CVR number: 37663808 January – March 2020 Published May 22, 2020



## **INITIATOR PHARMA: 1 QUARTER REPORT 2020**

## Clinical progress and expanded pipeline

#### **Business highlights in Q1 2020**

- On March 15<sup>th</sup> we reported the final data from the company's Phase 2a study with IPED2015, demonstrating statistically significant and clinically relevant results on key efficacy endpoints in patients with severe ED after a single administration of IPED2015. As previously reported, the Phase 2a study was completed satisfactorily with no observations of critical adverse events.
- On March 31st we announced that we have filed a Phase 2a Clinical Trial Application (CTA) to MHRA, UK, for our candidate drug IP2018. Through the submission of the CTA, we also exercised our option agreement with Saniona for IP2018.

## Significant events after this reporting period

 On April 27<sup>th</sup> we announced that we have completed a SEKM 3 direct share issue with warrants to Formue Nord, a Danish investment fund, and also announced a proposal to the Annual General Meeting for a SEKM 7 rights issue with warrants that has been fully guaranteed.

#### **Financial Highlights**

Initiator Pharma A/S is a Danish registered company, and is reporting its financial situation in Danish kroner (DKK). Initiator Pharma A/S was registered on May 2, 2016.

## First Quarter (2020-01-01 - 2020-03-31)

- Net revenues were TDKK 0 (0)
- EBIT was TDKK -2,392 (-1,463)
- Earnings per share was DKK -0.11 (-0.22)
- Cash and bank: TDKK 7,082 (13,346)
- Solidity: 82%

Group earnings per share: period result divided by a number of 23 591 375 stocks (on 2020-03-31). Solidity: equity divided by

#### **Comments from the CEO**

"Q1 has been another eventful quarter for Initiator Pharma: First of all we announced the final data from the IPED2015 Phase 2a clinical trial with IPED2015. Secondly, we filed a Clinical Trial Application (CTA) to the UK regulatory body: the filing also allowed us to exercise the option on IP2108 with Saniona and we can now fully integrate the compound into the Initiator Pharma pipeline. 2020 will be a truly exciting year for the company, with a series of upcoming inflection events in the near to mid-term future"

#### For more information, please contact

Claus Olesen, CEO, Initiator Pharma, Mobile: +45-61 26 00 35, E-mail: <a href="mailto:ceo@initiatorpharma.com">ceo@initiatorpharma.com</a> Torgeir Vaage, CFO, Initiator Pharma, Mobile: +47-924 05 235, E-mail: tv@initiatorpharma.com

## **About Initiator Pharma**

Initiator Pharma A/S is a Danish biotechnology company focusing on the development of innovative drugs, targeting key unmet medical needs within the central and peripheral nervous system. Our research is focusing on monoamine reuptake inhibitors, molecules that are affecting the synaptic concentrations of neurotransmitters such as dopamine, serotonin and noradrenaline. Our lead candidate drug, IPED2015 is targeting the medical condition Erectile Dysfunction (ED), and specifically patients

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with ED that are non-responsive to drugs within the PDE5i class, including the approved drugs Viagra ©, Cialis © and Levitra ©.

Initiator Pharma is based in Aarhus, Denmark. Initiator Pharma is listed on Spotlight Stockmarket and has about 3.800 shareholders. Read more at www.initiatorpharma.com.

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## **Initiator** Pharma

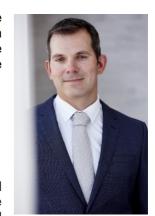
#### Letter from the CEO

The first quarter of 2020 did come off to a good start, with the final report on the successfully completed Phase 2a clinical Proof of Concept trial for IPED2015 in erectile dysfunction. The trial results strengthened our belief that our candidate drug IPED2015 has strong potential to become the first-line treatment of erectile dysfunction for the PDE5i non-responders.

"To obtain data that show Proof of Concept in clinical Phase 2a was truly a gratifying moment for Initiator Pharma. We have met some challenges on the way with the recruitment of qualified subjects but despite this we have still managed to complete the trial within budget."

The outcome of the Phase 2a trial enables us to further map the clinical and regulatory pathway for IPED2015, including pivotal studies that will form the basis in an application for market approval. This will further highlight the full

potential and value of IPED2015 for potential partners. We strongly believe that this growing interest will lead to an attractive future deal or partnership for Initiator Pharma.



Furthermore, the successful completion of the Phase 2a trial demonstrates how Initiator Pharma in a cost effective way can generate solid clinical data for innovative candidate drugs in areas where there are no, or very limited, therapeutic treatments available.

