Annual Report


Initiator Pharma

We are committed to providing a better medical treatment option for the growing number of untreated patients suffering from Sexual Dysfunction, and thereby improving the quality of life for them and their partners.

## Initiator Pharma




## Key Figures

| Income Statement, TDKK | 2018 | 2017 | 2016 |
| :---: | :---: | :---: | :---: |
| Net sales | 0 | 0 | 0 |
| Total operating expenses | -12 611 | -9 561 | -887 |
| Operating profit/loss | -12 611 | -9 561 | -887 |
| Financial items, net | -93 | -801 | -5 |
| Profit/loss before tax | -12704 | -10 362 | -892 |
| Tax on net profit | 2406 | 1780 | 0 |
| Profit/loss for the year | -10 298 | -8 582 | -892 |
| Balance Sheet, TDKK | 2018 | 2017 | 2016 |
| Intangible assets | 56 | 78 | 101 |
| Property, plant and equipment | 68 | 134 | 64 |
| Current receivables | 2713 | 1917 | 231 |
| Cash and cash equivalents | 14491 | 7169 | 167 |
| Total assets | 17328 | 9298 | 563 |
| Equity | 16570 | 5964 | -371 |
| Current liabilities | 758 | 3334 | 934 |
| Total equity and liabilities | 17328 | 9298 | 563 |
| Cash flow, TDKK | 2018 | 2017 | 2016 |
| Cash flow from operating activities before changes in working capital | -12 523 | -9 477 | -876 |
| Cash flow from operating activities | -13 582 | -7 784 | -178 |
| Cash flow from investing activities | 0 | -132 | -177 |
| Cash flow from financing activities | 20904 | 14917 | 521 |
| Cash flow for the year | 7322 | 7002 | 167 |


| Key figures, \% | 2018 | 2017 | 2016 |
| :---: | :---: | :---: | :---: |
| Operating margin | na | na | na |
| Liquidity ratio | 2270\% | 273\% | 43\% |
| Equity ratio | 96\% | 64\% | -66\% |
| Share data, DKK | 2018 | 2017 | 2016 |
| Diluted earnings per share | -0,51 | -1,04 | -0,18 |
| Equity per share | 0,72 | 0,69 | -0,04 |
| Dividend | 0 | 0 | 0 |
| Cash flow per share | 0,32 | 0,81 | 0,12 |
| Share data, \# | 2018 | 2017 | 2016 |
| Shares outstanding | 23157178 | 8683943 | 8683943 |
| Warrants outstanding | 868394 | 434197 | 0 |
| Diluted shares outstanding | 24025572 | 9118140 | 8683943 |
| Weighted average number of shares | 20081616 | 8218732 | 4932202 |



## 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 will be a leading biotech company within the field of mono-amine reuptake transporters and be dedicated to the development of paradigm changing drug 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 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.


## 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 erectile dysfunction 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.

## 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:

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 ${ }^{\oplus}$, Cialis ${ }^{\oplus}$, Levitra ${ }^{\oplus}$ ). 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 erectile dysfunction in patients suffering from erectile dysfunction due to metabolic syndrome and diabetes.

IPED2015 entered clinical development in H2:2018, and we expect to report phase 1 data during H1:2019. If successful we plan to immediately progress the compound into a phase 2a clinical proof of concept trial, with headline data available mid 2019.

In Q4:18 we announced that we had secured a 1 year exclusive option agreement for AN788, a Phase 2 ready compound that has previously undergone clinical development for anxiety and depressive disorders but it has never be tested in a Phase 2 clinical trial. Initiator Pharma intends to reposition the drug candidate based on our expertise with monoamine-reuptake inhibitors. The drug candidate has through the clinical studies already conducted been de-risked to a significant degree, and may therefor be assessed in a cost-effective Phase Ila, Clinical Proof of Concept study in a patient population with a high unmet medical need.

## Drug candidate phases



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## Letter from the CEO


#### Abstract

2018 was an eventful year for Initiator Pharma. We have made significant progress with the clinical development of IPED2015 and our ambition to develop a First-in-line product for men that do not respond to already approved drugs or have tolerability issues with these drugs for the treatment of Erectile dysfunction.


We have also acquired the rights to an attractive Phase 2 ready asset through an option agreement with Saniona. We have high expectation for this program as well, and we look forward to advancing the clinical development of this asset to reach another significant value inflection point by generating a Proof-of-Concept in a not yet disclosed medical condition with a high unmet medical need.

## J

"We are on track to achieve a clinical phase 2a Proof of Concept mid 2019 and are now ramping up the business development activities to find the right partner for the IPED2015 drug candidate asset"

In early January we completed the preclinical development of our drug candidate IPED2015, and after a fast approval of the Clinical Trial Application by MHRA and ethics committee we started the first in man clinical phase 1 study. After a somewhat challenging start, we are now progressing steadily forward, and the in-life phase of IPED2015 is now delivering essential data providing the basis for the conductance of the Clinical Phase 2a Proof-of-Concept.

To finance the clinical phase I study and the clinical phase lla study for a Proof-of-Concept, we completed a preferential rights issue in March 2018, raising approximately SEK 19 million, and an additional SEK 12 million in Q4 as part of a warrant program. With these resources, we have the financing to complete the Phase 2a proof of concept study with IPED2015, with headline results expected mid 2019.

After the completion of the second round of financing through the closing of Warrant subscription Initiator Pharma has now raised approx. 52 mio MSEK. Also, we have seen an upward trend in the trading of the share and with increasing share price, and Initiator Pharma now has a market Cap of 130 MSEK. We are delighted that the investors find interest and trust in our robust programs and competent development team.

We are looking forward to the upcoming completion of the Phase 1 study and are working on the preparation of the clinical phase 2a study that will commence as soon as possible. Our goal is to complete it with a clinical phase 2a Proof of Concept in mid-2019, roughly a year ahead of the original schedule and at a lower cost for the Company and its shareholders. With a successful clinical phase 2a study, we expect to have a data package for IPED2015 which is attractive to potential pharmaceutical partners. This would potentially allow us to reach a deal end of 2019 or during 2020
"Since listing the Company we have been able to maintain momentum in advancing IPED2015 despite challenges like the incident that was observed during the first sentinel dosing. I think this demonstrates Initiator Pharmas expertise and capabilities to handle and lead complicated drug development programs."

Besides the IPED2015 program the option agreement, with Saniona for the IP2018 Phase 2 ready asset represents a cornerstone in our strategic plan to build the future Initiator Pharma. We plan to establish Initiator Pharma as an internationally recognized and cost-effective biotech, that generates value to its shareholders by delivering valuable clinical Proof-of-Concept in high unmet medical conditions followed by attractive deal making. Also, the expansion of the pipeline also provides more opportunities of success and importantly also secures a desirable de-risking as the company transitions from being a one clinical asset company, to now having two Phase 2a clinical programs with clear clinical endpoints and relative fast read out at low development cost.

