

**Q1**  
2022

# BUSINESS HIGHLIGHTS

## Business highlights in Q1 2022

- On January 20th the initiation of dosing in the IPTN2021 program Phase 1 to assess pain reducing effects in healthy volunteers was announced.
- On March 22nd it was announced that the inclusion of test subjects in the IPTN2021 Phase 1 study had been completed.

## Business highlights after this reporting period

- On April 5th the Company announced that it has signed an option agreement for a Phase 2/3 ready drug asset for an undisclosed pain indication.
- On April 13th the Board of Directors proposed a directed share issue and fully guaranteed rights issue of a total of approximately SEK 61 million to finance its clinical programs into the beginning of 2024.

## Financial review

| TDKK                                    | 1Q:2022 | 1Q:2021 | 2021    |
|---|---------|---------|---------|
| Net sales                               | -       | -       | -       |
| Total operating expenses                | -15 075 | -1 792  | -23 072 |
| Operating profit/loss                   | -15 075 | -1 792  | -23 072 |
| Net result                              | -15 152 | -1 807  | -21 064 |
| Earnings per share (DKK)                | -0,35   | -0,07   | -0,48   |
| Earnings per share, fully diluted (DKK) | -0,31   | -0,06   | -0,44   |
| Cash flow from operating activities     | -7 994  | -2 217  | -34 097 |

|                              | 1Q:2022 | 1Q:2021 | 2021   |
|------------------------------|---------|---------|--------|
| Cash and cash equivalents    | 26 352  | 13 504  | 34 346 |
| Equity                       | 19 412  | 14 409  | 34 994 |
| Total equity and liabilities | 37 275  | 15 603  | 53 701 |
| Equity ratio, %              | 52%     | 92%     | 65%    |

|   |            |            |            |
|---|------------|------------|------------|
| <i>Number of shares outstanding</i>         | 43 772 462 | 27 705 728 | 43 772 462 |
| <i>Number of shares, diluted</i>            | 48 165 325 | 28 574 121 | 48 165 325 |
| <i>Average number of shares outstanding</i> | 43 772 462 | 27 705 728 | 35 088 333 |
| <i>Average number of shares, diluted</i>    | 48 165 325 | 28 574 121 | 39 685 393 |

## LETTER FROM THE CEO



The first quarter of 2022 has been intense for Initiator Pharma. With the Covid-19 pandemic slowing down dramatically, and less restrictions affecting our operations, we have seen good progress in all our current clinical programs; IPED2015, IP2018 and IPTN2021. During the quarter, and the following period, we have also strengthened the management team, signed an option agreement for an exciting new drug asset and announced a proposed capitalization which would secure the financing of our clinical program and the runway for Initiator into the beginning of 2024.

### Dosing completed in the IPTN2021 program Phase I trial

Our clinical Phase 1 study to assess pain-reducing effects has, despite the still ongoing Covid-19 restrictions in the beginning of the year, progressed fully according to plan. The study, comprising 24 healthy male subjects challenged with the pain-inducing ingredient (capsaicin), dosed its first subject with the drug substance IP2015 in January. Almost exactly three months later, in April, we announced that all planned subjects have had the last visit in the study and all planned clinical activities had taken place. This is a major milestone for Initiator as this is the first clinical trial in our IPTN2021 program, that aims to target the treatment of the orphan drug pain indication trigeminal neuralgia using the drug substance IP2015. The trial will provide important pain related efficacy, biomarker and safety information to support further clinical development of the drug substance IP2015 in different indications.

The obtained clinical data from the study will now be undergoing data management, quality and statistical analysis and we expect to be able to present the first results at the end of the second quarter. We are really looking forward to receiving the data and, if positive outcome, use it to design the next clinical study in the IPTN2021 program aimed at trigeminal neuralgia.

### Potential pipeline expansion with a late-stage clinical asset

After the period, in the beginning of April, we announced the signing of an exclusive option agreement for a Phase 2/3 ready drug asset for an undisclosed pain indication. This drug candidate matches and complements Initiator's current pipeline and ongoing clinical activities very well, including our other pain program IPTN2021, and furthermore strengthens our ambition of targeting the CNS for a broad range of indications. A major advantage with this late stage asset, and a prerequisite for a time and cost-efficient pathway to the market, is that it has already been de-risked to a high extent through previously conducted clinical studies, demonstrating exploratory clinical efficacy in the selected indication.