The development of our second candidate drug, IP2018, has progressed well and according to plan. In March we reached another goal when a Clinical Trial Application (CTA) for IP2018 was filed to the Medicines and Healthcare products Regulatory Agency, MHRA, in the UK. The submission was not only a significant development milstone, but also a prerequisite for our continuoued development of the IP2018 project as it allowed us to exercise the exclusive option agreement we entered with Saniona at the end of 2018. We expect to obtain a clinical trial approval during the summer of 2020, and pending the development of the COVID-19 situation, dose the first patient shortly thereafter.

IP2018 is a candidate drug for the combined treatment of depression and erectile dysfunction, which is a clear differentiation from other antidepressants on the market today. In the upcoming clinical phase 2a trial, we intend to primarily confirm the effect of IP2018 on the erectile function of patients, and, if the outcome is positive, follow up with further clinical safety trials on multiple dosage parameters. The development of IP2018 will instigate a paradigm shift for patients who have psychogenic erectile dysfunction with a first in class treatment that can increase these patients' quality of life in a significant way.

"We are looking positively at the advancement of IP2018 and believe that we are in a unique position to solve a major unmet medical need for the psycogenic erectile dysfunction patients with this candidate drug."

The completion of the phase 2a trial with IPED2015, and the initiation of the upcoming IP2018 trial, are important steps on our trajectory to establish Initiator Pharma as a recognized biotech company that, with lean and effective performance, creates significant value through well designed and conducted Proof of Concept clinical trials. This was demonstrated through the recently announced direct placement by Formue Nord. As a strong and experienced investor in the biotech arena over the last couple of year's we see it as a clear validation that they now have decided to invest in Initiator Pharma.

The directed issue of shares and warrants to Formue Nord is part of a financing plan which includes a rights issue of shares and warrants. The issues, which all are subject to approval of Initator Pharma's AGM, can potentially, if all warrants are exercised, bring total proceeds of SEK 26.4 million (before issue costs) to our company. These funds will be essential to further increase the commercial value and opportunities for attractive agreements for Initiator Pharma

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The ongoing COVID-19 pandemic has affected us all. Initiator Pharma has implemented measures to protect its employees, to take its social responsibility and at the same time to minimize the negative impact the COVID-19 pandemic may have on our operations. At this moment, we do not see that the pandemic affects our upcoming clinical trial, but we are monitoring the situation closely to estimate if and how this and other clinical studies may be affected.

Finally, I would like to thank all our existing shareholders and welcome new shareholders to become part of an exciting future together with a cost-effective biotech company, now with an emerging pipeline of two phase 2 assets within commercially attractive indications. With a humble approach to the current COVID-19 situation, I look forward to Initiator Pharma's future progress with confidence.

Claus Elsborg Olesen CEO, Initiator Pharma A/S

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#### **About Initiator Pharma**

Initiator Pharma is a Biotech company established in Aarhus, Denmark. Its main asset IPED2015 represents a novel treatment paradigm for the treatment of Erectile Dysfunction (ED) and will improve the quality of life for the growing number for patients (and their partners) that do not respond or cannot be treated with the current marketed medication. Initiator Pharma is based in Århus, Denmark.

#### Vision

Initiator Pharma's vision is to become a recognized biotech company dedicated to the development of paradigm changing drugs for unmet medical needs, to the benefit of both patients and the society.

#### **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 this year:

Program	Profile	Indication	Discovery & Preclinical	Phase 1	Phase 2
IPED2015	DAT(SERT/NET)	Erectile dysfunction (Organic)			
IP2018*	SERT>DAT>>NET	Erectile dysfunction (Psychogenic)			
IPDP2015	DAT/SERT/NET	Depression			
IPNP2015	DAT/SERT/NET	Neuropathic Pain			

<sup>\*</sup>Option agreement with Saniona AB

## **IPED2015**:

IPED2015, our most advanced drug candidate, 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

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- is unique and aimed for treatment of ED in patients suffering from ED due to metabolic syndrome and diabetes.

#### Data from the Phase 2a clinical proof of concept study

In March we announced the final data from the successful Phase 2a Clinical Proof of Concept study for IPED2015. The Phase 2a study which included patients suffering from servere Erectile Dysfunction (ED) has been completed satisfactorily. The study demonstrated statistical significant efficacy data on ED. Besides, there has been no reporting of critical safety observations which is in line with the previously reported results from the Phase I trial in healthy volunteers.