In conclusion, we are looking forward to prosperous 2019 where we will complete the Phase 1 SAD study and advance IPED2015 to value creating Phase 2a Clinical Proof-of-Concept study in men suffering from ED. In parallel, we are looking to advance other assets in the pipeline and plan to reveal the targeted medical indication for the Phase 2 ready asset IP2018. We also need to secure financing for this program to proceed with the value-creating Proof-of-Concept Phase 2a clinical trial. So, 2019 potentially could be the year where Initiator Pharma will have two programs in Phase 2, which should bring significant value to the company and its shareholders.

I want to use this opportunity to thank our shareholders for your continuing support and participation in the recent rights issue, and look forward to reporting significant progress on our IPED2015 program in 2019 and starting additional value-creating activities in 2019.

## Claus Elsborg Olese

CEO, Initiator Pharma A/S
 lot of people."


## Business concept and strategy

## About Initiator Pharma and its business concept

Initiator Pharma was founded in 2016 as a spin out company from Saniona, with the business concept of further developing a family of three drug candidates based on Monoamine Reuptake Inhibitor (MRI) technology. Of these three drug candidates, IPED2015 in development for treating patients with Erectile Dysfunction (ED) is the most advanced. In Q4 2018 we entered a 1 year option agreement with Saniona for AN788, a phase 2 ready compound, and we are currently evaluating the clinical and commercial opportunities for this compound, with the aim of reaching a decision on whether to execute the agreement or not no later than Q3 this year.

## Business Model and Financing Strategy

The Company's goal is to progress our portfolio of drug candidates to key value inflection points, where we anticipate significant partnering interest from international pharma industry for the further development of our drug candidates. For IPED2015 we believe the first such key value inflection point to be Clinical Proof of Concept in the planned Phase 2a clinical trial this year. If successful the Phase 2a will establish the efficacy of IPED2015 in the treatment of Erectile Dysfunction, paving the way for a de-risked full clinical development program to reach regulatory approval. With this drug candidate, it is the Company's objective to be able to create a new first-in-line treatment (i.e., recommended treatment) for the large group of men who suffer from ED, but who, for various reasons, do not adequately respond to the currently recommended treatment with PDE5i.

After successful Clinical Proof of Concept for IPED2015, the Company intends to either license out the drug candidate, or alternatively to sell some or all of the Company, and thus provide an exit for its shareholders.

In order to minimize the development costs and retain flexibility - and maximize the investors potential returns - the Company is using a virtual organization model. With the exception of CEO the management team is on consultancy contracts with the Company. The bulk of the research, drug development and the regulatory work will be outsourced via contracts with Contract Research Organizations (CROs). The work is conducted under the direction and supervision of Initiator Pharma.

## Product Portfolio and patent coverage

Currently, Initiator Pharma has three drug candidates in its product portfolio, all based on Monoamine Reuptake Inhibitor technology (called "MRI" in short). The technology relates to inhibiting the reuptake of monoamines in the body's nerves and via this increasing the dopamine levels in various parts of the body. Dopamine is a vital neurological neurotransmitter, and by increasing the body's dopamine level, a number of different indications can be treated.

Our most advanced drug candidate, IPED2015, is a type of monoamine reuptake inhibitor that is primarily intended to treat ED in men. This drug candidate has been administered in animal experiments in preclinical studies and has shown promising results. IPED2015 is currently in Phase 1, and if successful, will be extended with a Phase 2a proof of concept study. In addition to IPED2015, the Company also owns the drug candidates IPDP2015 (intended for the treatment of depression) and IPNP2015 (intended for the treatment of neuropathic pain). These are based on the same fundamental mono-amine reuptake inhibitor technology as IPED2015. Currently, our focus has been on the IPED2015 program, but in 2019 we increase our focus on advancing these pipeline assets through academic and industrial collaborations.

With the signing of an option agreement for AN788 Initiator Pharma has acquired a Phase 2 ready drug candidate. The asset has previously undergone clinical development for anxiety and depressive disorders and has to a great extent been de-
risked with the completion of the Phase 1 safety and tolerability. Initiator Pharma intends to reposition the drug candidate based on our expertise with monoamine-reuptake inhibitors and internal R\&D results. Initiator Pharma wants to conduct a costeffective Phase Ila, Clinical Proof-of-Concept study in high unmet need medical condition. Subsequent, to generating a PoC the drug candidate will be ready for continued clinical development either in collaboration with a pharmaceutical company or available for out-licensing or potential deal-making.

## Overview of patent coverage:

| Drug candidate | Patent status |
| :---: | :---: |
| IPED2015 | - Approved in the U.S. until the end of 2031 |
| IPDP2015 | - Approved in the U.S. until the end of 2028 <br> - Presently in process patent application in Europe (EPO) |
| IPNP2015 | - Approved in the U.S. until the end of 2028 <br> - European Patent has been approved and validated in Switzerland, Germany, France and the United Kingdom until the end of 2028 |

## Goals and milestones

2019 will be a pivotal year for the Company. During the first half of 2019 we anticipate the complete the currently ongoing Phase 1 with IPED2015. If successful we will immediately progress IPED2015 into a phase 2a clinical proof of concept study, with headline results expected to be available around mid-year. If positive proof of concept data we plan to initiate a business development process to explore the potential for entering a pharma partnership for the further clinical development of IPED2015.

We are also evaluating the clinical and commercial potential for AN788 (to be renamed IP2018 if we select to exercise the option agreement with Saniona), A decision to exercise the agreement or not is expected to be reached no later than Q3 this year. A key part of the evaluation work is to establish an optimal clinical development plan for the drug candidate, including timeline and development costs until key value inflection points.

## Drug candidate phases



EXPLORATORY


PRECLINICAL


PHASE 2
PHASE 3


All three drug candidates have been purchased in their entirety from Saniona, after Initiator Pharma was established, including all patent rights for the three drug candidates. These patents were previously owned by Saniona's subsidiary Saniona A/S. The patent for the primary drug candidate IPED2015 is registered in the U.S. and runs until the end of 2031. See the table below for further details on Initiator Pharma's portfolio with regard to intellectual property rights.

