CVR number: 37663808 January – June 2020 Published August 21, 2020



# **INITIATOR PHARMA: H1 2020 report**

# **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.

# Second Quarter (2020-04-01 - 2020-06-30)

- Net revenues were TDKK 0 (0)
- EBIT was TDKK -3,013 (-3,404)
- Earnings per share was DKK –0.13 (-0.15)

# First Six Months of the Year (2020-01-01 – 2020-06-30)

- Net revenues were TDKK 0 (0)
- EBIT was TDKK -5,405 (-4,867)
- Earnings per share was DKK –0.23 (-0.21)
- Cash and bank: TDKK 8,189 (11,501)
- Solidity: 75% (82%)

Group earnings per share: period result divided by a number of 24 146 930 shares (on 2020-06-30). Solidity: equity divided by assets.

# **Business highlights in Q2 2020**

- On April 27<sup>th</sup> we announced the completion of a directed issue of 555,555 shares and 1,224,490 warrants to Formue Nord, and also proposed a fully guaranteed rights issue of units consisting of in total 1,420,406 shares and 2,130,609 warrants of Series TO2.
- On June 18<sup>th</sup> we announced that the rights issue of units were subscribed to a total of 387%.
- On June 29<sup>th</sup> we announded that we had received approval from MHRA in UK for a Phase 2a clinical proof of concept study for IP2018, a candidate drug being developed for the treatment of erectile dysfunction in patients with major depression disorder.

## Significant events after this reporting period

- On July 2<sup>nd</sup> we announced that the last day of trading in BTU (paid-up for units) would be on July 7<sup>th</sup>. In the press release regarding last day of trading in BTU, an incorrect total number of shares after registration was stated. The correct total number of shares in Initiator Pharma as per after the registration of the issue is 25,567,336 shares.
- On July 13<sup>th</sup> we announced that the incentive program in Initiator Pharma, approved by the AGM on May 22<sup>nd</sup> had been fully subscribed. If all warrants are exercised the company will issue a total of 434.197 new shares, representing 1.7% of issued shares, with par value of DKK 0.105 and with an exercise price of SEK 6,52 and a subscription price of SEK 1.33 per warrant.

#### Comments from the CEO

Following up on a very positive first quarter in 2020, where we obtained clinical Proof of Concept (PoC) data for IPED2015, the second quarter has come of to a very different start do to the ongoing Covid-19 Pandemic. The PoC has strengthened our belief that our candidate drug IPED2015 has strong potential to become the first-line treatment of erectile dysfunction for the majority of the PDE5i non-responders, supporting our ongoing business development activities with IPED2105.

## For more information, please contact

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#### **About Initiator Pharma**

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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 drug candidates are: IPED2015 is targeting the medical condition Erectile Dysfunction (ED), and specifically patients with ED that are non-responsive to drugs within the PDE5i class, including the approved drugs Viagra©, Cialis© and Levitra©. IP2018 is a monoamine reuptake inhibitor for the treatment of psychogenic Erectile Dysfunction (mainly caused by anxiety and depression) primarily targeting the serotonin followed by 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.

Initiator Pharma is based in Aarhus, Denmark. Initiator Pharma is listed on Spotlight Stockmarket and has about 3.500 shareholders. Read more at www.initiatorpharma.com.

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# **Initiator Pharma**

#### Letter from the CEO

Following up on a very positive first quarter in 2020, where we obtained clinical Proof of Concept (PoC) data for IPED2015, the second quarter has come of to a very different start do to the ongoing Covid-19 Pandemic. The PoC has strengthened our belief that our candidate drug IPED2015 has strong potential to become the first-line treatment of erectile dysfunction for the majority of the PDE5i non-responders, supporting our ongoing business development activities with IPED2105. The current Covid-19 situation limited us in having physical meetings with potential buyers or partners for IPED2015, but it has fortunately still been possible to continue our business development efforts via TC and video meetings. We now look forward to secure the continued development of IPED2015 to maximize the value creation for our shareholders and to the benefit of our patients.



