25 August 2023 10 November 2023 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, May 5, 2023

**Magnus Persson** Chairman

Board member

*Henrik Moltke Board member* 

**Peter Holm** Board member **Gunilla Ekström** Board member

Annette Colin

**Claus Olesen** Board member and CEO

## Statement of income

| КДКК                         | Q1:2023 | Q1:2022 | Full Year 2022 |
|------------------------------|---------|---------|----------------|
| Gross loss                   | -8 033  | -14 569 | -38 425        |
| Staff costs                  | -644    | -506    | -3 315         |
| Depreciation and write-downs | -       | -       | -              |
| Operating profit/loss        | -8 677  | -15 075 | -41 740        |
|                              |         |         |                |
| Other financial items        | -590    | -77     | -2 392         |
| Profit/loss before tax       | -9 267  | -15 152 | -44 132        |
| -                            |         |         |                |
| Tax                          | -       | -       | 5 677          |
| Net loss for the period      | -9 267  | -15 152 | -38 455        |

## Statement of financial position

| кокк                                      | Q1:2023 | Q1:2022 | Year End 2022 |
|---|---------|---------|---------------|
| ASSETS                                    |         |         |               |
| Patents, acquired rights                  | -       | -       | -             |
| Intangible assets                         | -       | -       | -             |
| Property, plant and equipment             | -       | -       | 17            |
| Fixed assets                              | -       | -       | 17            |
| Other receivables                         | 338     | 873     | 849           |
| Income tax receivables                    | 5 500   | 3 180   | 5 500         |
| Prepayments                               | -       | 6 870   | 2 010         |
| Current receivables                       | 5 838   | 10 923  | 8 359         |
| Cash and cash equivalents                 | 33 719  | 26 352  | 39 112        |
| Current assets                            | 39 557  | 37 275  | 47 471        |
| Assets                                    | 39 557  | 37 275  | 47 488        |
| EQUITY AND LIABILITIES                    |         |         |               |
| Contributed capital                       | 5 498   | 4 596   | 5 498         |
| Retained earnings                         | 19 259  | 14 816  | 28 525        |
| Equity                                    | 24 757  | 19 412  | 34 023        |
| Convertible credit agreement              | 12 708  | 13 290  | 12 577        |
| Long-term liabilities                     | 12 708  | 13 290  | 12 577        |
| Trade payables                            | 1 927   | 4 041   | 701           |
| Other payables                            | 165     | 532     | -654          |
| Accrued expenses                          | 387     | -       | 841           |
| Current liabilities other than provisions | 2 092   | 4 573   | 888           |
| Liabilities                               | 14 800  | 17 863  | 13 465        |
| Equity and liabilities                    | 39 557  | 37 275  | 47 488        |

## 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                | -                   | -430              | -430    |
| Profit/loss for the period | -                   | -15 152           | -15 152 |
| March 31, 2022             | 4 596               | 14 816            | 19 412  |
| January 1, 2023            | 5 498               | 28 525            | 34 023  |
| Share issue                | -                   | -                 | -       |
| Profit/loss for the period | -                   | -9 267            | -9 267  |
| March 31, 2023             | 5 498               | 19 258            | 24 757  |
|                            |                     |                   |         |

## Statement of cash flow

| КДКК  | Q1:2023 | Q1:2022 | Full Year 2022 |
|---|---------|---------|----------------|
| Profit/loss before tax                                | -9 267  | -15 152 | -44 132        |
| Adjustments for non-cash transactions                 | 149     | -       | -536           |
| Profit/loss before tax, adj for non-cash transactions | -9 118  | -15 152 | -44 668        |
| Tax paid/received                                     | -       | -       | 3 180          |
| Cash flow before change in working capital            | -9 118  | -15 152 | -41 488        |
|   |         |         |                |
| Changes in working capital                            | 3 725   | 7 158   | 8 787          |
| Cash flow from operating activities                   | -5 393  | -7 994  | -32 701        |
|   |         |         |                |
| Investing activities                                  | -       | -       | -17            |
| Cash flow from investing activities                   | -       | -       | -17            |
|   |         |         |                |
| Financing activities                                  |         |         |                |
| New share issue                                       | -       | -       | 37 484         |
| Credit agreement with MAC                             | -       | -       | -              |
| Cash flow from financing activities                   | -       | -       | 37 484         |
| Cash flow for the reporting period                    | -5 393  | -7 994  | 4 766          |
|   |         |         |                |
| Cash and cash equivalents at the beginning of period  | 39 112  | 34 346  | 34 346         |
| Cash and cash equivalents at the end of period        | 33 719  | 26 352  | 39 112         |

### 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**

#### 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

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