## Phase 2a Study Design

The Phase II part study for IPED2015 included twelve patients suffering from severe ED who were enrolled after a thorough selection and screening process and dosed with a single dose of IPED2015 and placebo in a cross-over study design. The patients were enrolled to the MAC Phase I unit, Manchester, UK and in-housed during the dosing and observation period. Efficacy assessment was done with the RigiScan device with stimulus challenge assessment (Erotic Movie presentation) to assess penile rigidity and tumescence. RigiScan is a state-of-the-art model to evaluate erectile function. Safety and PK was also assessed during the trial.

#### **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 for IPED2015 and thereby generate substantial commercial value for Initiator Pharma.

#### IP2018:

#### **Development plans for IP2018**

In March we also announced that we had exercised an option agreement for in-licensing IP2018, a clinical stage compund, from Saniona.

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.

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

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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.

Depression is a mood disorder that affects feelings, thoughts, and behaviour and leads to a variety of emotional and physical illnesses. If left untreated, depression significantly reduces quality of life and may ultimately result in premature death from medical conditions or suicide. The main treatments for depression are drugs that modulate the levels of serotonin, noradrenaline and dopamine by either inhibiting the reuptake of these signalling substances ("reuptake inhibitors") or by influencing their degradation. A key side effect of the currently available antidepressants is their significant impact on male sexual function (desire-arousal-excitement-orgasm). In a survey, it was observed that 41.7 % of men discontinued psychiatric medications due to perceived sexual side effects (Rosenberg KP et al "A survey of sexual side effects among severely mentally ill patients taking psychotropic medications: impact on compliance", J. Sex Marital Ther. 2003;29(4):289-96). Between 14 and 35% of young men experience ED. The causes of ED can be caused by psychological, neurological, or lifestyle issues. ED can also be the result of side effects of specific medications (including some antidepressants), performance anxiety, depression, schizophrenia, and other psychological disorders.

Major depressive disorder is one of the main causes of disability worldwide due to its high prevalence and associated impairments. Lifetime prevalence is 14.3% in high-income countries. The Global Burden of Disease study showed a 37.5% burden increase due to major depressive disorder from 1990 to 2010, and major depressive disorder is the second leading cause of Disability Adjusted life years in 2020. About 13% of all Americans take anti-depression medication summing up to more than 23 million prescriptions per year (National Center for Health Statistics). The global revenue for antidepressants is forecasted to reach \$18 bn in 2020. The biggest players, accounting for more than 60% of the antidepressant drugs sold, are Pfizer, Eli Lilly, GlaxoSmithKline, AstraZeneca and H. Lundbeck A/S - all facing a significant patent cliff over the next few years, with revenues projected to be hit hard by generics and biosimilars. All current marketed drugs have to varying degree been associated with erectile dysfunction emphasising the need to develop an attractive and superior alternative.

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#### Financial review

Initiator Pharma A/S is a Danish registered company, and is reporting its financial figures in Danish kroner (DKK). Initiator Pharma A/S was registered on May 2, 2016.

#### **Financial review**

I III aliciai l'eview	<u> </u>		
токк	1Q:2020	1Q:2019	2019
Net sales	0	0	0
Total operating expenses	-2 392	-1 463	-9 339
Operating profit/loss	-2 392	-1 463	-9 339
Cash flow from operating activities	-480	-1 146	-8 553
Operating margin, %	neg	neg	neg
Average number of employees, #	1	2	1
Earnings per share, DKK	-0,11	-0,22	-0,41
Diluted earnings per share, DKK	-0,11	-0,22	-0,41
	31.03.2020	31.03.2019	31.12.2019
Cash and cash equivalents	7 082	13 346	7 562
Equity	7 424	15 072	9 908
Total equity and liabilities	9 095	16 009	11 438
Equity ratio, %	82%	94%	87%
Number of shares outstanding	23 591 375	8 683 943	23 591 375
Number of shares, fully diluted	24 459 769	8 683 943	24 459 769
Weighted number of shares	23 591 375	6 823 099	24 242 671

#### Revenues and result of the operation

#### Revenue

Initiator Pharma generated total revenues of TDKK 0 for the first quarter of 2020 (0).

#### Operating profit/loss

The company recognized an operating loss of TDKK 2,392 for the first quarter of 2020 (-1,463). The increase in operating costs for the first quarter reflects the completion of the Phase 2a for IPED2015.

External R&D costs in the first quarter amounted to TDKK 1,485, compared to 734 in the same period in 2019.