[^1]
## Year Activity

2019 - Complete the Phase 1 clinical trial for IPED2015

- Conduct a Phase 2a clinical trial for IPED2015 (Proof-of-Concept)
- Initiate discussion with potential industry partners for IPED2015
- Scientific Collaborations on Pipeline assets with big Pharma
2020 - Deal-making with IPED2015
- Completion of AN788/IP2018 Phase 2a trial if option is exercised
- Clinical Development of Pipeline or in-licensed assets
- Scientific Collaborations on Pipeline assets with big Pharma


## The market for treatments for ED

In pace with inter alia that the global population is reaching an increasingly high average age and suffers to an ever-increasing extent from lifestyle-related diseases such as diabetes and obesity, increasingly a problematic side effect also arises for the male part of the population - erectile dysfunction ("ED"). ED, colloquially called impotence, is defined as the inability of a man to achieve and maintain an erection and thereby be able to engage in sexual intercourse. In the present situation, the problem is already huge, and is affecting a growing part of the population - today ED affects about 150 million men worldwide, and this figure is expected to rise to around 322 million by 2025.5 The medical indication ED only affects the man's sexual performance; however, research has shown that the problem can have many serious consequences. Men suffering from ED have, among other issues, a greater tendency to commit suicide compared to the general population, and also have a higher likelihood of suffering from other illnesses and ailments.

In addition, the indication may lead i.e. to lower self-esteem, depression, relationship problems and a general deterioration of the quality of life for both the man and his eventual partners.

The problem of ED has been addressed, to some extent, in connection with the introduction to the market of medicines based on Phosphodiesterase inhibitors, called PDE5 inhibitors ("PDE5i"), such as sildenafil, vardenafil (Levitra) and tadalafil (Cialis). The best-known drug in this category, sildenafil citrate, is marketed under the brand name Viagra ${ }^{\ominus}$, and in the present situation this drug is the recommended regimen of the indication.

The market for traditional treatments of ED amounts to about USD 4.125 billion (2015 figures). ${ }^{1}$ The Board of Directors has made the assessment that in 2019 the value of the market for these treatments will amount to as much as USD 4-5 billion, partly due to the fact that patents for several of the drugs within the category will expire and the number of patients increases.

PDE5 inhibitors have usually shown good effect but there are also major problems directly associated with them - about $30-40 \%$ of the men who suffer from ED do not respond to this type of medication. The group of patients who may be resistant to PDE5i treatment for ED include, among other patients, those with neurological injuries or disorders, diabetes or serious cardiovascular diseases. Other groups that may have a resistance to PDE5i treatment include patients who are being treated with certain antidepressants and anxiolytics. Overall, as the Board of Directors sees it, by 2025 there may be over 100 million men suffering from ED who for various reasons can not be treated with PDE5i. There is thus a great unmet medical need and thus also a need for an alternative treatment for ED that can satisfy the group of patients that are resistant to the currently the recommended regimen.

Assuming that up to $30-40 \%$ of the patients do not respond to conventional treatment methods2, the Board of Directors is of the view that the IPED2015 program has a great potential financial value, and it is the Board's hope that IPED2015 will become established as the recommended treatment for all patients suffering from ED and who are resistant to the treatment with PDE5 inhibitors. The target group for IPED2015 can include, due to the large group suffering from ED who do not respond to PDE5i treatment, over 100 million men worldwide by 2025, according to the Board's assessment.

## Competitors

There are, according to Initiator Pharma's Board of Directors, a small number of other treatment methods for ED under development by other pharmaceutical companies which could be considered as competitors to Initiator Pharma and their primary drug candidate IPED2015. The competing methodologies are based primarily, according to the board's assessment, on different variants of testosterone treatments, further developments of existing treatments with PDE5 inhibitors, as well as certain technical or more surgical solutions such shockwave therapy. However Initiator Pharma's assesses that IPED2015 represents a unique treatment that could be able to fulfill the needs of the large group of patients who do not respond to existing therapies, and that the actual competition is therefore limited.

There is also a competitive situation to some degree with regard to the companies which market the existing method of treatment with PDE5 inhibitors (for instance Viagra), in that these drugs also treat patients who suffer from ED. Initiator Pharma's goal with IPED2015 however, is that the drug candidate should treat the patient group that is not being helped by the PDE5 inhibitors, which is why these drugs can rather be seen as a complement, and not as a competitor, to IPED2015.

## The share, share capital and ownership structure

At December 31, 2018, the number of shares outstanding amounted to $23,157,178$. The company has as of December 31 a total of 868,394 outstanding warrants, representing $3.7 \%$ of the number of issued shares.

## Top 25 shareholders as of December 31, 2018

| Owners | Number of shares | Shares (\%) |
| :--- | ---: | ---: |
| BNY Mellon SA/NV (Former BNY) | 1380078 | $5,96 \%$ |
| Nordnet Pensionsförsäkring AB | 1356617 | $5,86 \%$ |
| Försäkringsaktiebolaget, Avanza Pension | 1317828 | $5,69 \%$ |
| Swedish Growth Fund AB | 726804 | $3,14 \%$ |
| Claus Olesen Holding APS | 692738 | $2,99 \%$ |
| UBS Switzerland AG | 575853 | $2,49 \%$ |
| DanPet AB | 537438 | $2,32 \%$ |
| Mikael Södergård Thomsen APS | 505946 | $2,18 \%$ |
| Lars Hendriksen A/S | 452711 | $1,95 \%$ |
| Peters, Leif Anders Rudolf | 451511 | $1,95 \%$ |
| Sv Handelsbanken Copenhagen branch | 418552 | $1,81 \%$ |
| Olofsson, Christian | 360000 | $1,55 \%$ |
| Thauser Holding ApS | 295156 | $1,27 \%$ |
| Härlin, Thomas | 279580 | $1,21 \%$ |
| Feldthus, Thomas | 267143 | $1,15 \%$ |
| Leif Andersen Consulting ApS | 250859 | $1,08 \%$ |
| Clearstream Banking S.A, W8IMY | 225754 | $0,97 \%$ |
| Olin, Lennart | 219898 | $0,95 \%$ |
| Ålandsbanken i ågares ställe | 211965 | $0,92 \%$ |
| Muller, Christina Matthias | 185000 | $0,80 \%$ |
| SEB Life - CJ Wachtmeister Consult | 181728 | $0,78 \%$ |
| Coolmate ApS | 173416 | $0,75 \%$ |
| Hendriksen, Lars | 170353 | $0,74 \%$ |
| Marnfeldt, Bengt | 165000 | $0,71 \%$ |
| Trygg, Jonny Oscar | 151565 | $0,65 \%$ |
| Other shareholders | 11603685 | $50,11 \%$ |
| Total | 23157178 | $100,00 \%$ |

At December 31, 2018 the company had around 3,600 shareholders. The 25 largest shareholders in the company on December 31 owned $49,9 \%$ of all outstanding shares:

## Shareholders by size

| Shareholding | Number of shareholders | Number of <br> shares | Shares (\%) |
| :--- | ---: | ---: | ---: |
| $1-500$ | 2082 | 285138 | $1,23 \%$ |
| $501-1000$ | 404 | 306431 | $1,32 \%$ |
| $1001-5000$ | 675 | 1662155 | $7,18 \%$ |
| $5001-10000$ | 183 | 1354279 | $5,85 \%$ |
| $10001-15000$ | 61 | 765022 | $3,30 \%$ |
| $15000-20000$ | 54 | 1005335 | $4,34 \%$ |
| $20000-$ | 154 | 17778818 | $76,77 \%$ |
| Total | $\mathbf{3 6 1 4}$ | 23157178 | $\mathbf{1 0 0 , 0 0 \%}$ |

Shareholders by geography

| Shareholding | Number of shareholders | Number of <br> shares | Shares (\%) |
| :--- | ---: | ---: | ---: |
| Sweden | 2772 | 14230859 | $61,45 \%$ |
| Nordics, excl Sweden | 775 | 5906144 | $25,50 \%$ |
| Europe, excl Sweden | 46 | 2897344 | $12,51 \%$ |
| USA | 3 | 65229 | $0,28 \%$ |
| Other | 18 | 57602 | $0,25 \%$ |
| Total | $\mathbf{3 6 1 4}$ | $\mathbf{2 3 1 5 7 1 7 8}$ | $\mathbf{1 0 0 , 0 0 \%}$ |

Share Information
The share price started at SEK 2.76 at the beginning of the year and ended at SEK 2.89 at 31 December 2018. The Initiator Pharma share is listed on Spotlight Stockmarket, and 19.1 mill shares were traded and 11935 transactions were registered at the Spotlight Stockmarket during 2018. Initiator Pharma had 3,614 shareholders on 31 December 2018. 49\% of the shares were owned by foreign shareholders. Initiator Pharma A/S owned no treasury shares at 31 December 2018. The total number of outstanding shares at 31 December 2018 was 23157178.

## Report from the Board of Directors and the Chief Executive Officer

## The Board of Directors and the Chief Executive Officer of Initiator Pharma (publ), corporate identity number 37663808, hereby present the Annual Report for the calendar year 2018.

Initiator Pharma is a limited liability company registered and headquartered in Aarhus, Denmark. The address of the head office is Lyngsiesvej 18,8230 Åbyhøj, Denmark. Initiator Pharma incorporated on May 2, 2016 and was listed on Spotlight Stock Market on March 16, 2017.

## ABOUT INITIATOR PHARMA

Initiator Pharma is a research and development company focusing on the development of innovative drugs targeting key unmet medical needs within the central and peripheral nervous system. The company's research is focusing on monoamine reuptake inhibitors, molecules that are affecting the synaptic concentrations of neurotransmitters such as dopamine, serotonin and noradrenaline.

The Company's lead drug candidate, 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 ${ }^{\circledR}$, Cialis ${ }^{\circledR}$ and Levitra ${ }^{\ominus}$. Initiator Pharma is currently conducting a Phase 1 study with IPED2015, and if successful we plan to proceed into a Phase 2 proof of concept study in patients, with headline results to planned to be reported mid-2019.

## SIGNIFICANT EVENTS IN 2018

- In January we announced that we had successfully completed the preclinical development of our drug candidate IPED2015. The studies were concluded ahead of the previously announced schedule and included experimental work with most of the recent positive data from the cardiovascular telemetry study, the respiratory study and a clean genotoxicity profile.
- We announced that the company has received an Intention to Grant notice from the European Patent Office ("EPO") for its patent application for the IPDP2015 product candidate. In essence, this means that the EPO intends to approve the company's application.
- In February the board proposed an Extraordinary General Meeting to conduct a rights issue of up to 8683941 shares and 5789294 attached consideration-free share options of series TO1, as units. Fully subscribed rights issue provides Initiator Pharma initially with approximately SEK 19.1 million through subscription of shares and a further approximately SEK 12.7 million in the case that all attached share options are exercised. In total, approximately SEK 31.8 million before issuing costs.
- On April 5th we announced that the rights issue had been oversubscribed, raising SEK 19.1 million to the company before issuing costs and SEK 16.8 net of issuing costs
- On May 3rd we called for the Annual General Meeting, to take place on May 25th, and published our Annual Report for 2017.
- On May 23rd we announced that we have filed a Clinical Trial Application, CTA for Drug candidate IPED2015 with the Medicines \& Healthcare products Regulatory Agency, MHRA.UK.
- On June 4th we announced that we had selected MAC Clinical Research Unit as our collaborator for the upcoming clinical development of IPED2015
- On June 26th we announced that the Medicines \& Healthcare products Regulatory Agency, MHRA.UK had approved our CTA for the Phase 1 for IPED2015.
- On August 22nd we announced that we had started dosing of the first healthy subjects in the Phase 1 study with IPED2015 at MAC Clinical Trial Center in Manchester. A cardiovascular incident in one subject was observed, and the trial was put on pause while awaiting full examination of the case.
- On August 24th we reported that the incentive warrant program approved by the AGM had been fully subscribed for
- On September 13th we announced that the examination of the cardiovascular incident in the Phase 1 study reported on August 22nd had been concluded, and that plans were to submit an amendment to the clinical trial protocol with the Medicines \& Healthcare products Regulatory Agency, MHRA.UK.
- On September 21st we announced that the amendment to the clinical trial protocol for the Phase 1 study with IPED2015 had been submitted to the Medicines \& Healthcare products Regulatory Agency, MHRA, UK.
- On October 3rd we announced that we had received approval for an amendment to the clinical trial protocol to the Medicines \& Healthcare products Regulatory Agency, MHRA, UK as well as the Ethics Committee, EC.
- On October 29th we announced that we were ready to continue the Phase Clinical trials with IPED2015 in the week of the 12th of November.
- On November 6th we announced that we had raised SEKM 12,7 in gross proceeds from the TO1 warrant program and a directed share issue in connection with the warrant program.
- On November 8th we announced that we had signed an option agreement with Saniona AB, for a phase 2 ready drug candidate.
- On November 23rd we announced that we had completed first dosing of the re-started Phase I study.


## EVENTS AFTER THE BALANCE SHEET DATE

- None


## FINANCIAL DEVELOPMENT IN 2018

Initiator Pharma A/S was incorporated on May 2, 2016. Consequently, there are no available comparative financial figures for the previous periods. Initiator Pharma A/S is a Danish registered company, and is reporting its financial figures in Danish kroner (DKK).

## Revenue and results of operation

As a development Company Initiator Pharma generated no revenues in the financial year 2018, unchanged from 2017. The company recognized an operating loss of KDKK 12,611 for the full year 2018, compared to KDKK 9,561 for the full year.