"To obtain data that demonstrated 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."

At the end of June we obtained approval from the Medicines and Healthcare products Regulatory Agency, MHRA, and the Ethical committee (EC) UK, for a Phase 2a clinical trial for our second candidate drug, IP2018. The candidate drug is being developed for the combined treatment of depression and erectile dysfunction, which is a clear differentiation from other antidepressants on the market today. Up to 68 percent of patients with major depressive disorder suffer from sexual dysfunction, which for only 5 to 30 percent of these patients is resolved with antidepressant treatment. The clinical Phase 2a trial with IP2018 aims to obtain proof of concept for effect on erectile dysfunction in young patients with depression.

"We are very pleased with the CTA approval IP2018, and as we strongly believe that we have identified a unique and the right indication for this drug candidate. The potential to develop IP2018 as first in class treatment of Psychogenic ED patients, would cover a hugh unmet medical need with a clear differentiation to IPED2015 for the treatment of organic ED."

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. It 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. Pending the development of the COVID-19 situation, our intention is to start dosing the first patient during the month of September and top-line data is expected end of first half year of 2021. 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

In middle of June we announced the result from Initiator Pharma's rights issue, which was subscribed to a total of approximately 387 percent. I am very grateful for the interest we have seen in the issue and I want to use this opportunity to thank existing shareholders for your continuing support and trust, and to welcome new investors to our company. Initiator Pharma is on the trajectaory to deliver even more exciting value inflections points in the coming year. With the capital provided in the share issue, we look forward to continuing the company's development, and in the immediate future looking to get the Phase 2a for IP2018 clinical trial started.

I remain confident that the strengthening of our pipeline, has added considerable value and opportunity for success to Initiator Pharma. Changing Initiator Pharma from a one clinical trial asset to multiple

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clinical assets are vital steps in the transformation and positions Initiator Pharma as a capable and recognized player with a track record of adding significant value to drug candidates through well established POC clinical trials. We are looking forward to reporting significant progress on both IPED2015 and IP2018 programs in the near future.

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					
TDKK	2Q:2020	2Q:2019	1H:2020	1H:2019	2019
Net sales	0	0	0	0	0
Total operating expenses	-3 013	-3 404	-5 405	-4 867	-9 339
Operating profit/loss	-3 013	-3 404	-5 405	-4 867	-9 339
Cash flow from operating activities	-663	-1 845	-1 143	-2 991	-8 553
Operating margin, %	neg	neg	neg	neg	neg
Average number of employees, #	1	1	1	1	1
Earnings per share, DKK	-0,13	-0,15	-0,23	-0,21	-0,41
Diluted earnings per share, DKK	-0,13	-0,15	-0,23	-0,21	-0,41
	30.06.2020	30.06.2019			31.12.2019
Cash and cash equivalents	8 189	11 501			7 562
Equity	6 196	11 669			9 908
Total equity and liabilities	8 271	14 149			11 438
Equity ratio, %	75%	82%			87%
Number of shares outstanding	24 146 930	23 157 178	24 146 930	23 157 178	23 591 375
Number of shares, fully diluted	25 015 324	24 025 572	25 015 324	24 025 572	24 459 769
Weighted number of shares	23 980 264	23 157 178	23 785 819	23 157 178	24 242 671

### Revenues and result of the operation

#### Revenue

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

#### Operating profit/loss

The company recognized an operating loss of TDKK 3,013 for the second quarter of 2020 (-3,404). For the first half of the year the operating loss was TDKK 5,405 (-4,867). The increase in operating costs for the first half of the year compared to the same period last year reflects the completion of the Phase 2a clinical proof of concept study for IPED2015 and the preparations for the planned Phase 2a clinical proof of concept study for IP2018, to be initiated during H2:2020.