We are now initiating a deeper evaluation of the asset aiming to design a potential regulatory and clinical development plan that fulfills the Target Product Profile for the undisclosed pain indication. I look forward to sharing more information about the asset, the indication and terms after having completed the evaluation during the option period ending at year-end 2022.

# LETTER FROM THE CEO

## IPED2015 and IP2018 clinical programs on track

Our most advanced program in erectile dysfunction (ED), IPED2015, is being evaluated in an ongoing Phase 2b trial conducted in the UK in collaboration with MAC Clinical Research. The patient recruitment rate is progressing well, and we still anticipate that inclusion and dosing of the planned 120 patients should be completed in the second half of this year.

The patient enrollment in our Phase 2a study with the monoamine reuptake inhibitor IP2018 in depressed ED patients, is still ongoing though the patient recruitment rate has increased significantly since we obtained approval from the regulatory authorities to modify certain inclusion criteria last summer. With the Covid-19 pandemic slowing down significantly we hope to be able to complete patient recruitment soon.

## Proposed capitalization secures ongoing development and creates opportunities

Initiator Pharma's Board of Directors proposed in April a directed share issue and fully guaranteed rights issue of a total of approximately SEK 61 million in order to secure the long-term financing of the company and ongoing programs to the early part of 2024. This financing will be an important capital injection allowing us to advance all our clinical programs according to set plans and priorities. Furthermore, it also supports our business strategy of identifying attractive but undervalued clinical-stage assets and advancing these through cost-efficient clinical trials to deliver key-value inflection points in indications with significant unmet medical needs.

I am truly grateful for the continued trust shown by our anchor investors, Linc AB and Adrigo Asset Management AB, now even further shown by their significant increase in ownership in Initiator Pharma as a result of this proposed financing. Having two truly experienced and skilled anchor investors in our company is of immense value to us as management team and to all shareholders in the short as well as the long term.

The proposed directed share issue and rights issue is to be resolved on an Extraordinary General Meeting at May 18.

With a plan for secured financing, an attractive portfolio of clinical assets progressing according to plan, and our latest management team member Christina Guldberg onboard as Senior Director, Clinical Development and Outcomes Research (Rare Diseases), a new position designed to strengthen our clinical development and Orphan drug capabilities, I see the future with confidence and look forward to keep you updated on our progress.

Copenhagen, May 6, 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:

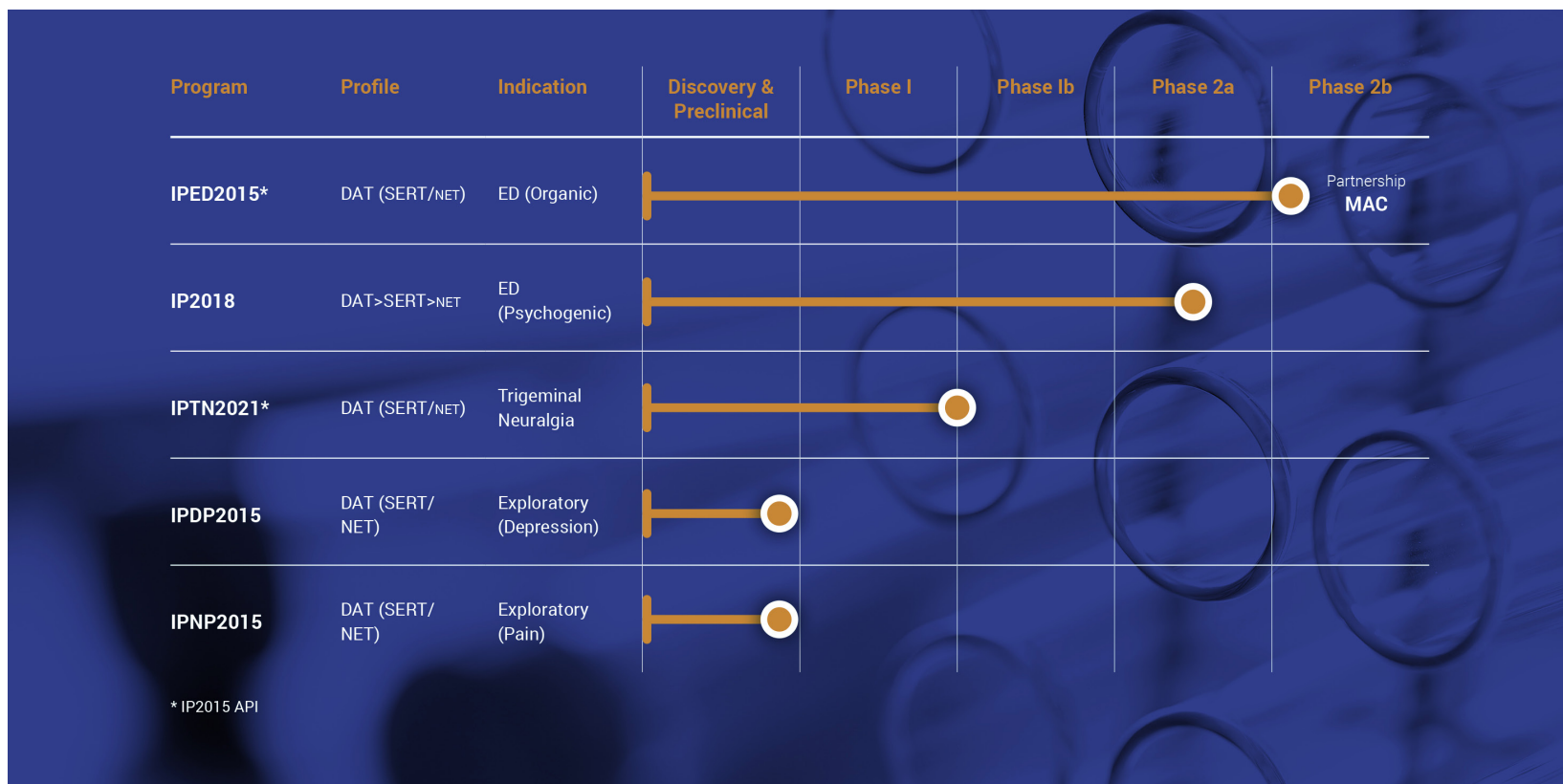
- By internal development of selected programs through the early phases of drug development before out-licensing to pharmaceutical companies who will take over the further clinical development of Initiator Pharma's programs and typical with upfront payments, milestone and royalty payments on product 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. On April 13th we announced that we had further expanded our development pipeline with IPTN2021, aiming to develop the IP2015 molecule for neuropathic pain, and specifically Trigeminal Neuralgia:



# ERECTILE DYSFUNCTION

**IPED2015:** IPED2015, our most advanced development program, is 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®). IPED2015 - 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 sexual 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 1 study regarding safety and tolerability with IPED2015, and in March 2020, Initiator achieved successful Phase 2a results for IPED2015. 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 IPED2015 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 IPED2015. Within the agreement, MAC Clinical Research (MAC) will

take on the cost, up to 23 MSEK, for conducting a clinical Phase 2b intercourse study for IPED2015 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. Inclusion and dosing of patients should be completed in H2 2022, pending the development of the Covid-19 pandemic.

## 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 unmet medical need. This is exactly our primary target group and will clearly distinguish us from 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 for IPED2015 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<sup>2</sup>. With our IPTN2021 program aim to address this significant unmet medical need<sup>3</sup>.

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

We aim in a Proof-of-Principle study to examine the effect of IP2015 in subjects exposed to the sensory nerve stimulant capsaicin. On March

30th this year we announced that we had completed the inclusion phase of the Phase 1 proof of principal study in which IP2015 will be evaluated for analgesic effects in healthy subjects challenged with capsaicin as a pain inducing agent. This is a well established pain model of neuropathic pain for early evaluation of analgesic effect, and if positive is planned to be followed by a Phase 2a study in patients suffering from Trigeminal Neuralgia. Pending current and future Covid-19 restrictions, headline results of the Phase 1 proof of concept study are expected sometimes during the second quarter 2022.