The increase in operating costs during 2018 reflects the start-up of the clinical development pogram for IPED2015.

External R\&D costs in 2018 amounted to TDKK 8,666, compared to 6,088 in the same period in 2017.

## Financial position

The equity as of December 31, 2018 was TDKK 16,570. Cash and cash equivalents amounted to TDKK 14,491 as of December 31, 2018. Total assets as of December 31, 2018, were TDKK 17,328.

On April 5th the company successfully completed a preferential rights issue raising approximately MDKK 13.8 gross and MDKK 12.1 net of transaction related costs. In connection with the share issue the company issued $5,789,294 \mathrm{TO}$ warrants, with each warrant giving the right to subscribe to one share at a share price of SEK 2,20 during Q4. On November 6th the company announced that $94.4 \%$ of the T01 warrant program was subscribed for. Combined with a directed share issue of 326,451 shares the TO1 warrant program raised approx MDKK 9.2 before transaction related costs.

On August 23rd 2018 the board approved the subscription of warrants as part of the company's incentive program, approved on the AGM in May 2018. The program was fully subscribed, with a total of 434,197 warrants being subscribed at a subscription price of SEK 0.47 per warrant, totaling net proceeds to the company of TDKK 144.

With these proceeds the company expects to have sufficient capital to fund the planned development activities through 2019 and the data read-out from the clinical phase 2 proof of concept trial.

## Cash flow

The operating cash flow for the financial year 2018 wasTDKK - 15,224 , incl a negative change in working capital of TDKK 2,701. Cash flow from investment activities was TDKK 0 and cash flow from financing activities was TDKK 20,904

## RISKS

Initiator Pharma is exposed to various kinds of risks that may impact the Company's results and financial position. The risks can be divided into operational risks and financial risks.

## Operational risks

Brief history
Initiator Pharma was incorporated in 2016 as a spin-out from Saniona AB. Consequently, the Company has a relatively short history, which should be taken into consideration when evaluating the Company.

Financing needs and capital
Initiator Pharma's research and development activities involve significant costs for the Company. Initiator Pharma is thus depending on that capital can be accessed to finance its planned activities. Any delays in product development could affect the cash flow negatively. There is a risk that the Company is unable to raise the additional capital needed. This may lead to the development being temporarily stopped or that Initiator Pharma is required to operate at a lower speed than wanted, which may affect the Company's operations negatively. In case Initiator Pharma is unable to raise capital there is a risk that the Company cannot further develop its business. If the Company cannot finance the operations, there is a risk that Initiator Pharma's drug development stops.

## Suppliers

Initiator Pharma has entered an agreement with the Indian service provider Syngene regarding the production and preclinical development of IPED2015. The Company will enter less comprehensive agreements with other suppliers in order to develop IPED2015. There is a risk that one or more of Initiator Pharma's suppliers choose to discontinue its cooperation with the Company, which could have a negative impact on the business. There is also a risk that Initiator Pharma's suppliers do not fully meet the quality standards set by the Company. There is also a risk that the establishment of new suppliers or replacement of existing suppliers becomes more costly and/or takes longer than the Company estimates, which may negatively affect the Company's results and financial position.

## Key individuals and employees

Initiator Pharma's key individuals and employees have high competence and long experience in the Company's business. A loss of one or more key individuals or employees may have negative consequences for the Company's operations and results. It is not possible to fully protect against unauthorized disclosure of information, with the risk that competitors can gain access to and benefit from the know-how developed by Initiator Pharma, which could be detrimental to the Company. There is a risk that the loss of one or more key in- dividuals, employees and consultants leads to delays in the Company's work to develop drugs. Any delays can cause increased costs for the Company. Thus, there is also a risk that delays could negatively affect the Company's results

## Competitors

Initiator Pharma is a research and development company engaged in pharmaceutical development of drugs to be used for erectile dysfunction, depression and pain. Initiator Pharma's research is focused in the area of monoamine reuptake inhibitors. The Company's drug research will be conducted primarily through its own pharmaceutical development in the early phase and through potential cooperations with other major pharmaceutical companies. Some of the Company's competitors are multinational companies with large financial resources. A comprehensive investment and product development from a competitor may result in less favorable market conditions for Initiator Pharma. Furthermore, companies with global operations, which in the current situation are working in related areas, can also establish themselves within the Company's business. Increased competition could lead to could lead to negative sales and earnings effects for the Company in the future.

Economic development and currency risk
External factors such as inflation, currency and interest rate fluctuations, supply and demand as well as economic recessions and booms may have an impact on operating costs, sales prices and share valuations. A significant share of Initiator Pharma's development costs is
in international currencies. Exchange rates can change substantially. There is a risk that Initiator Pharma's future operating costs, revenue and share valuation may be negatively affected by these factors, which are beyond the control of the Company.

## Political risk

The Company, through its pharmaceutical development operates in a number of different countries and can therefore be affected by political and economic uncertainties in these countries. There is a risk that Initiator Pharma is negatively affected by changes in laws, taxes, duties, exchange rates and terms for foreign companies. The Company may also be negatively affected by any domestic policy decisions. The above could have negative consequences for the Company's research in pharmaceutical development and can thus affect the Company's future results and financial position.

Patents and other intellectual property
Currently Initiator Pharma holds 3 different patent families. There is a risk that any future patent applications will not be approved and there is also a risk that an approved patent will not constitute a total commercial protection in the future. Patents have a limited life. If
the Company is forced to defend future patent rights against a competitor, this will involve considerable costs, which may negatively affect the Company's research, results and financial position. Furthermore, in the industry Initiator Pharma operates there is always the risk that the Company may or is alleged to infringe patent held by third parties. Other actors' patents may also limit the ability of one or more of the Company's future partners to freely use the product or production method concerned. The risk associated with patent protection implies that the outcome of such disputes is difficult to predict. Negative outcome of litigation relating to intellectual property rights may lead to loss of protection, prohibition to continue to use the right or obligation to pay damages. In addition, the costs of litigation, even in case of a favorable outcome for Initiator Pharma, may be substantial, which could negatively affect the Company's results and financial position. The above could imply difficulties or delays in the commercialization of future products and thus also difficulties in generating revenue.

Development expenditure
Initiator Pharma will continue to develop drug candidates in its operating area. Time and cost aspects of drug development can be difficult to determine in advance with accuracy. This creates the risk of a planned product development program becoming more costly than planned, which may affect the Company's future results and financial position.

## Financial risks

Financial risks relate to a potential negative impact on the financial position resulting from changes in the financial risk factors. The Board of Directors is ultimately responsible for the exposure, management and monitoring of the Company's financial risks. The Board of Directors sets the framework that applies to the exposure, management and monitoring of the financial risks and this framework is evaluated and revised yearly. The Board of Directors can decide on temporary departures from its predetermined framework. Below is a brief description of the financial risk factors that are deemed the most significant for Initiator Pharma.