#### Financial position

As of March 31, 2020 the equity was TDKK 7,424 and cash and cash equivalents amounted to TDKK 7,082. Total assets as of March 31, 2020, were TDKK 9,095.

#### Cash flow

In the first quarter of 2020 the total operating cash flow was TDKK - 480, incl a positive change in working capital of TDKK 1,995. Cash flow from investment activities was TDKK 0. Cash flow from financing activities was TDKK 0.

On April 27<sup>th</sup> we announced that we have completed a SEKM 3 direct share issue with warrants to Formue Nord, a Danish investment fund. We also announced a proposal to the Annual General Meeting for a SEKM 7 rights issue with warrants that has been fully guaranteed. The warrants program has an exercise period between November 24<sup>th</sup> and December 15<sup>th</sup> this year, and will if fully exercised raise an additional SEKM 16.4 to the company, before issuing costs.

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In connection with the directed share issue we also established a SEKM 10 loan facility that may be drawn upon if needed to support the Phase 2a for IP2018.

## The share, share capital and ownership structure

At March 31, 2029, the number of shares outstanding amounted to 23,591,375. The company had as of March 31 a total of 868,394 outstanding incentive warrants, representing 3.7% of the number of issued shares.

The board has proposed to the Annual General Meeting that a new incentive warrant program of 434,197 warrants is established.

At March 31, 2019 the company had around 3,800 shareholders. The 25 largest shareholders in the company on December 31 owned 44,8% of all outstanding shares:

Top 25 shareholders as of March 31, 2020		
Owners	Number of shares	Shares %
Försäkringsaktiebolaget, Avanza Pension	1 325 701	5,62%
BNY Mellon SA/NV (Former BNY)	1 057 500	4,48%
Ålandsbanken i ågares ställe	1 007 098	4,27%
Claus Olesen Holding APS	692 738	2,94%
Nordnet Pensionsförsäkring AB	643 906	2,73%
UBS Switzerland AG	596 167	2,53%
DanPet AB	585 200	2,48%
Mikael Södergård Thomsen APS	584 101	2,48%
Lars Hendriksen A/S	489 717	2,08%
Peters, Dan	451 511	1,91%
Handelsbanken Copenhagen non-danish clients	320 000	1,36%
Thauser Holding ApS	295 156	1,25%
Härlin, Thomas	254 520	1,08%
Coolmate ApS	249 820	1,06%
Clearstream Banking S.A, W8IMY	225 754	0,96%
Müller, Christian Matthias	220 000	0,93%
Feldthus, Thomas	216 034	0,92%
JPM Chase	212 689	0,90%
Leif Andersen Consulting ApS	203 618	0,86%
Hendriksen, Lars	170 353	0,72%
Olofsson, Christian	168 924	0,72%
Caerus Capital AS	161 701	0,69%
Kaa, Michael Nicholai Lägård	156 594	0,66%
Olin, Lennart	148 156	0,63%
Wall, Magnus	146 610	0,62%
Other shareholders	13 007 807	55,14%
Total	23 591 375	100,00%

#### Directed share issue and proposed rights issue during Q2:2020

On April 27<sup>th</sup> we announced that the Board of Directors has decided to carry out a directed share issue of approximately SEK 3 million at a share price of SEK 5,40 per share and a directed issue of

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1,224,490 warrants that can provide the Company with up to SEK 6 mill in additional capital at a later stage. The directed issues have been subscribed by Formue Nord Markedsneutral A/S.

The Board of Directors has also decided, subject to approval by the Annual General Meeting on May 22, 2020, to carry out a rights issue of units of initially approximately SEK 7 million. The directed share issue and the rights issue thus initially provides Initiator Pharma a total of about SEK 10 million (before issue costs). In addition, through the issues, warrants are issued which during Q4 2020 can provide Initiator Pharma with a total of approximately SEK 16.4 million, of which approximately SEK 10.4 million pertains to warrants issued through the rights issue. With regards to the rights issue, the Company has received subscription commitments of approximately SEK 1.3 million and issue guarantees (top-down) of approximately SEK 5.7 million, corresponding to a total of 100 percent of the initial issue proceeds. The public is also given the opportunity to subscribe for units in the rights issue.

The total issue proceeds from both the directed issue, the rights issue and warrants thus amount to approximately SEK 26.4 million (before issue costs). In addition, Initiator Pharma has entered into an agreement on a loan facility that gives the Company the right to lend up to SEK 10 million, as a security if the warrants are not exercised.