## Trigeminal Neuralgia Market

The neuropathic Pain Market according to Garner a Valuation of US\$ 9,862.3 Million by 2027, at CAGR of 6.4 percent by the end of 2027<sup>4</sup>. 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 be able to obtain premium pricing significantly strengthening the commercial opportunity with the potential to reach high hundreds of MUSD in sales.

<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>.

# 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 will be conducted in 24 patients at the MAC Phase I unit in Manchester, UK.

On December 17th we announced that the patient recruitment rate in the ongoing Phase 2a study with the drug substance IP2018 has increased significantly since Initiator in July 2021 obtained approval from the regulatory authorities to modify certain inclusion criteria. However, recruitment rate is still impacted by the Covid-19 pandemic, especially the patient segment targeted in this trial seems to be significantly impacted. The patient recruitment is expected to be completed in the first part of 2022.



# PSYCHOGENIC ERECTILE DYSFUNCTION

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 <sup>5</sup>. 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 <sup>6</sup>. About 13 percent of all Americans take antidepressant drugs, which means over 23 million prescriptions per year <sup>7</sup>. 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 <sup>8</sup>. 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 IPED2015 and IP2018 in the USA; and in the USA, Israel, Japan, the United Kingdom, Germany, France, and Switzerland, respectively.

The IPED2015 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 Europe, USA, China, Japan, South Korea and a number of other relevant markets. The patent family is projected to expire in 2040.

<sup>5</sup> Rosenberg, K. P., Bleiberg, K. L., Kosci, 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

<sup>7</sup> 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.

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

## Revenue

Initiator Pharma generated total revenues of TDKK 0 for the first quarter of 2022 (0).

## Result

The company recognized an operating loss of TDKK 15,075 for the first quarter of 2022 (-1,792). The increase in operating costs during the first quarter reflects the three clinical trials that the company has ongoing, as well as increased corporate costs, including build-out of the organisation.

External R&D costs in the first quarter amounted to TDKK 12,578, compared to TDKK 169 in the same period in 2021.

Net financial expenses in the first quarter amounted to TDKK 77, compared to net financial expenses of TDKK 15 in the same period in 2021. The increase in net financial expenses for the first quarter 2022 is related to foreign exchange movements in the period.

## Financial position

The equity as of March 31, was TDKK 19,412 (34,994). Cash and cash equivalents amounted to TDKK 26,352 (34,346) as of March 31, and total assets were TDKK 37,275 (53,701).

As of March 31 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 first quarter the total operating cash flow was TDKK -7 994 (TDKK -2,217), incl. a positive change in working capital of

TDKK 7,158 (TDKK -417). The positive change in working capital is related to the reduction in pre-payments to MAC Clinical Research for the ongoing clinical trials. Cash flow from investment activities was TDKK 0 (TDKK 0). Cash flow from financing activities was 0 (TDKK 0).

## The share, share capital and ownership structure

At March 31, 2022, the number of shares outstanding totalled to 43,772,462 shares and on a fully diluted basis 48 165 325, 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 proposes a directed share issue and fully guaranteed rights issue of a total of approximately SEK 61 million to finance its clinical programs into the beginning of 2024. The Board of Directors has convened an Extraordinary General Assembly ("EGM") to be held on May 18 to resolve the proposal. If the proposal is approved the Company will issue 2.666.666 new shares in the directed share issue and an additional 5.463.426 shares in the rights issue, increasing the number of outstanding shares to 51.902.554.

As of March 31, 2022 the company had around 4,300 shareholders. The 10 largest shareholders in the company on March 31 owned approx 36.7% of all outstanding shares.