Currency risks is the risk that the fair value of future cash flows fluctuate because of changed exchange rates. Exposure to currency risk is primarily sourced from payment flows in foreign currency and from the translation of balance sheet items in foreign currency, as well as upon the translation of foreign subsidiaries' income statements and balance sheets to the Company's reporting currency, which is DKK

Interest risk is the risk that fair value or future cash flows fluctuates as a result of changed market interest rates.

Liquidity risk is the risk that the Company encounters difficulties in satisfying commitments related to the Company's financial liabilities.

Credit risk is the risk that a counterparty in a transaction generates a loss for the Company by being unable to satisfy its contracted obligations. Credit risk may also arise if the Company's surplus liquidity is invested in various types of financial instrument.

## Corporate governance

Initiator Pharma does not provide a Corporate Governance Report for 2018. The Board of Directors has reviewed the governance structure for Initiator Pharma in relation to the Company's plans for listing at Spotlight Stock Market. The Board of Directors has adapted the following policies:

- Rules of Procedure for the Board of Directors
- Instructions for the CEO
- Information Policy


## Organisation

The average number of employees in the Company during the year amounted to 1 of whom none were women. As of December 31 2018, the number of employees was 1 of which none were women. Of these employees, none were full-time employees, 1 were part-time employees

In addition to its employees Initiator Pharma has a number of consultants who work with the Company on an ongoing basis

## Remuneration

The AGM resolves on remuneration to the Chair of the Board and other Board members. The AGM also resolves on guidelines for remunerating the CEO and other senior executives. For more information on remuneration in the year, see note 1
Noss Statement

## Balance Sheet on December 31, 2018

| ASSETS <br> (TDKK) | Notes | 2018 | 2017 |
| :---: | :---: | :---: | :---: |
| Patents, acquired rights |  | 56 | 78 |
| Intangible assets | 5 | 56 | 78 |
| Other fixtures and fittings, tools and equipment |  | 68 | 134 |
| Property, plant and equipment | 6 | 68 | 134 |
| Fixed assets |  | 124 | 212 |
| Other receivables |  | 307 | 182 |
| Income Tax receivable |  | 2406 | 1735 |
| Current receivables |  | 2713 | 1917 |
| Cash and cash equivalents | 7 | 14491 | 7169 |
| Current assets |  | 17204 | 9086 |
| Assets |  | 17328 | 9298 |


| EQUITY AND LIABILITIES |  |  |  |
| :--- | ---: | ---: | ---: |
| (TDKK) | Notes | $\mathbf{2 0 1 8}$ | $\mathbf{2 0 1 7}$ |
|  |  |  |  |
| Contributed capital | 8 | 2432 | 912 |
| Retained earnings |  | 14138 | 5052 |
| Equity | 16570 | $\mathbf{5 9 6 4}$ |  |
| Trade payables |  |  |  |
| Other payables | 239 | 1416 |  |
| Current liabilities other than provisions | 519 | 1918 |  |
| Liabilities other than provisions |  | 758 | $\mathbf{3 3 3 4}$ |
| Equity and liabilities |  |  |  |

## Statement of changes in equity for 2018

| (TDKK) | Contributed capital | Retained earnings | Total |
| :--- | ---: | ---: | ---: |
| January 1, 2018 | $\mathbf{9 1 2}$ | $\mathbf{5 0 5 2}$ | $\mathbf{5 9 6 4}$ |
|  |  |  |  |
| Increase of capital | 1520 | 19240 | 20760 |
| Issue of warrants |  | 144 | 144 |
| Profit/loss for the year |  | -10298 | -10298 |
| December 31, 2018 | $\mathbf{2 4 3 2}$ | $\mathbf{1 4 1 3 8}$ | $\mathbf{1 6 5 7 0}$ |

## Statement of cash flow

| (TDKK) | Notes | 2018 | 2017 |
| :---: | :---: | :---: | :---: |
| Operating profit/loss |  | -12611 | -9 561 |
| Amortisation, depreciation and impairment losses |  | 88 | 84 |
| Changes in working capital | 9 | -2 701 | 2449 |
| Cash flow from ordinary operating activities before financial items |  | -15224 | -7028 |
| Interest income received |  | 238 | 118 |
| Interest expense paid |  | -331 | -919 |
| Income tax refunded/(paid) |  | 1735 | 45 |
| Cash flow from operating activities |  | -13582 | -7784 |
| Investing activities |  |  |  |
| Investments in intangible assets |  | 0 | -132 |
| Cash flow from investing activities |  | 0 | -132 |
| Financing activities |  |  |  |
| New share issue |  | 20760 | 14751 |
| Issue of warrants |  | 144 | 166 |
| Cash flow from financing activities |  | 20904 | 14917 |
| Increase/decrease in cash and cash equivalents |  | 7322 | 7002 |
| Cash and cash equivalents at the end of period |  | 14491 | 7169 |

## Accounting policies

## Reporting class

This annual report has been presented in accordance with the provisions of the Danish Financial Statements Act governing reporting class B enterprises with addition of certain provisions for reporting class C .

The accounting policies applied to these financial statements are as stated below.

## Recognition and measurement

Assets are recognised in the balance sheet when it is probable as a result of a prior event that future economic benefits will flow to the Entity, and the value of the asset can be measured reliably.

Liabilities are recognised in the balance sheet when the Entity has a legal or constructive obligation as a result of a prior event, and it is probable that future economic benefits will flow out of the Entity, and the value of the liability can be measured reliably.

On initial recognition, assets and liabilities are measured at cost. Measurement subsequent to initial recognition is effected as described below for each financial statement item.

Anticipated risks and losses that arise before the time of presentation of the annual report and that confirm or invalidate affairs and conditions existing at the balance sheet date are considered at recognition and measurement.

Income is recognised in the income statement when earned, whereas costs are recognised by the amounts attributable to this financial year.

## Income statement

## Gross profit or loss

Gross profit or loss comprises revenue, other operating income, cost of raw materials and consumables and external expenses.

## Other external expenses

Other external expenses include expenses relating to the Entity's ordinary activities, including expenses for premises, stationery and office supplies, marketing costs, etc.

## Staff costs

Staff costs comprise salaries and wages as well as social security contributions, pension contributions, etc for entity staff.

## Depreciation, amortisation and impairment losses

Amortisation, depreciation and impairment losses relating to intangible assets and equipment comprise amortisation, depreciation and impairment losses for the financial year, calculated on the basis of the residual values and useful lives of the individual assets and impairment testing as well as gains and losses from the sale of intangible assets as well as equipment

## Other financial expenses

Other financial expenses comprise interest expenses, payables and transactions in foreign currencies etc.