External R&D costs in the second quarter amounted to TDKK 1,381, compared to TDKK 2,336 in the same period in 2019. For the first six months of the year external R&D costs totalled TDKK 2,865 compared to TDDK 3,034 in same period in 2019.

# **Financial position**

The equity as of June 30, 2020 was TDKK 6,196. Cash and cash equivalents amounted to TDKK 8,189 as of June 30, 2020 and total assets were TDKK 8,271.

The financial position as of June 30, 2020 does not reflect the closing of the rights issue announced on June 18<sup>th</sup>. Through the rights issue the company raised approx SEK 7 mill (approx DKK 4.8 mill) before issuer costs.

In connection with the direct share issue announced on April 27<sup>th</sup> and the rights issue announced on June 18<sup>th</sup> the company issued a total of 3,355,099 warrants of series TO2. The exercise price for the series TO2 warrants is SEK 4,90 and the warrants can be exercised during the period November 24-December 15. If fully exercised the series TO2 warrants can raise an additional approx SEK 16 mill (approx DKK 11 mill) before issuer costs to the company.

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### Cash flow

In the second quarter of 2020 the total operating cash flow was TDKK -663 (TDKK -1,845), incl a positive change in working capital of TDKK 2,333 (TDKK 1,536). Cash flow from investment activities was TDKK -0 (TDKK 0). Cash flow from financing activities was TDKK 1,770 (TDKK 0).

For the first half 2020 the operating cash flow was TDKK -1,143 (TDKK -2,991), incl a positive change in working capital of TDKK 4,328 (TDKK 1,867). Cash flow from investment activities was TDKK -0 (TDKK 0) and cash flow from financing activities was TDKK 1,770 (TDKK 0).

# The share, share capital and ownership structure

At June 30, 2020, the number of shares outstanding amounted to 24,146,930 and 2,092,884 warrants (of which 868,394 are incentive warrants and 1,224,490 are series TO2 warrants), representing 8.7% of the number of issued shares.

The above number of shares and warrants do not include the rights issue of 1,420,406 shares and 2,130,609 series TO2 warrants that was announced on June 18<sup>th</sup>. The issue of shares and warrants were fully registered with the Danish Business Authority on July 2<sup>nd</sup>. Following the rights issue the total number of shares outstanding is 25,567,336 and 4,223,493 warrants (of which 868,394 are incentive warrants and 3,355,099 are series TO2 warrants), representing 16.5% of the total number of shares.

The Annual General Meeting on May 22<sup>nd</sup> approved an incentive program totalling 434,197 warrants. On July 13<sup>th</sup> we announced that the warrant program had been fully subscribed, increasing the number of outstanding incentive warrants by 434,197 to a total of 1,302,591, representing 5.1% of the number of issued shares.

At June 30, 2020 the company had around 3,500 shareholders. The 25 largest shareholders in the company on June 30 owned approx 45% of all outstanding shares:

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Top 25 shareholders as of June 30, 2020		
Owners	Number of shares	Shares %
Försäkringsaktiebolaget, Avanza Pension	1 337 972	5,54%
BNY Mellon SA/NV (Former BNY)	1 048 240	4,34%
Ålandsbanken i ågares ställe	887 098	3,67%
Nordnet Pensionsförsäkring AB	706 248	2,92%
Claus Olesen Holding APS	692 738	2,87%
UBS Switzerland AG	590 907	2,45%
DanPet AB	585 200	2,42%
Mikael Södergård Thomsen APS	584 101	2,42%
Formue Nord Markedsneutral	555 555	2,30%
Peters, Dan	451 511	1,87%
Lars Hendriksen A/S	436 217	1,81%
Sv Handelsbanken Copenhagen branch	320 000	1,33%
Thauser Holding ApS	295 156	1,22%
Härlin, Tobias	249 885	1,03%
Coolmate ApS	229 820	0,95%
Clearstream Banking S.A, W8IMY	225 873	0,94%
JPM Chase	212 689	0,88%
Leif Andersen Consulting ApS	203 618	0,84%
Feldthus, Thomas	172 535	0,71%
Hendriksen, Lars	170 353	0,71%
Olofsson, Christian	168 924	0,70%
Müller, Christian Matthias	165 000	0,68%
Caerus Capital	161 701	0,67%
Olin, Lennart	154 700	0,64%
Kaae, Michael Nicolai Lägård	150 282	0,62%
Other shareholders	13 390 607	55,45%
Total	24 146 930	100,00%

#### Personnel

As of June 30, 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 memorandum published in May 2020.