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

**Top 10 shareholders as of March 31, 2022**

| Owners                                  | Number of shares  | Shares %       |
|---|-------------------|----------------|
| LINC AB                                 | 5 780 781         | 13,21%         |
| Försäkringsaktiebolaget, Avanza Pension | 2 978 130         | 6,80%          |
| Adrigo Small and Midcap L/S             | 1 240 203         | 2,83%          |
| BNY Mellon SA/NV                        | 1 194 283         | 2,73%          |
| Ålandsbanken i Ågares ställe            | 973 309           | 2,22%          |
| Nordnet Pensionsförsäkring              | 908 262           | 2,07%          |
| UBS Switzerland                         | 812 628           | 1,86%          |
| Thorén, Mats                            | 806 559           | 1,84%          |
| DanPet AB                               | 700 920           | 1,60%          |
| Claus Olesen Holding AB                 | 692 738           | 1,58%          |
| Ten largest shareholders                | 16 087 813        | 36,75%         |
| Other shareholders                      | 27 684 649        | 63,25%         |
| <b>Total</b>                            | <b>43 772 462</b> | <b>100,00%</b> |

**Personnel**

As of March 31, the number of employees was 2 (1), of which 1 woman. Initiator Pharma follows a strategy of using an extensive network of consultants to support the development activities in the company. Such a strategy is well established in drug development and ensures the company the optimal balance of access to leading edge expertise, costs and flexibility.

**Operational risks and uncertainties**

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

The main risks and uncertainties which Initiator Pharma is exposed to are related to drug development, the company's collabo-

ration agreements, competition, technology development, patent, regulatory requirements, capital requirements and currencies.

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 May 2022 the clinical development programs of the company have been impacted by Covid-19. The company currently has three 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)
- a Phase 1 proof of principal clinical trial in Neuropathic pain (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

|                              |                  |
|------------------------------|------------------|
| Annual General Meeting 2022  | 24 May 2022      |
| Interim report 1st half 2022 | 19 August 2022   |
| Interim Q3 2022 report       | 4 November 2022  |
| Year-end report 2022 (Q4)    | 17 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).

Aarhus, May 6, 2022

**Magnus Persson**  
Chairman

**Annette Colin**  
Board member

**Henrik Moltke**  
Board member

**Claus Olesen**  
Board member and CEO

**Peter Holm**  
Board member

## Statement of income

| TDKK                           | 1Q:2022        | 1Q:2021       | 2021           |
|--------------------------------|----------------|---------------|----------------|
| Gross loss                     | -14 569        | -1 584        | -21 626        |
| Staff costs                    | -506           | -168          | -1 435         |
| Depreciation and write-downs   | -              | -6            | -11            |
| <b>Operating profit/loss</b>   | <b>-15 075</b> | <b>-1 792</b> | <b>-23 072</b> |
| Other financial items          | -77            | -15           | -1 172         |
| <b>Profit/loss before tax</b>  | <b>-15 152</b> | <b>-1 807</b> | <b>-24 244</b> |
| Tax                            | -              | -             | 3 180          |
| <b>Net loss for the period</b> | <b>-15 152</b> | <b>-1 807</b> | <b>-21 064</b> |



## Statement of financial position

| TDKK   | 1Q:2022       | 1Q:2021       | 2021          |
|--|---------------|---------------|---------------|
| <b>ASSETS</b>                                    |               |               |               |
| Patents, acquired rights                         | -             | 6             | -             |
| <b>Intangible assets</b>                         | -             | <b>6</b>      | -             |
| <b>Property, plant and equipment</b>             | -             | -             | -             |
| <b>Fixed assets</b>                              | -             | <b>6</b>      | -             |
| Other receivables                                | 873           | 193           | 945           |
| Income tax receivables                           | 3 180         | 1 543         | 3 180         |
| Prepayments                                      | 6 870         | -             | 15 230        |
| <b>Current receivables</b>                       | <b>10 923</b> | <b>1 736</b>  | <b>19 355</b> |
| <b>Cash and cash equivalents</b>                 | <b>26 352</b> | <b>11 287</b> | <b>34 346</b> |
| <b>Current assets</b>                            | <b>37 275</b> | <b>13 023</b> | <b>53 701</b> |
| <b>Assets</b>                                    | <b>37 275</b> | <b>13 029</b> | <b>53 701</b> |
| <b>EQUITY AND LIABILITIES</b>                    |               |               |               |
| Contributed capital                              | 4 596         | 2 909         | 4 596         |
| Retained earnings                                | 14 816        | 9 694         | 30 398        |
| <b>Equity</b>                                    | <b>19 412</b> | <b>12 603</b> | <b>34 994</b> |
| Convertible credit agreement                     | 13 290        | -             | 13 290        |
| <b>Long-term liabilities</b>                     | <b>13 290</b> | -             | <b>13 290</b> |
| Trade payables                                   | 4 041         | 240           | 4 800         |
| Other payables                                   | 532           | 186           | 617           |
| <b>Current liabilities other than provisions</b> | <b>4 573</b>  | <b>426</b>    | <b>5 417</b>  |
| <b>Liabilities other than provisions</b>         | <b>4 573</b>  | <b>426</b>    | <b>18 707</b> |
| <b>Equity and liabilities</b>                    | <b>37 275</b> | <b>13 029</b> | <b>53 701</b> |