## Tax on profit/loss for the year

Tax for the year, which consists of current tax for the year and changes in deferred tax, is recognised in the income statement by the portion attributable to the profit for the year and recognised directly in equity by the portion attributable to entries directly in equity.

## Balance Sheet

Intellectual property rights, etc.
Intellectual property rights etc comprise acquired intellectual property rights and prepayments for intangible assets.

Intellectual property rights acquired are measured at cost less accumulated amortisation Patents are amortised over their remaining duration, and licences are amortised over the term of the agreement, but over no more than 20 years.

Intellectual property rights etc are written down to the lower of recoverable amount and carrying amount.

## Property, plant and equipment

Other fixtures and fittings, tools and equipment are measured at cost less accumulated depreciation and impairment losses.

Cost comprises the acquisition price, costs directly attributable to the acquisition and preparation costs of the asset until the time when it is ready to be put into operation.

The basis of depreciation is cost less estimated residual value after the end of useful life. Straight-line depreciation is made on the basis of the following estimated useful lives of the assets:

Other fixtures and fittings, tools and equipment:
3 years

Estimated useful lives and residual values are reassessed annually.

Items of property, plant and equipment are written down to the lower of recoverable amount and carrying amount

## Receivables

Receivables are measured at amortised cost, usually equalling nominal value less writedowns for bad and doubtful debts.

## Income tax payable or receivable

Current tax payable or receivable is recognised in the balance sheet, stated as tax computed on this year's taxable income, adjusted for prepaid tax.

## Cash

Cash comprises cash in hand and bank deposits.

## Other financial liabilities

Other financial liabilities are measured at amortised cost, which usually corresponds to nominal value.

## Cash flow statement

The cash flow statement shows cash flows from operating, investing and financing activities as well as cash and cash equivalents at the beginning and the end of the financial year.

Cash flows from operating activities are presented using the indirect method and calculated as the operating profit/loss adjusted for non-cash operating items, working capital changes and income taxes paid.

Cash flows from investing activities comprise payments in connection with acquisition and divestment of enterprises, activities and fixed asset investments as well as purchase, development, improvement and sale, etc of intangible assets and property, plant and equipment, including acquisition of assets held under finance leases.

Cash flows from financing activities comprise changes in the size or composition of the contributed capital and related costs as well as the raising of loans, inception of finance leases, repayments of interest-bearing debt, purchase of treasury shares and payment of dividend.

Cash and cash equivalents comprise cash and short-term securities with an insignificant price risk less shortterm bank loans.

## Notes to the financial statements

| Note 1 - Staff costs | $\begin{array}{r} 2018 \\ \text { (TDKK) } \end{array}$ | $\begin{array}{r} 2017 \\ \text { (TDKK) } \\ \hline \end{array}$ |
| :---: | :---: | :---: |
| Wages and salaries | 1068 | 1270 |
| Pension costs | 0 | 10 |
| Other social security costs | 3 | 5 |
| Other staff costs | 14 | 12 |
| Staff costs | 1085 | 1297 |
| Average number of employees | 1 | 2 |
| Remuneration to the Excecutive Board has not been disclosed with reference to The Danish Financial Statements Acts § 98 B. |  |  |
| Note 2 - Depreciation, amortisation and impairment losses | $\begin{array}{r} 2018 \\ \text { (TDKK) } \end{array}$ | $\begin{array}{r} 2017 \\ \text { (TDKK) } \end{array}$ |
| Amortisation of intangible assets | 22 | 22 |
| Depreciation of property, plant and equipment | 66 | 62 |
| Depreciation and write-downs | 88 | 84 |
| Note 3-Tax on profit/loss for the year | $\begin{array}{r} 2018 \\ \text { (TDKK) } \end{array}$ | $\begin{array}{r} 2017 \\ \text { (TDKK) } \\ \hline \end{array}$ |
| Tax on current year taxable income | 2406 | 1735 |
| Adjustment concerning previous years | 0 | 45 |
|  | 2406 | 1780 |


| Note 4 - Proposed distribution of profit/loss | 2018 <br> (TDKK) | 2017 <br> (TDKK) |
| :--- | ---: | ---: |
| Retained earnings | 10298 | 8582 |
| Note 5 - Intangible assets | 10298 | $\mathbf{8 5 8 2}$ |
| (DKK) |  |  |
| Acquired rights |  |  |

Note 6 - Property, plant and equipment
(TDKK)

| Cost beginning of year | 196 |
| :--- | ---: |
| Cost end of year | 196 |
|  |  |
| Depreciation and impairment losses beginning of the year | 62 |
| Depreciation for the year | 66 |
| Depreciation and impairment losses end of the year | $\mathbf{1 2 8}$ |

## Carrying amount end of yea

Other fixtures and fittings, tools and equipment

## Note 7 - Cash

Total cash funds amounts to 14.491 t.kr, of which 200 t.kr is pledged as security for the guarantee provided by the Company's bank.

| Note 8 - Contributed capital | Number | Nominal value <br> (TDKK) |
| :--- | ---: | ---: |
| Shares | 23157178 | 2431 |
|  | 23157178 | $\mathbf{2 4 3 1}$ |

The company has an established a warrant program, approved by the AGM in 2017 and in 2018. The purpose of the warrant program is to align the long-term incentives of board members, management and key consultants with those of our shareholders.

The warrant programs currently outstanding have a ceiling of 868394 warrants representing $3.7 \%$ of outstanding shares:

| Year approved | Number of <br> warrants | Subscription <br> price | Pct of issued <br> shares | Exercise <br> price | Exercise <br> deadline |
| :--- | ---: | ---: | ---: | ---: | ---: |
| AGM 2017 | 434197 | SEK 0.49 | $1.9 \%$ | 4,34 | Jan 31, 2020 |
| AGM 2018 | 434197 | SEK 0.47 | $1.9 \%$ | 3,99 | Dec 31, 2020 |
| Total | $\mathbf{8 6 8 ~ 3 9 4}$ |  | $\mathbf{3 . 7 \%}$ |  |  |

The warrants are subject to vesting conditions. The 2017 program is fully vested by Dec 31, 2018.

| Note 9 - Change in working capital | 2018 <br> (TDKK) | 2017 <br> (TDKK) |
| :--- | ---: | ---: |
|  |  |  |
| Increase/decrease in receivables | 125 | 49 |
| Increase/decrease in trade payables etc | 2577 | 2400 |
| Change in working capital | $\mathbf{2 7 0 2}$ | $\mathbf{2 4 4 9}$ |

## Note 10 - Contingent liabilities

On behalf of the company the bank has issued a guarantee to third party for an amount of 150 t.kr. The company has in this connection pledged a bank account with a balance of 200 t.dkr.