The capital from the directed issue, the rights issue and the warrants intends to secure the funding needed to develop the drug candidate IP2018 through a Phase IIa clinical trial and conduct partner discussions for the same, as well as expand and develop the Company's existing pipeline with IPED2015 and additional candidates for clinical trials.

#### Personnel

As of March 31, 2020, the number of employees was 1, of which 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 the biotech industry 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.

A more detailed description of the company's risk exposure and risk management is included in the prospectus published in March 2018.

#### **Impact of COVID-19**

As of May 2020 the board and management do not expect material impact on the financial position of the company. This is related to the fact that the company currently have no ongoing clinical development activities. However, depending on the length and severity of the covid-19 pandemic the board and management believe future risks are related to:

- Potential delay in the planned start-up of a Phase 2a proof-of-concept clinical trial for IP2018.
- Potential risk that the ongoing business development efforts for IPED2015 are delayed or that the probability of securing a partnering deal on acceptable terms is reduced.
- Potential risk that it will be difficult to secure additional funding on acceptable terms for the further development of the company and our projects.

The board and management will continue to carefully monitor the covid-19 pandemic and its potential for impacting our operations and development plans.

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#### **Audit review**

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

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## Financial calendar

Interim Report Q1	May 22, 2020
Annual General Meeting	May 22, 2020
Interim Report Q2	August 21, 2020
Interim Report Q3	November 20, 2020
Year-End Report 2019	February 19, 2021

Aarhus, May 22, 2020	
Magnus Persson - Chairman	Henrik Moltke – Board member
Peter Holm – Board member	Claus Olesen – Board member and

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## **Financial Statements**

## Statement of income

1Q:2020	1Q:2019	2019
-2 215	-1 255	-8 366
-168	-186	-886
-9	-22	-87
-2 392	-1 463	-9 339
-92	-36	-636
-2 484	-1 499	-9 975
		1 687
-2 484	1 400	-8 288
	-2 215 -168 -9 -2 392 -92 -2 484	-2 215 -1 255  -168 -186 -9 -22  -2 392 -1 463  -92 -36 -2 484 -1 499

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# **Initiator** Pharma

Statement of financial position

Statement of financial position			
TDKK	1Q:2020	1Q:2019	2019
ASSETS			
Patents, acquired rights	28	50	34
Intangible assets	28	50	34
Other fixtures, fittings, tools and equipment	0	52	4
Property, plant and equipment	0	52	4
Fixed assets	28	102	37
Other receivables	298	155	1 286
Income tax receivables	1 687	2 406	1 687
Prepayments	0	0	866
Current receivables	1 985	2 561	3 839
Cash and cash equivalents	7 082	13 346	7 562
Current assets	9 067	15 907	11 401
Assets	9 095	16 009	11 438
EQUITY AND LIABILITIES			
Contributed capital	2 477	2 432	2 477
Retained earnings	4 947	12 640	7 431
Equity	7 424	15 072	9 908
Trade payables	1 365	469	1 141
Other payables	306	468	389
Current liabilities other than provisions	1 671	937	1 530
Liabilities other than provisions	1 671	937	1 530
Equity and liabilities	9 095	16 009	11 438

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Statement of changes in shareholder equity

ТОКК	Contributed capital	Retained earnings	Total
January 1, 2020	2 477	7 431	9 908
Increase of capital Profit/loss for the period	0	0 -2 484	0 -2 484
March 31, 2020	2 477	4 947	7 424

#### Statement of cash flow

TDKK	1Q:2020	1Q:2019	2019
Operating profit/loss	-2 392	-1 463	-9 339
Amortisation, depreciation and impairment losses	9	22	87
Changes in working capital	1 995	331	-1 072
Cash flow from operating activities before financial	-388	-1 110	-10 323
items			
Other financial expenses	-92	-36	-636
Tax credit			2 406
Cash flow from operating activities	-480	-1 146	-8 553
Investing activities			
Investment in intangible assets			0
Investments in tangible assets			0
Investments in other financial assets			0
Cash flow from investing activities	0	0	0
Financing activities			
New share issue			1 351
Issue of warrants			273
Cash flow from financing activities	0	0	1 625
Increase/decrease in cash and cash equivalents	-480	-1 145	-6 929
Cash and cash equivalents at the end of period	7 082	13 346	7 562

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## **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

#### INC

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©)

## 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<sup>©</sup>, Cialis<sup>©</sup> and Levitra<sup>©</sup> are used in the treatment of erectile and were the first effective oral treatment available for the condition.

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## **Financial Glossary**

## Earnings per share

Profit/loss for the period divided by the average number of shares outstanding at the end of the period

#### **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