## Statement of changes in shareholder equity

| TDKK                       | Contributed capital | Retained earnings | Total         |
|----------------------------|---------------------|-------------------|---------------|
| <b>January 1, 2021</b>     | <b>2 909</b>        | <b>11 501</b>     | <b>14 410</b> |
| Share issue                | 1 687               | 39 961            | 41 648        |
| Profit/loss for the period | -                   | -21 064           | -21 064       |
| <b>December 31, 2021</b>   | <b>4 596</b>        | <b>30 398</b>     | <b>34 994</b> |
| <b>January 1, 2021</b>     | <b>2 909</b>        | <b>11 501</b>     | <b>14 410</b> |
| Share issue                | -                   | -                 | -             |
| Profit/loss for the period | -                   | -1 807            | -1 807        |
| <b>March 31, 2021</b>      | <b>2 909</b>        | <b>9 694</b>      | <b>12 603</b> |
| <b>January 1, 2022</b>     | <b>4 596</b>        | <b>30 398</b>     | <b>34 994</b> |
| Share issue                | -                   | -430              | -430          |
| Profit/loss for the period | -                   | -15 152           | -15 152       |
| <b>March 31, 2022</b>      | <b>4 596</b>        | <b>14 816</b>     | <b>19 412</b> |

## Statement of cash flow

| TDKK   | 1Q:2022        | 1Q:2021       | 2021           |
|--|----------------|---------------|----------------|
| Profit/loss before tax                                       | -15 152        | -1 807        | -24 244        |
| Adjustments for non-cash transactions                        | -              | 6             | 11             |
| <b>Profit/loss before tax, adj for non-cash transactions</b> | <b>-15 152</b> | <b>-1 801</b> | <b>-24 233</b> |
| Tax paid/received  | -              | -             | 1 543          |
| <b>Cash flow before change in working capital</b>            | <b>-15 152</b> | <b>-1 801</b> | <b>-22 690</b> |
| Changes in working capital                                   | 7 158          | -416          | -11 407        |
| <b>Cash flow from operating activities</b>                   | <b>-7 994</b>  | <b>-2 217</b> | <b>-34 097</b> |
| <b>Investing activities</b>                                  | -              | -             | -              |
| <b>Cash flow from investing activities</b>                   | -              | -             | -              |
| <b>Financing activities</b>                                  | -              | -             | -              |
| New share issue  | -              | -             | 41 648         |
| Credit agreement with MAC                                    | -              | -             | 13 290         |
| <b>Cash flow from financing activities</b>                   | -              | -             | <b>54 938</b>  |
| <b>Cash flow for the reporting period</b>                    | <b>-7 994</b>  | <b>-2 217</b> | <b>20 841</b>  |
| Cash and cash equivalents at the beginning of period         | 34 346         | 13 504        | 13 504         |
| <b>Cash and cash equivalents at the end of period</b>        | <b>26 352</b>  | <b>11 287</b> | <b>34 346</b>  |

## 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).

### IPED2015

IPED2015, 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





**Q1**  
2022

**Initiator Pharma**

[www.initiatorpharma.com](http://www.initiatorpharma.com)

*Ole Maaloes vej 3, 2200 Copenhagen, DENMARK*