## **Impact of COVID-19**

As of Aug 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

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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.

#### **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, August 20, 2020	
Magnus Persson - Chairman	Henrik Moltke – Board member
Peter Holm – Board member	Claus Olesen – Board member and CEO

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# **Financial Statements**

# Statement of income

токк	2Q:2020	2Q:2019	1H:2020	1H:2019	2019
Gross loss	-2 578	-2 943	-4 793	-4 198	-8 366
Staff costs	-433	-439	-601	-625	-886
Depreciation and write-downs	-2	-22	-11	-44	-87
Operating profit/loss	-3 013	-3 404	-5 405	-4 867	-9 339
Other financial expenses	15	1	-77	-35	-636
Profit/loss	-2 998	-3 403	-5 482	-4 902	-9 975
Тах					1 687
Net profit for the period	-2 998	-3 403	-5 482	-4 902	-8 288

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Statement of financial position			
ТДКК	30.06.2020	30.06.2019	2019
ASSETS			
Patents, acquired rights	26	45	34
Intangible assets	26	45	34
Other fixtures, fittings, tools and equipment	0	35	4
Property, plant and equipment	0	35	4
Fixed assets	26	80	37
Other receivables	56	162	1 286
Income tax receivables	0	2 406	1 687
Prepayments	0	0	866
Current receivables	56	2 568	3 839
Cash and cash equivalents	8 189	11 501	7 562
Current assets	8 245	14 069	11 401
Assets	8 271	14 149	11 438
EQUITY AND LIABILITIES			
Contributed capital	2 535	2 432	2 477
Retained earnings	3 661	9 237	7 431
Equity	6 196	11 669	9 908
Trade payables	1 745	1 841	1 141
Other payables	330	639	389
Current liabilities other than provisions	2 075	2 480	1 530
Liabilities other than provisions	2 075	2 480	1 530
Equity and liabilities	8 271	14 149	11 438

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Statement of changes in shareholder equity

Statement of changes in shareholder equit	. у		
ТОКК	Contributed capital	Retained earnings	Total
January 1, 2020	2 477	7 431	9 908
Increase of capital	58	1 712	1 770
Profit/loss for the period	0	-5 482	-5 482
June 30, 2020	2 535	3 661	6 196

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Statement of cash flow	,	· ·	· ·		
TDKK	2Q:2020	2Q:2019	1H:2020	1H:2019	2019
Operating profit/loss	-3 013	-3 404	-5 405	-4 867	-9 339
Amortisation, depreciation and impairment losses	2	22	11	44	87
Changes in working capital	2 333	1 536	4 328	1 867	-1 072
Cash flow from operating activities before financial items	-678	-1 846	-1 066	-2 956	-10 323
Other financial expenses	15	1	-77	-35	-636
Tax credit					2 406
Cash flow from operating activities	-663	-1 845	-1 143	-2 991	-8 553
Investing activities					
Investment in intangible assets					0
Investments in tangible assets					0
Cash flow from investing activities	0	0	0	0	0
Financing activities					
New share issue	1 770		1 770		1 351
Issue of warrants					273
Cash flow from financing activities	1 770	0	1 770	0	1 625
Increase/decrease in cash and cash equivalents	1 107	-1 845	627	-2 990	-6 929
Cash and cash equivalents at the end of period	8 189	11 501	8 189	11 501	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