## Statement by Management concerning the Annual Report

The Board of Directors and the Executive Board have today considered and approved the Annual Report of Initiator Pharma A/S for the fiscal year 01/01/2018-12/31/2018.

The annual report is presented in accordance with the Danish Financial Statements Act.
In our opinion, the financial statements give a true and fair view of the entity's financial position at 12/31/2018 and of the results of its operations and cash flows for the fiscal year 01/01/2018-12/31/2018.

We believe that the management commentary contains a fair review of the affairs and conditions referred to therein.

We recommend that the Annual Report with its accompanying financial statements be adopted at the Annual General Meeting.

Copenhagen, 24/04/2019

Executive Board

Claus Elsborg Olesen

Board of Directors

## Independent Auditor's Report

## To the shareholders of Initiator Pharma A/S

## Opinion

We have audited the financial statements of Initiator Pharma A/S for the financial year 01.01.2018-31.12.2018, which comprise the income statement, balance sheet, statement of changes in equity, cash flow statement and notes, including a summary of significant accounting policies. The financial statements are prepared in accordance with the Danish Financial Statements Act.

In our opinion, the financial statements give a true and fair view of the Entity's financial position at 31.12.2018 and of the results of its operations and cash flows for the financial year 01.01.2018-31.12.2018 in accordance with the Danish Financial Statements Act.

## Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs) and additional requirements applicable in Denmark. Our responsibilities under those standards and requirements are further described in the Auditor's responsibilities for the audit of the financial statements section of this auditor's report. We are independent of the Entity in accordance with the International Ethics Standards Board of Accountants' Code of Ethics for Professional Accountants (IESBA Code) and the additional requirements applicable in Denmark, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

## Management's responsibilities for the financial statements

Management is responsible for the preparation of financial statements that give a true and fair view in accordance with the Danish Financial Statements Act, and for such internal control as Management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, Management is responsible for assessing the Entity's ability to continue as a going concern, for disclosing, as applicable, matters related to going concern, and for using the going concern basis of accounting in preparing the financial statements unless Management either intends to liquidate the Entity or to cease operations, or has no realistic alternative but to do so

## Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statementss as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark will always detect a material misstatement when it exits. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Entity's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.
- Conclude on the appropriateness of Management's use of the going concern basis of accounting in preparing the financial statements, and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Entity's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Entity to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures in the notes, and whether the financial statements represent the underlying transactions and events in a manner that gives a true and fair view.


We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

## Statement on the management commentary

 Management is responsible for the management commentary.Our opinion on the financial statements does not cover the management commentary, and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the management commentary and, in doing so, consider whether the management commentary is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

Moreover, it is our responsibility to consider whether the management commentary provides the information required under the Danish Financial Statements Act

Based on the work we have performed, we conclude that the management commentary is in accordance with the financial Statements and has been prepared in accordance with the requirements of the Danish Financial statements Act. We did not identify any material misstatement of the management commentary

Copenhagen, 24.04.2019

## Deloitte

Statsautoriseret Revisionspartnerselskab Central Business Registration No: 33963556

## Jens Sejer Pedersen

State Authorised Public Accountant
Identification number (MNE) mne14986


## Initiator Pharma's Board of Directors, Senior Management, and Auditors

Members of the Board of Directors and Senior Management


Member of the Board of Directors since 2016

Education: Ph.D. in biochemistry from the Karolinska Institute and a Master's degree in chemistry from the University of Linköping

No. of shares held: 0

Warrants held: 0


Member of the Board of Directors and CEO of Initiator Pharma since 2016 and co-founder of the Company

Education: Ph.D. in Physiology and Biophysics from Aarhus University

No. of shares held : 692738 through companies
Warrants held: 173680 personally and through companies


CFO of Initiator Pharma A/S since 2016
Education: Ph.D. in business administration from UC Berkeley and master's degree from the Norwegian School of Economics

No. of shares held: 83546 through companies
Warrants held: 147627 personally and through companies


ULF SIMONSEN (b. 1963)

CMO of Initiator Pharma A/S since 2016 and cofounder of the Company

Education: Medical doctor (Aarhus University) and Ph.D. in Physiology (Complutense University, Madrid). Currently Professor of Pharmacology and head of Department of Pharmacology at Aarhus University.

No. of shares held: 537438 through companies
Warrants held: 99866 personally and through companies


MIKAEL THOMSEN (b. 1968)
CSO of Initiator Pharma A/S since 2016 and cofounder of the Company

Education: Ph.D. in Pharmacology and Toxicology (University of Copenhagen) and two M. Sc. degrees in Pharmacy and Human Biology (from University of Pharmaceutical Sciences, Copenhagen and University of Copenhagen, Medical Faculty).

No. of shares held: 540036 through companies
Warrants held: 164994 personally and through companies


CTO of Initiator Pharma since 2016 and cofounder of the Company.

Education: Ph.D. in Organic Chemistry (University of Lund). Previously with NeuroSearch, heading their monoamine reuptake inhibitor program. Peters has published more than 70 scientific papers and holds more than 100 patents.

No of shares: 537438 through companies
Warrants held: 99866 personally and through companies

## Auditor: Deloitte Statsautoriseret Revisionspartnerselskab.

[^2]
## Glossary

## Business terms

## 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 ${ }^{\oplus}$, Cialis ${ }^{\oplus}$, Levitra ${ }^{\odot}$ )

## 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 ${ }^{\oplus}$, Cialis ${ }^{\oplus}$ and Levitra ${ }^{\ominus}$ are used in the treatment of erectile and were the first effective oral treatment available for the condition.

## Financial

## 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

## Financial calendar and contact information

FINANCIAL CALENDAR

| Year-End Report 2018 | February 22, 2019 |
| :--- | ---: |
| Annual General Meeting | May 23, 2019 |
| Interim Report Q1 | May 23, 2019 |
| Interim Report Q2 | August 23, 2019 |
| Interim Report Q3 | November 22, 2019 |
| Year-End Report 2019 | February 21, 2020 |

CONTACT INFORMATION
Initiator Pharma A/S
Lyngsiesvej 18
DK-8230 Åbyhøj
Denmark

Telephone: +45 61260035
E-mail: ceo@initiatorpharma.com

# Initiator Pharma 


[^0]:    1. One year exclusive option agreement, entered in November 2018
[^1]:    1. Internal drug candidate name IP2018 should we decide to execute the option agreement with Saniona
[^2]:    Auditor in charge: Jens Sejer Pedersen. Address: Deloitte Statsautoriseret Revisionspartnerselskab, Weidekampsgade 6, 2300 Copenhagen S, Denmark

